

### SECTION 1: Identification of the substance/mixture and of the company/undertaking

#### 1.1. Product identifier

Trade name : [CONJ IgA] [CONJ IgA2]

#### 1.2. Relevant identified uses of the substance or mixture and uses advised against

##### 1.2.1. Relevant identified uses

Use of the substance/mixture : In vitro diagnostics

##### 1.2.2. Uses advised against

No additional information available

#### 1.3. Details of the supplier of the safety data sheet

##### Supplier

Virotech Diagnostics GmbH  
Waldstraße 23 A2  
DE- 63128 Dietzenbach  
Deutschland  
T +49 6074 236980  
[qualitymanagement@virotechdiagnostics.com](mailto:qualitymanagement@virotechdiagnostics.com)

##### Email competent person

sds@kft.de

#### 1.4. Emergency telephone number

Country	Organisation/Company	Address	Emergency number	Comment
United Kingdom	National Health Service (NHS) England / Scotland / Wales / Northern Ireland	-	England / Scotland: 111 Wales: 111 or 0845 46 47 Northern Ireland: call your local General Practitioner. For life-threatening emergencies: call 999 for an ambulance.	24 h medical helpline for general public

### SECTION 2: Hazards identification

#### 2.1. Classification of the substance or mixture

##### Classification according to Regulation (EC) No. 1272/2008 [CLP]

Skin sensitisation, Category 1 H317

Full text of H- and EUH-statements: see section 16

##### Adverse physicochemical, human health and environmental effects

May cause an allergic skin reaction.

#### 2.2. Label elements

##### Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP) :



GHS07

Signal word (CLP) :

Warning

Contains :

reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)

Hazard statements (CLP) :

H317 - May cause an allergic skin reaction.

# [CONJ IgA] [CONJ IgA2]

## Safety Data Sheet

According to REACH Regulation (EC) No 1907/2006, as retained and amended in UK law

Precautionary statements (CLP) : P261 - Avoid breathing mist, vapours, spray.  
P280 - Wear protective gloves, protective clothing, eye protection.  
P333+P313 - If skin irritation or rash occurs: Get medical advice/attention.  
P362+P364 - Take off contaminated clothing and wash it before reuse.

### 2.3. Other hazards

This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII

This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

Contains no PBT/vPvB substances  $\geq 0.1\%$  assessed in accordance with REACH Annex XIII

Component	
reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) (55965-84-9)	This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

## SECTION 3: Composition/information on ingredients

### 3.1. Substances

Not applicable

### 3.2. Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) (Note B)	CAS-No.: 55965-84-9 EC Index-No.: 613-167-00-5	0.001 – 0.0025	Acute Tox. 2 (Inhalation), H330 (ATE=0.33 mg/l/4h) Acute Tox. 2 (Dermal), H310 (ATE=87.12 mg/kg bodyweight) Acute Tox. 3 (Oral), H301 (ATE=64 mg/kg bodyweight) Skin Corr. 1C, H314 Eye Dam. 1, H318 Skin Sens. 1A, H317 Aquatic Acute 1, H400 (M=100) Aquatic Chronic 1, H410 (M=100) EUH071

### Specific concentration limits:

Name	Product identifier	Specific concentration limits
reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)	CAS-No.: 55965-84-9 EC Index-No.: 613-167-00-5	( 0.0015 $\leq$ C $\leq$ 100) Skin Sens. 1A, H317 ( 0.06 $\leq$ C < 0.6) Eye Irrit. 2, H319 ( 0.06 $\leq$ C < 0.6) Skin Irrit. 2, H315 ( 0.6 $\leq$ C $\leq$ 100) Eye Dam. 1, H318 ( 0.6 $\leq$ C $\leq$ 100) Skin Corr. 1C, H314

Note B: Some substances (acids, bases, etc.) are placed on the market in aqueous solutions at various concentrations and, therefore, these solutions require different classification and labelling since the hazards vary at different concentrations. In Part 3 entries with Note B have a general designation of the following type: '... %'. In this case the supplier must state the percentage concentration of the solution on the label. Unless otherwise stated, it is assumed that the percentage concentration is calculated on a weight/weight basis.

Full text of H- and EUH-statements: see section 16

# [CONJ IgA] [CONJ IgA2]

## Safety Data Sheet

According to REACH Regulation (EC) No 1907/2006, as retained and amended in UK law

### SECTION 4: First aid measures

#### 4.1. Description of first aid measures

First-aid measures general	: In all cases of doubt, or when symptoms persist, seek medical attention.
First-aid measures after inhalation	: Remove person to fresh air and keep comfortable for breathing.
First-aid measures after skin contact	: Wash skin with plenty of water. Take off contaminated clothing. If skin irritation or rash occurs: Get medical advice/attention.
First-aid measures after eye contact	: Rinse eyes with water as a precaution.
First-aid measures after ingestion	: Call a poison center or a doctor if you feel unwell.

#### 4.2. Most important symptoms and effects, both acute and delayed

Symptoms/effects after skin contact	: May cause an allergic skin reaction.
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#### 4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

### SECTION 5: Firefighting measures

#### 5.1. Extinguishing media

Suitable extinguishing media	: Use extinguishing media appropriate for surrounding fire. Water spray. Dry powder. Foam. Carbon dioxide.
Unsuitable extinguishing media	: Strong water jet.

#### 5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire	: Toxic fumes may be released. release of harmful/irritant gases/vapours. Carbon monoxide. Carbon dioxide (CO <sub>2</sub> ). Nitrogen oxides. Sulphur oxides.
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#### 5.3. Advice for firefighters

Protection during firefighting	: Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.
Other information	: Cool closed containers exposed to fire with water spray. Do not allow run-off from fire fighting to enter drains or water courses. Disposal must be done according to official regulations.

### SECTION 6: Accidental release measures

#### 6.1. Personal precautions, protective equipment and emergency procedures

##### 6.1.1. For non-emergency personnel

Emergency procedures	: Ventilate spillage area. Avoid contact with skin and eyes. Avoid breathing spray, vapours, mist.
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##### 6.1.2. For emergency responders

Protective equipment	: Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".
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#### 6.2. Environmental precautions

Prevent entry to sewers and public waters. Avoid sub-soil penetration. Notify authorities if product enters sewers or public waters.

#### 6.3. Methods and material for containment and cleaning up

Methods for cleaning up	: Take up liquid spill into absorbent material. Take up mechanically (sweeping, shovelling) and collect in suitable container for disposal.
Other information	: Dispose of materials or solid residues at an authorized site. Disposal must be done according to official regulations.

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According to REACH Regulation (EC) No 1907/2006, as retained and amended in UK law

### 6.4. Reference to other sections

Information for safe handling. See section 7. Concerning personal protective equipment to use, see section 8. For further information refer to section 13.

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

- Precautions for safe handling : Ensure good ventilation of the work station. Avoid contact with skin and eyes. Avoid breathing mist, vapours, spray. Wear personal protective equipment.
- Hygiene measures : Contaminated work clothing should not be allowed out of the workplace. Wash contaminated clothing before reuse. Do not eat, drink or smoke when using this product. Always wash hands after handling the product.

### 7.2. Conditions for safe storage, including any incompatibilities

- Storage conditions : Store in a well-ventilated place. Keep cool.
- Information about storage in one common storage facility : Keep away from food, drink and animal feeding stuffs.

### 7.3. Specific end use(s)

In vitro diagnostics.

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

#### 8.1.1 National occupational exposure and biological limit values

No additional information available

#### 8.1.2. Recommended monitoring procedures

No additional information available

#### 8.1.3. Air contaminants formed

No additional information available

#### 8.1.4. DNEL and PNEC

No additional information available

#### 8.1.5. Control banding

No additional information available

### 8.2. Exposure controls

#### 8.2.1. Appropriate engineering controls

##### Appropriate engineering controls:

Ensure good ventilation of the work station.

#### 8.2.2. Personal protection equipment

##### 8.2.2.1. Eye and face protection

###### Eye protection:

Use splash goggles when eye contact due to splashing is possible. ISO 16321-1

##### 8.2.2.2. Skin protection

###### Skin and body protection:

Wear suitable protective clothing. EN ISO 13688. EN 13034

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### Hand protection:

Chemically resistant protective gloves. ISO 374-1. Nitrile rubber. Choosing the proper glove is a decision that depends not only on the type of material, but also on other quality features, which differ for each manufacturer. Please follow the instructions related to the permeability and the penetration time provided by the manufacturer. Gloves must be replaced after each use and whenever signs of wear or perforation appear

### 8.2.2.3. Respiratory protection

#### Respiratory protection:

In case of inadequate ventilation wear respiratory protection. In case of unintended release: Particle filter. P2. EN 143. In case of insufficient ventilation, wear suitable respiratory equipment. . Breathing apparatus with filter. Breathing equipment is only to be used in order to handle the residual risk of short term jobs if all other risk minimizing measures have been carried out e.g. retention and/or local exhaust

### 8.2.2.4. Thermal hazards

No additional information available

### 8.2.3. Environmental exposure controls

#### Environmental exposure controls:

Avoid release to the environment.

#### Other information:

Do not eat, drink or smoke when using this product. Avoid contact with skin and eyes. Always wash hands after handling the product.

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Colour	: red.
Odour	: odourless.
Odour threshold	: Not available
Melting point	: Not applicable
Freezing point	: Not available
Boiling point	: Not available
Flammability	: Not applicable
Explosive properties	: Product is not explosive.
Oxidising properties	: Non oxidizing.
Explosive limits	: Not available
Lower explosion limit	: Not available
Upper explosion limit	: Not available
Flash point	: Not available
Auto-ignition temperature	: Not available
Decomposition temperature	: Not available
pH	: 7.5 – 7.7 (20 °C)
Viscosity, kinematic	: Not available
Solubility	: Water: Soluble
Partition coefficient n-octanol/water (Log Kow)	: Not available
Vapour pressure	: Not available
Vapour pressure at 50°C	: Not available
Density	: Not available
Relative density	: Not available
Relative vapour density at 20°C	: Not available
Particle characteristics	: Not applicable

### 9.2. Other information

#### 9.2.1. Information with regard to physical hazard classes

No additional information available

#### 9.2.2. Other safety characteristics

No additional information available

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### SECTION 10: Stability and reactivity

#### 10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

#### 10.2. Chemical stability

Stable under normal conditions.

#### 10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

#### 10.4. Conditions to avoid

None under recommended storage and handling conditions (see section 7).

#### 10.5. Incompatible materials

No additional information available.

#### 10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

### SECTION 11: Toxicological information

#### 11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity (oral) : Not classified (Based on available data, the classification criteria are not met)  
Acute toxicity (dermal) : Not classified (Based on available data, the classification criteria are not met)  
Acute toxicity (inhalation) : Not classified (Based on available data, the classification criteria are not met)

reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) (55965-84-9)	
LD50 oral rat	64 mg/kg bodyweight (male)
LD50 dermal rabbit	87.12 mg/kg bodyweight (Active substance; male)
LC50 Inhalation - Rat (Dust/Mist)	0.33 mg/l/4h (Active substance; (OECD 403 method))

Skin corrosion/irritation : Not classified (Based on available data, the classification criteria are not met)  
pH: 7.5 – 7.7 (20 °C)  
Serious eye damage/irritation : Not classified (Based on available data, the classification criteria are not met)  
pH: 7.5 – 7.7 (20 °C)  
Respiratory or skin sensitisation : May cause an allergic skin reaction. (Based on available data, the classification criteria are not met)  
Germ cell mutagenicity : Not classified (No data available. Based on available data, the classification criteria are not met)  
Carcinogenicity : Not classified (Based on available data, the classification criteria are not met)  
Reproductive toxicity : Not classified (Based on available data, the classification criteria are not met)  
STOT-single exposure : Not classified (Based on available data, the classification criteria are not met)  
STOT-repeated exposure : Not classified (Based on available data, the classification criteria are not met)  
Aspiration hazard : Not classified (Based on available data, the classification criteria are not met)

#### 11.2. Information on other hazards

No additional information available

### SECTION 12: Ecological information

#### 12.1. Toxicity

Ecology - general : The product has not been tested.

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Hazardous to the aquatic environment, short-term (acute) : Not classified (Based on available data, the classification criteria are not met)

Hazardous to the aquatic environment, long-term (chronic) : Not classified (Based on available data, the classification criteria are not met)

<b>reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) (55965-84-9)</b>	
LC50 - Fish [1]	0.19 mg/l (96 h; Oncorhynchus mykiss; EPA OPP 72-1)
EC50 - Crustacea [1]	0.18 mg/l (48 h; Daphnia magna; EPA OPP 72-2)
ErC50 algae	0.0063 mg/l (72 h; Skeletonema costatum (marine diatom); (OECD 201 method))
NOEC chronic fish	0.098 mg/l (28 d; Oncorhynchus mykiss; (OECD 215 method))
NOEC chronic crustacea	0.328 mg/l (21 d; Daphnia magna; (OECD 211 method))
NOEC chronic algae	0.0005 mg/l (48 h; Skeletonema costatum (marine diatom); (OECD 201 method))

### 12.2. Persistence and degradability

<b>IgA-Conjugate (anti-human)</b>	
Persistence and degradability	No additional information available.
<b>reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) (55965-84-9)</b>	
Persistence and degradability	Not readily biodegradable. Readily biodegradable, failing 10-d window.
Biodegradation	62 % (29 d; (OECD 301B method))

### 12.3. Bioaccumulative potential

<b>IgA-Conjugate (anti-human)</b>	
Bioaccumulative potential	No additional information available.
<b>reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) (55965-84-9)</b>	
Bioconcentration factor (BCF REACH)	≈ 41 (20 °C; 0.12 mg/L; EPA OPP 165-4)
Partition coefficient n-octanol/water (Log Pow)	-0.32 – 0.7 (20 °C; (OECD 117 method))

### 12.4. Mobility in soil

<b>IgA-Conjugate (anti-human)</b>	
Ecology - soil	No additional information available.
<b>reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) (55965-84-9)</b>	
Surface tension	73 mN/m (19.5 °C; 1 g/L; Test method EU A.5)
Ecology - soil	Low mobility (soil).

### 12.5. Results of PBT and vPvB assessment

<b>IgA-Conjugate (anti-human)</b>	
This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII	
This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII	
<b>Component</b>	
reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) (55965-84-9)	This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

### 12.6. Endocrine disrupting properties

No additional information available

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### 12.7. Other adverse effects

Other adverse effects : No additional information available.

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

Waste treatment methods : Disposal must be done according to official regulations. European waste catalogue. Do not discharge into drains or the environment. Do not dispose of with domestic waste.

Product/Packaging disposal recommendations : Comply with local regulations for disposal. Recycle or dispose of in compliance with current legislation.

## SECTION 14: Transport information

In accordance with ADR / IMDG / IATA / ADN / RID

ADR	IMDG	IATA	ADN	RID
<b>14.1. UN number or ID number</b>				
Not applicable	Not regulated	Not regulated	Not applicable	Not applicable
<b>14.2. UN proper shipping name</b>				
Not applicable	Not regulated	Not regulated	Not applicable	Not applicable
<b>14.3. Transport hazard class(es)</b>				
Not applicable	Not regulated	Not regulated	Not applicable	Not applicable
<b>14.4. Packing group</b>				
Not applicable	Not regulated	Not regulated	Not applicable	Not applicable
<b>14.5. Environmental hazards</b>				
Not applicable	Not regulated	Not regulated	Not applicable	Not applicable
No supplementary information available				

### 14.6. Special precautions for user

#### Overland transport

Not applicable

#### Transport by sea

Not regulated

#### Air transport

Not regulated

#### Inland waterway transport

Not applicable

#### Rail transport

Not applicable

### 14.7. Maritime transport in bulk according to IMO instruments

Not applicable



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## Safety Data Sheet

According to REACH Regulation (EC) No 1907/2006, as retained and amended in UK law

### SECTION 15: Regulatory information

#### 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

##### 15.1.1. EU-Regulations

Other information, restriction and prohibition regulations : This product is a medical device and has not to be classified and labelled according to the current laws and regulations. Take note of Directive 94/33/EC on the protection of young people at work.

##### REACH Annex XVII (Restriction List)

EU restriction list (REACH Annex XVII)	
Reference code	Applicable on
3(b)	IgA-Conjugate (anti-human) ; reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)
3(c)	reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)

##### REACH Annex XIV (Authorisation List)

Contains no substance(s) listed on REACH Annex XIV (Authorisation List)

##### REACH Candidate List (SVHC)

Contains no substance(s) listed on the REACH Candidate List

##### PIC Regulation (Prior Informed Consent)

Contains no substance(s) listed on the PIC list (Regulation EU 649/2012 concerning the export and import of hazardous chemicals)

##### POP Regulation (Persistent Organic Pollutants)

Contains no substance(s) listed on the POP list (Regulation EU 2019/1021 on persistent organic pollutants)

##### Ozone Regulation (1005/2009)

Contains no substance(s) listed on the Ozone Depletion list (Regulation EU 1005/2009 on substances that deplete the ozone layer)

##### Explosives Precursors Regulation (2019/1148)

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

##### Drug Precursors Regulation (273/2004)

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

##### 15.1.2. National regulations

No additional information available

#### 15.2. Chemical safety assessment

No chemical safety assessment has been carried out

No chemical safety assessment has been carried out

### SECTION 16: Other information

Indication of changes			
Section	Changed item	Change	Comments
	General revision		
2.1	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Modified	
2.2	Labelling according to Regulation (EC) No. 1272/2008 [CLP]	Modified	
11.1	Toxicological information	Modified	

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## Safety Data Sheet

According to REACH Regulation (EC) No 1907/2006, as retained and amended in UK law

<b>Abbreviations and acronyms:</b>	
ADN	Accord européen relatif au transport international des marchandises dangereuses par voie de navigation intérieure (European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways)
ADR	Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
IATA	International Air Transport Association
IMDG	International Maritime Code for Dangerous Goods
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
ATE	Acute Toxicity Estimate
BCF	Bioconcentration factor
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008
DMEL	Derived Minimal Effect level
DNEL	Derived-No Effect Level
EC50	Median effective concentration
IARC	International Agency for Research on Cancer
IATA	International Air Transport Association
IMDG	International Maritime Dangerous Goods
LC50	Median lethal concentration
LD50	Median lethal dose
LOAEL	Lowest Observed Adverse Effect Level
NOAEC	No-Observed Adverse Effect Concentration
NOAEL	No-Observed Adverse Effect Level
NOEC	No-Observed Effect Concentration
OECD	Organisation for Economic Co-operation and Development
PBT	Persistent Bioaccumulative Toxic
PNEC	Predicted No-Effect Concentration
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
SDS	Safety Data Sheet
STP	Sewage treatment plant
TLM	Median Tolerance Limit
vPvB	Very Persistent and Very Bioaccumulative
CAS-No.	Chemical Abstract Service number

Data sources : Information provided by the manufacturer. MSDS of the supplier. European Chemicals Agency, <http://echa.europa.eu/>.

Department issuing data specification sheet: : KFT Chemieservice GmbH  
Im Leuschnerpark 3  
D-64347 Griesheim

Phone: +49 6155-8981-400  
Fax: +49 6155 8981-500  
SDS Service: +49 6155 8981-522

Contact person : Dr. Andreas Kretzschmar

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## Safety Data Sheet

According to REACH Regulation (EC) No 1907/2006, as retained and amended in UK law

Other information : This safety data sheet is for informational purposes only and does not comply with national legal requirements without reference to a national distributor. The national distributor is responsible for a legally compliant safety data sheet.

<b>Full text of H- and EUH-statements:</b>	
Acute Tox. 2 (Dermal)	Acute toxicity (dermal), Category 2
Acute Tox. 2 (Inhalation)	Acute toxicity (inhal.), Category 2
Acute Tox. 3 (Oral)	Acute toxicity (oral), Category 3
Aquatic Acute 1	Hazardous to the aquatic environment – Acute Hazard, Category 1
Aquatic Chronic 1	Hazardous to the aquatic environment – Chronic Hazard, Category 1
EUH071	Corrosive to the respiratory tract.
Eye Dam. 1	Serious eye damage/eye irritation, Category 1
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
H301	Toxic if swallowed.
H310	Fatal in contact with skin.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H330	Fatal if inhaled.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
Skin Corr. 1C	Skin corrosion/irritation, Category 1, Sub-Category 1C
Skin Irrit. 2	Skin corrosion/irritation, Category 2
Skin Sens. 1	Skin sensitisation, Category 1
Skin Sens. 1A	Skin sensitisation, category 1A

<b>Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:</b>		
Skin Sens. 1	H317	Calculation method

KFT SDS EU 00

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.



**[CONTROL 3 - IgX] [CONTROL 3 + IgX]  
[CONTROL 3 +/- IgX] [CSF AI] [CSF AI IgG L1]  
[CSF AI IgG L2] [CSF AI IgG S1] [CSF AI IgG S2]  
[CSF STD 1 IgX] [CSF STD 2 IgX] [CSF STD 3 IgX]  
[CSF STD 4 IgX] [CONTROL PIP] [CONTROL VAL]  
[HIGHPOS IgG] [LOWPOS IgG] [CAL]**

**Safety Data Sheet**

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878  
Issue date: 26/01/2023 Revision date: 26/01/2023 Supersedes version of: 19/05/2020 Version: 5.00

**SECTION 1: Identification of the substance/mixture and of the company/undertaking**

**1.1. Product identifier**

Product form : Mixture  
Trade name : [CONTROL 3 - IgX] [CONTROL 3 + IgX] [CONTROL 3 +/- IgX] [CSF AI] [CSF AI IgG L1]  
[CSF AI IgG L2] [CSF AI IgG S1] [CSF AI IgG S2] [CSF STD 1 IgX] [CSF STD 2 IgX] [CSF  
STD 3 IgX] [CSF STD 4 IgX] [CONTROL PIP] [CONTROL VAL] [HIGHPOS IgG] [LOWPOS  
IgG] [CAL]

**1.2. Relevant identified uses of the substance or mixture and uses advised against**

**1.2.1. Relevant identified uses**

Use of the substance/mixture : In vitro diagnostics

**1.2.2. Uses advised against**

No additional information available

**1.3. Details of the supplier of the safety data sheet**

**Supplier**

Virotech Diagnostics GmbH  
Waldstraße 23 A2  
DE- 63128 Dietzenbach  
Deutschland  
T +49 6074 236980  
[qualitymanagement@virotechdiagnostics.com](mailto:qualitymanagement@virotechdiagnostics.com)

**Email competent person**

sds@kft.de

**1.4. Emergency telephone number**

Emergency number : National Health Service (NHS)  
24 hour national number consumer  
England and Scotland: 111  
Wales: 0845 46 47  
Northern Ireland: call your local General Practitioner  
  
Call 999 if there is a life-threatening incident.

**SECTION 2: Hazards identification**

**2.1. Classification of the substance or mixture**

**Classification according to Regulation (EC) No. 1272/2008 [CLP]**

Not classified

**Adverse physicochemical, human health and environmental effects**

To our knowledge, this product does not present any particular risk, provided it is handled in accordance with good occupational hygiene and safety practice.

**2.2. Label elements**

**Labelling according to Regulation (EC) No. 1272/2008 [CLP]**

No labelling applicable

# [CONTROL 3 - IgX] [CONTROL 3 + IgX] [CONTROL 3 +/- IgX] [CSF AI] [CSF AI IgG L1] [CSF AI IgG L2] [CSF AI IgG S1] [CSF AI IgG S2] [CSF STD 1 IgX] [CSF STD 2 IgX] [CSF STD 3 IgX] [CSF STD 4 IgX] [CONTROL PIP] [CONTROL VAL] [HIGHPOS IgG] [LOWPOS IgG] [CAL]

## Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

### 2.3. Other hazards

Contains no PBT/vPvB substances  $\geq 0.1\%$  assessed in accordance with REACH Annex XIII

The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %

## SECTION 3: Composition/information on ingredients

### 3.1. Substances

Not applicable

### 3.2. Mixtures

This mixture does not contain any substances to be mentioned according to the criteria of section 3.2 of REACH Annex II

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

First-aid measures general	: In all cases of doubt, or when symptoms persist, seek medical attention.
First-aid measures after inhalation	: Remove person to fresh air and keep comfortable for breathing.
First-aid measures after skin contact	: Wash skin with plenty of water.
First-aid measures after eye contact	: Rinse eyes with water as a precaution.
First-aid measures after ingestion	: Call a poison center or a doctor if you feel unwell.

### 4.2. Most important symptoms and effects, both acute and delayed

No additional information available

### 4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

## SECTION 5: Firefighting measures

### 5.1. Extinguishing media

Suitable extinguishing media	: Use extinguishing media appropriate for surrounding fire. Water spray. Dry powder. Foam. Carbon dioxide.
Unsuitable extinguishing media	: Strong water jet.

### 5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire	: Toxic fumes may be released. In traces: Carbon dioxide, Carbon monoxide, Phosphorus oxides, Hydrogen chloride, Sodium hydroxide.
--------------------------------------------------	------------------------------------------------------------------------------------------------------------------------------------

### 5.3. Advice for firefighters

Protection during firefighting	: Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.
Other information	: Do not allow run-off from fire fighting to enter drains or water courses. Disposal must be done according to official regulations.

**[CONTROL 3 - IgX] [CONTROL 3 + IgX] [CONTROL 3 +/- IgX] [CSF AI]  
[CSF AI IgG L1] [CSF AI IgG L2] [CSF AI IgG S1] [CSF AI IgG S2]  
[CSF STD 1 IgX] [CSF STD 2 IgX] [CSF STD 3 IgX] [CSF STD 4 IgX]  
[CONTROL PIP] [CONTROL VAL] [HIGHPOS IgG] [LOWPOS IgG]  
[CAL]**

**Safety Data Sheet**

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

**SECTION 6: Accidental release measures**

**6.1. Personal precautions, protective equipment and emergency procedures**

**6.1.1. For non-emergency personnel**

Emergency procedures : Ventilate spillage area.

**6.1.2. For emergency responders**

Protective equipment : Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

**6.2. Environmental precautions**

Prevent entry to sewers and public waters. Avoid sub-soil penetration. Notify authorities if product enters sewers or public waters.

**6.3. Methods and material for containment and cleaning up**

Methods for cleaning up : Take up liquid spill into absorbent material. Take up mechanically (sweeping, shovelling) and collect in suitable container for disposal.

Other information : Disposal must be done according to official regulations.

**6.4. Reference to other sections**

Information for safe handling. See section 7. Concerning personal protective equipment to use, see section 8. For further information refer to section 13.

**SECTION 7: Handling and storage**

**7.1. Precautions for safe handling**

Precautions for safe handling : Ensure good ventilation of the work station. Wear personal protective equipment.

Hygiene measures : Do not eat, drink or smoke when using this product. Always wash hands after handling the product.

**7.2. Conditions for safe storage, including any incompatibilities**

Storage conditions : Store in a well-ventilated place. Keep cool.

Information about storage in one common storage facility : Keep away from food, drink and animal feeding stuffs.

**7.3. Specific end use(s)**

In vitro diagnostics.

**SECTION 8: Exposure controls/personal protection**

**8.1. Control parameters**

**8.1.1 National occupational exposure and biological limit values**

No additional information available

**8.1.2. Recommended monitoring procedures**

No additional information available

**8.1.3. Air contaminants formed**

No additional information available

# [CONTROL 3 - IgX] [CONTROL 3 + IgX] [CONTROL 3 +/- IgX] [CSF AI] [CSF AI IgG L1] [CSF AI IgG L2] [CSF AI IgG S1] [CSF AI IgG S2] [CSF STD 1 IgX] [CSF STD 2 IgX] [CSF STD 3 IgX] [CSF STD 4 IgX] [CONTROL PIP] [CONTROL VAL] [HIGHPOS IgG] [LOWPOS IgG] [CAL]

## Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

### 8.1.4. DNEL and PNEC

No additional information available

### 8.1.5. Control banding

No additional information available

## 8.2. Exposure controls

### 8.2.1. Appropriate engineering controls

#### Appropriate engineering controls:

Ensure good ventilation of the work station.

### 8.2.2. Personal protection equipment

#### 8.2.2.1. Eye and face protection

##### Eye protection:

Use splash goggles when eye contact due to splashing is possible. ISO 16321-1

#### 8.2.2.2. Skin protection

##### Skin and body protection:

Wear suitable protective clothing. EN ISO 13688. EN 13034

##### Hand protection:

In case of repeated or prolonged contact wear gloves. Nitrile rubber. ISO 374-1. Choosing the proper glove is a decision that depends not only on the type of material, but also on other quality features, which differ for each manufacturer. Please follow the instructions related to the permeability and the penetration time provided by the manufacturer. Gloves must be replaced after each use and whenever signs of wear or perforation appear

#### 8.2.2.3. Respiratory protection

##### Respiratory protection:

In case of insufficient ventilation, wear suitable respiratory equipment. Breathing apparatus with filter. A-P2. EN 143. . Breathing equipment is only to be used in order to handle the residual risk of short term jobs if all other risk minimizing measures have been carried out e.g. retention and/or local exhaust

#### 8.2.2.4. Thermal hazards

No additional information available

### 8.2.3. Environmental exposure controls

#### Environmental exposure controls:

Avoid release to the environment.

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Colour	: colourless.
Odour	: odourless.
Odour threshold	: Not available
Melting point	: Not available
Freezing point	: Not available
Boiling point	: Not available
Flammability	: Not applicable
Explosive properties	: Product is not explosive.
Oxidising properties	: Non oxidizing.
Explosive limits	: Not available
Lower explosion limit	: Not available

# [CONTROL 3 - IgX] [CONTROL 3 + IgX] [CONTROL 3 +/- IgX] [CSF AI] [CSF AI IgG L1] [CSF AI IgG L2] [CSF AI IgG S1] [CSF AI IgG S2] [CSF STD 1 IgX] [CSF STD 2 IgX] [CSF STD 3 IgX] [CSF STD 4 IgX] [CONTROL PIP] [CONTROL VAL] [HIGHPOS IgG] [LOWPOS IgG] [CAL]

## Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

Upper explosion limit	: Not available
Flash point	: Not available
Auto-ignition temperature	: Not available
Decomposition temperature	: Not available
pH	: 7 – 7.4 (20 °C)
pH solution concentration	: 100 %
Viscosity, kinematic	: Not available
Solubility	: Water: Soluble
Partition coefficient n-octanol/water (Log Kow)	: Not available
Vapour pressure	: Not available
Vapour pressure at 50°C	: Not available
Density	: Not available
Relative density	: Not available
Relative vapour density at 20°C	: Not available
Particle characteristics	: Not applicable

### 9.2. Other information

#### 9.2.1. Information with regard to physical hazard classes

No additional information available

#### 9.2.2. Other safety characteristics

No additional information available

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

### 10.2. Chemical stability

Stable under normal conditions.

### 10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

### 10.4. Conditions to avoid

None under recommended storage and handling conditions (see section 7).

### 10.5. Incompatible materials

No additional information available.

### 10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

## SECTION 11: Toxicological information

### 11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity (oral)	: Not classified (Based on available data, the classification criteria are not met)
Acute toxicity (dermal)	: Not classified (Based on available data, the classification criteria are not met)
Acute toxicity (inhalation)	: Not classified (Based on available data, the classification criteria are not met)



**[CONTROL 3 - IgX] [CONTROL 3 + IgX] [CONTROL 3 +/- IgX] [CSF AI]  
[CSF AI IgG L1] [CSF AI IgG L2] [CSF AI IgG S1] [CSF AI IgG S2]  
[CSF STD 1 IgX] [CSF STD 2 IgX] [CSF STD 3 IgX] [CSF STD 4 IgX]  
[CONTROL PIP] [CONTROL VAL] [HIGHPOS IgG] [LOWPOS IgG]  
[CAL]**

**Safety Data Sheet**

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

Skin corrosion/irritation	: Not classified (Based on available data, the classification criteria are not met) pH: 7 – 7.4 (20 °C)
Serious eye damage/irritation	: Not classified (Based on available data, the classification criteria are not met) pH: 7 – 7.4 (20 °C)
Respiratory or skin sensitisation	: Not classified (Based on available data, the classification criteria are not met)
Germ cell mutagenicity	: Not classified (Based on available data, the classification criteria are not met)
Carcinogenicity	: Not classified (Based on available data, the classification criteria are not met)
Reproductive toxicity	: Not classified (Based on available data, the classification criteria are not met)
STOT-single exposure	: Not classified (Based on available data, the classification criteria are not met)
STOT-repeated exposure	: Not classified (Based on available data, the classification criteria are not met)
Aspiration hazard	: Not classified (Based on available data, the classification criteria are not met)

**11.2. Information on other hazards**

No additional information available

**SECTION 12: Ecological information**

**12.1. Toxicity**

Ecology - general	: The product has not been tested.
Hazardous to the aquatic environment, short-term (acute)	: Not classified (No data available. Based on available data, the classification criteria are not met)
Hazardous to the aquatic environment, long-term (chronic)	: Not classified (Based on available data, the classification criteria are not met)

**12.2. Persistence and degradability**

No additional information available

**12.3. Bioaccumulative potential**

**IgG / IgM / IgA Control Sera (negative, cut off, positive control), Pipetting control in buffer ZB200.3**

Bioaccumulative potential	No additional information available.
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**12.4. Mobility in soil**

**IgG / IgM / IgA Control Sera (negative, cut off, positive control), Pipetting control in buffer ZB200.3**

Ecology - soil	No additional information available.
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**12.5. Results of PBT and vPvB assessment**

No additional information available

**12.6. Endocrine disrupting properties**

No additional information available

**12.7. Other adverse effects**

Other adverse effects : No additional information available

**[CONTROL 3 - IgX] [CONTROL 3 + IgX] [CONTROL 3 +/- IgX] [CSF AI] [CSF AI IgG L1] [CSF AI IgG L2] [CSF AI IgG S1] [CSF AI IgG S2] [CSF STD 1 IgX] [CSF STD 2 IgX] [CSF STD 3 IgX] [CSF STD 4 IgX] [CONTROL PIP] [CONTROL VAL] [HIGHPOS IgG] [LOWPOS IgG] [CAL]**

**Safety Data Sheet**

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

**SECTION 13: Disposal considerations**

**13.1. Waste treatment methods**

Waste treatment methods : Disposal must be done according to official regulations. European waste catalogue. Do not discharge into drains or the environment. Do not dispose of with domestic waste.

Product/Packaging disposal recommendations : Recycle or dispose of in compliance with current legislation.

**SECTION 14: Transport information**

In accordance with ADR / IMDG / IATA / ADN / RID

ADR	IMDG	IATA	ADN	RID
<b>14.1. UN number or ID number</b>				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
<b>14.2. UN proper shipping name</b>				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
<b>14.3. Transport hazard class(es)</b>				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
<b>14.4. Packing group</b>				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
<b>14.5. Environmental hazards</b>				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
No supplementary information available				

**14.6. Special precautions for user**

**Overland transport**

Not applicable

**Transport by sea**

Not applicable

**Air transport**

Not applicable

**Inland waterway transport**

Not applicable

**Rail transport**

Not applicable

**14.7. Maritime transport in bulk according to IMO instruments**

Not applicable

**[CONTROL 3 - IgX] [CONTROL 3 + IgX] [CONTROL 3 +/- IgX] [CSF AI]  
[CSF AI IgG L1] [CSF AI IgG L2] [CSF AI IgG S1] [CSF AI IgG S2]  
[CSF STD 1 IgX] [CSF STD 2 IgX] [CSF STD 3 IgX] [CSF STD 4 IgX]  
[CONTROL PIP] [CONTROL VAL] [HIGHPOS IgG] [LOWPOS IgG]  
[CAL]**

**Safety Data Sheet**

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

**SECTION 15: Regulatory information**

**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture**

**15.1.1. EU-Regulations**

Other information, restriction and prohibition regulations : This product is a medical device and has not to be classified and labelled according to the current laws and regulations.

**REACH Annex XVII (Restriction List)**

Contains no substance(s) listed on REACH Annex XVII (Restriction Conditions)

**REACH Annex XIV (Authorisation List)**

Contains no substance(s) listed on REACH Annex XIV (Authorisation List)

**REACH Candidate List (SVHC)**

Contains no substance(s) listed on the REACH Candidate List

**PIC Regulation (Prior Informed Consent)**

Contains no substance(s) listed on the PIC list (Regulation EU 649/2012 concerning the export and import of hazardous chemicals)

**POP Regulation (Persistent Organic Pollutants)**

Contains no substance(s) listed on the POP list (Regulation EU 2019/1021 on persistent organic pollutants)

**Ozone Regulation (1005/2009)**

Contains no substance(s) listed on the Ozone Depletion list (Regulation EU 1005/2009 on substances that deplete the ozone layer)

**Explosives Precursors Regulation (2019/1148)**

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

**Drug Precursors Regulation (273/2004)**

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

**15.1.2. National regulations**

No additional information available

**15.2. Chemical safety assessment**

No chemical safety assessment has been carried out

**SECTION 16: Other information**

**Indication of changes**

Section	Changed item	Change	Comments
	General revision		
1.1	Trade name	Modified	
1.3	SDS EU addresses	Modified	

**Abbreviations and acronyms:**

ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
ATE	Acute Toxicity Estimate

**[CONTROL 3 - IgX] [CONTROL 3 + IgX] [CONTROL 3 +/- IgX] [CSF AI]  
 [CSF AI IgG L1] [CSF AI IgG L2] [CSF AI IgG S1] [CSF AI IgG S2]  
 [CSF STD 1 IgX] [CSF STD 2 IgX] [CSF STD 3 IgX] [CSF STD 4 IgX]  
 [CONTROL PIP] [CONTROL VAL] [HIGHPOS IgG] [LOWPOS IgG]  
 [CAL]**

**Safety Data Sheet**

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

BCF	Bioconcentration factor
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008
DMEL	Derived Minimal Effect level
DNEL	Derived-No Effect Level
EC50	Median effective concentration
IARC	International Agency for Research on Cancer
IATA	International Air Transport Association
IMDG	International Maritime Dangerous Goods
LC50	Median lethal concentration
LD50	Median lethal dose
LOAEL	Lowest Observed Adverse Effect Level
NOAEC	No-Observed Adverse Effect Concentration
NOAEL	No-Observed Adverse Effect Level
NOEC	No-Observed Effect Concentration
OECD	Organisation for Economic Co-operation and Development
PBT	Persistent Bioaccumulative Toxic
PNEC	Predicted No-Effect Concentration
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
SDS	Safety Data Sheet
STP	Sewage treatment plant
TLM	Median Tolerance Limit
vPvB	Very Persistent and Very Bioaccumulative
CAS-No.	Chemical Abstract Service number

Data sources : Information provided by the manufacturer. MSDS of the supplier. European Chemicals Agency, <http://echa.europa.eu/>.

Department issuing data specification sheet: : KFT Chemieservice GmbH  
 Im Leuschnerpark 3  
 D-64347 Griesheim

Phone: +49 6155-8981-400  
 Fax: +49 6155 8981-500  
 SDS Service: +49 6155 8981-522

Contact person : Dr. Andreas Kretzschmar

Other information : This safety data sheet is for informational purposes only and does not fully comply with national legal requirements. The national distributor is responsible for a legally compliant safety data sheet.

KFT SDS EU 00

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

# [CONJ IgG]

## Safety Data Sheet

According to REACH Regulation (EC) No 1907/2006, as retained and amended in UK law  
Issue date: 24/08/2023 Revision date: 24/08/2023 Supersedes version of: 24/01/2023 Version: 6.00

### SECTION 1: Identification of the substance/mixture and of the company/undertaking

#### 1.1. Product identifier

Product form : Mixture  
Trade name : [CONJ IgG]  
Type of product : Medical device

#### 1.2. Relevant identified uses of the substance or mixture and uses advised against

##### 1.2.1. Relevant identified uses

Use of the substance/mixture : In vitro diagnostics

##### 1.2.2. Uses advised against

No additional information available

#### 1.3. Details of the supplier of the safety data sheet

##### Supplier

Virotech Diagnostics GmbH  
Waldstraße 23 A2  
DE- 63128 Dietzenbach  
Deutschland  
T +49 6074 236980  
[qualitymanagement@virotechdiagnostics.com](mailto:qualitymanagement@virotechdiagnostics.com)

##### Email competent person

sds@kft.de

#### 1.4. Emergency telephone number

Emergency number : National Health Service (NHS)  
24 hour national number consumer  
England and Scotland: 111  
Wales: 0845 46 47  
Northern Ireland: call your local General Practitioner  
  
Call 999 if there is a life-threatening incident.

Country	Organisation/Company	Address	Emergency number	Comment
United Kingdom	National Health Service (NHS) England / Scotland / Wales / Northern Ireland	-	England / Scotland: 111 Wales: 111 or 0845 46 47 Northern Ireland: call your local General Practitioner. For life-threatening emergencies: call 999 for an ambulance.	24 h medical helpline for general public

### SECTION 2: Hazards identification

#### 2.1. Classification of the substance or mixture

##### Classification according to Regulation (EC) No. 1272/2008 [CLP]

Skin sensitisation, Category 1 H317

Full text of H- and EUH-statements: see section 16

##### Adverse physicochemical, human health and environmental effects

To our knowledge, this product does not present any particular risk, provided it is handled in accordance with good occupational hygiene and safety practice.

# [CONJ IgG]

## Safety Data Sheet

According to REACH Regulation (EC) No 1907/2006, as retained and amended in UK law

### 2.2. Label elements

#### Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP)



GHS07

Signal word (CLP)

: Warning

Contains

: reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)

Hazard statements (CLP)

: H317 - May cause an allergic skin reaction.

Precautionary statements (CLP)

: P261 - Avoid breathing mist, vapours, spray.

P280 - Wear protective gloves, protective clothing, eye protection.

P333+P313 - If skin irritation or rash occurs: Get medical advice/attention.

P362+P364 - Take off contaminated clothing and wash it before reuse.

### 2.3. Other hazards

This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII

This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

Contains no PBT/vPvB substances  $\geq 0.1\%$  assessed in accordance with REACH Annex XIII

Component	
sodium chloride (7647-14-5)	This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII
calcium chloride (10043-52-4)	This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII
reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) (55965-84-9)	This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %

## SECTION 3: Composition/information on ingredients

### 3.1. Substances

Not applicable

# [CONJ IgG]

## Safety Data Sheet

According to REACH Regulation (EC) No 1907/2006, as retained and amended in UK law

### 3.2. Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) (Note B)	CAS-No.: 55965-84-9 EC Index-No.: 613-167-00-5	0.001 – 0.0025	Acute Tox. 2 (Inhalation), H330 (ATE=0.33 mg/l/4h) Acute Tox. 2 (Dermal), H310 (ATE=87.12 mg/kg bodyweight) Acute Tox. 3 (Oral), H301 (ATE=64 mg/kg bodyweight) Skin Corr. 1C, H314 Eye Dam. 1, H318 Skin Sens. 1A, H317 Aquatic Acute 1, H400 (M=100) Aquatic Chronic 1, H410 (M=100) EUH071

Specific concentration limits:		
Name	Product identifier	Specific concentration limits
reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)	CAS-No.: 55965-84-9 EC Index-No.: 613-167-00-5	( 0.0015 ≤C ≤ 100) Skin Sens. 1A, H317 ( 0.06 ≤C < 0.6) Eye Irrit. 2, H319 ( 0.06 ≤C < 0.6) Skin Irrit. 2, H315 ( 0.6 ≤C ≤ 100) Eye Dam. 1, H318 ( 0.6 ≤C ≤ 100) Skin Corr. 1C, H314

Note B: Some substances (acids, bases, etc.) are placed on the market in aqueous solutions at various concentrations and, therefore, these solutions require different classification and labelling since the hazards vary at different concentrations. In Part 3 entries with Note B have a general designation of the following type: '... %'. In this case the supplier must state the percentage concentration of the solution on the label. Unless otherwise stated, it is assumed that the percentage concentration is calculated on a weight/weight basis.

Full text of H- and EUH-statements: see section 16

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

First-aid measures general	: In all cases of doubt, or when symptoms persist, seek medical attention.
First-aid measures after inhalation	: Remove person to fresh air and keep comfortable for breathing.
First-aid measures after skin contact	: Take off contaminated clothing. Wash skin with plenty of water. If skin irritation or rash occurs: Get medical advice/attention.
First-aid measures after eye contact	: Rinse eyes with water as a precaution.
First-aid measures after ingestion	: Call a poison center or a doctor if you feel unwell.

### 4.2. Most important symptoms and effects, both acute and delayed

Symptoms/effects after skin contact	: May cause an allergic skin reaction.
-------------------------------------	----------------------------------------

### 4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

## SECTION 5: Firefighting measures

### 5.1. Extinguishing media

Suitable extinguishing media	: Use extinguishing media appropriate for surrounding fire. Water spray. Dry powder. Foam. Carbon dioxide.
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# [CONJ IgG]

## Safety Data Sheet

According to REACH Regulation (EC) No 1907/2006, as retained and amended in UK law

Unsuitable extinguishing media : Strong water jet.

### 5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire : Toxic fumes may be released. release of harmful/irritant gases/vapours. Carbon monoxide. Carbon dioxide (CO<sub>2</sub>). Nitrogen oxides. Sulphur oxides.

### 5.3. Advice for firefighters

Protection during firefighting : Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.

Other information : Cool closed containers exposed to fire with water spray. Do not allow run-off from fire fighting to enter drains or water courses. Disposal must be done according to official regulations.

## SECTION 6: Accidental release measures

### 6.1. Personal precautions, protective equipment and emergency procedures

#### 6.1.1. For non-emergency personnel

Emergency procedures : Ventilate spillage area. Avoid contact with skin and eyes.

#### 6.1.2. For emergency responders

Protective equipment : Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

### 6.2. Environmental precautions

Prevent entry to sewers and public waters. Avoid sub-soil penetration.

### 6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Take up liquid spill into absorbent material. Take up mechanically (sweeping, shovelling) and collect in suitable container for disposal.

Other information : Dispose of materials or solid residues at an authorized site. Disposal must be done according to official regulations.

### 6.4. Reference to other sections

Information for safe handling. See section 7. Concerning personal protective equipment to use, see section 8. For further information refer to section 13.

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

Precautions for safe handling : Ensure good ventilation of the work station. Wear personal protective equipment. Avoid contact with skin and eyes. Avoid breathing mist, vapours, spray.

Hygiene measures : Contaminated work clothing should not be allowed out of the workplace. Wash contaminated clothing before reuse. Do not eat, drink or smoke when using this product. Always wash hands after handling the product.

### 7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in a well-ventilated place. Keep cool.

Information about storage in one common storage facility : Keep away from food, drink and animal feeding stuffs.

### 7.3. Specific end use(s)

In vitro diagnostics.



# [CONJ IgG]

## Safety Data Sheet

According to REACH Regulation (EC) No 1907/2006, as retained and amended in UK law

### SECTION 8: Exposure controls/personal protection

#### 8.1. Control parameters

##### 8.1.1 National occupational exposure and biological limit values

No additional information available

##### 8.1.2. Recommended monitoring procedures

No additional information available

##### 8.1.3. Air contaminants formed

No additional information available

##### 8.1.4. DNEL and PNEC

reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) (55965-84-9)	
<b>DNEL/DMEL (Workers)</b>	
Acute - local effects, inhalation	0.04 mg/m <sup>3</sup>
Long-term - local effects, inhalation	0.02 mg/m <sup>3</sup>
<b>DNEL/DMEL (General population)</b>	
Acute - systemic effects, oral	0.11 mg/kg bodyweight
Acute - local effects, inhalation	0.04 mg/m <sup>3</sup>
Long-term - systemic effects, oral	0.09 mg/kg bodyweight/day
Long-term - local effects, inhalation	0.02 mg/m <sup>3</sup>
<b>PNEC (Water)</b>	
PNEC aqua (freshwater)	0.00339 mg/l
PNEC aqua (marine water)	0.00339 mg/l
PNEC aqua (intermittent, freshwater)	0.00339 mg/l
PNEC aqua (intermittent, marine water)	0.00339 mg/l
<b>PNEC (Sediment)</b>	
PNEC sediment (freshwater)	0.027 mg/kg dwt
PNEC sediment (marine water)	0.027 mg/kg dwt
<b>PNEC (Soil)</b>	
PNEC soil	0.01 mg/kg dwt
<b>PNEC (STP)</b>	
PNEC sewage treatment plant	0.23 mg/l

##### 8.1.5. Control banding

No additional information available

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## Safety Data Sheet

According to REACH Regulation (EC) No 1907/2006, as retained and amended in UK law

### 8.2. Exposure controls

#### 8.2.1. Appropriate engineering controls

**Appropriate engineering controls:**

Ensure good ventilation of the work station.

#### 8.2.2. Personal protection equipment

##### 8.2.2.1. Eye and face protection

**Eye protection:**

Use splash goggles when eye contact due to splashing is possible. ISO 16321-1

##### 8.2.2.2. Skin protection

**Skin and body protection:**

Wear suitable protective clothing. EN ISO 13688. EN 13034

**Hand protection:**

Chemically resistant protective gloves. ISO 374-1. Nitrile rubber. Please follow the instructions related to the permeability and the penetration time provided by the manufacturer. Choosing the proper glove is a decision that depends not only on the type of material, but also on other quality features, which differ for each manufacturer. Gloves must be replaced after each use and whenever signs of wear or perforation appear

##### 8.2.2.3. Respiratory protection

**Respiratory protection:**

In case of inadequate ventilation wear respiratory protection. In case of unintended release: Particle filter. P2. EN 143. In case of insufficient ventilation, wear suitable respiratory equipment. . Breathing apparatus with filter. Breathing equipment is only to be used in order to handle the residual risk of short term jobs if all other risk minimizing measures have been carried out e.g. retention and/or local exhaust

##### 8.2.2.4. Thermal hazards

No additional information available

#### 8.2.3. Environmental exposure controls

**Environmental exposure controls:**

Avoid release to the environment.

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Colour	: Green.
Odour	: odourless.
Odour threshold	: Not available
Melting point	: Not applicable
Freezing point	: Not available
Boiling point	: Not available
Flammability	: Not applicable
Explosive properties	: No data available. Product is not explosive.
Oxidising properties	: Non oxidizing.
Explosive limits	: Not available
Lower explosion limit	: Not available
Upper explosion limit	: Not available
Flash point	: Not available
Auto-ignition temperature	: Not available
Decomposition temperature	: Not available
pH	: 7 – 7.2 (20 °C)
Viscosity, kinematic	: (No available data)
Viscosity, dynamic	: (No available data)
Solubility	: Water: Soluble
Partition coefficient n-octanol/water (Log Kow)	: Not available
Vapour pressure	: Not available
Vapour pressure at 50°C	: Not available
Density	: Not available

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## Safety Data Sheet

According to REACH Regulation (EC) No 1907/2006, as retained and amended in UK law

Relative density : Not available  
Relative vapour density at 20°C : Not available  
Particle characteristics : Not applicable

### 9.2. Other information

#### 9.2.1. Information with regard to physical hazard classes

No additional information available

#### 9.2.2. Other safety characteristics

No additional information available

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

### 10.2. Chemical stability

Stable under normal conditions.

### 10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

### 10.4. Conditions to avoid

None under recommended storage and handling conditions (see section 7).

### 10.5. Incompatible materials

No additional information available.

### 10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

## SECTION 11: Toxicological information

### 11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity (oral) : Not classified (Based on available data, the classification criteria are not met)  
Acute toxicity (dermal) : Not classified (Based on available data, the classification criteria are not met)  
Acute toxicity (inhalation) : Not classified (Based on available data, the classification criteria are not met)

reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) (55965-84-9)	
LD50 oral rat	64 mg/kg bodyweight (male)
LD50 dermal rabbit	87.12 mg/kg bodyweight (Active substance; male)
LC50 Inhalation - Rat (Dust/Mist)	0.33 mg/l/4h (Active substance; (OECD 403 method))

Skin corrosion/irritation : Not classified (No data available. Based on available data, the classification criteria are not met)  
pH: 7 – 7.2 (20 °C)

Serious eye damage/irritation : Not classified (No data available. Based on available data, the classification criteria are not met)  
pH: 7 – 7.2 (20 °C)

Respiratory or skin sensitisation : May cause an allergic skin reaction.

Germ cell mutagenicity : Not classified (No data available. Based on available data, the classification criteria are not met)

Carcinogenicity : Not classified (No data available. Based on available data, the classification criteria are not met)

Reproductive toxicity : Not classified (No data available. Based on available data, the classification criteria are not met)

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STOT-single exposure	: Not classified (No data available. Based on available data, the classification criteria are not met)
STOT-repeated exposure	: Not classified (No data available. Based on available data, the classification criteria are not met)
Aspiration hazard	: Not classified (Based on available data, the classification criteria are not met)

<b>IgG-Conjugate (anti-human)</b>	
Viscosity, kinematic	(No available data)

### 11.2. Information on other hazards

No additional information available

## SECTION 12: Ecological information

### 12.1. Toxicity

Ecology - general	: The product has not been tested.
Hazardous to the aquatic environment, short-term (acute)	: Not classified (Based on available data, the classification criteria are not met)
Hazardous to the aquatic environment, long-term (chronic)	: Not classified (Based on available data, the classification criteria are not met)

<b>reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) (55965-84-9)</b>	
LC50 - Fish [1]	0.19 mg/l (96 h; Oncorhynchus mykiss; EPA OPP 72-1)
EC50 - Crustacea [1]	0.18 mg/l (48 h; Daphnia magna; EPA OPP 72-2)
ErC50 algae	0.0063 mg/l (72 h; Skeletonema costatum (marine diatom); (OECD 201 method))
NOEC chronic fish	0.098 mg/l (28 d; Oncorhynchus mykiss; (OECD 215 method))
NOEC chronic crustacea	0.328 mg/l (21 d; Daphnia magna; (OECD 211 method))
NOEC chronic algae	0.0005 mg/l (48 h; Skeletonema costatum (marine diatom); (OECD 201 method))

### 12.2. Persistence and degradability

<b>IgG-Conjugate (anti-human)</b>	
Persistence and degradability	No additional information available.
<b>reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) (55965-84-9)</b>	
Persistence and degradability	Not readily biodegradable. Readily biodegradable, failing 10-d window.
Biodegradation	62 % (29 d; (OECD 301B method))

### 12.3. Bioaccumulative potential

<b>IgG-Conjugate (anti-human)</b>	
Bioaccumulative potential	No additional information available.
<b>reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) (55965-84-9)</b>	
Bioconcentration factor (BCF REACH)	≈ 41 (20 °C; 0.12 mg/L; EPA OPP 165-4)
Partition coefficient n-octanol/water (Log Pow)	-0.32 – 0.7 (20 °C; (OECD 117 method))

### 12.4. Mobility in soil

<b>IgG-Conjugate (anti-human)</b>	
Ecology - soil	No additional information available.

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reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) (55965-84-9)	
Surface tension	73 mN/m (19.5 °C; 1 g/L; Test method EU A.5)
Ecology - soil	Low mobility (soil).

### 12.5. Results of PBT and vPvB assessment

IgG-Conjugate (anti-human)	
This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII	
This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII	
Component	
sodium chloride (7647-14-5)	This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII
calcium chloride (10043-52-4)	This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII
reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) (55965-84-9)	This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

### 12.6. Endocrine disrupting properties

No additional information available

### 12.7. Other adverse effects

Other adverse effects : No additional information available.

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

Waste treatment methods : Disposal must be done according to official regulations. European waste catalogue. Do not discharge into drains or the environment. Do not dispose of with domestic waste.

Product/Packaging disposal recommendations : Comply with local regulations for disposal. Recycle or dispose of in compliance with current legislation.

## SECTION 14: Transport information

In accordance with ADR / IMDG / IATA / ADN / RID

# [CONJ IgG]

## Safety Data Sheet

According to REACH Regulation (EC) No 1907/2006, as retained and amended in UK law

ADR	IMDG	IATA	ADN	RID
<b>14.1. UN number or ID number</b>				
Not applicable	Not regulated	Not regulated	Not applicable	Not applicable
<b>14.2. UN proper shipping name</b>				
Not applicable	Not regulated	Not regulated	Not applicable	Not applicable
<b>14.3. Transport hazard class(es)</b>				
Not applicable	Not regulated	Not regulated	Not applicable	Not applicable
<b>14.4. Packing group</b>				
Not applicable	Not regulated	Not regulated	Not applicable	Not applicable
<b>14.5. Environmental hazards</b>				
Not applicable	Not regulated	Not regulated	Not applicable	Not applicable
No supplementary information available				

### 14.6. Special precautions for user

#### Overland transport

Not applicable

#### Transport by sea

Not regulated

#### Air transport

Not regulated

#### Inland waterway transport

Not applicable

#### Rail transport

Not applicable

### 14.7. Maritime transport in bulk according to IMO instruments

Not applicable

## SECTION 15: Regulatory information

### 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

#### 15.1.1. EU-Regulations

Other information, restriction and prohibition regulations

: This product is a medical device and has not to be classified and labelled according to the current laws and regulations.

#### REACH Annex XVII (Restriction List)

##### EU restriction list (REACH Annex XVII)

Reference code	Applicable on
3(b)	IgG-Conjugate (anti-human) ; reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)
3(c)	reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)

#### REACH Annex XIV (Authorisation List)

Contains no substance(s) listed on REACH Annex XIV (Authorisation List)

# [CONJ IgG]

## Safety Data Sheet

According to REACH Regulation (EC) No 1907/2006, as retained and amended in UK law

### REACH Candidate List (SVHC)

Contains no substance(s) listed on the REACH Candidate List

### PIC Regulation (Prior Informed Consent)

Contains no substance(s) listed on the PIC list (Regulation EU 649/2012 concerning the export and import of hazardous chemicals)

### POP Regulation (Persistent Organic Pollutants)

Contains no substance(s) listed on the POP list (Regulation EU 2019/1021 on persistent organic pollutants)

### Ozone Regulation (1005/2009)

Contains no substance(s) listed on the Ozone Depletion list (Regulation EU 1005/2009 on substances that deplete the ozone layer)

### Explosives Precursors Regulation (2019/1148)

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

### Drug Precursors Regulation (273/2004)

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

### 15.1.2. National regulations

No additional information available

### 15.2. Chemical safety assessment

No chemical safety assessment has been carried out

No chemical safety assessment has been carried out

## SECTION 16: Other information

### Indication of changes

Section	Changed item	Change	Comments
	General revision		
2.1	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Modified	
2.2	Labelling according to Regulation (EC) No. 1272/2008 [CLP]	Modified	
11.1	Toxicological information	Modified	
15.1	REACH Annex XVII	Modified	

### Abbreviations and acronyms:

ADN	Accord européen relatif au transport international des marchandises dangereuses par voie de navigation intérieure (European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways)
ADR	Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
IATA	International Air Transport Association
IMDG	International Maritime Code for Dangerous Goods
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
ATE	Acute Toxicity Estimate
BCF	Bioconcentration factor
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008
DMEL	Derived Minimal Effect level
DNEL	Derived-No Effect Level

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EC50	Median effective concentration
IARC	International Agency for Research on Cancer
IATA	International Air Transport Association
IMDG	International Maritime Dangerous Goods
LC50	Median lethal concentration
LD50	Median lethal dose
LOAEL	Lowest Observed Adverse Effect Level
NOAEC	No-Observed Adverse Effect Concentration
NOAEL	No-Observed Adverse Effect Level
NOEC	No-Observed Effect Concentration
OECD	Organisation for Economic Co-operation and Development
PBT	Persistent Bioaccumulative Toxic
PNEC	Predicted No-Effect Concentration
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
SDS	Safety Data Sheet
STP	Sewage treatment plant
TLM	Median Tolerance Limit
vPvB	Very Persistent and Very Bioaccumulative
CAS-No.	Chemical Abstract Service number

Data sources : Information provided by the manufacturer. MSDS of the supplier. European Chemicals Agency, <http://echa.europa.eu/>.

Department issuing data specification sheet: : KFT Chemieservice GmbH  
Im Leuschnerpark 3  
D-64347 Griesheim

Phone: +49 6155-8981-400  
Fax: +49 6155 8981-500  
SDS Service: +49 6155 8981-522

Contact person : Dr. Andreas Kretzschmar

Other information : This safety data sheet is for informational purposes only and does not comply with national legal requirements without reference to a national distributor. The national distributor is responsible for a legally compliant safety data sheet.

### Full text of H- and EUH-statements:

Acute Tox. 2 (Dermal)	Acute toxicity (dermal), Category 2
Acute Tox. 2 (Inhalation)	Acute toxicity (inhal.), Category 2
Acute Tox. 3 (Oral)	Acute toxicity (oral), Category 3
Aquatic Acute 1	Hazardous to the aquatic environment – Acute Hazard, Category 1
Aquatic Chronic 1	Hazardous to the aquatic environment – Chronic Hazard, Category 1
EUH071	Corrosive to the respiratory tract.
Eye Dam. 1	Serious eye damage/eye irritation, Category 1
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
H301	Toxic if swallowed.
H310	Fatal in contact with skin.



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## Safety Data Sheet

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H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H330	Fatal if inhaled.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
Skin Corr. 1C	Skin corrosion/irritation, Category 1, Sub-Category 1C
Skin Irrit. 2	Skin corrosion/irritation, Category 2
Skin Sens. 1	Skin sensitisation, Category 1
Skin Sens. 1A	Skin sensitisation, category 1A

### Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:

Skin Sens. 1	H317	Calculation method
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KFT SDS EU 00

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

# [CONJ IgM]

## Safety Data Sheet

According to REACH Regulation (EC) No 1907/2006, as retained and amended in UK law  
 Issue date: 20/09/2023 Revision date: 20/09/2023 Supersedes version of: 24/01/2023 Version: 6.00

### SECTION 1: Identification of the substance/mixture and of the company/undertaking

#### 1.1. Product identifier

Trade name : [CONJ IgM]

#### 1.2. Relevant identified uses of the substance or mixture and uses advised against

##### 1.2.1. Relevant identified uses

Use of the substance/mixture : In vitro diagnostics

##### 1.2.2. Uses advised against

No additional information available

#### 1.3. Details of the supplier of the safety data sheet

##### Supplier

Virotech Diagnostics GmbH  
 Waldstraße 23 A2  
 DE- 63128 Dietzenbach  
 Deutschland  
 T +49 6074 236980  
[qualitymanagement@virotechdiagnostics.com](mailto:qualitymanagement@virotechdiagnostics.com)

##### Email competent person

sds@kft.de

#### 1.4. Emergency telephone number

Country	Organisation/Company	Address	Emergency number	Comment
United Kingdom	National Health Service (NHS) England / Scotland / Wales / Northern Ireland	-	England / Scotland: 111 Wales: 111 or 0845 46 47 Northern Ireland: call your local General Practitioner. For life-threatening emergencies: call 999 for an ambulance.	24 h medical helpline for general public

### SECTION 2: Hazards identification

#### 2.1. Classification of the substance or mixture

##### Classification according to Regulation (EC) No. 1272/2008 [CLP]

Skin sensitisation, Category 1 H317

Full text of H- and EUH-statements: see section 16

##### Adverse physicochemical, human health and environmental effects

May cause an allergic skin reaction.

#### 2.2. Label elements

##### Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP) :



GHS07

Signal word (CLP) :

Warning

Contains :

reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)

Hazard statements (CLP) :

H317 - May cause an allergic skin reaction.

# [CONJ IgM]

## Safety Data Sheet

According to REACH Regulation (EC) No 1907/2006, as retained and amended in UK law

Precautionary statements (CLP) : P261 - Avoid breathing mist, vapours, spray.  
P280 - Wear protective gloves, protective clothing, eye protection.  
P333+P313 - If skin irritation or rash occurs: Get medical advice/attention.  
P362+P364 - Take off contaminated clothing and wash it before reuse.

### 2.3. Other hazards

Contains no PBT/vPvB substances  $\geq 0.1\%$  assessed in accordance with REACH Annex XIII

Component	
reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) (55965-84-9)	This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

## SECTION 3: Composition/information on ingredients

### 3.1. Substances

Not applicable

### 3.2. Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) (Note B)	CAS-No.: 55965-84-9 EC Index-No.: 613-167-00-5	0.001 – 0.0025	Acute Tox. 2 (Inhalation), H330 (ATE=0.33 mg/l/4h) Acute Tox. 2 (Dermal), H310 (ATE=87.12 mg/kg bodyweight) Acute Tox. 3 (Oral), H301 (ATE=64 mg/kg bodyweight) Skin Corr. 1C, H314 Eye Dam. 1, H318 Skin Sens. 1A, H317 Aquatic Acute 1, H400 (M=100) Aquatic Chronic 1, H410 (M=100) EUH071

### Specific concentration limits:

Name	Product identifier	Specific concentration limits
reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)	CAS-No.: 55965-84-9 EC Index-No.: 613-167-00-5	( 0.0015 $\leq$ C $\leq$ 100) Skin Sens. 1A, H317 ( 0.06 $\leq$ C < 0.6) Eye Irrit. 2, H319 ( 0.06 $\leq$ C < 0.6) Skin Irrit. 2, H315 ( 0.6 $\leq$ C $\leq$ 100) Eye Dam. 1, H318 ( 0.6 $\leq$ C $\leq$ 100) Skin Corr. 1C, H314

Note B: Some substances (acids, bases, etc.) are placed on the market in aqueous solutions at various concentrations and, therefore, these solutions require different classification and labelling since the hazards vary at different concentrations. In Part 3 entries with Note B have a general designation of the following type: '... %'. In this case the supplier must state the percentage concentration of the solution on the label. Unless otherwise stated, it is assumed that the percentage concentration is calculated on a weight/weight basis.

Full text of H- and EUH-statements: see section 16

# [CONJ IgM]

## Safety Data Sheet

According to REACH Regulation (EC) No 1907/2006, as retained and amended in UK law

### SECTION 4: First aid measures

#### 4.1. Description of first aid measures

First-aid measures general	: In all cases of doubt, or when symptoms persist, seek medical attention.
First-aid measures after inhalation	: Remove person to fresh air and keep comfortable for breathing.
First-aid measures after skin contact	: Wash skin with plenty of water. Take off contaminated clothing. If skin irritation or rash occurs: Get medical advice/attention.
First-aid measures after eye contact	: Rinse eyes with water as a precaution.
First-aid measures after ingestion	: Call a poison center or a doctor if you feel unwell.

#### 4.2. Most important symptoms and effects, both acute and delayed

Symptoms/effects after skin contact	: May cause an allergic skin reaction.
-------------------------------------	----------------------------------------

#### 4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

### SECTION 5: Firefighting measures

#### 5.1. Extinguishing media

Suitable extinguishing media	: Use extinguishing media appropriate for surrounding fire. Water spray. Dry powder. Foam. Carbon dioxide.
Unsuitable extinguishing media	: Strong water jet.

#### 5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire	: Toxic fumes may be released. Carbon dioxide. Carbon monoxide.
--------------------------------------------------	-----------------------------------------------------------------

#### 5.3. Advice for firefighters

Protection during firefighting	: Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.
Other information	: Do not allow run-off from fire fighting to enter drains or water courses. Disposal must be done according to official regulations.

### SECTION 6: Accidental release measures

#### 6.1. Personal precautions, protective equipment and emergency procedures

##### 6.1.1. For non-emergency personnel

Emergency procedures	: Ventilate spillage area. Avoid contact with skin and eyes. Avoid breathing mist, vapours, spray.
----------------------	----------------------------------------------------------------------------------------------------

##### 6.1.2. For emergency responders

Protective equipment	: Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".
----------------------	-------------------------------------------------------------------------------------------------------------------------------------------------------------

#### 6.2. Environmental precautions

Avoid sub-soil penetration. Prevent entry to sewers and public waters. Notify authorities if product enters sewers or public waters.

#### 6.3. Methods and material for containment and cleaning up

Methods for cleaning up	: Take up liquid spill into absorbent material. Take up mechanically (sweeping, shovelling) and collect in suitable container for disposal.
Other information	: Disposal must be done according to official regulations.

#### 6.4. Reference to other sections

Information for safe handling. See section 7. Concerning personal protective equipment to use, see section 8. For further information refer to section 13.

# [CONJ IgM]

## Safety Data Sheet

According to REACH Regulation (EC) No 1907/2006, as retained and amended in UK law

### SECTION 7: Handling and storage

#### 7.1. Precautions for safe handling

- Precautions for safe handling : Ensure good ventilation of the work station. Wear personal protective equipment. Avoid contact with skin and eyes. Avoid breathing mist, vapours, spray.
- Hygiene measures : Do not eat, drink or smoke when using this product. Always wash hands after handling the product. Contaminated work clothing should not be allowed out of the workplace. Wash contaminated clothing before reuse.

#### 7.2. Conditions for safe storage, including any incompatibilities

- Storage conditions : Store in a well-ventilated place. Keep cool.
- Information about storage in one common storage facility : Keep away from food, drink and animal feeding stuffs.

#### 7.3. Specific end use(s)

In vitro diagnostics.

### SECTION 8: Exposure controls/personal protection

#### 8.1. Control parameters

##### 8.1.1 National occupational exposure and biological limit values

No additional information available

##### 8.1.2. Recommended monitoring procedures

No additional information available

##### 8.1.3. Air contaminants formed

No additional information available

##### 8.1.4. DNEL and PNEC

No additional information available

##### 8.1.5. Control banding

No additional information available

#### 8.2. Exposure controls

##### 8.2.1. Appropriate engineering controls

###### Appropriate engineering controls:

Ensure good ventilation of the work station.

##### 8.2.2. Personal protection equipment

###### 8.2.2.1. Eye and face protection

###### Eye protection:

Use splash goggles when eye contact due to splashing is possible. ISO 16321-1

###### 8.2.2.2. Skin protection

###### Skin and body protection:

Wear suitable protective clothing. EN ISO 13688. EN 13034

# [CONJ IgM]

## Safety Data Sheet

According to REACH Regulation (EC) No 1907/2006, as retained and amended in UK law

### Hand protection:

Chemically resistant protective gloves. ISO 374-1. Nitrile rubber. Choosing the proper glove is a decision that depends not only on the type of material, but also on other quality features, which differ for each manufacturer. Please follow the instructions related to the permeability and the penetration time provided by the manufacturer. Gloves must be replaced after each use and whenever signs of wear or perforation appear

### 8.2.2.3. Respiratory protection

#### Respiratory protection:

In case of insufficient ventilation, wear suitable respiratory equipment. In case of unintended release: Breathing apparatus with filter. Particle filter. P2. EN 143. . Breathing equipment is only to be used in order to handle the residual risk of short term jobs if all other risk minimizing measures have been carried out e.g. retention and/or local exhaust

### 8.2.2.4. Thermal hazards

No additional information available

### 8.2.3. Environmental exposure controls

#### Environmental exposure controls:

Avoid release to the environment.

#### Other information:

Do not eat, drink or smoke when using this product. Avoid contact with skin and eyes. Always wash hands after handling the product.

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Colour	: red.
Odour	: odourless.
Odour threshold	: Not available
Melting point	: Not available
Freezing point	: Not available
Boiling point	: Not available
Flammability	: Not applicable
Explosive properties	: Product is not explosive.
Oxidising properties	: Non oxidizing.
Explosive limits	: Not available
Lower explosion limit	: Not available
Upper explosion limit	: Not available
Flash point	: Not available
Auto-ignition temperature	: Not available
Decomposition temperature	: Not available
pH	: 7.5 – 7.7 (20 °C)
Viscosity, kinematic	: Not available
Solubility	: Water: Soluble
Partition coefficient n-octanol/water (Log Kow)	: Not available
Vapour pressure	: Not available
Vapour pressure at 50°C	: Not available
Density	: Not available
Relative density	: Not available
Relative vapour density at 20°C	: Not available
Particle characteristics	: Not applicable

### 9.2. Other information

#### 9.2.1. Information with regard to physical hazard classes

No additional information available

#### 9.2.2. Other safety characteristics

No additional information available

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## Safety Data Sheet

According to REACH Regulation (EC) No 1907/2006, as retained and amended in UK law

### SECTION 10: Stability and reactivity

#### 10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

#### 10.2. Chemical stability

Stable under normal conditions.

#### 10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

#### 10.4. Conditions to avoid

No additional information available

#### 10.5. Incompatible materials

No additional information available.

#### 10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

### SECTION 11: Toxicological information

#### 11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity (oral) : Not classified (Based on available data, the classification criteria are not met)  
Acute toxicity (dermal) : Not classified (Based on available data, the classification criteria are not met)  
Acute toxicity (inhalation) : Not classified (Based on available data, the classification criteria are not met)

#### reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) (55965-84-9)

LD50 oral rat	64 mg/kg bodyweight (male)
LD50 dermal rabbit	87.12 mg/kg bodyweight (Active substance; male)
LC50 Inhalation - Rat (Dust/Mist)	0.33 mg/l/4h (Active substance; (OECD 403 method))

Skin corrosion/irritation : Not classified (Based on available data, the classification criteria are not met)  
pH: 7.5 – 7.7 (20 °C)  
Serious eye damage/irritation : Not classified (Based on available data, the classification criteria are not met)  
pH: 7.5 – 7.7 (20 °C)  
Respiratory or skin sensitisation : May cause an allergic skin reaction.  
Germ cell mutagenicity : Not classified (Based on available data, the classification criteria are not met)  
Carcinogenicity : Not classified (Based on available data, the classification criteria are not met)  
Reproductive toxicity : Not classified (Based on available data, the classification criteria are not met)  
STOT-single exposure : Not classified (Based on available data, the classification criteria are not met)  
STOT-repeated exposure : Not classified (Based on available data, the classification criteria are not met)  
Aspiration hazard : Not classified (Based on available data, the classification criteria are not met)

#### 11.2. Information on other hazards

No additional information available

### SECTION 12: Ecological information

#### 12.1. Toxicity

Ecology - general : The product has not been tested.  
Hazardous to the aquatic environment, short-term (acute) : Not classified (Based on available data, the classification criteria are not met)

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## Safety Data Sheet

According to REACH Regulation (EC) No 1907/2006, as retained and amended in UK law

Hazardous to the aquatic environment, long-term (chronic) : Not classified (Based on available data, the classification criteria are not met)

reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) (55965-84-9)	
LC50 - Fish [1]	0.19 mg/l (96 h; Oncorhynchus mykiss; EPA OPP 72-1)
EC50 - Crustacea [1]	0.18 mg/l (48 h; Daphnia magna; EPA OPP 72-2)
ErC50 algae	0.0063 mg/l (72 h; Skeletonema costatum (marine diatom); (OECD 201 method))
NOEC chronic fish	0.098 mg/l (28 d; Oncorhynchus mykiss; (OECD 215 method))
NOEC chronic crustacea	0.328 mg/l (21 d; Daphnia magna; (OECD 211 method))
NOEC chronic algae	0.0005 mg/l (48 h; Skeletonema costatum (marine diatom); (OECD 201 method))

### 12.2. Persistence and degradability

reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) (55965-84-9)	
Persistence and degradability	Not readily biodegradable. Readily biodegradable, failing 10-d window.
Biodegradation	62 % (29 d; (OECD 301B method))

### 12.3. Bioaccumulative potential

IgM-Conjugate (anti-human)	
Bioaccumulative potential	No additional information available.

reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) (55965-84-9)	
Bioconcentration factor (BCF REACH)	≈ 41 (20 °C; 0.12 mg/L; EPA OPP 165-4)
Partition coefficient n-octanol/water (Log Pow)	-0.32 – 0.7 (20 °C; (OECD 117 method))

### 12.4. Mobility in soil

IgM-Conjugate (anti-human)	
Ecology - soil	No additional information available.

reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) (55965-84-9)	
Surface tension	73 mN/m (19.5 °C; 1 g/L; Test method EU A.5)
Ecology - soil	Low mobility (soil).

### 12.5. Results of PBT and vPvB assessment

Component	
reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) (55965-84-9)	This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

### 12.6. Endocrine disrupting properties

No additional information available

### 12.7. Other adverse effects

Other adverse effects : No additional information available.



# [CONJ IgM]

## Safety Data Sheet

According to REACH Regulation (EC) No 1907/2006, as retained and amended in UK law

### SECTION 13: Disposal considerations

#### 13.1. Waste treatment methods

Waste treatment methods : Disposal must be done according to official regulations. European waste catalogue. Do not discharge into drains or the environment. Do not dispose of with domestic waste.

Product/Packaging disposal recommendations : Recycle or dispose of in compliance with current legislation.

### SECTION 14: Transport information

In accordance with ADR / IMDG / IATA / ADN / RID

ADR	IMDG	IATA	ADN	RID
<b>14.1. UN number or ID number</b>				
Not applicable	Not regulated	Not regulated	Not applicable	Not applicable
<b>14.2. UN proper shipping name</b>				
Not applicable	Not regulated	Not regulated	Not applicable	Not applicable
<b>14.3. Transport hazard class(es)</b>				
Not applicable	Not regulated	Not regulated	Not applicable	Not applicable
<b>14.4. Packing group</b>				
Not applicable	Not regulated	Not regulated	Not applicable	Not applicable
<b>14.5. Environmental hazards</b>				
Not applicable	Not regulated	Not regulated	Not applicable	Not applicable
No supplementary information available				

#### 14.6. Special precautions for user

##### Overland transport

Not applicable

##### Transport by sea

Not regulated

##### Air transport

Not regulated

##### Inland waterway transport

Not applicable

##### Rail transport

Not applicable

#### 14.7. Maritime transport in bulk according to IMO instruments

Not applicable

### SECTION 15: Regulatory information

#### 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

##### 15.1.1. EU-Regulations

Other information, restriction and prohibition regulations : This product is a medical device and has not to be classified and labelled according to the current laws and regulations. Take note of Directive 94/33/EC on the protection of young people at work.

# [CONJ IgM]

## Safety Data Sheet

According to REACH Regulation (EC) No 1907/2006, as retained and amended in UK law

### REACH Annex XVII (Restriction List)

EU restriction list (REACH Annex XVII)	
Reference code	Applicable on
3(b)	IgM-Conjugate (anti-human) ; reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)
3(c)	reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)

### REACH Annex XIV (Authorisation List)

Contains no substance(s) listed on REACH Annex XIV (Authorisation List)

### REACH Candidate List (SVHC)

Contains no substance(s) listed on the REACH Candidate List

### PIC Regulation (Prior Informed Consent)

Contains no substance(s) listed on the PIC list (Regulation EU 649/2012 concerning the export and import of hazardous chemicals)

### POP Regulation (Persistent Organic Pollutants)

Contains no substance(s) listed on the POP list (Regulation EU 2019/1021 on persistent organic pollutants)

### Ozone Regulation (1005/2009)

Contains no substance(s) listed on the Ozone Depletion list (Regulation EU 1005/2009 on substances that deplete the ozone layer)

### Explosives Precursors Regulation (2019/1148)

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

### Drug Precursors Regulation (273/2004)

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

### 15.1.2. National regulations

No additional information available

### 15.2. Chemical safety assessment

No chemical safety assessment has been carried out

## SECTION 16: Other information

Indication of changes			
Section	Changed item	Change	Comments
	General revision		
2.1	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Modified	
2.2	Labelling according to Regulation (EC) No. 1272/2008 [CLP]	Modified	
12.1	Ecotoxicity	Modified	

### Abbreviations and acronyms:

ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
ATE	Acute Toxicity Estimate
BCF	Bioconcentration factor
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008
DMEL	Derived Minimal Effect level

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DNEL	Derived-No Effect Level
EC50	Median effective concentration
IARC	International Agency for Research on Cancer
IATA	International Air Transport Association
IMDG	International Maritime Dangerous Goods
LC50	Median lethal concentration
LD50	Median lethal dose
LOAEL	Lowest Observed Adverse Effect Level
NOAEC	No-Observed Adverse Effect Concentration
NOAEL	No-Observed Adverse Effect Level
NOEC	No-Observed Effect Concentration
OECD	Organisation for Economic Co-operation and Development
PBT	Persistent Bioaccumulative Toxic
PNEC	Predicted No-Effect Concentration
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
SDS	Safety Data Sheet
STP	Sewage treatment plant
TLM	Median Tolerance Limit
vPvB	Very Persistent and Very Bioaccumulative
CAS-No.	Chemical Abstract Service number

Data sources : Information provided by the manufacturer. MSDS of the supplier. European Chemicals Agency, <http://echa.europa.eu/>.

Department issuing data specification sheet: : KFT Chemieservice GmbH  
Im Leuschnerpark 3  
D-64347 Griesheim

Phone: +49 6155-8981-400  
Fax: +49 6155 8981-500  
SDS Service: +49 6155 8981-522

Contact person : Dr. Andreas Kretzschmar

Other information : This safety data sheet is for informational purposes only and does not comply with national legal requirements without reference to a national distributor. The national distributor is responsible for a legally compliant safety data sheet.

<b>Full text of H- and EUH-statements:</b>	
Acute Tox. 2 (Dermal)	Acute toxicity (dermal), Category 2
Acute Tox. 2 (Inhalation)	Acute toxicity (inhal.), Category 2
Acute Tox. 3 (Oral)	Acute toxicity (oral), Category 3
Aquatic Acute 1	Hazardous to the aquatic environment – Acute Hazard, Category 1
Aquatic Chronic 1	Hazardous to the aquatic environment – Chronic Hazard, Category 1
EUH071	Corrosive to the respiratory tract.
Eye Dam. 1	Serious eye damage/eye irritation, Category 1
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
H301	Toxic if swallowed.

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H310	Fatal in contact with skin.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H330	Fatal if inhaled.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
Skin Corr. 1C	Skin corrosion/irritation, Category 1, Sub-Category 1C
Skin Irrit. 2	Skin corrosion/irritation, Category 2
Skin Sens. 1	Skin sensitisation, Category 1
Skin Sens. 1A	Skin sensitisation, category 1A

### Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:

Skin Sens. 1	H317	Calculation method
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KFT SDS EU 00

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

**SECTION 1: Identification of the substance/mixture and of the company/undertaking****1.1. Product identifier**

Product form : Mixture  
Trade name : [MTP] [MTPR]

**1.2. Relevant identified uses of the substance or mixture and uses advised against****1.2.1. Relevant identified uses**

Use of the substance/mixture : In vitro diagnostics

**1.2.2. Uses advised against**

No additional information available

**1.3. Details of the supplier of the safety data sheet****Supplier**

Virotech Diagnostics GmbH  
Waldstraße 23 A2  
DE- 63128 Dietzenbach  
Deutschland  
T +49 6074 236980  
[qualitymanagement@virotechdiagnostics.com](mailto:qualitymanagement@virotechdiagnostics.com)

**Email competent person**

sds@kft.de

**1.4. Emergency telephone number**

Emergency number : National Health Service (NHS)  
24 hour national number consumer  
England and Scotland: 111  
Wales: 0845 46 47  
Northern Ireland: call your local General Practitioner  
  
Call 999 if there is a life-threatening incident.

**SECTION 2: Hazards identification****2.1. Classification of the substance or mixture****Classification according to Regulation (EC) No. 1272/2008 [CLP]**

Not classified

**Adverse physicochemical, human health and environmental effects**

To our knowledge, this product does not present any particular risk, provided it is handled in accordance with good occupational hygiene and safety practice.

**2.2. Label elements****Labelling according to Regulation (EC) No. 1272/2008 [CLP]**

No labelling applicable

**2.3. Other hazards**

Contains no PBT/vPvB substances  $\geq 0.1\%$  assessed in accordance with REACH Annex XIII

The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %

# [MTP] [MTPR]

## Safety Data Sheet

A safety data sheet is not required for this product. This document was created on a voluntary basis

### SECTION 3: Composition/information on ingredients

#### 3.1. Substances

Not applicable

#### 3.2. Mixtures

This mixture does not contain any substances to be mentioned according to the criteria of section 3.2 of REACH Annex II

### SECTION 4: First aid measures

#### 4.1. Description of first aid measures

First-aid measures general	: In all cases of doubt, or when symptoms persist, seek medical attention.
First-aid measures after inhalation	: Remove person to fresh air and keep comfortable for breathing. Call a doctor.
First-aid measures after skin contact	: Wash skin with plenty of water.
First-aid measures after eye contact	: Rinse eyes with water as a precaution.
First-aid measures after ingestion	: Call a poison center or a doctor if you feel unwell.

#### 4.2. Most important symptoms and effects, both acute and delayed

No additional information available

#### 4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

### SECTION 5: Firefighting measures

#### 5.1. Extinguishing media

Suitable extinguishing media	: Use extinguishing media appropriate for surrounding fire. Water spray. Dry powder. Foam. Carbon dioxide.
Unsuitable extinguishing media	: Strong water jet.

#### 5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire	: Toxic fumes may be released. release of harmful/irritant gases/vapours. Carbon monoxide. Carbon dioxide (CO <sub>2</sub> ). Nitrogen oxides. Sulphur oxides.
--------------------------------------------------	----------------------------------------------------------------------------------------------------------------------------------------------------------------

#### 5.3. Advice for firefighters

Protection during firefighting	: Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.
Other information	: Do not allow run-off from fire fighting to enter drains or water courses. Disposal must be done according to official regulations.

### SECTION 6: Accidental release measures

#### 6.1. Personal precautions, protective equipment and emergency procedures

##### 6.1.1. For non-emergency personnel

Emergency procedures	: Ventilate spillage area.
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##### 6.1.2. For emergency responders

Protective equipment	: Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".
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#### 6.2. Environmental precautions

Avoid release to the environment. Avoid sub-soil penetration. Prevent entry to sewers and public waters.

# [MTP] [MTPR]

## Safety Data Sheet

A safety data sheet is not required for this product. This document was created on a voluntary basis

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### 6.3. Methods and material for containment and cleaning up

- Methods for cleaning up : Take up mechanically (sweeping, shovelling) and collect in suitable container for disposal.  
Other information : Dispose of materials or solid residues at an authorized site. Disposal must be done according to official regulations.

### 6.4. Reference to other sections

Information for safe handling. See section 7. Concerning personal protective equipment to use, see section 8. For further information refer to section 13.

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

- Precautions for safe handling : Ensure good ventilation of the work station. Wear personal protective equipment.  
Hygiene measures : Do not eat, drink or smoke when using this product. Always wash hands after handling the product.

### 7.2. Conditions for safe storage, including any incompatibilities

- Storage conditions : Store in a well-ventilated place. Keep cool.  
Information about storage in one common storage facility : Keep away from food, drink and animal feeding stuffs.

### 7.3. Specific end use(s)

In vitro diagnostics.

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

#### 8.1.1 National occupational exposure and biological limit values

No additional information available

#### 8.1.2. Recommended monitoring procedures

No additional information available

#### 8.1.3. Air contaminants formed

No additional information available

#### 8.1.4. DNEL and PNEC

No additional information available

#### 8.1.5. Control banding

No additional information available

### 8.2. Exposure controls

#### 8.2.1. Appropriate engineering controls

##### Appropriate engineering controls:

Ensure good ventilation of the work station.

#### 8.2.2. Personal protection equipment

##### 8.2.2.1. Eye and face protection

###### Eye protection:

In case of dust production: protective goggles. ISO 16321-1

##### 8.2.2.2. Skin protection

###### Skin and body protection:

Wear suitable protective clothing. EN ISO 13688

# [MTP] [MTPR]

## Safety Data Sheet

A safety data sheet is not required for this product. This document was created on a voluntary basis

### Hand protection:

In case of repeated or prolonged contact wear gloves. Nitrile rubber. ISO 374-1. Choosing the proper glove is a decision that depends not only on the type of material, but also on other quality features, which differ for each manufacturer. Please follow the instructions related to the permeability and the penetration time provided by the manufacturer. Gloves must be replaced after each use and whenever signs of wear or perforation appear

### Other skin protection

#### Materials for protective clothing:

Use protective clothing

#### 8.2.2.3. Respiratory protection

##### Respiratory protection:

In case of insufficient ventilation, wear suitable respiratory equipment. Dust production: dust mask with filter type P2. EN 143. . Breathing equipment is only to be used in order to handle the residual risk of short term jobs if all other risk minimizing measures have been carried out e.g. retention and/or local exhaust

#### 8.2.2.4. Thermal hazards

No additional information available

#### 8.2.3. Environmental exposure controls

##### Environmental exposure controls:

Avoid release to the environment.

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

Physical state	: Solid
Colour	: Transparent.
Odour	: Not available
Odour threshold	: Not available
Melting point	: Not applicable
Freezing point	: Not applicable
Boiling point	: Not available
Flammability	: Not determined.
Explosive properties	: Product is not explosive. Dust may form explosive mixture in air.
Oxidising properties	: Non oxidizing.
Explosive limits	: Not applicable
Lower explosion limit	: Not applicable
Upper explosion limit	: Not applicable
Flash point	: Not applicable
Auto-ignition temperature	: Not applicable
Decomposition temperature	: Not available
pH	: Not available
pH solution	: Not available
Viscosity, kinematic	: Not applicable
Viscosity, dynamic	: Not applicable
Solubility	: Not available
Partition coefficient n-octanol/water (Log Kow)	: Not available
Vapour pressure	: Not applicable
Vapour pressure at 50°C	: Not available
Density	: Not available
Relative density	: Not available
Relative vapour density at 20°C	: Not applicable
Particle size	: Not available
Particle size distribution	: Not available
Particle shape	: Not available
Particle aspect ratio	: Not available
Particle aggregation state	: Not available
Particle agglomeration state	: Not available
Particle specific surface area	: Not available
Particle dustiness	: Not available



# [MTP] [MTPR]

## Safety Data Sheet

A safety data sheet is not required for this product. This document was created on a voluntary basis

### 9.2. Other information

#### 9.2.1. Information with regard to physical hazard classes

No additional information available

#### 9.2.2. Other safety characteristics

Relative evaporation rate (butylacetate=1) : Not applicable

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

### 10.2. Chemical stability

Stable under normal conditions.

### 10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

### 10.4. Conditions to avoid

No additional information available

### 10.5. Incompatible materials

No additional information available.

### 10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

## SECTION 11: Toxicological information

### 11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity (oral)	: Not classified (Based on available data, the classification criteria are not met)
Acute toxicity (dermal)	: Not classified (Based on available data, the classification criteria are not met)
Acute toxicity (inhalation)	: Not classified (Based on available data, the classification criteria are not met)
Skin corrosion/irritation	: Not classified (Based on available data, the classification criteria are not met)
Serious eye damage/irritation	: Not classified (Based on available data, the classification criteria are not met)
Respiratory or skin sensitisation	: Not classified (Based on available data, the classification criteria are not met)
Germ cell mutagenicity	: Not classified (Based on available data, the classification criteria are not met)
Carcinogenicity	: Not classified (Based on available data, the classification criteria are not met)
Reproductive toxicity	: Not classified (Based on available data, the classification criteria are not met)
STOT-single exposure	: Not classified (Based on available data, the classification criteria are not met)
STOT-repeated exposure	: Not classified (Based on available data, the classification criteria are not met)
Aspiration hazard	: Not classified (Not relevant)

#### Microtiter-Plate coated with antigen (teststrips)

Viscosity, kinematic	Not applicable
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### 11.2. Information on other hazards

No additional information available

## SECTION 12: Ecological information

### 12.1. Toxicity

Ecology - general : The product has not been tested.

# [MTP] [MTPR]

## Safety Data Sheet

A safety data sheet is not required for this product. This document was created on a voluntary basis

Hazardous to the aquatic environment, short-term (acute) : Not classified (No data available)

Hazardous to the aquatic environment, long-term (chronic) : Not classified (No data available)

### 12.2. Persistence and degradability

No additional information available

### 12.3. Bioaccumulative potential

Microtiter-Plate coated with antigen (teststrips)	
Bioaccumulative potential	No additional information available.

### 12.4. Mobility in soil

Microtiter-Plate coated with antigen (teststrips)	
Ecology - soil	No additional information available.

### 12.5. Results of PBT and vPvB assessment

No additional information available

### 12.6. Endocrine disrupting properties

No additional information available

### 12.7. Other adverse effects

Other adverse effects : No additional information available

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

Waste treatment methods : Disposal must be done according to official regulations. European waste catalogue. Do not discharge into drains or the environment. Do not dispose of with domestic waste.

Product/Packaging disposal recommendations : Recycle or dispose of in compliance with current legislation.

## SECTION 14: Transport information

In accordance with ADR / IMDG / IATA / ADN / RID

ADR	IMDG	IATA	ADN	RID
<b>14.1. UN number or ID number</b>				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
<b>14.2. UN proper shipping name</b>				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
<b>14.3. Transport hazard class(es)</b>				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
<b>14.4. Packing group</b>				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
<b>14.5. Environmental hazards</b>				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
No supplementary information available				

# [MTP] [MTPR]

## Safety Data Sheet

A safety data sheet is not required for this product. This document was created on a voluntary basis

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### 14.6. Special precautions for user

#### Overland transport

Not applicable

#### Transport by sea

Not applicable

#### Air transport

Not applicable

#### Inland waterway transport

Not applicable

#### Rail transport

Not applicable

### 14.7. Maritime transport in bulk according to IMO instruments

Not applicable

## SECTION 15: Regulatory information

### 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

#### 15.1.1. EU-Regulations

Other information, restriction and prohibition regulations

: This product is a medical device and has not to be classified and labelled according to the current laws and regulations. A safety data sheet is not required for this product under Article 31 of REACH. This Product Safety Information Sheet has been created on a voluntary basis.

#### REACH Annex XVII (Restriction List)

Contains no substance(s) listed on REACH Annex XVII (Restriction Conditions)

#### REACH Annex XIV (Authorisation List)

Contains no substance(s) listed on REACH Annex XIV (Authorisation List)

#### REACH Candidate List (SVHC)

Contains no substance(s) listed on the REACH Candidate List

#### PIC Regulation (Prior Informed Consent)

Contains no substance(s) listed on the PIC list (Regulation EU 649/2012 concerning the export and import of hazardous chemicals)

#### POP Regulation (Persistent Organic Pollutants)

Contains no substance(s) listed on the POP list (Regulation EU 2019/1021 on persistent organic pollutants)

#### Ozone Regulation (1005/2009)

Contains no substance(s) listed on the Ozone Depletion list (Regulation EU 1005/2009 on substances that deplete the ozone layer)

#### Explosives Precursors Regulation (2019/1148)

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

#### Drug Precursors Regulation (273/2004)

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

#### 15.1.2. National regulations

No additional information available

### 15.2. Chemical safety assessment

No chemical safety assessment has been carried out

# [MTP] [MTPR]

## Safety Data Sheet

A safety data sheet is not required for this product. This document was created on a voluntary basis

### SECTION 16: Other information

Indication of changes			
Section	Changed item	Change	Comments
	General revision		
1.1	Trade name	Modified	
1.3	SDS EU addresses	Modified	
2.2	Labelling according to Regulation (EC) No. 1272/2008 [CLP]	Removed	

Abbreviations and acronyms:	
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
ATE	Acute Toxicity Estimate
BCF	Bioconcentration factor
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008
DMEL	Derived Minimal Effect level
DNEL	Derived-No Effect Level
EC50	Median effective concentration
IARC	International Agency for Research on Cancer
IATA	International Air Transport Association
IMDG	International Maritime Dangerous Goods
LC50	Median lethal concentration
LD50	Median lethal dose
LOAEL	Lowest Observed Adverse Effect Level
NOAEC	No-Observed Adverse Effect Concentration
NOAEL	No-Observed Adverse Effect Level
NOEC	No-Observed Effect Concentration
OECD	Organisation for Economic Co-operation and Development
PBT	Persistent Bioaccumulative Toxic
PNEC	Predicted No-Effect Concentration
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
SDS	Safety Data Sheet
STP	Sewage treatment plant
TLM	Median Tolerance Limit
vPvB	Very Persistent and Very Bioaccumulative
CAS-No.	Chemical Abstract Service number

Data sources

: Information provided by the manufacturer. MSDS of the supplier. European Chemicals Agency, <http://echa.europa.eu/>.

# [MTP] [MTPR]

## Safety Data Sheet

A safety data sheet is not required for this product. This document was created on a voluntary basis

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Department issuing data specification sheet: : KFT Chemieservice GmbH  
Im Leuschnerpark 3  
D-64347 Griesheim

Phone: +49 6155-8981-400  
Fax: +49 6155 8981-500  
SDS Service: +49 6155 8981-522

Contact person : Dr. Andreas Kretzschmar

Other information : This safety data sheet is for informational purposes only and does not fully comply with national legal requirements. The national distributor is responsible for a legally compliant safety data sheet.

KFT SDS EU 00

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

### SECTION 1: Identification of the substance/mixture and of the company/undertaking

#### 1.1. Product identifier

Product form : Mixture  
Trade name : [DILBUF RTU]

#### 1.2. Relevant identified uses of the substance or mixture and uses advised against

##### 1.2.1. Relevant identified uses

Use of the substance/mixture : In vitro diagnostics

##### 1.2.2. Uses advised against

No additional information available

#### 1.3. Details of the supplier of the safety data sheet

##### Supplier

Virotech Diagnostics GmbH  
Waldstraße 23 A2  
DE- 63128 Dietzenbach  
Deutschland  
T +49 6074 236980  
[qualitymanagement@virotechdiagnostics.com](mailto:qualitymanagement@virotechdiagnostics.com)

##### Email competent person

sds@kft.de

#### 1.4. Emergency telephone number

Emergency number : National Health Service (NHS)  
24 hour national number consumer  
England and Scotland: 111  
Wales: 0845 46 47  
Northern Ireland: call your local General Practitioner  
  
Call 999 if there is a life-threatening incident.

### SECTION 2: Hazards identification

#### 2.1. Classification of the substance or mixture

##### Classification according to Regulation (EC) No. 1272/2008 [CLP]

Skin sensitisation, Category 1 H317  
Full text of H- and EUH-statements: see section 16

##### Adverse physicochemical, human health and environmental effects

May cause an allergic skin reaction.

#### 2.2. Label elements

##### Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP) :



GHS07

Signal word (CLP) :

Warning

Contains :

reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)

Hazard statements (CLP) :

H317 - May cause an allergic skin reaction.

Precautionary statements (CLP) :

P280 - Wear protective gloves.  
P302+P352 - IF ON SKIN: Wash with plenty of water.  
P333+P313 - If skin irritation or rash occurs: Get medical advice/attention.

# [DILBUF RTU]

## Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

### 2.3. Other hazards

Contains no PBT/vPvB substances  $\geq 0.1\%$  assessed in accordance with REACH Annex XIII

Component	
reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) (55965-84-9)	This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %

## SECTION 3: Composition/information on ingredients

### 3.1. Substances

Not applicable

### 3.2. Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) (Note B)	CAS-No.: 55965-84-9 EC Index-No.: 613-167-00-5	< 0.1	Acute Tox. 2 (Inhalation), H330 (ATE=0.33 mg/l/4h) Acute Tox. 2 (Dermal), H310 (ATE=87.12 mg/kg bodyweight) Acute Tox. 3 (Oral), H301 (ATE=64 mg/kg bodyweight) Skin Corr. 1C, H314 Eye Dam. 1, H318 Skin Sens. 1A, H317 Aquatic Acute 1, H400 (M=100) Aquatic Chronic 1, H410 (M=100) EUH071

### Specific concentration limits:

Name	Product identifier	Specific concentration limits
reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)	CAS-No.: 55965-84-9 EC Index-No.: 613-167-00-5	( 0.0015 $\leq$ C $\leq$ 100) Skin Sens. 1A, H317 ( 0.06 $\leq$ C < 0.6) Eye Irrit. 2, H319 ( 0.06 $\leq$ C < 0.6) Skin Irrit. 2, H315 ( 0.6 $\leq$ C $\leq$ 100) Eye Dam. 1, H318 ( 0.6 $\leq$ C $\leq$ 100) Skin Corr. 1C, H314

Note B : Some substances (acids, bases, etc.) are placed on the market in aqueous solutions at various concentrations and, therefore, these solutions require different classification and labelling since the hazards vary at different concentrations. In Part 3 entries with Note B have a general designation of the following type: 'nitric acid ... %'. In this case the supplier must state the percentage concentration of the solution on the label. Unless otherwise stated, it is assumed that the percentage concentration is calculated on a weight/weight basis.  
Full text of H- and EUH-statements: see section 16

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

First-aid measures general : In all cases of doubt, or when symptoms persist, seek medical attention.  
First-aid measures after inhalation : Remove person to fresh air and keep comfortable for breathing. Call a doctor.

# [DILBUF RTU]

## Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

First-aid measures after skin contact	: Wash skin with plenty of water. Take off contaminated clothing. If skin irritation or rash occurs: Get medical advice/attention.
First-aid measures after eye contact	: Rinse eyes with water as a precaution.
First-aid measures after ingestion	: Call a poison center or a doctor if you feel unwell.

### 4.2. Most important symptoms and effects, both acute and delayed

Symptoms/effects after skin contact	: May cause an allergic skin reaction.
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### 4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

## SECTION 5: Firefighting measures

### 5.1. Extinguishing media

Suitable extinguishing media	: Use extinguishing media appropriate for surrounding fire. Water spray. Dry powder. Foam. Carbon dioxide.
Unsuitable extinguishing media	: Strong water jet.

### 5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire	: Toxic fumes may be released. In traces: Carbon dioxide, Carbon monoxide. Sulphur oxides. Nitrogen oxides.
--------------------------------------------------	-------------------------------------------------------------------------------------------------------------

### 5.3. Advice for firefighters

Protection during firefighting	: Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.
Other information	: Cool closed containers exposed to fire with water spray. Do not allow run-off from fire fighting to enter drains or water courses. Disposal must be done according to official regulations.

## SECTION 6: Accidental release measures

### 6.1. Personal precautions, protective equipment and emergency procedures

#### 6.1.1. For non-emergency personnel

Emergency procedures	: Ventilate spillage area. Avoid contact with skin and eyes. Avoid breathing spray, vapours, mist.
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#### 6.1.2. For emergency responders

Protective equipment	: Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".
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### 6.2. Environmental precautions

Prevent entry to sewers and public waters. Avoid sub-soil penetration. Notify authorities if product enters sewers or public waters.

### 6.3. Methods and material for containment and cleaning up

Methods for cleaning up	: Take up liquid spill into absorbent material. Take up mechanically (sweeping, shovelling) and collect in suitable container for disposal.
Other information	: Dispose of materials or solid residues at an authorized site. Disposal must be done according to official regulations.

### 6.4. Reference to other sections

Information for safe handling. See section 7. Concerning personal protective equipment to use, see section 8. For further information refer to section 13.



# [DILBUF RTU]

## Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

### SECTION 7: Handling and storage

#### 7.1. Precautions for safe handling

Precautions for safe handling : Ensure good ventilation of the work station. Wear personal protective equipment. Avoid contact with skin and eyes. Avoid breathing mist, vapours, spray.

Hygiene measures : Contaminated work clothing should not be allowed out of the workplace. Wash contaminated clothing before reuse. Do not eat, drink or smoke when using this product. Always wash hands after handling the product.

#### 7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in a well-ventilated place. Keep cool.

Information about storage in one common storage facility : Keep away from food, drink and animal feeding stuffs.

#### 7.3. Specific end use(s)

In vitro diagnostics.

### SECTION 8: Exposure controls/personal protection

#### 8.1. Control parameters

##### 8.1.1 National occupational exposure and biological limit values

No additional information available

##### 8.1.2. Recommended monitoring procedures

No additional information available

##### 8.1.3. Air contaminants formed

No additional information available

##### 8.1.4. DNEL and PNEC

reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) (55965-84-9)	
<b>DNEL/DMEL (Workers)</b>	
Acute - local effects, inhalation	0.04 mg/m <sup>3</sup>
Long-term - local effects, inhalation	0.02 mg/m <sup>3</sup>
<b>DNEL/DMEL (General population)</b>	
Acute - systemic effects, oral	0.11 mg/kg bodyweight
Acute - local effects, inhalation	0.04 mg/m <sup>3</sup>
Long-term - systemic effects, oral	0.09 mg/kg bodyweight/day
Long-term - local effects, inhalation	0.02 mg/m <sup>3</sup>
<b>PNEC (Water)</b>	
PNEC aqua (freshwater)	0.00339 mg/l
PNEC aqua (marine water)	0.00339 mg/l
PNEC aqua (intermittent, freshwater)	0.00339 mg/l
PNEC aqua (intermittent, marine water)	0.00339 mg/l
<b>PNEC (Sediment)</b>	
PNEC sediment (freshwater)	0.027 mg/kg dwt
PNEC sediment (marine water)	0.027 mg/kg dwt

# [DILBUF RTU]

## Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

<b>PNEC (Soil)</b>	
PNEC soil	0.01 mg/kg dwt
<b>PNEC (STP)</b>	
PNEC sewage treatment plant	0.23 mg/l

### 8.1.5. Control banding

No additional information available

## 8.2. Exposure controls

### 8.2.1. Appropriate engineering controls

#### Appropriate engineering controls:

Ensure good ventilation of the work station.

### 8.2.2. Personal protection equipment

#### 8.2.2.1. Eye and face protection

##### Eye protection:

Use splash goggles when eye contact due to splashing is possible. ISO 16321-1

#### 8.2.2.2. Skin protection

##### Skin and body protection:

Wear suitable protective clothing. EN 13034. EN ISO 13688

##### Hand protection:

Chemically resistant protective gloves. ISO 374-1. Nitrile rubber. Choosing the proper glove is a decision that depends not only on the type of material, but also on other quality features, which differ for each manufacturer. Please follow the instructions related to the permeability and the penetration time provided by the manufacturer. Gloves must be replaced after each use and whenever signs of wear or perforation appear

##### Other skin protection

##### Materials for protective clothing:

Use protective clothing

#### 8.2.2.3. Respiratory protection

##### Respiratory protection:

In case of insufficient ventilation, wear suitable respiratory equipment. Breathing apparatus with filter. A-P2. EN 143. . Breathing equipment is only to be used in order to handle the residual risk of short term jobs if all other risk minimizing measures have been carried out e.g. retention and/or local exhaust

#### 8.2.2.4. Thermal hazards

No additional information available

### 8.2.3. Environmental exposure controls

#### Environmental exposure controls:

Avoid release to the environment.

#### Other information:

Do not eat, drink or smoke when using this product. Avoid contact with skin and eyes. Always wash hands after handling the product.

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Colour	: Blue.
Odour	: odourless.
Odour threshold	: Not available
Melting point	: Not available
Freezing point	: Not available
Boiling point	: Not available
Flammability	: Not applicable

# [DILBUF RTU]

## Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

Explosive properties	: No data available. Product is not explosive.
Oxidising properties	: Non oxidizing.
Explosive limits	: Not available
Lower explosion limit	: Not available
Upper explosion limit	: Not available
Flash point	: Not available
Auto-ignition temperature	: Not available
Decomposition temperature	: Not available
pH	: 7.2 (20 °C)
Viscosity, kinematic	: Not available
Solubility	: Water: Soluble
Partition coefficient n-octanol/water (Log Kow)	: Not available
Vapour pressure	: Not available
Vapour pressure at 50°C	: Not available
Density	: Not available
Relative density	: Not available
Relative vapour density at 20°C	: Not available
Particle characteristics	: Not applicable

### 9.2. Other information

#### 9.2.1. Information with regard to physical hazard classes

No additional information available

#### 9.2.2. Other safety characteristics

No additional information available

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

### 10.2. Chemical stability

Stable under normal conditions.

### 10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

### 10.4. Conditions to avoid

None under recommended storage and handling conditions (see section 7).

### 10.5. Incompatible materials

No additional information available.

### 10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

## SECTION 11: Toxicological information

### 11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity (oral)	: Not classified (Based on available data, the classification criteria are not met)
Acute toxicity (dermal)	: Not classified (Based on available data, the classification criteria are not met)
Acute toxicity (inhalation)	: Not classified (Based on available data, the classification criteria are not met)
Skin corrosion/irritation	: Not classified (Based on available data, the classification criteria are not met) pH: 7.2 (20 °C)
Serious eye damage/irritation	: Not classified (Based on available data, the classification criteria are not met) pH: 7.2 (20 °C)

# [DILBUF RTU]

## Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

Respiratory or skin sensitisation	: May cause an allergic skin reaction.
Germ cell mutagenicity	: Not classified (Based on available data, the classification criteria are not met)
Carcinogenicity	: Not classified (Based on available data, the classification criteria are not met)
Reproductive toxicity	: Not classified (Based on available data, the classification criteria are not met)
STOT-single exposure	: Not classified (Based on available data, the classification criteria are not met)
STOT-repeated exposure	: Not classified (Based on available data, the classification criteria are not met)
Aspiration hazard	: Not classified (Based on available data, the classification criteria are not met)

### 11.2. Information on other hazards

No additional information available

## SECTION 12: Ecological information

### 12.1. Toxicity

Ecology - general	: The product has not been tested.
Hazardous to the aquatic environment, short-term (acute)	: Not classified (No data available)
Hazardous to the aquatic environment, long-term (chronic)	: Not classified (No data available)

#### reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) (55965-84-9)

LC50 - Fish [1]	0.19 mg/l (96 h; Oncorhynchus mykiss; EPA OPP 72-1)
EC50 - Crustacea [1]	0.18 mg/l (48 h; Daphnia magna; EPA OPP 72-2)
ErC50 algae	0.0273 mg/l (72 h; Pseudokirchneriella subcapitata; (OECD 201 method))
NOEC chronic fish	0.098 mg/l (28 d; Oncorhynchus mykiss; (OECD 215 method))
NOEC chronic crustacea	0.328 mg/l (21 d; Daphnia magna; (OECD 211 method))
NOEC chronic algae	0.0066 mg/l (72 h; Skeletonema costatum (marine diatom); (OECD 201 method))

### 12.2. Persistence and degradability

#### PBS-Dilution Buffer (blue, ready to use)

Persistence and degradability	No additional information available.
-------------------------------	--------------------------------------

#### reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) (55965-84-9)

Persistence and degradability	Readily biodegradable, failing 10-d window.
Biodegradation	62 % (29 d; (OECD 301B method))

### 12.3. Bioaccumulative potential

#### PBS-Dilution Buffer (blue, ready to use)

Bioaccumulative potential	No additional information available.
---------------------------	--------------------------------------

#### reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) (55965-84-9)

Bioconcentration factor (BCF REACH)	≈ 41 (20 °C; 0.12 mg/L; EPA OPP 165-4)
Partition coefficient n-octanol/water (Log Pow)	-0.32 – 0.7 (20 °C; (OECD 117 method))

### 12.4. Mobility in soil

#### PBS-Dilution Buffer (blue, ready to use)

Ecology - soil	No additional information available.
----------------	--------------------------------------

# [DILBUF RTU]

## Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

<b>reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) (55965-84-9)</b>	
Surface tension	73 mN/m (19.5 °C; 1 g/L; Test method EU A.5)
Ecology - soil	Low mobility (soil).

### 12.5. Results of PBT and vPvB assessment

No additional information available

### 12.6. Endocrine disrupting properties

No additional information available

### 12.7. Other adverse effects

Other adverse effects : No additional information available

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

Waste treatment methods : Disposal must be done according to official regulations. European waste catalogue. Do not discharge into drains or the environment. Do not dispose of with domestic waste.  
Product/Packaging disposal recommendations : Comply with local regulations for disposal. Recycle or dispose of in compliance with current legislation.

## SECTION 14: Transport information

In accordance with ADR / IMDG / IATA / ADN / RID

ADR	IMDG	IATA	ADN	RID
<b>14.1. UN number or ID number</b>				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
<b>14.2. UN proper shipping name</b>				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
<b>14.3. Transport hazard class(es)</b>				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
<b>14.4. Packing group</b>				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
<b>14.5. Environmental hazards</b>				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
No supplementary information available				

### 14.6. Special precautions for user

#### Overland transport

Not applicable

#### Transport by sea

Not applicable

#### Air transport

Not applicable

# [DILBUF RTU]

## Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

### Inland waterway transport

Not applicable

### Rail transport

Not applicable

### 14.7. Maritime transport in bulk according to IMO instruments

Not applicable

## SECTION 15: Regulatory information

### 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

#### 15.1.1. EU-Regulations

Other information, restriction and prohibition regulations : This product is a medical device and has not to be classified and labelled according to the current laws and regulations. Take note of Directive 94/33/EC on the protection of young people at work.

#### REACH Annex XVII (Restriction List)

EU restriction list (REACH Annex XVII)	
Reference code	Applicable on
3(b)	PBS-Dilution Buffer (blue, ready to use) ; reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)
3(c)	reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)

#### REACH Annex XIV (Authorisation List)

Contains no substance(s) listed on REACH Annex XIV (Authorisation List)

#### REACH Candidate List (SVHC)

Contains no substance(s) listed on the REACH Candidate List

#### PIC Regulation (Prior Informed Consent)

Contains no substance(s) listed on the PIC list (Regulation EU 649/2012 concerning the export and import of hazardous chemicals)

#### POP Regulation (Persistent Organic Pollutants)

Contains no substance(s) listed on the POP list (Regulation EU 2019/1021 on persistent organic pollutants)

#### Ozone Regulation (1005/2009)

Contains no substance(s) listed on the Ozone Depletion list (Regulation EU 1005/2009 on substances that deplete the ozone layer)

#### Explosives Precursors Regulation (2019/1148)

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

#### Drug Precursors Regulation (273/2004)

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

#### 15.1.2. National regulations

No additional information available

### 15.2. Chemical safety assessment

No chemical safety assessment has been carried out

No chemical safety assessment has been carried out

# [DILBUF RTU]

## Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

### SECTION 16: Other information

Indication of changes			
Section	Changed item	Change	Comments
	General revision		
1.1	Trade name	Modified	
1.3	SDS EU addresses	Modified	

Abbreviations and acronyms:	
ADN	Accord européen relatif au transport international des marchandises dangereuses par voie de navigation intérieure (European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways)
ADR	Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
BCF	Bioconcentration factor
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008
DNEL	Derived-No Effect Level
EC50	Median effective concentration
IATA	International Air Transport Association
IMDG	International Maritime Code for Dangerous Goods
LC50	Median lethal concentration
LOAEL	Lowest Observed Adverse Effect Level
NOAEC	No-Observed Adverse Effect Concentration
NOAEL	No-Observed Adverse Effect Level
NOEC	No-Observed Effect Concentration
PBT	Persistent Bioaccumulative Toxic
PNEC	Predicted No-Effect Concentration
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
STP	Sewage treatment plant
vPvB	Very Persistent and Very Bioaccumulative
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
ATE	Acute Toxicity Estimate
DMEL	Derived Minimal Effect level
IARC	International Agency for Research on Cancer
IATA	International Air Transport Association
IMDG	International Maritime Dangerous Goods
LD50	Median lethal dose
OECD	Organisation for Economic Co-operation and Development
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
SDS	Safety Data Sheet
TLM	Median Tolerance Limit

# [DILBUF RTU]

## Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

CAS-No.	Chemical Abstract Service number
---------	----------------------------------

Data sources : Information provided by the manufacturer. MSDS of the supplier. European Chemicals Agency, <http://echa.europa.eu/>.

Department issuing data specification sheet: : KFT Chemieservice GmbH  
Im Leuschnerpark 3  
D-64347 Griesheim

Phone: +49 6155-8981-400  
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SDS Service: +49 6155 8981-522

Contact person : Dr. Andreas Kretzschmar

Other information : This safety data sheet is for informational purposes only and does not fully comply with national legal requirements. The national distributor is responsible for a legally compliant safety data sheet.

Full text of H- and EUH-statements:	
Acute Tox. 2 (Dermal)	Acute toxicity (dermal), Category 2
Acute Tox. 2 (Inhalation)	Acute toxicity (inhal.), Category 2
Acute Tox. 3 (Oral)	Acute toxicity (oral), Category 3
Aquatic Acute 1	Hazardous to the aquatic environment – Acute Hazard, Category 1
Aquatic Chronic 1	Hazardous to the aquatic environment – Chronic Hazard, Category 1
EUH071	Corrosive to the respiratory tract.
Eye Dam. 1	Serious eye damage/eye irritation, Category 1
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
H301	Toxic if swallowed.
H310	Fatal in contact with skin.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H330	Fatal if inhaled.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
Skin Corr. 1C	Skin corrosion/irritation, Category 1, Sub-Category 1C
Skin Irrit. 2	Skin corrosion/irritation, Category 2
Skin Sens. 1	Skin sensitisation, Category 1
Skin Sens. 1A	Skin sensitisation, category 1A

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:		
Skin Sens. 1	H317	Calculation method

KFT SDS EU 00

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.



### SECTION 1: Identification of the substance/mixture and of the company/undertaking

#### 1.1. Product identifier

Product form : Mixture  
Trade name : [WASHBUF 20x]

#### 1.2. Relevant identified uses of the substance or mixture and uses advised against

##### 1.2.1. Relevant identified uses

Use of the substance/mixture : In vitro diagnostics

##### 1.2.2. Uses advised against

No additional information available

#### 1.3. Details of the supplier of the safety data sheet

##### Supplier

Virotech Diagnostics GmbH  
Waldstraße 23 A2  
DE- 63128 Dietzenbach  
Deutschland  
T +49 6074 236980  
[qualitymanagement@virotechdiagnostics.com](mailto:qualitymanagement@virotechdiagnostics.com)

##### Email competent person

sds@kft.de

#### 1.4. Emergency telephone number

Emergency number : National Health Service (NHS)  
24 hour national number consumer  
England and Scotland: 111  
Wales: 0845 46 47  
Northern Ireland: call your local General Practitioner  
  
Call 999 if there is a life-threatening incident.

### SECTION 2: Hazards identification

#### 2.1. Classification of the substance or mixture

##### Classification according to Regulation (EC) No. 1272/2008 [CLP]

Skin sensitisation, Category 1 H317  
Full text of H- and EUH-statements: see section 16

##### Adverse physicochemical, human health and environmental effects

May cause an allergic skin reaction.

#### 2.2. Label elements

##### Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP) :



GHS07

Signal word (CLP) : Warning  
Contains : reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)  
Hazard statements (CLP) : H317 - May cause an allergic skin reaction.  
Precautionary statements (CLP) : P280 - Wear protective gloves.  
P302+P352 - IF ON SKIN: Wash with plenty of water.  
P333+P313 - If skin irritation or rash occurs: Get medical advice/attention.

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## Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

### 2.3. Other hazards

Contains no PBT/vPvB substances  $\geq 0.1\%$  assessed in accordance with REACH Annex XIII

Component	
reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) (55965-84-9)	This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %

## SECTION 3: Composition/information on ingredients

### 3.1. Substances

Not applicable

### 3.2. Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) (Note B)	CAS-No.: 55965-84-9 EC Index-No.: 613-167-00-5	< 0.1	Acute Tox. 2 (Inhalation), H330 (ATE=0.33 mg/l/4h) Acute Tox. 2 (Dermal), H310 (ATE=87.12 mg/kg bodyweight) Acute Tox. 3 (Oral), H301 (ATE=64 mg/kg bodyweight) Skin Corr. 1C, H314 Eye Dam. 1, H318 Skin Sens. 1A, H317 Aquatic Acute 1, H400 (M=100) Aquatic Chronic 1, H410 (M=100) EUH071

### Specific concentration limits:

Name	Product identifier	Specific concentration limits
reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)	CAS-No.: 55965-84-9 EC Index-No.: 613-167-00-5	( 0.0015 $\leq$ C $\leq$ 100) Skin Sens. 1A, H317 ( 0.06 $\leq$ C < 0.6) Eye Irrit. 2, H319 ( 0.06 $\leq$ C < 0.6) Skin Irrit. 2, H315 ( 0.6 $\leq$ C $\leq$ 100) Eye Dam. 1, H318 ( 0.6 $\leq$ C $\leq$ 100) Skin Corr. 1C, H314

Note B : Some substances (acids, bases, etc.) are placed on the market in aqueous solutions at various concentrations and, therefore, these solutions require different classification and labelling since the hazards vary at different concentrations. In Part 3 entries with Note B have a general designation of the following type: 'nitric acid ... %'. In this case the supplier must state the percentage concentration of the solution on the label. Unless otherwise stated, it is assumed that the percentage concentration is calculated on a weight/weight basis.  
Full text of H- and EUH-statements: see section 16

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

First-aid measures general : In all cases of doubt, or when symptoms persist, seek medical attention.  
First-aid measures after inhalation : Remove person to fresh air and keep comfortable for breathing.

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according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

First-aid measures after skin contact	: Wash skin with plenty of water. Take off contaminated clothing. If skin irritation or rash occurs: Get medical advice/attention.
First-aid measures after eye contact	: Rinse eyes with water as a precaution.
First-aid measures after ingestion	: Call a poison center or a doctor if you feel unwell.

### 4.2. Most important symptoms and effects, both acute and delayed

Symptoms/effects after skin contact	: May cause an allergic skin reaction.
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### 4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

## SECTION 5: Firefighting measures

### 5.1. Extinguishing media

Suitable extinguishing media	: Use extinguishing media appropriate for surrounding fire. Water spray. Dry powder. Foam. Carbon dioxide.
Unsuitable extinguishing media	: Strong water jet.

### 5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire	: Toxic fumes may be released. release of harmful/irritant gases/vapours. Carbon monoxide. Carbon dioxide (CO <sub>2</sub> ). Nitrogen oxides. Sulphur oxides.
--------------------------------------------------	----------------------------------------------------------------------------------------------------------------------------------------------------------------

### 5.3. Advice for firefighters

Protection during firefighting	: Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.
Other information	: Cool closed containers exposed to fire with water spray. Do not allow run-off from fire fighting to enter drains or water courses. Disposal must be done according to official regulations.

## SECTION 6: Accidental release measures

### 6.1. Personal precautions, protective equipment and emergency procedures

#### 6.1.1. For non-emergency personnel

Emergency procedures	: Ventilate spillage area. Avoid contact with skin and eyes. Avoid breathing spray, vapours, mist.
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#### 6.1.2. For emergency responders

Protective equipment	: Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".
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### 6.2. Environmental precautions

Prevent entry to sewers and public waters. Avoid sub-soil penetration. Notify authorities if product enters sewers or public waters.

### 6.3. Methods and material for containment and cleaning up

Methods for cleaning up	: Take up liquid spill into absorbent material. Take up mechanically (sweeping, shovelling) and collect in suitable container for disposal.
Other information	: Dispose of materials or solid residues at an authorized site. Disposal must be done according to official regulations.

### 6.4. Reference to other sections

Information for safe handling. See section 7. Concerning personal protective equipment to use, see section 8. For further information refer to section 13.

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according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

### SECTION 7: Handling and storage

#### 7.1. Precautions for safe handling

Precautions for safe handling : Ensure good ventilation of the work station. Avoid contact with skin and eyes. Avoid breathing mist, vapours, spray. Wear personal protective equipment.

Hygiene measures : Contaminated work clothing should not be allowed out of the workplace. Wash contaminated clothing before reuse. Do not eat, drink or smoke when using this product. Always wash hands after handling the product.

#### 7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in a well-ventilated place. Keep cool.

Information about storage in one common storage facility : Keep away from food, drink and animal feeding stuffs.

#### 7.3. Specific end use(s)

In vitro diagnostics.

### SECTION 8: Exposure controls/personal protection

#### 8.1. Control parameters

##### 8.1.1 National occupational exposure and biological limit values

No additional information available

##### 8.1.2. Recommended monitoring procedures

No additional information available

##### 8.1.3. Air contaminants formed

No additional information available

##### 8.1.4. DNEL and PNEC

reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) (55965-84-9)	
<b>DNEL/DMEL (Workers)</b>	
Acute - local effects, inhalation	0.04 mg/m <sup>3</sup>
Long-term - local effects, inhalation	0.02 mg/m <sup>3</sup>
<b>DNEL/DMEL (General population)</b>	
Acute - systemic effects, oral	0.11 mg/kg bodyweight
Acute - local effects, inhalation	0.04 mg/m <sup>3</sup>
Long-term - systemic effects, oral	0.09 mg/kg bodyweight/day
Long-term - local effects, inhalation	0.02 mg/m <sup>3</sup>
<b>PNEC (Water)</b>	
PNEC aqua (freshwater)	0.00339 mg/l
PNEC aqua (marine water)	0.00339 mg/l
PNEC aqua (intermittent, freshwater)	0.00339 mg/l
PNEC aqua (intermittent, marine water)	0.00339 mg/l
<b>PNEC (Sediment)</b>	
PNEC sediment (freshwater)	0.027 mg/kg dwt
PNEC sediment (marine water)	0.027 mg/kg dwt

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<b>PNEC (Soil)</b>	
PNEC soil	0.01 mg/kg dwt
<b>PNEC (STP)</b>	
PNEC sewage treatment plant	0.23 mg/l

### 8.1.5. Control banding

No additional information available

## 8.2. Exposure controls

### 8.2.1. Appropriate engineering controls

#### Appropriate engineering controls:

Ensure good ventilation of the work station.

### 8.2.2. Personal protection equipment

#### 8.2.2.1. Eye and face protection

##### Eye protection:

Use splash goggles when eye contact due to splashing is possible. ISO 16321-1

#### 8.2.2.2. Skin protection

##### Skin and body protection:

Wear suitable protective clothing. EN 13034. EN ISO 13688

##### Hand protection:

Chemically resistant protective gloves. ISO 374-1. Nitrile rubber. Please follow the instructions related to the permeability and the penetration time provided by the manufacturer. Choosing the proper glove is a decision that depends not only on the type of material, but also on other quality features, which differ for each manufacturer. Gloves must be replaced after each use and whenever signs of wear or perforation appear

##### Other skin protection

##### Materials for protective clothing:

Use protective clothing

#### 8.2.2.3. Respiratory protection

##### Respiratory protection:

In case of inadequate ventilation wear respiratory protection. EN 143. In case of unintended release: Particle filter. P2. Breathing equipment is only to be used in order to handle the residual risk of short term jobs if all other risk minimizing measures have been carried out e.g. retention and/or local exhaust. . In case of insufficient ventilation, wear suitable respiratory equipment. Breathing apparatus with filter

#### 8.2.2.4. Thermal hazards

No additional information available

### 8.2.3. Environmental exposure controls

#### Environmental exposure controls:

Avoid release to the environment.

#### Other information:

Do not eat, drink or smoke when using this product. Avoid contact with skin and eyes. Always wash hands after handling the product.

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Colour	: colourless.
Odour	: odourless.
Odour threshold	: Not available
Melting point	: Not applicable
Freezing point	: Not available
Boiling point	: Not available
Flammability	: Not applicable

# [WASHBUF 20x]

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Explosive properties	: Product is not explosive.
Oxidising properties	: Non oxidizing.
Explosive limits	: Not available
Lower explosion limit	: Not available
Upper explosion limit	: Not available
Flash point	: Not available
Auto-ignition temperature	: Not available
Decomposition temperature	: Not available
pH	: 7.2 (20 °C)
Viscosity, kinematic	: Not available
Solubility	: Water: Soluble
Partition coefficient n-octanol/water (Log Kow)	: Not available
Vapour pressure	: Not available
Vapour pressure at 50°C	: Not available
Density	: Not available
Relative density	: Not available
Relative vapour density at 20°C	: Not available
Particle characteristics	: Not applicable

### 9.2. Other information

#### 9.2.1. Information with regard to physical hazard classes

No additional information available

#### 9.2.2. Other safety characteristics

No additional information available

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

### 10.2. Chemical stability

Stable under normal conditions.

### 10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

### 10.4. Conditions to avoid

None under recommended storage and handling conditions (see section 7).

### 10.5. Incompatible materials

No additional information available.

### 10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

## SECTION 11: Toxicological information

### 11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity (oral)	: Not classified (Based on available data, the classification criteria are not met)
Acute toxicity (dermal)	: Not classified (Based on available data, the classification criteria are not met)
Acute toxicity (inhalation)	: Not classified (Based on available data, the classification criteria are not met)
Skin corrosion/irritation	: Not classified (Based on available data, the classification criteria are not met) pH: 7.2 (20 °C)
Serious eye damage/irritation	: Not classified (Based on available data, the classification criteria are not met) pH: 7.2 (20 °C)

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Respiratory or skin sensitisation	: May cause an allergic skin reaction.
Germ cell mutagenicity	: Not classified (No data available. Based on available data, the classification criteria are not met)
Carcinogenicity	: Not classified (Based on available data, the classification criteria are not met)
Reproductive toxicity	: Not classified (Based on available data, the classification criteria are not met)
STOT-single exposure	: Not classified (Based on available data, the classification criteria are not met)
STOT-repeated exposure	: Not classified (Based on available data, the classification criteria are not met)
Aspiration hazard	: Not classified (Based on available data, the classification criteria are not met)

### 11.2. Information on other hazards

No additional information available

## SECTION 12: Ecological information

### 12.1. Toxicity

Ecology - general	: The product has not been tested.
Hazardous to the aquatic environment, short-term (acute)	: Not classified (No data available)
Hazardous to the aquatic environment, long-term (chronic)	: Not classified (No data available)

#### reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) (55965-84-9)

LC50 - Fish [1]	0.19 mg/l (96 h; Oncorhynchus mykiss; EPA OPP 72-1)
EC50 - Crustacea [1]	0.18 mg/l (48 h; Daphnia magna; EPA OPP 72-2)
ErC50 algae	0.0273 mg/l (72 h; Pseudokirchneriella subcapitata; (OECD 201 method))
NOEC chronic fish	0.098 mg/l (28 d; Oncorhynchus mykiss; (OECD 215 method))
NOEC chronic crustacea	0.328 mg/l (21 d; Daphnia magna; (OECD 211 method))
NOEC chronic algae	0.0066 mg/l (72 h; Skeletonema costatum (marine diatom); (OECD 201 method))

### 12.2. Persistence and degradability

#### PBS-Washing Solution (20x concentrated)

Persistence and degradability	No additional information available.
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#### reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) (55965-84-9)

Persistence and degradability	Readily biodegradable, failing 10-d window.
Biodegradation	62 % (29 d; (OECD 301B method))

### 12.3. Bioaccumulative potential

#### PBS-Washing Solution (20x concentrated)

Bioaccumulative potential	No additional information available.
---------------------------	--------------------------------------

#### reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) (55965-84-9)

Bioconcentration factor (BCF REACH)	≈ 41 (20 °C; 0.12 mg/L; EPA OPP 165-4)
Partition coefficient n-octanol/water (Log Pow)	-0.32 – 0.7 (20 °C; (OECD 117 method))

### 12.4. Mobility in soil

#### PBS-Washing Solution (20x concentrated)

Ecology - soil	No additional information available.
----------------	--------------------------------------

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## Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

<b>reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) (55965-84-9)</b>	
Surface tension	73 mN/m (19.5 °C; 1 g/L; Test method EU A.5)
Ecology - soil	Low mobility (soil).

### 12.5. Results of PBT and vPvB assessment

No additional information available

### 12.6. Endocrine disrupting properties

No additional information available

### 12.7. Other adverse effects

Other adverse effects : No additional information available

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

Waste treatment methods : Disposal must be done according to official regulations. European waste catalogue. Do not discharge into drains or the environment. Do not dispose of with domestic waste.  
Product/Packaging disposal recommendations : Comply with local regulations for disposal. Recycle or dispose of in compliance with current legislation.

## SECTION 14: Transport information

In accordance with ADR / IMDG / IATA / ADN / RID

ADR	IMDG	IATA	ADN	RID
<b>14.1. UN number or ID number</b>				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
<b>14.2. UN proper shipping name</b>				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
<b>14.3. Transport hazard class(es)</b>				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
<b>14.4. Packing group</b>				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
<b>14.5. Environmental hazards</b>				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
No supplementary information available				

### 14.6. Special precautions for user

#### Overland transport

Not applicable

#### Transport by sea

Not applicable

#### Air transport

Not applicable



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## Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

### Inland waterway transport

Not applicable

### Rail transport

Not applicable

### 14.7. Maritime transport in bulk according to IMO instruments

Not applicable

## SECTION 15: Regulatory information

### 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

#### 15.1.1. EU-Regulations

Other information, restriction and prohibition regulations : This product is a medical device and has not to be classified and labelled according to the current laws and regulations. Take note of Directive 94/33/EC on the protection of young people at work.

#### REACH Annex XVII (Restriction List)

EU restriction list (REACH Annex XVII)	
Reference code	Applicable on
3(b)	PBS-Washing Solution (20x concentrated) ; reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)
3(c)	reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)

#### REACH Annex XIV (Authorisation List)

Contains no substance(s) listed on REACH Annex XIV (Authorisation List)

#### REACH Candidate List (SVHC)

Contains no substance(s) listed on the REACH Candidate List

#### PIC Regulation (Prior Informed Consent)

Contains no substance(s) listed on the PIC list (Regulation EU 649/2012 concerning the export and import of hazardous chemicals)

#### POP Regulation (Persistent Organic Pollutants)

Contains no substance(s) listed on the POP list (Regulation EU 2019/1021 on persistent organic pollutants)

#### Ozone Regulation (1005/2009)

Contains no substance(s) listed on the Ozone Depletion list (Regulation EU 1005/2009 on substances that deplete the ozone layer)

#### Explosives Precursors Regulation (2019/1148)

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

#### Drug Precursors Regulation (273/2004)

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

#### 15.1.2. National regulations

No additional information available

### 15.2. Chemical safety assessment

No chemical safety assessment has been carried out

# [WASHBUF 20x]

## Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

### SECTION 16: Other information

Indication of changes			
Section	Changed item	Change	Comments
	General revision		
1.1	Trade name	Modified	
1.3	SDS EU addresses	Modified	

Abbreviations and acronyms:	
ADN	Accord européen relatif au transport international des marchandises dangereuses par voie de navigation intérieure (European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways)
ADR	Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
BCF	Bioconcentration factor
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008
DNEL	Derived-No Effect Level
EC50	Median effective concentration
IATA	International Air Transport Association
IMDG	International Maritime Code for Dangerous Goods
LC50	Median lethal concentration
LOAEL	Lowest Observed Adverse Effect Level
NOAEC	No-Observed Adverse Effect Concentration
NOAEL	No-Observed Adverse Effect Level
NOEC	No-Observed Effect Concentration
PBT	Persistent Bioaccumulative Toxic
PNEC	Predicted No-Effect Concentration
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
STP	Sewage treatment plant
vPvB	Very Persistent and Very Bioaccumulative
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
ATE	Acute Toxicity Estimate
DMEL	Derived Minimal Effect level
IARC	International Agency for Research on Cancer
IATA	International Air Transport Association
IMDG	International Maritime Dangerous Goods
LD50	Median lethal dose
OECD	Organisation for Economic Co-operation and Development
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
SDS	Safety Data Sheet
TLM	Median Tolerance Limit

# [WASHBUF 20x]

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according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

CAS-No.	Chemical Abstract Service number
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Data sources : Information provided by the manufacturer. MSDS of the supplier. European Chemicals Agency, <http://echa.europa.eu/>.

Department issuing data specification sheet: : KFT Chemieservice GmbH  
Im Leuschnerpark 3  
D-64347 Griesheim

Phone: +49 6155-8981-400  
Fax: +49 6155 8981-500  
SDS Service: +49 6155 8981-522

Contact person : Dr. Andreas Kretzschmar

Other information : This safety data sheet is for informational purposes only and does not fully comply with national legal requirements. The national distributor is responsible for a legally compliant safety data sheet.

Full text of H- and EUH-statements:	
Acute Tox. 2 (Dermal)	Acute toxicity (dermal), Category 2
Acute Tox. 2 (Inhalation)	Acute toxicity (inhal.), Category 2
Acute Tox. 3 (Oral)	Acute toxicity (oral), Category 3
Aquatic Acute 1	Hazardous to the aquatic environment – Acute Hazard, Category 1
Aquatic Chronic 1	Hazardous to the aquatic environment – Chronic Hazard, Category 1
EUH071	Corrosive to the respiratory tract.
Eye Dam. 1	Serious eye damage/eye irritation, Category 1
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
H301	Toxic if swallowed.
H310	Fatal in contact with skin.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H330	Fatal if inhaled.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
Skin Corr. 1C	Skin corrosion/irritation, Category 1, Sub-Category 1C
Skin Irrit. 2	Skin corrosion/irritation, Category 2
Skin Sens. 1	Skin sensitisation, Category 1
Skin Sens. 1A	Skin sensitisation, category 1A

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:		
Skin Sens. 1	H317	Calculation method

KFT SDS EU 00

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

### SECTION 1: Identification of the substance/mixture and of the company/undertaking

#### 1.1. Product identifier

Product form : Mixture  
Trade name : [RFSORBO]

#### 1.2. Relevant identified uses of the substance or mixture and uses advised against

##### 1.2.1. Relevant identified uses

Use of the substance/mixture : In vitro diagnostics

##### 1.2.2. Uses advised against

No additional information available

#### 1.3. Details of the supplier of the safety data sheet

##### Supplier

Virotech Diagnostics GmbH  
Waldstraße 23 A2  
DE- 63128 Dietzenbach  
Deutschland  
T +49 6074 236980  
[qualitymanagement@virotechdiagnostics.com](mailto:qualitymanagement@virotechdiagnostics.com)

##### Email competent person

sds@kft.de

#### 1.4. Emergency telephone number

Emergency number : National Health Service (NHS)  
24 hour national number consumer  
England and Scotland: 111  
Wales: 0845 46 47  
Northern Ireland: call your local General Practitioner  
  
Call 999 if there is a life-threatening incident.

### SECTION 2: Hazards identification

#### 2.1. Classification of the substance or mixture

##### Classification according to Regulation (EC) No. 1272/2008 [CLP]

Not classified

##### Adverse physicochemical, human health and environmental effects

To our knowledge, this product does not present any particular risk, provided it is handled in accordance with good occupational hygiene and safety practice.

#### 2.2. Label elements

##### Labelling according to Regulation (EC) No. 1272/2008 [CLP]

No labelling applicable

#### 2.3. Other hazards

Contains no PBT/vPvB substances  $\geq 0.1\%$  assessed in accordance with REACH Annex XIII

The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %

# [RFSORBO]

## Safety Data Sheet

A safety data sheet is not required for this product. This document was created on a voluntary basis

### SECTION 3: Composition/information on ingredients

#### 3.1. Substances

Not applicable

#### 3.2. Mixtures

This mixture does not contain any substances to be mentioned according to the criteria of section 3.2 of REACH Annex II

### SECTION 4: First aid measures

#### 4.1. Description of first aid measures

First-aid measures general	: In all cases of doubt, or when symptoms persist, seek medical attention.
First-aid measures after inhalation	: Remove person to fresh air and keep comfortable for breathing.
First-aid measures after skin contact	: Wash skin with plenty of water. Take off contaminated clothing. If skin irritation or rash occurs: Get medical advice/attention.
First-aid measures after eye contact	: Rinse eyes with water as a precaution.
First-aid measures after ingestion	: Call a poison center or a doctor if you feel unwell.

#### 4.2. Most important symptoms and effects, both acute and delayed

No additional information available

#### 4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

### SECTION 5: Firefighting measures

#### 5.1. Extinguishing media

Suitable extinguishing media	: Use extinguishing media appropriate for surrounding fire. Water spray. Dry powder. Foam. Carbon dioxide.
Unsuitable extinguishing media	: Strong water jet.

#### 5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire	: Toxic fumes may be released. release of harmful/irritant gases/vapours. Carbon monoxide. Carbon dioxide (CO <sub>2</sub> ). Nitrogen oxides. Sulphur oxides.
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#### 5.3. Advice for firefighters

Protection during firefighting	: Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.
Other information	: Cool closed containers exposed to fire with water spray. Do not allow run-off from fire fighting to enter drains or water courses. Disposal must be done according to official regulations.

### SECTION 6: Accidental release measures

#### 6.1. Personal precautions, protective equipment and emergency procedures

##### 6.1.1. For non-emergency personnel

Emergency procedures	: Ventilate spillage area. Avoid contact with skin and eyes. Avoid breathing spray, vapours, mist.
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##### 6.1.2. For emergency responders

Protective equipment	: Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".
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# [RFSORBO]

## Safety Data Sheet

A safety data sheet is not required for this product. This document was created on a voluntary basis

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### 6.2. Environmental precautions

Prevent entry to sewers and public waters. Avoid sub-soil penetration. Notify authorities if product enters sewers or public waters.

### 6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Take up liquid spill into absorbent material. Take up mechanically (sweeping, shovelling) and collect in suitable container for disposal.

Other information : Dispose of materials or solid residues at an authorized site. Disposal must be done according to official regulations.

### 6.4. Reference to other sections

Information for safe handling. See section 7. Concerning personal protective equipment to use, see section 8. For further information refer to section 13.

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

Precautions for safe handling : Ensure good ventilation of the work station. Avoid contact with skin and eyes. Wear personal protective equipment.

Hygiene measures : Contaminated work clothing should not be allowed out of the workplace. Wash contaminated clothing before reuse. Do not eat, drink or smoke when using this product. Always wash hands after handling the product.

### 7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in a well-ventilated place. Keep cool.

Information about storage in one common storage facility : Keep away from food, drink and animal feeding stuffs.

### 7.3. Specific end use(s)

In vitro diagnostics.

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

#### 8.1.1 National occupational exposure and biological limit values

No additional information available

#### 8.1.2. Recommended monitoring procedures

No additional information available

#### 8.1.3. Air contaminants formed

No additional information available

#### 8.1.4. DNEL and PNEC

No additional information available

#### 8.1.5. Control banding

No additional information available

### 8.2. Exposure controls

#### 8.2.1. Appropriate engineering controls

##### Appropriate engineering controls:

Ensure good ventilation of the work station.

# [RFSORBO]

## Safety Data Sheet

A safety data sheet is not required for this product. This document was created on a voluntary basis

### 8.2.2. Personal protection equipment

#### 8.2.2.1. Eye and face protection

**Eye protection:**

Use splash goggles when eye contact due to splashing is possible. ISO 16321-1

#### 8.2.2.2. Skin protection

**Skin and body protection:**

Wear suitable protective clothing. EN ISO 13688. EN 13034

**Hand protection:**

In case of repeated or prolonged contact wear gloves. Nitrile rubber. ISO 374-1. Choosing the proper glove is a decision that depends not only on the type of material, but also on other quality features, which differ for each manufacturer. Please follow the instructions related to the permeability and the penetration time provided by the manufacturer. Gloves must be replaced after each use and whenever signs of wear or perforation appear

#### 8.2.2.3. Respiratory protection

**Respiratory protection:**

In case of inadequate ventilation wear respiratory protection. In case of unintended release: Particle filter. P2. EN 143. In case of insufficient ventilation, wear suitable respiratory equipment. . Breathing apparatus with filter. Breathing equipment is only to be used in order to handle the residual risk of short term jobs if all other risk minimizing measures have been carried out e.g. retention and/or local exhaust

#### 8.2.2.4. Thermal hazards

No additional information available

### 8.2.3. Environmental exposure controls

**Environmental exposure controls:**

Avoid release to the environment.

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Colour	: light yellow.
Odour	: odourless.
Odour threshold	: Not available
Melting point	: Not applicable
Freezing point	: Not available
Boiling point	: Not available
Flammability	: Not applicable
Explosive properties	: Product is not explosive.
Oxidising properties	: Non oxidizing.
Explosive limits	: Not available
Lower explosion limit	: Not available
Upper explosion limit	: Not available
Flash point	: Not available
Auto-ignition temperature	: Not available
Decomposition temperature	: Not available
pH	: Not available
Viscosity, kinematic	: Not available
Solubility	: Water: Soluble
Partition coefficient n-octanol/water (Log Kow)	: Not available
Vapour pressure	: Not available
Vapour pressure at 50°C	: Not available
Density	: Not available
Relative density	: Not available
Relative vapour density at 20°C	: Not available
Particle characteristics	: Not applicable

# [RFSORBO]

## Safety Data Sheet

A safety data sheet is not required for this product. This document was created on a voluntary basis

### 9.2. Other information

#### 9.2.1. Information with regard to physical hazard classes

No additional information available

#### 9.2.2. Other safety characteristics

No additional information available

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

### 10.2. Chemical stability

Stable under normal conditions.

### 10.3. Possibility of hazardous reactions

Contact with acids liberates very toxic gas.

### 10.4. Conditions to avoid

None under recommended storage and handling conditions (see section 7).

### 10.5. Incompatible materials

Acids.

### 10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

## SECTION 11: Toxicological information

### 11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity (oral)	: Not classified (Based on available data, the classification criteria are not met)
Acute toxicity (dermal)	: Not classified (Based on available data, the classification criteria are not met)
Acute toxicity (inhalation)	: Not classified (Based on available data, the classification criteria are not met)
Skin corrosion/irritation	: Not classified (Based on available data, the classification criteria are not met)
Serious eye damage/irritation	: Not classified (Based on available data, the classification criteria are not met)
Respiratory or skin sensitisation	: Not classified (Based on available data, the classification criteria are not met)
Germ cell mutagenicity	: Not classified (No data available)
Carcinogenicity	: Not classified (Based on available data, the classification criteria are not met)
Reproductive toxicity	: Not classified (Based on available data, the classification criteria are not met)
STOT-single exposure	: Not classified (Based on available data, the classification criteria are not met)
STOT-repeated exposure	: Not classified (Based on available data, the classification criteria are not met)
Aspiration hazard	: Not classified (Based on available data, the classification criteria are not met)

### 11.2. Information on other hazards

No additional information available

## SECTION 12: Ecological information

### 12.1. Toxicity

Ecology - general	: The product has not been tested.
Hazardous to the aquatic environment, short-term (acute)	: Not classified (No data available)



# [RFSORBO]

## Safety Data Sheet

A safety data sheet is not required for this product. This document was created on a voluntary basis

Hazardous to the aquatic environment, long-term (chronic) : Not classified (No data available)

### 12.2. Persistence and degradability

No additional information available

### 12.3. Bioaccumulative potential

RF-SorboTech	
Bioaccumulative potential	No additional information available.

### 12.4. Mobility in soil

RF-SorboTech	
Ecology - soil	No additional information available.

### 12.5. Results of PBT and vPvB assessment

No additional information available

### 12.6. Endocrine disrupting properties

No additional information available

### 12.7. Other adverse effects

Other adverse effects : No additional information available

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

Waste treatment methods : Disposal must be done according to official regulations. European waste catalogue. Do not discharge into drains or the environment. Do not dispose of with domestic waste.  
Product/Packaging disposal recommendations : Comply with local regulations for disposal. Recycle or dispose of in compliance with current legislation.

## SECTION 14: Transport information

In accordance with ADR / IMDG / IATA / ADN / RID

ADR	IMDG	IATA	ADN	RID
<b>14.1. UN number or ID number</b>				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
<b>14.2. UN proper shipping name</b>				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
<b>14.3. Transport hazard class(es)</b>				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
<b>14.4. Packing group</b>				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
<b>14.5. Environmental hazards</b>				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
No supplementary information available				

# [RFSORBO]

## Safety Data Sheet

A safety data sheet is not required for this product. This document was created on a voluntary basis

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### 14.6. Special precautions for user

#### Overland transport

Not applicable

#### Transport by sea

Not applicable

#### Air transport

Not applicable

#### Inland waterway transport

Not applicable

#### Rail transport

Not applicable

### 14.7. Maritime transport in bulk according to IMO instruments

Not applicable

## SECTION 15: Regulatory information

### 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

#### 15.1.1. EU-Regulations

Other information, restriction and prohibition regulations : A safety data sheet is not required for this product under Article 31 of REACH. This Product Safety Information Sheet has been created on a voluntary basis. This product is a medical device and has not to be classified and labelled according to the current laws and regulations.

#### REACH Annex XVII (Restriction List)

Contains no substance(s) listed on REACH Annex XVII (Restriction Conditions)

#### REACH Annex XIV (Authorisation List)

Contains no substance(s) listed on REACH Annex XIV (Authorisation List)

#### REACH Candidate List (SVHC)

Contains no substance(s) listed on the REACH Candidate List

#### PIC Regulation (Prior Informed Consent)

Contains no substance(s) listed on the PIC list (Regulation EU 649/2012 concerning the export and import of hazardous chemicals)

#### POP Regulation (Persistent Organic Pollutants)

Contains no substance(s) listed on the POP list (Regulation EU 2019/1021 on persistent organic pollutants)

#### Ozone Regulation (1005/2009)

Contains no substance(s) listed on the Ozone Depletion list (Regulation EU 1005/2009 on substances that deplete the ozone layer)

#### Explosives Precursors Regulation (2019/1148)

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

#### Drug Precursors Regulation (273/2004)

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

#### 15.1.2. National regulations

No additional information available

### 15.2. Chemical safety assessment

No chemical safety assessment has been carried out

# [RFSORBO]

## Safety Data Sheet

A safety data sheet is not required for this product. This document was created on a voluntary basis

### SECTION 16: Other information

Indication of changes			
Section	Changed item	Change	Comments
	General revision		
1.1	Trade name	Modified	
1.3	SDS EU addresses	Modified	

Abbreviations and acronyms:	
ADN	Accord européen relatif au transport international des marchandises dangereuses par voie de navigation intérieure (European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways)
ADR	Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
IATA	International Air Transport Association
IMDG	International Maritime Code for Dangerous Goods
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
ATE	Acute Toxicity Estimate
BCF	Bioconcentration factor
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008
DMEL	Derived Minimal Effect level
DNEL	Derived-No Effect Level
EC50	Median effective concentration
IARC	International Agency for Research on Cancer
IATA	International Air Transport Association
IMDG	International Maritime Dangerous Goods
LC50	Median lethal concentration
LD50	Median lethal dose
LOAEL	Lowest Observed Adverse Effect Level
NOAEC	No-Observed Adverse Effect Concentration
NOAEL	No-Observed Adverse Effect Level
NOEC	No-Observed Effect Concentration
OECD	Organisation for Economic Co-operation and Development
PBT	Persistent Bioaccumulative Toxic
PNEC	Predicted No-Effect Concentration
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
SDS	Safety Data Sheet
STP	Sewage treatment plant
TLM	Median Tolerance Limit
vPvB	Very Persistent and Very Bioaccumulative

# [RFSORBO]

## Safety Data Sheet

A safety data sheet is not required for this product. This document was created on a voluntary basis

CAS-No.	Chemical Abstract Service number
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Data sources : Information provided by the manufacturer. MSDS of the supplier. European Chemicals Agency, <http://echa.europa.eu/>.

Department issuing data specification sheet: : KFT Chemieservice GmbH  
Im Leuschnerpark 3  
D-64347 Griesheim

Phone: +49 6155-8981-400  
Fax: +49 6155 8981-500  
SDS Service: +49 6155 8981-522

Contact person : Dr. Andreas Kretzschmar

Other information : This safety data sheet is for informational purposes only and does not fully comply with national legal requirements. The national distributor is responsible for a legally compliant safety data sheet.

KFT SDS EU 00

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.



# [SUBS TMB RTU]

## Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878  
Issue date: 31/01/2023 Revision date: 31/01/2023 Supersedes version of: 14/05/2020 Version: 5.00

### SECTION 1: Identification of the substance/mixture and of the company/undertaking

#### 1.1. Product identifier

Product form : Mixture  
Trade name : [SUBS TMB RTU]

#### 1.2. Relevant identified uses of the substance or mixture and uses advised against

##### 1.2.1. Relevant identified uses

Use of the substance/mixture : In vitro diagnostics

##### 1.2.2. Uses advised against

No additional information available

#### 1.3. Details of the supplier of the safety data sheet

##### Supplier

Virotech Diagnostics GmbH  
Waldstraße 23 A2  
DE- 63128 Dietzenbach  
Deutschland  
T +49 6074 236980  
[qualitymanagement@virotechdiagnostics.com](mailto:qualitymanagement@virotechdiagnostics.com)

##### Email competent person

sds@kft.de

#### 1.4. Emergency telephone number

Emergency number : National Health Service (NHS)  
24 hour national number consumer  
England and Scotland: 111  
Wales: 0845 46 47  
Northern Ireland: call your local General Practitioner  
  
Call 999 if there is a life-threatening incident.

### SECTION 2: Hazards identification

#### 2.1. Classification of the substance or mixture

##### Classification according to Regulation (EC) No. 1272/2008 [CLP]

Not classified

##### Adverse physicochemical, human health and environmental effects

To our knowledge, this product does not present any particular risk, provided it is handled in accordance with good occupational hygiene and safety practice.

#### 2.2. Label elements

##### Labelling according to Regulation (EC) No. 1272/2008 [CLP]

EUH-statements : EUH208 - Contains METHYLCHLOROISOTHIAZOLINONE (AND) METHYLISOTHIAZOLINONE. May produce an allergic reaction.  
EUH210 - Safety data sheet available on request.

#### 2.3. Other hazards

Contains no PBT/vPvB substances  $\geq 0.1\%$  assessed in accordance with REACH Annex XIII

#### Component

reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) (55965-84-9)	This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII
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# [SUBS TMB RTU]

## Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %

### SECTION 3: Composition/information on ingredients

#### 3.1. Substances

Not applicable

#### 3.2. Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) (Note B)	CAS-No.: 55965-84-9 EC Index-No.: 613-167-00-5	< 0.1	Acute Tox. 2 (Inhalation), H330 (ATE=0.33 mg/l/4h) Acute Tox. 2 (Dermal), H310 (ATE=87.12 mg/kg bodyweight) Acute Tox. 3 (Oral), H301 (ATE=64 mg/kg bodyweight) Skin Corr. 1C, H314 Eye Dam. 1, H318 Skin Sens. 1A, H317 Aquatic Acute 1, H400 (M=100) Aquatic Chronic 1, H410 (M=100) EUH071

#### Specific concentration limits:

Name	Product identifier	Specific concentration limits
reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)	CAS-No.: 55965-84-9 EC Index-No.: 613-167-00-5	( 0.0015 ≤C ≤ 100) Skin Sens. 1A, H317 ( 0.06 ≤C < 0.6) Eye Irrit. 2, H319 ( 0.06 ≤C < 0.6) Skin Irrit. 2, H315 ( 0.6 ≤C ≤ 100) Eye Dam. 1, H318 ( 0.6 ≤C ≤ 100) Skin Corr. 1C, H314

Note B : Some substances (acids, bases, etc.) are placed on the market in aqueous solutions at various concentrations and, therefore, these solutions require different classification and labelling since the hazards vary at different concentrations. In Part 3 entries with Note B have a general designation of the following type: 'nitric acid ... %'. In this case the supplier must state the percentage concentration of the solution on the label.

Unless otherwise stated, it is assumed that the percentage concentration is calculated on a weight/weight basis.

Full text of H- and EUH-statements: see section 16

### SECTION 4: First aid measures

#### 4.1. Description of first aid measures

First-aid measures general	: In all cases of doubt, or when symptoms persist, seek medical attention.
First-aid measures after inhalation	: Remove person to fresh air and keep comfortable for breathing. Call a physician immediately. Call a doctor.
First-aid measures after skin contact	: Wash skin with plenty of water. If skin irritation or rash occurs: Get medical advice/attention.
First-aid measures after eye contact	: Rinse eyes with water as a precaution.
First-aid measures after ingestion	: Call a poison center or a doctor if you feel unwell.

#### 4.2. Most important symptoms and effects, both acute and delayed

Symptoms/effects after skin contact	: May cause an allergic skin reaction.
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# [SUBS TMB RTU]

## Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

### 4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

## SECTION 5: Firefighting measures

### 5.1. Extinguishing media

- Suitable extinguishing media : Use extinguishing media appropriate for surrounding fire. Water spray. Dry powder. Foam. Carbon dioxide.
- Unsuitable extinguishing media : Strong water jet.

### 5.2. Special hazards arising from the substance or mixture

- Hazardous decomposition products in case of fire : Toxic fumes may be released. Carbon dioxide. Carbon monoxide.

### 5.3. Advice for firefighters

- Protection during firefighting : Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.
- Other information : Do not allow run-off from fire fighting to enter drains or water courses. Disposal must be done according to official regulations.

## SECTION 6: Accidental release measures

### 6.1. Personal precautions, protective equipment and emergency procedures

#### 6.1.1. For non-emergency personnel

- Emergency procedures : Ventilate spillage area.

#### 6.1.2. For emergency responders

- Protective equipment : Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

### 6.2. Environmental precautions

Avoid release to the environment.

### 6.3. Methods and material for containment and cleaning up

- Methods for cleaning up : Take up liquid spill into absorbent material. Take up mechanically (sweeping, shovelling) and collect in suitable container for disposal.
- Other information : Disposal must be done according to official regulations.

### 6.4. Reference to other sections

Information for safe handling. See section 7. Concerning personal protective equipment to use, see section 8. For further information refer to section 13.

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

- Precautions for safe handling : Ensure good ventilation of the work station. Wear personal protective equipment.
- Hygiene measures : Do not eat, drink or smoke when using this product. Always wash hands after handling the product.

### 7.2. Conditions for safe storage, including any incompatibilities

- Storage conditions : Store in a well-ventilated place. Keep cool.
- Information about storage in one common storage facility : Keep away from food, drink and animal feeding stuffs.

# [SUBS TMB RTU]

## Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

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### 7.3. Specific end use(s)

No additional information available

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

#### 8.1.1 National occupational exposure and biological limit values

No additional information available

#### 8.1.2. Recommended monitoring procedures

No additional information available

#### 8.1.3. Air contaminants formed

No additional information available

#### 8.1.4. DNEL and PNEC

No additional information available

#### 8.1.5. Control banding

No additional information available

### 8.2. Exposure controls

#### 8.2.1. Appropriate engineering controls

**Appropriate engineering controls:**

Ensure good ventilation of the work station.

#### 8.2.2. Personal protection equipment

##### 8.2.2.1. Eye and face protection

**Eye protection:**

Use splash goggles when eye contact due to splashing is possible. ISO 16321-1

##### 8.2.2.2. Skin protection

**Skin and body protection:**

Wear suitable protective clothing. EN ISO 13688. EN 13034

**Hand protection:**

In case of repeated or prolonged contact wear gloves. Nitrile rubber. ISO 374-1. Choosing the proper glove is a decision that depends not only on the type of material, but also on other quality features, which differ for each manufacturer. Please follow the instructions related to the permeability and the penetration time provided by the manufacturer. Gloves must be replaced after each use and whenever signs of wear or perforation appear

##### 8.2.2.3. Respiratory protection

**Respiratory protection:**

In case of insufficient ventilation, wear suitable respiratory equipment. Breathing apparatus with filter. A-P2. EN 143. Breathing equipment is only to be used in order to handle the residual risk of short term jobs if all other risk minimizing measures have been carried out e.g. retention and/or local exhaust.

##### 8.2.2.4. Thermal hazards

No additional information available

#### 8.2.3. Environmental exposure controls

**Environmental exposure controls:**

Avoid release to the environment.

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

Physical state : Liquid



# [SUBS TMB RTU]

## Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

Colour	: Not available
Odour	: Not available
Odour threshold	: Not available
Melting point	: Not applicable
Freezing point	: Not available
Boiling point	: Not available
Flammability	: Not available
Explosive properties	: Product is not explosive.
Oxidising properties	: Non oxidizing.
Explosive limits	: Not available
Lower explosion limit	: Not available
Upper explosion limit	: Not available
Flash point	: Not available
Auto-ignition temperature	: Not available
Decomposition temperature	: Not available
pH	: Not available
Viscosity, kinematic	: Not available
Solubility	: Not available
Partition coefficient n-octanol/water (Log Kow)	: Not available
Vapour pressure	: Not available
Vapour pressure at 50°C	: Not available
Density	: Not available
Relative density	: Not available
Relative vapour density at 20°C	: Not available
Particle characteristics	: Not applicable

### 9.2. Other information

#### 9.2.1. Information with regard to physical hazard classes

No additional information available

#### 9.2.2. Other safety characteristics

No additional information available

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

### 10.2. Chemical stability

Stable under normal conditions.

### 10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

### 10.4. Conditions to avoid

No additional information available

### 10.5. Incompatible materials

No additional information available

### 10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

## SECTION 11: Toxicological information

### 11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity (oral) : Not classified (Based on available data, the classification criteria are not met)

# [SUBS TMB RTU]

## Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

Acute toxicity (dermal)	: Not classified (Based on available data, the classification criteria are not met)
Acute toxicity (inhalation)	: Not classified (Based on available data, the classification criteria are not met)
Skin corrosion/irritation	: Not classified (Based on available data, the classification criteria are not met)
Serious eye damage/irritation	: Not classified (Based on available data, the classification criteria are not met)
Respiratory or skin sensitisation	: Not classified (Based on available data, the classification criteria are not met)
Additional information	: May cause sensitisation of susceptible persons
Germ cell mutagenicity	: Not classified (Based on available data, the classification criteria are not met)
Carcinogenicity	: Not classified (Based on available data, the classification criteria are not met)
Reproductive toxicity	: Not classified (Based on available data, the classification criteria are not met)
STOT-single exposure	: Not classified (Based on available data, the classification criteria are not met)
STOT-repeated exposure	: Not classified (Based on available data, the classification criteria are not met)
Aspiration hazard	: Not classified (Based on available data, the classification criteria are not met)

### 11.2. Information on other hazards

No additional information available

## SECTION 12: Ecological information

### 12.1. Toxicity

Hazardous to the aquatic environment, short-term (acute)	: Not classified (Based on available data, the classification criteria are not met)
Hazardous to the aquatic environment, long-term (chronic)	: Not classified (Based on available data, the classification criteria are not met)

### 12.2. Persistence and degradability

reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) (55965-84-9)	
Persistence and degradability	Readily biodegradable, failing 10-d window.
Biodegradation	62 % (29 d; (OECD 301B method))

### 12.3. Bioaccumulative potential

reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) (55965-84-9)	
Bioconcentration factor (BCF REACH)	≈ 41 (20 °C; 0.12 mg/L; EPA OPP 165-4)
Partition coefficient n-octanol/water (Log Pow)	-0.32 – 0.7 (20 °C; (OECD 117 method))

### 12.4. Mobility in soil

reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) (55965-84-9)	
Surface tension	73 mN/m (19.5 °C; 1 g/L; Test method EU A.5)
Ecology - soil	Low mobility (soil).

### 12.5. Results of PBT and vPvB assessment

No additional information available

### 12.6. Endocrine disrupting properties

No additional information available

### 12.7. Other adverse effects

No additional information available

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### SECTION 13: Disposal considerations

#### 13.1. Waste treatment methods

Waste treatment methods : Disposal must be done according to official regulations. European waste catalogue. Do not discharge into drains or the environment. Do not dispose of with domestic waste.

Product/Packaging disposal recommendations : Recycle or dispose of in compliance with current legislation.

### SECTION 14: Transport information

In accordance with ADR / IMDG / IATA / ADN / RID

ADR	IMDG	IATA	ADN	RID
<b>14.1. UN number or ID number</b>				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
<b>14.2. UN proper shipping name</b>				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
<b>14.3. Transport hazard class(es)</b>				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
<b>14.4. Packing group</b>				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
<b>14.5. Environmental hazards</b>				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
No supplementary information available				

#### 14.6. Special precautions for user

##### Overland transport

Not applicable

##### Transport by sea

Not applicable

##### Air transport

Not applicable

##### Inland waterway transport

Not applicable

##### Rail transport

Not applicable

#### 14.7. Maritime transport in bulk according to IMO instruments

Not applicable

### SECTION 15: Regulatory information

#### 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

##### 15.1.1. EU-Regulations

Other information, restriction and prohibition regulations : This product is a medical device and has not to be classified and labelled according to the current laws and regulations.

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### REACH Annex XVII (Restriction List)

EU restriction list (REACH Annex XVII)	
Reference code	Applicable on
3(b)	reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)
3(c)	reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)

### REACH Annex XIV (Authorisation List)

Contains no substance(s) listed on REACH Annex XIV (Authorisation List)

### REACH Candidate List (SVHC)

Contains no substance(s) listed on the REACH Candidate List

### PIC Regulation (Prior Informed Consent)

Contains no substance(s) listed on the PIC list (Regulation EU 649/2012 concerning the export and import of hazardous chemicals)

### POP Regulation (Persistent Organic Pollutants)

Contains no substance(s) listed on the POP list (Regulation EU 2019/1021 on persistent organic pollutants)

### Ozone Regulation (1005/2009)

Contains no substance(s) listed on the Ozone Depletion list (Regulation EU 1005/2009 on substances that deplete the ozone layer)

### Explosives Precursors Regulation (2019/1148)

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

### Drug Precursors Regulation (273/2004)

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

#### 15.1.2. National regulations

No additional information available

#### 15.2. Chemical safety assessment

No chemical safety assessment has been carried out

## SECTION 16: Other information

Indication of changes			
Section	Changed item	Change	Comments
	General revision		
1.1	Trade name	Modified	
1.3	SDS EU addresses	Modified	

Abbreviations and acronyms:	
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
ATE	Acute Toxicity Estimate
BCF	Bioconcentration factor
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008
DMEL	Derived Minimal Effect level
DNEL	Derived-No Effect Level
EC50	Median effective concentration

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IARC	International Agency for Research on Cancer
IATA	International Air Transport Association
IMDG	International Maritime Dangerous Goods
LC50	Median lethal concentration
LD50	Median lethal dose
LOAEL	Lowest Observed Adverse Effect Level
NOAEC	No-Observed Adverse Effect Concentration
NOAEL	No-Observed Adverse Effect Level
NOEC	No-Observed Effect Concentration
OECD	Organisation for Economic Co-operation and Development
PBT	Persistent Bioaccumulative Toxic
PNEC	Predicted No-Effect Concentration
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
SDS	Safety Data Sheet
STP	Sewage treatment plant
TLM	Median Tolerance Limit
vPvB	Very Persistent and Very Bioaccumulative
CAS-No.	Chemical Abstract Service number

Data sources : Information provided by the manufacturer. European Chemicals Agency, <http://echa.europa.eu/>.

Department issuing data specification sheet: : KFT Chemieservice GmbH  
Im Leuschnerpark 3  
D-64347 Griesheim

Phone: +49 6155-8981-400  
Fax: +49 6155 8981-500  
SDS Service: +49 6155 8981-522

Contact person : Dr. Andreas Kretzschmar

Other information : This safety data sheet is for informational purposes only and does not fully comply with national legal requirements. The national distributor is responsible for a legally compliant safety data sheet.

Full text of H- and EUH-statements:	
Acute Tox. 2 (Dermal)	Acute toxicity (dermal), Category 2
Acute Tox. 2 (Inhalation)	Acute toxicity (inhal.), Category 2
Acute Tox. 3 (Oral)	Acute toxicity (oral), Category 3
Aquatic Acute 1	Hazardous to the aquatic environment – Acute Hazard, Category 1
Aquatic Chronic 1	Hazardous to the aquatic environment – Chronic Hazard, Category 1
EUH071	Corrosive to the respiratory tract.
EUH208	Contains METHYLCHLOROISOTHIAZOLINONE (AND) METHYLISOTHIAZOLINONE. May produce an allergic reaction.
EUH210	Safety data sheet available on request.
Eye Dam. 1	Serious eye damage/eye irritation, Category 1
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2

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H301	Toxic if swallowed.
H310	Fatal in contact with skin.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H330	Fatal if inhaled.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
Skin Corr. 1C	Skin corrosion/irritation, Category 1, Sub-Category 1C
Skin Irrit. 2	Skin corrosion/irritation, Category 2
Skin Sens. 1A	Skin sensitisation, category 1A

KFT SDS EU 00

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

### SECTION 1: Identification of the substance/mixture and of the company/undertaking

#### 1.1. Product identifier

Product form : Mixture  
Trade name : [VZVDILBUF] [RTU]

#### 1.2. Relevant identified uses of the substance or mixture and uses advised against

##### 1.2.1. Relevant identified uses

Use of the substance/mixture : In vitro diagnostics

##### 1.2.2. Uses advised against

No additional information available

#### 1.3. Details of the supplier of the safety data sheet

##### Supplier

Virotech Diagnostics GmbH  
Waldstraße 23 A2  
DE- 63128 Dietzenbach  
Deutschland  
T +49 6074 236980  
[qualitymanagement@virotechdiagnostics.com](mailto:qualitymanagement@virotechdiagnostics.com)

##### Email competent person

sds@kft.de

#### 1.4. Emergency telephone number

Emergency number : National Health Service (NHS)  
24 hour national number consumer  
England and Scotland: 111  
Wales: 0845 46 47  
Northern Ireland: call your local General Practitioner  
  
Call 999 if there is a life-threatening incident.

### SECTION 2: Hazards identification

#### 2.1. Classification of the substance or mixture

##### Classification according to Regulation (EC) No. 1272/2008 [CLP]

Skin sensitisation, Category 1 H317  
Full text of H- and EUH-statements: see section 16

##### Adverse physicochemical, human health and environmental effects

May cause an allergic skin reaction.

#### 2.2. Label elements

##### Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP) :



GHS07

Signal word (CLP) : Warning  
Contains : reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)  
Hazard statements (CLP) : H317 - May cause an allergic skin reaction.  
Precautionary statements (CLP) : P280 - Wear protective gloves.  
P302+P352 - IF ON SKIN: Wash with plenty of water.  
P333+P313 - If skin irritation or rash occurs: Get medical advice/attention.

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### 2.3. Other hazards

Contains no PBT/vPvB substances  $\geq 0.1\%$  assessed in accordance with REACH Annex XIII

Component	
reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) (55965-84-9)	This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %

## SECTION 3: Composition/information on ingredients

### 3.1. Substances

Not applicable

### 3.2. Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) (Note B)	CAS-No.: 55965-84-9 EC Index-No.: 613-167-00-5	< 0.1	Acute Tox. 2 (Inhalation), H330 (ATE=0.33 mg/l/4h) Acute Tox. 2 (Dermal), H310 (ATE=87.12 mg/kg bodyweight) Acute Tox. 3 (Oral), H301 (ATE=64 mg/kg bodyweight) Skin Corr. 1C, H314 Eye Dam. 1, H318 Skin Sens. 1A, H317 Aquatic Acute 1, H400 (M=100) Aquatic Chronic 1, H410 (M=100) EUH071

### Specific concentration limits:

Name	Product identifier	Specific concentration limits
reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)	CAS-No.: 55965-84-9 EC Index-No.: 613-167-00-5	( 0.0015 $\leq$ C $\leq$ 100) Skin Sens. 1A, H317 ( 0.06 $\leq$ C < 0.6) Eye Irrit. 2, H319 ( 0.06 $\leq$ C < 0.6) Skin Irrit. 2, H315 ( 0.6 $\leq$ C $\leq$ 100) Eye Dam. 1, H318 ( 0.6 $\leq$ C $\leq$ 100) Skin Corr. 1C, H314

Note B : Some substances (acids, bases, etc.) are placed on the market in aqueous solutions at various concentrations and, therefore, these solutions require different classification and labelling since the hazards vary at different concentrations. In Part 3 entries with Note B have a general designation of the following type: 'nitric acid ... %'. In this case the supplier must state the percentage concentration of the solution on the label. Unless otherwise stated, it is assumed that the percentage concentration is calculated on a weight/weight basis.  
Full text of H- and EUH-statements: see section 16

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

First-aid measures general : In all cases of doubt, or when symptoms persist, seek medical attention.  
First-aid measures after inhalation : Remove person to fresh air and keep comfortable for breathing. Call a doctor.



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First-aid measures after skin contact	: Wash skin with plenty of water. Take off contaminated clothing. If skin irritation or rash occurs: Get medical advice/attention.
First-aid measures after eye contact	: Rinse eyes with water as a precaution.
First-aid measures after ingestion	: Call a poison center or a doctor if you feel unwell.

### 4.2. Most important symptoms and effects, both acute and delayed

Symptoms/effects after skin contact	: May cause an allergic skin reaction.
-------------------------------------	----------------------------------------

### 4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

## SECTION 5: Firefighting measures

### 5.1. Extinguishing media

Suitable extinguishing media	: Use extinguishing media appropriate for surrounding fire. Water spray. Dry powder. Foam. Carbon dioxide.
Unsuitable extinguishing media	: Strong water jet.

### 5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire	: Toxic fumes may be released. release of harmful/irritant gases/vapours. Carbon monoxide. Carbon dioxide (CO <sub>2</sub> ). Nitrogen oxides. Sulphur oxides.
--------------------------------------------------	----------------------------------------------------------------------------------------------------------------------------------------------------------------

### 5.3. Advice for firefighters

Protection during firefighting	: Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.
Other information	: Cool closed containers exposed to fire with water spray. Do not allow run-off from fire fighting to enter drains or water courses. Disposal must be done according to official regulations.

## SECTION 6: Accidental release measures

### 6.1. Personal precautions, protective equipment and emergency procedures

#### 6.1.1. For non-emergency personnel

Emergency procedures	: Ventilate spillage area. Avoid contact with skin and eyes. Avoid breathing spray, vapours, mist.
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#### 6.1.2. For emergency responders

Protective equipment	: Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".
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### 6.2. Environmental precautions

Prevent entry to sewers and public waters. Avoid sub-soil penetration. Notify authorities if product enters sewers or public waters.

### 6.3. Methods and material for containment and cleaning up

Methods for cleaning up	: Take up liquid spill into absorbent material. Take up mechanically (sweeping, shovelling) and collect in suitable container for disposal.
Other information	: Dispose of materials or solid residues at an authorized site. Disposal must be done according to official regulations.

### 6.4. Reference to other sections

Information for safe handling. See section 7. Concerning personal protective equipment to use, see section 8. For further information refer to section 13.

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### SECTION 7: Handling and storage

#### 7.1. Precautions for safe handling

Precautions for safe handling : Ensure good ventilation of the work station. Avoid contact with skin and eyes. Avoid breathing mist, vapours, spray. Wear personal protective equipment.

Hygiene measures : Contaminated work clothing should not be allowed out of the workplace. Wash contaminated clothing before reuse. Do not eat, drink or smoke when using this product. Always wash hands after handling the product.

#### 7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in a well-ventilated place. Keep cool.

Information about storage in one common storage facility : Keep away from food, drink and animal feeding stuffs.

#### 7.3. Specific end use(s)

In vitro diagnostics.

### SECTION 8: Exposure controls/personal protection

#### 8.1. Control parameters

##### 8.1.1 National occupational exposure and biological limit values

No additional information available

##### 8.1.2. Recommended monitoring procedures

No additional information available

##### 8.1.3. Air contaminants formed

No additional information available

##### 8.1.4. DNEL and PNEC

reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) (55965-84-9)	
<b>DNEL/DMEL (Workers)</b>	
Acute - local effects, inhalation	0.04 mg/m <sup>3</sup>
Long-term - local effects, inhalation	0.02 mg/m <sup>3</sup>
<b>DNEL/DMEL (General population)</b>	
Acute - systemic effects, oral	0.11 mg/kg bodyweight
Acute - local effects, inhalation	0.04 mg/m <sup>3</sup>
Long-term - systemic effects, oral	0.09 mg/kg bodyweight/day
Long-term - local effects, inhalation	0.02 mg/m <sup>3</sup>
<b>PNEC (Water)</b>	
PNEC aqua (freshwater)	0.00339 mg/l
PNEC aqua (marine water)	0.00339 mg/l
PNEC aqua (intermittent, freshwater)	0.00339 mg/l
PNEC aqua (intermittent, marine water)	0.00339 mg/l
<b>PNEC (Sediment)</b>	
PNEC sediment (freshwater)	0.027 mg/kg dwt
PNEC sediment (marine water)	0.027 mg/kg dwt

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<b>PNEC (Soil)</b>	
PNEC soil	0.01 mg/kg dwt
<b>PNEC (STP)</b>	
PNEC sewage treatment plant	0.23 mg/l

### 8.1.5. Control banding

No additional information available

## 8.2. Exposure controls

### 8.2.1. Appropriate engineering controls

#### Appropriate engineering controls:

Ensure good ventilation of the work station.

### 8.2.2. Personal protection equipment

#### 8.2.2.1. Eye and face protection

##### Eye protection:

Use splash goggles when eye contact due to splashing is possible. ISO 16321-1

#### 8.2.2.2. Skin protection

##### Skin and body protection:

Wear suitable protective clothing. EN ISO 13688. EN 13034

##### Hand protection:

Chemically resistant protective gloves. ISO 374-1. Nitrile rubber. Choosing the proper glove is a decision that depends not only on the type of material, but also on other quality features, which differ for each manufacturer. Please follow the instructions related to the permeability and the penetration time provided by the manufacturer. Gloves must be replaced after each use and whenever signs of wear or perforation appear

#### 8.2.2.3. Respiratory protection

##### Respiratory protection:

In case of inadequate ventilation wear respiratory protection. In case of unintended release: Particle filter. P2. EN 143. In case of insufficient ventilation, wear suitable respiratory equipment. . Breathing apparatus with filter. Breathing equipment is only to be used in order to handle the residual risk of short term jobs if all other risk minimizing measures have been carried out e.g. retention and/or local exhaust

#### 8.2.2.4. Thermal hazards

No additional information available

### 8.2.3. Environmental exposure controls

#### Environmental exposure controls:

Avoid release to the environment.

#### Other information:

Do not eat, drink or smoke when using this product. Avoid contact with skin and eyes. Always wash hands after handling the product.

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Colour	: Green.
Odour	: odourless.
Odour threshold	: Not available
Melting point	: Not applicable
Freezing point	: Not available
Boiling point	: Not available
Flammability	: Not applicable
Explosive properties	: Product is not explosive.
Oxidising properties	: Non oxidizing.
Explosive limits	: Not available
Lower explosion limit	: Not available

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Upper explosion limit	: Not available
Flash point	: Not available
Auto-ignition temperature	: Not available
Decomposition temperature	: Not available
pH	: 7 – 7.4 (20 °C)
Viscosity, kinematic	: Not available
Solubility	: Water: Soluble
Partition coefficient n-octanol/water (Log Kow)	: Not available
Vapour pressure	: Not available
Vapour pressure at 50°C	: Not available
Density	: Not available
Relative density	: Not available
Relative vapour density at 20°C	: Not available
Particle characteristics	: Not applicable

### 9.2. Other information

#### 9.2.1. Information with regard to physical hazard classes

No additional information available

#### 9.2.2. Other safety characteristics

No additional information available

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

### 10.2. Chemical stability

Stable under normal conditions.

### 10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

### 10.4. Conditions to avoid

None under recommended storage and handling conditions (see section 7).

### 10.5. Incompatible materials

No additional information available.

### 10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

## SECTION 11: Toxicological information

### 11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity (oral)	: Not classified (Based on available data, the classification criteria are not met)
Acute toxicity (dermal)	: Not classified (Based on available data, the classification criteria are not met)
Acute toxicity (inhalation)	: Not classified (Based on available data, the classification criteria are not met)
Skin corrosion/irritation	: Not classified (Based on available data, the classification criteria are not met) pH: 7 – 7.4 (20 °C)
Serious eye damage/irritation	: Not classified (Based on available data, the classification criteria are not met) pH: 7 – 7.4 (20 °C)
Respiratory or skin sensitisation	: May cause an allergic skin reaction.
Germ cell mutagenicity	: Not classified (No data available. Based on available data, the classification criteria are not met)
Carcinogenicity	: Not classified (Based on available data, the classification criteria are not met)

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Reproductive toxicity	: Not classified (Based on available data, the classification criteria are not met)
STOT-single exposure	: Not classified (Based on available data, the classification criteria are not met)
STOT-repeated exposure	: Not classified (Based on available data, the classification criteria are not met)
Aspiration hazard	: Not classified (Based on available data, the classification criteria are not met)

### 11.2. Information on other hazards

No additional information available

## SECTION 12: Ecological information

### 12.1. Toxicity

Ecology - general	: The product has not been tested.
Hazardous to the aquatic environment, short-term (acute)	: Not classified (Based on available data, the classification criteria are not met)
Hazardous to the aquatic environment, long-term (chronic)	: Not classified (Based on available data, the classification criteria are not met)

### 12.2. Persistence and degradability

VZV-IgM-Dilution Buffer (green, ready to use)	
Persistence and degradability	No additional information available.
reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) (55965-84-9)	
Persistence and degradability	Readily biodegradable, failing 10-d window.
Biodegradation	62 % (29 d; (OECD 301B method))

### 12.3. Bioaccumulative potential

VZV-IgM-Dilution Buffer (green, ready to use)	
Bioaccumulative potential	No additional information available.
reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) (55965-84-9)	
Bioconcentration factor (BCF REACH)	≈ 41 (20 °C; 0.12 mg/L; EPA OPP 165-4)
Partition coefficient n-octanol/water (Log Pow)	-0.32 – 0.7 (20 °C; (OECD 117 method))

### 12.4. Mobility in soil

VZV-IgM-Dilution Buffer (green, ready to use)	
Ecology - soil	No additional information available.
reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) (55965-84-9)	
Surface tension	73 mN/m (19.5 °C; 1 g/L; Test method EU A.5)
Ecology - soil	Low mobility (soil).

### 12.5. Results of PBT and vPvB assessment

No additional information available

### 12.6. Endocrine disrupting properties

No additional information available

### 12.7. Other adverse effects

Other adverse effects : No additional information available

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according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

### SECTION 13: Disposal considerations

#### 13.1. Waste treatment methods

Waste treatment methods : Disposal must be done according to official regulations. European waste catalogue. Do not discharge into drains or the environment. Do not dispose of with domestic waste.

Product/Packaging disposal recommendations : Comply with local regulations for disposal. Recycle or dispose of in compliance with current legislation.

### SECTION 14: Transport information

In accordance with ADR / IMDG / IATA / ADN / RID

ADR	IMDG	IATA	ADN	RID
<b>14.1. UN number or ID number</b>				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
<b>14.2. UN proper shipping name</b>				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
<b>14.3. Transport hazard class(es)</b>				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
<b>14.4. Packing group</b>				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
<b>14.5. Environmental hazards</b>				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
No supplementary information available				

#### 14.6. Special precautions for user

##### Overland transport

Not applicable

##### Transport by sea

Not applicable

##### Air transport

Not applicable

##### Inland waterway transport

Not applicable

##### Rail transport

Not applicable

#### 14.7. Maritime transport in bulk according to IMO instruments

Not applicable

# [VZVDILBUF] [RTU]

## Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

### SECTION 15: Regulatory information

#### 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

##### 15.1.1. EU-Regulations

Other information, restriction and prohibition regulations : This product is a medical device and has not to be classified and labelled according to the current laws and regulations. Take note of Directive 94/33/EC on the protection of young people at work.

##### REACH Annex XVII (Restriction List)

EU restriction list (REACH Annex XVII)	
Reference code	Applicable on
3(b)	VZV-IgM-Dilution Buffer (green, ready to use)

##### REACH Annex XIV (Authorisation List)

Contains no substance(s) listed on REACH Annex XIV (Authorisation List)

##### REACH Candidate List (SVHC)

Contains no substance(s) listed on the REACH Candidate List

##### PIC Regulation (Prior Informed Consent)

Contains no substance(s) listed on the PIC list (Regulation EU 649/2012 concerning the export and import of hazardous chemicals)

##### POP Regulation (Persistent Organic Pollutants)

Contains no substance(s) listed on the POP list (Regulation EU 2019/1021 on persistent organic pollutants)

##### Ozone Regulation (1005/2009)

Contains no substance(s) listed on the Ozone Depletion list (Regulation EU 1005/2009 on substances that deplete the ozone layer)

##### Explosives Precursors Regulation (2019/1148)

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

##### Drug Precursors Regulation (273/2004)

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

##### 15.1.2. National regulations

No additional information available

#### 15.2. Chemical safety assessment

No chemical safety assessment has been carried out

### SECTION 16: Other information

Indication of changes			
Section	Changed item	Change	Comments
	General revision		
1.1	Trade name	Modified	
1.3	SDS EU addresses	Modified	

#### Abbreviations and acronyms:

ADN	Accord européen relatif au transport international des marchandises dangereuses par voie de navigation intérieure (European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways)
ADR	Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

# [VZVDILBUF] [RTU]

## Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

IATA	International Air Transport Association
IMDG	International Maritime Code for Dangerous Goods
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
ATE	Acute Toxicity Estimate
BCF	Bioconcentration factor
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008
DMEL	Derived Minimal Effect level
DNEL	Derived-No Effect Level
EC50	Median effective concentration
IARC	International Agency for Research on Cancer
IATA	International Air Transport Association
IMDG	International Maritime Dangerous Goods
LC50	Median lethal concentration
LD50	Median lethal dose
LOAEL	Lowest Observed Adverse Effect Level
NOAEC	No-Observed Adverse Effect Concentration
NOAEL	No-Observed Adverse Effect Level
NOEC	No-Observed Effect Concentration
OECD	Organisation for Economic Co-operation and Development
PBT	Persistent Bioaccumulative Toxic
PNEC	Predicted No-Effect Concentration
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
SDS	Safety Data Sheet
STP	Sewage treatment plant
TLM	Median Tolerance Limit
vPvB	Very Persistent and Very Bioaccumulative
CAS-No.	Chemical Abstract Service number

Data sources : Information provided by the manufacturer. MSDS of the supplier. European Chemicals Agency, <http://echa.europa.eu/>.

Department issuing data specification sheet: : KFT Chemieservice GmbH  
Im Leuschnerpark 3  
D-64347 Griesheim

Phone: +49 6155-8981-400  
Fax: +49 6155 8981-500  
SDS Service: +49 6155 8981-522

Contact person : Dr. Andreas Kretzschmar

Other information : This safety data sheet is for informational purposes only and does not fully comply with national legal requirements. The national distributor is responsible for a legally compliant safety data sheet.



# [VZVDILBUF] [RTU]

## Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

<b>Full text of H- and EUH-statements:</b>	
Acute Tox. 2 (Dermal)	Acute toxicity (dermal), Category 2
Acute Tox. 2 (Inhalation)	Acute toxicity (inhal.), Category 2
Acute Tox. 3 (Oral)	Acute toxicity (oral), Category 3
Aquatic Acute 1	Hazardous to the aquatic environment – Acute Hazard, Category 1
Aquatic Chronic 1	Hazardous to the aquatic environment – Chronic Hazard, Category 1
EUH071	Corrosive to the respiratory tract.
Eye Dam. 1	Serious eye damage/eye irritation, Category 1
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
H301	Toxic if swallowed.
H310	Fatal in contact with skin.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H330	Fatal if inhaled.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
Skin Corr. 1C	Skin corrosion/irritation, Category 1, Sub-Category 1C
Skin Irrit. 2	Skin corrosion/irritation, Category 2
Skin Sens. 1	Skin sensitisation, Category 1
Skin Sens. 1A	Skin sensitisation, category 1A

<b>Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:</b>		
Skin Sens. 1	H317	Calculation method

KFT SDS EU 00

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

### SECTION 1: Identification of the substance/mixture and of the company/undertaking

#### 1.1. Product identifier

Product form : Mixture  
Trade name : [CONJ D IgG]

#### 1.2. Relevant identified uses of the substance or mixture and uses advised against

##### 1.2.1. Relevant identified uses

Use of the substance/mixture : In vitro diagnostics

##### 1.2.2. Uses advised against

No additional information available

#### 1.3. Details of the supplier of the safety data sheet

##### Supplier

Virotech Diagnostics GmbH  
Waldstraße 23 A2  
DE- 63128 Dietzenbach  
Deutschland  
T +49 6074 236980

[qualitymanagement@virotechdiagnostics.com](mailto:qualitymanagement@virotechdiagnostics.com)

##### Email competent person

sds@kft.de

#### 1.4. Emergency telephone number

Country	Organisation/Company	Address	Emergency number	Comment
United Kingdom	National Health Service (NHS) England / Scotland / Wales / Northern Ireland	-	England / Scotland: 111 Wales: 111 or 0845 46 47 Northern Ireland: call your local General Practitioner. For life-threatening emergencies: call 999 for an ambulance.	24 h medical helpline for general public

### SECTION 2: Hazards identification

#### 2.1. Classification of the substance or mixture

##### Classification according to Regulation (EC) No. 1272/2008 [CLP]

Skin sensitisation, Category 1 H317  
Full text of H- and EUH-statements: see section 16

##### Adverse physicochemical, human health and environmental effects

May cause an allergic skin reaction.

#### 2.2. Label elements

##### Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP) :



GHS07

Signal word (CLP) :

Warning

Contains :

reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)

Hazard statements (CLP) :

H317 - May cause an allergic skin reaction.

# [CONJ D IgG]

## Safety Data Sheet

According to REACH Regulation (EC) No 1907/2006, as retained and amended in UK law

Precautionary statements (CLP) : P261 - Avoid breathing mist, vapours, spray.  
P280 - Wear protective gloves, protective clothing, eye protection.  
P333+P313 - If skin irritation or rash occurs: Get medical advice/attention.  
P362+P364 - Take off contaminated clothing and wash it before reuse.

### 2.3. Other hazards

Contains no PBT/vPvB substances  $\geq 0.1\%$  assessed in accordance with REACH Annex XIII

Component	
reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) (55965-84-9)	This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %

## SECTION 3: Composition/information on ingredients

### 3.1. Substances

Not applicable

### 3.2. Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) (Note B)	CAS-No.: 55965-84-9 EC Index-No.: 613-167-00-5	0.001 – 0.0025	Acute Tox. 2 (Inhalation), H330 (ATE=0.33 mg/l/4h) Acute Tox. 2 (Dermal), H310 (ATE=87.12 mg/kg bodyweight) Acute Tox. 3 (Oral), H301 (ATE=64 mg/kg bodyweight) Skin Corr. 1C, H314 Eye Dam. 1, H318 Skin Sens. 1A, H317 Aquatic Acute 1, H400 (M=100) Aquatic Chronic 1, H410 (M=100) EUH071

Specific concentration limits:		
Name	Product identifier	Specific concentration limits
reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)	CAS-No.: 55965-84-9 EC Index-No.: 613-167-00-5	( 0.0015 $\leq$ C $\leq$ 100) Skin Sens. 1A, H317 ( 0.06 $\leq$ C < 0.6) Eye Irrit. 2, H319 ( 0.06 $\leq$ C < 0.6) Skin Irrit. 2, H315 ( 0.6 $\leq$ C $\leq$ 100) Eye Dam. 1, H318 ( 0.6 $\leq$ C $\leq$ 100) Skin Corr. 1C, H314

Note B: Some substances (acids, bases, etc.) are placed on the market in aqueous solutions at various concentrations and, therefore, these solutions require different classification and labelling since the hazards vary at different concentrations. In Part 3 entries with Note B have a general designation of the following type: '... %'. In this case the supplier must state the percentage concentration of the solution on the label. Unless otherwise stated, it is assumed that the percentage concentration is calculated on a weight/weight basis.

Full text of H- and EUH-statements: see section 16

# [CONJ D IgG]

## Safety Data Sheet

According to REACH Regulation (EC) No 1907/2006, as retained and amended in UK law

### SECTION 4: First aid measures

#### 4.1. Description of first aid measures

First-aid measures general	: In all cases of doubt, or when symptoms persist, seek medical attention.
First-aid measures after inhalation	: Remove person to fresh air and keep comfortable for breathing.
First-aid measures after skin contact	: Wash skin with plenty of water. Take off contaminated clothing. If skin irritation or rash occurs: Get medical advice/attention.
First-aid measures after eye contact	: Rinse eyes with water as a precaution.
First-aid measures after ingestion	: Call a poison center or a doctor if you feel unwell.

#### 4.2. Most important symptoms and effects, both acute and delayed

Symptoms/effects after skin contact	: May cause an allergic skin reaction.
-------------------------------------	----------------------------------------

#### 4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

### SECTION 5: Firefighting measures

#### 5.1. Extinguishing media

Suitable extinguishing media	: Use extinguishing media appropriate for surrounding fire. Water spray. Dry powder. Foam. Carbon dioxide.
Unsuitable extinguishing media	: Strong water jet.

#### 5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire	: Toxic fumes may be released. release of harmful/irritant gases/vapours. Carbon monoxide. Carbon dioxide. Nitrogen oxides.
--------------------------------------------------	-----------------------------------------------------------------------------------------------------------------------------

#### 5.3. Advice for firefighters

Protection during firefighting	: Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.
Other information	: Do not allow run-off from fire fighting to enter drains or water courses. Disposal must be done according to official regulations.

### SECTION 6: Accidental release measures

#### 6.1. Personal precautions, protective equipment and emergency procedures

##### 6.1.1. For non-emergency personnel

Emergency procedures	: Ventilate spillage area. Avoid contact with skin and eyes. Avoid breathing mist, vapours, spray.
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##### 6.1.2. For emergency responders

Protective equipment	: Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".
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#### 6.2. Environmental precautions

Prevent entry to sewers and public waters. Avoid sub-soil penetration. Notify authorities if product enters sewers or public waters.

#### 6.3. Methods and material for containment and cleaning up

Methods for cleaning up	: Take up liquid spill into absorbent material. Take up mechanically (sweeping, shovelling) and collect in suitable container for disposal.
Other information	: Disposal must be done according to official regulations.

#### 6.4. Reference to other sections

Information for safe handling. See section 7. Concerning personal protective equipment to use, see section 8. For further information refer to section 13.

# [CONJ D IgG]

## Safety Data Sheet

According to REACH Regulation (EC) No 1907/2006, as retained and amended in UK law

### SECTION 7: Handling and storage

#### 7.1. Precautions for safe handling

Precautions for safe handling : Ensure good ventilation of the work station. Wear personal protective equipment. Avoid contact with skin and eyes. Avoid breathing mist, vapours, spray.

Hygiene measures : Do not eat, drink or smoke when using this product. Always wash hands after handling the product. Contaminated work clothing should not be allowed out of the workplace. Wash contaminated clothing before reuse.

#### 7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in a well-ventilated place. Keep cool.

Information about storage in one common storage facility : Keep away from food, drink and animal feeding stuffs.

#### 7.3. Specific end use(s)

In vitro diagnostics.

### SECTION 8: Exposure controls/personal protection

#### 8.1. Control parameters

##### 8.1.1 National occupational exposure and biological limit values

No additional information available

##### 8.1.2. Recommended monitoring procedures

No additional information available

##### 8.1.3. Air contaminants formed

No additional information available

##### 8.1.4. DNEL and PNEC

reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) (55965-84-9)	
<b>DNEL/DMEL (Workers)</b>	
Acute - local effects, inhalation	0.04 mg/m <sup>3</sup>
Long-term - local effects, inhalation	0.02 mg/m <sup>3</sup>
<b>DNEL/DMEL (General population)</b>	
Acute - systemic effects, oral	0.11 mg/kg bodyweight
Acute - local effects, inhalation	0.04 mg/m <sup>3</sup>
Long-term - systemic effects, oral	0.09 mg/kg bodyweight/day
Long-term - local effects, inhalation	0.02 mg/m <sup>3</sup>
<b>PNEC (Water)</b>	
PNEC aqua (freshwater)	0.00339 mg/l
PNEC aqua (marine water)	0.00339 mg/l
PNEC aqua (intermittent, freshwater)	0.00339 mg/l
PNEC aqua (intermittent, marine water)	0.00339 mg/l
<b>PNEC (Sediment)</b>	
PNEC sediment (freshwater)	0.027 mg/kg dwt
PNEC sediment (marine water)	0.027 mg/kg dwt
<b>PNEC (Soil)</b>	
PNEC soil	0.01 mg/kg dwt

# [CONJ D IgG]

## Safety Data Sheet

According to REACH Regulation (EC) No 1907/2006, as retained and amended in UK law

PNEC (STP)	
PNEC sewage treatment plant	0.23 mg/l

### 8.1.5. Control banding

No additional information available

## 8.2. Exposure controls

### 8.2.1. Appropriate engineering controls

#### Appropriate engineering controls:

Ensure good ventilation of the work station.

### 8.2.2. Personal protection equipment

#### 8.2.2.1. Eye and face protection

##### Eye protection:

Use splash goggles when eye contact due to splashing is possible. ISO 16321-1

#### 8.2.2.2. Skin protection

##### Skin and body protection:

Wear suitable protective clothing. EN ISO 13688. EN 13034

##### Hand protection:

Chemically resistant protective gloves. ISO 374-1. Nitrile rubber. Choosing the proper glove is a decision that depends not only on the type of material, but also on other quality features, which differ for each manufacturer. Please follow the instructions related to the permeability and the penetration time provided by the manufacturer. Gloves must be replaced after each use and whenever signs of wear or perforation appear

#### 8.2.2.3. Respiratory protection

##### Respiratory protection:

In case of insufficient ventilation, wear suitable respiratory equipment. In case of unintended release: Breathing apparatus with filter. Particle filter. P2. EN 143. . Breathing equipment is only to be used in order to handle the residual risk of short term jobs if all other risk minimizing measures have been carried out e.g. retention and/or local exhaust

#### 8.2.2.4. Thermal hazards

No additional information available

### 8.2.3. Environmental exposure controls

#### Environmental exposure controls:

Avoid release to the environment.

#### Other information:

Do not eat, drink or smoke when using this product. Avoid contact with skin and eyes. Always wash hands after handling the product.

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Colour	: red.
Odour	: odourless.
Odour threshold	: Not available
Melting point	: Not available
Freezing point	: Not available
Boiling point	: Not available
Flammability	: Not applicable
Explosive properties	: Product is not explosive.
Oxidising properties	: Non oxidizing.
Explosive limits	: Not available
Lower explosion limit	: Not available
Upper explosion limit	: Not available
Flash point	: Not available
Auto-ignition temperature	: Not available

# [CONJ D IgG]

## Safety Data Sheet

According to REACH Regulation (EC) No 1907/2006, as retained and amended in UK law

Decomposition temperature	: Not available
pH	: 7.5 – 7.7 (20 °C)
Viscosity, kinematic	: Not available
Solubility	: Water: Soluble
Partition coefficient n-octanol/water (Log Kow)	: Not available
Vapour pressure	: Not available
Vapour pressure at 50°C	: Not available
Density	: Not available
Relative density	: Not available
Relative vapour density at 20°C	: Not available
Particle characteristics	: Not applicable

### 9.2. Other information

#### 9.2.1. Information with regard to physical hazard classes

No additional information available

#### 9.2.2. Other safety characteristics

No additional information available

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

### 10.2. Chemical stability

Stable under normal conditions.

### 10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

### 10.4. Conditions to avoid

No additional information available

### 10.5. Incompatible materials

No additional information available.

### 10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

## SECTION 11: Toxicological information

### 11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity (oral)	: Not classified (Based on available data, the classification criteria are not met)
Acute toxicity (dermal)	: Not classified (Based on available data, the classification criteria are not met)
Acute toxicity (inhalation)	: Not classified (Based on available data, the classification criteria are not met)

reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) (55965-84-9)	
LD50 oral rat	64 mg/kg bodyweight (male)
LD50 dermal rabbit	87.12 mg/kg bodyweight (Active substance; male)
LC50 Inhalation - Rat (Dust/Mist)	0.33 mg/l/4h (Active substance; (OECD 403 method))

Skin corrosion/irritation	: Not classified (Based on available data, the classification criteria are not met) pH: 7.5 – 7.7 (20 °C)
Serious eye damage/irritation	: Not classified (Based on available data, the classification criteria are not met) pH: 7.5 – 7.7 (20 °C)
Respiratory or skin sensitisation	: May cause an allergic skin reaction.

# [CONJ D IgG]

## Safety Data Sheet

According to REACH Regulation (EC) No 1907/2006, as retained and amended in UK law

Germ cell mutagenicity	: Not classified (Based on available data, the classification criteria are not met)
Carcinogenicity	: Not classified (Based on available data, the classification criteria are not met)
Reproductive toxicity	: Not classified (Based on available data, the classification criteria are not met)
STOT-single exposure	: Not classified (Based on available data, the classification criteria are not met)
STOT-repeated exposure	: Not classified (Based on available data, the classification criteria are not met)
Aspiration hazard	: Not classified (Based on available data, the classification criteria are not met)

### 11.2. Information on other hazards

No additional information available

## SECTION 12: Ecological information

### 12.1. Toxicity

Ecology - general	: The product has not been tested.
Hazardous to the aquatic environment, short-term (acute)	: Not classified (Based on available data, the classification criteria are not met)
Hazardous to the aquatic environment, long-term (chronic)	: Not classified (Based on available data, the classification criteria are not met)

#### reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) (55965-84-9)

LC50 - Fish [1]	0.19 mg/l (96 h; Oncorhynchus mykiss; EPA OPP 72-1)
EC50 - Crustacea [1]	0.18 mg/l (48 h; Daphnia magna; EPA OPP 72-2)
ErC50 algae	0.0063 mg/l (72 h; Skeletonema costatum (marine diatom); (OECD 201 method))
NOEC chronic fish	0.098 mg/l (28 d; Oncorhynchus mykiss; (OECD 215 method))
NOEC chronic crustacea	0.328 mg/l (21 d; Daphnia magna; (OECD 211 method))
NOEC chronic algae	0.0005 mg/l (48 h; Skeletonema costatum (marine diatom); (OECD 201 method))

### 12.2. Persistence and degradability

#### reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) (55965-84-9)

Persistence and degradability	Not readily biodegradable. Readily biodegradable, failing 10-d window.
Biodegradation	62 % (29 d; (OECD 301B method))

### 12.3. Bioaccumulative potential

#### Anti-dog IgG conjugate

Bioaccumulative potential	No additional information available.
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#### reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) (55965-84-9)

Bioconcentration factor (BCF REACH)	≈ 41 (20 °C; 0.12 mg/L; EPA OPP 165-4)
Partition coefficient n-octanol/water (Log Pow)	-0.32 – 0.7 (20 °C; (OECD 117 method))

### 12.4. Mobility in soil

#### Anti-dog IgG conjugate

Ecology - soil	No additional information available.
----------------	--------------------------------------



# [CONJ D IgG]

## Safety Data Sheet

According to REACH Regulation (EC) No 1907/2006, as retained and amended in UK law

<b>reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) (55965-84-9)</b>	
Surface tension	73 mN/m (19.5 °C; 1 g/L; Test method EU A.5)
Ecology - soil	Low mobility (soil).

### 12.5. Results of PBT and vPvB assessment

<b>Component</b>	
reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) (55965-84-9)	This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

### 12.6. Endocrine disrupting properties

No additional information available

### 12.7. Other adverse effects

Other adverse effects : No additional information available.

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

Waste treatment methods : Disposal must be done according to official regulations. European waste catalogue. Do not discharge into drains or the environment. Do not dispose of with domestic waste.  
Product/Packaging disposal recommendations : Recycle or dispose of in compliance with current legislation.

## SECTION 14: Transport information

In accordance with ADR / IMDG / IATA / ADN / RID

ADR	IMDG	IATA	ADN	RID
<b>14.1. UN number or ID number</b>				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
<b>14.2. UN proper shipping name</b>				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
<b>14.3. Transport hazard class(es)</b>				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
<b>14.4. Packing group</b>				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
<b>14.5. Environmental hazards</b>				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
No supplementary information available				

### 14.6. Special precautions for user

#### Overland transport

Not regulated

#### Transport by sea

Not regulated

# [CONJ D IgG]

## Safety Data Sheet

According to REACH Regulation (EC) No 1907/2006, as retained and amended in UK law

### Air transport

Not regulated

### Inland waterway transport

Not regulated

### Rail transport

Not regulated

### 14.7. Maritime transport in bulk according to IMO instruments

Not applicable

## SECTION 15: Regulatory information

### 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

#### 15.1.1. EU-Regulations

Other information, restriction and prohibition regulations : This product is a medical device and has not to be classified and labelled according to the current laws and regulations. Take note of Directive 94/33/EC on the protection of young people at work.

#### REACH Annex XVII (Restriction List)

EU restriction list (REACH Annex XVII)	
Reference code	Applicable on
3(b)	Anti-dog IgG conjugate ; reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)
3(c)	reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)

#### REACH Annex XIV (Authorisation List)

Contains no substance(s) listed on REACH Annex XIV (Authorisation List)

#### REACH Candidate List (SVHC)

Contains no substance(s) listed on the REACH Candidate List

#### PIC Regulation (Prior Informed Consent)

Contains no substance(s) listed on the PIC list (Regulation EU 649/2012 concerning the export and import of hazardous chemicals)

#### POP Regulation (Persistent Organic Pollutants)

Contains no substance(s) listed on the POP list (Regulation EU 2019/1021 on persistent organic pollutants)

#### Ozone Regulation (1005/2009)

Contains no substance(s) listed on the Ozone Depletion list (Regulation EU 1005/2009 on substances that deplete the ozone layer)

#### Explosives Precursors Regulation (2019/1148)

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

#### Drug Precursors Regulation (273/2004)

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

#### 15.1.2. National regulations

No additional information available

### 15.2. Chemical safety assessment

No chemical safety assessment has been carried out

# [CONJ D IgG]

## Safety Data Sheet

According to REACH Regulation (EC) No 1907/2006, as retained and amended in UK law

### SECTION 16: Other information

Indication of changes			
Section	Changed item	Change	Comments
	General revision		
2.1	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Modified	
2.2	Labelling according to Regulation (EC) No. 1272/2008 [CLP]	Modified	
11.1	Toxicological information	Modified	

### Abbreviations and acronyms:

ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
ATE	Acute Toxicity Estimate
BCF	Bioconcentration factor
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008
DMEL	Derived Minimal Effect level
DNEL	Derived-No Effect Level
EC50	Median effective concentration
IARC	International Agency for Research on Cancer
IATA	International Air Transport Association
IMDG	International Maritime Dangerous Goods
LC50	Median lethal concentration
LD50	Median lethal dose
LOAEL	Lowest Observed Adverse Effect Level
NOAEC	No-Observed Adverse Effect Concentration
NOAEL	No-Observed Adverse Effect Level
NOEC	No-Observed Effect Concentration
OECD	Organisation for Economic Co-operation and Development
PBT	Persistent Bioaccumulative Toxic
PNEC	Predicted No-Effect Concentration
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
SDS	Safety Data Sheet
STP	Sewage treatment plant
TLM	Median Tolerance Limit
vPvB	Very Persistent and Very Bioaccumulative
CAS-No.	Chemical Abstract Service number

Data sources

: Information provided by the manufacturer. MSDS of the supplier. European Chemicals Agency, <http://echa.europa.eu/>.

# [CONJ D IgG]

## Safety Data Sheet

According to REACH Regulation (EC) No 1907/2006, as retained and amended in UK law

Department issuing data specification sheet: : KFT Chemieservice GmbH  
Im Leuschnerpark 3  
D-64347 Griesheim

Phone: +49 6155-8981-400  
Fax: +49 6155 8981-500  
SDS Service: +49 6155 8981-522

Contact person

: Dr. Andreas Kretzschmar

Other information

: This safety data sheet is for informational purposes only and does not comply with national legal requirements without reference to a national distributor. The national distributor is responsible for a legally compliant safety data sheet.

<b>Full text of H- and EUH-statements:</b>	
Acute Tox. 2 (Dermal)	Acute toxicity (dermal), Category 2
Acute Tox. 2 (Inhalation)	Acute toxicity (inhal.), Category 2
Acute Tox. 3 (Oral)	Acute toxicity (oral), Category 3
Aquatic Acute 1	Hazardous to the aquatic environment – Acute Hazard, Category 1
Aquatic Chronic 1	Hazardous to the aquatic environment – Chronic Hazard, Category 1
EUH071	Corrosive to the respiratory tract.
Eye Dam. 1	Serious eye damage/eye irritation, Category 1
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
H301	Toxic if swallowed.
H310	Fatal in contact with skin.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H330	Fatal if inhaled.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
Skin Corr. 1C	Skin corrosion/irritation, Category 1, Sub-Category 1C
Skin Irrit. 2	Skin corrosion/irritation, Category 2
Skin Sens. 1	Skin sensitisation, Category 1
Skin Sens. 1A	Skin sensitisation, category 1A

<b>Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:</b>		
Skin Sens. 1	H317	Calculation method

KFT SDS EU 00

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

### SECTION 1: Identification of the substance/mixture and of the company/undertaking

#### 1.1. Product identifier

Product form : Mixture  
 Trade name : [CONJ D IgM]

#### 1.2. Relevant identified uses of the substance or mixture and uses advised against

##### 1.2.1. Relevant identified uses

Use of the substance/mixture : In vitro diagnostics

##### 1.2.2. Uses advised against

No additional information available

#### 1.3. Details of the supplier of the safety data sheet

##### Supplier

Virotech Diagnostics GmbH  
 Waldstraße 23 A2  
 DE- 63128 Dietzenbach  
 Deutschland  
 T +49 6074 236980

[qualitymanagement@virotechdiagnostics.com](mailto:qualitymanagement@virotechdiagnostics.com)

##### Email competent person

sds@kft.de

#### 1.4. Emergency telephone number

Country	Organisation/Company	Address	Emergency number	Comment
United Kingdom	National Health Service (NHS) England / Scotland / Wales / Northern Ireland	-	England / Scotland: 111 Wales: 111 or 0845 46 47 Northern Ireland: call your local General Practitioner. For life-threatening emergencies: call 999 for an ambulance.	24 h medical helpline for general public

### SECTION 2: Hazards identification

#### 2.1. Classification of the substance or mixture

##### Classification according to Regulation (EC) No. 1272/2008 [CLP]

Skin sensitisation, Category 1 H317  
 Full text of H- and EUH-statements: see section 16

##### Adverse physicochemical, human health and environmental effects

May cause an allergic skin reaction.

#### 2.2. Label elements

##### Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP) :



GHS07

Signal word (CLP) :

Warning

Contains :

reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)

Hazard statements (CLP) :

H317 - May cause an allergic skin reaction.

# [CONJ D IgM]

## Safety Data Sheet

According to REACH Regulation (EC) No 1907/2006, as retained and amended in UK law

Precautionary statements (CLP) : P261 - Avoid breathing mist, vapours, spray.  
P280 - Wear protective gloves, protective clothing, eye protection.  
P333+P313 - If skin irritation or rash occurs: Get medical advice/attention.  
P362+P364 - Take off contaminated clothing and wash it before reuse.

### 2.3. Other hazards

PBT: not relevant – no registration required

vPvB: not relevant – no registration required

Contains no PBT/vPvB substances  $\geq 0.1\%$  assessed in accordance with REACH Annex XIII

Component	
reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) (55965-84-9)	This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %

## SECTION 3: Composition/information on ingredients

### 3.1. Substances

Not applicable

### 3.2. Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) (Note B)	CAS-No.: 55965-84-9 EC Index-No.: 613-167-00-5	0.001 – 0.0025	Acute Tox. 2 (Inhalation), H330 (ATE=0.33 mg/l/4h) Acute Tox. 2 (Dermal), H310 (ATE=87.12 mg/kg bodyweight) Acute Tox. 3 (Oral), H301 (ATE=64 mg/kg bodyweight) Skin Corr. 1C, H314 Eye Dam. 1, H318 Skin Sens. 1A, H317 Aquatic Acute 1, H400 (M=100) Aquatic Chronic 1, H410 (M=100) EUH071

### Specific concentration limits:

Name	Product identifier	Specific concentration limits
reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)	CAS-No.: 55965-84-9 EC Index-No.: 613-167-00-5	( 0.0015 $\leq$ C $\leq$ 100) Skin Sens. 1A, H317 ( 0.06 $\leq$ C < 0.6) Eye Irrit. 2, H319 ( 0.06 $\leq$ C < 0.6) Skin Irrit. 2, H315 ( 0.6 $\leq$ C $\leq$ 100) Eye Dam. 1, H318 ( 0.6 $\leq$ C $\leq$ 100) Skin Corr. 1C, H314

Note B: Some substances (acids, bases, etc.) are placed on the market in aqueous solutions at various concentrations and, therefore, these solutions require different classification and labelling since the hazards vary at different concentrations. In Part 3 entries with Note B have a general designation of the following type: '... %'. In this case the supplier must state the percentage concentration of the solution on the label. Unless otherwise stated, it is assumed that the percentage concentration is calculated on a weight/weight basis.

Full text of H- and EUH-statements: see section 16

# [CONJ D IgM]

## Safety Data Sheet

According to REACH Regulation (EC) No 1907/2006, as retained and amended in UK law

### SECTION 4: First aid measures

#### 4.1. Description of first aid measures

First-aid measures general	: In all cases of doubt, or when symptoms persist, seek medical attention.
First-aid measures after inhalation	: Remove person to fresh air and keep comfortable for breathing.
First-aid measures after skin contact	: Wash skin with plenty of water. Take off contaminated clothing. If skin irritation or rash occurs: Get medical advice/attention.
First-aid measures after eye contact	: Rinse eyes with water as a precaution.
First-aid measures after ingestion	: Call a poison center or a doctor if you feel unwell.

#### 4.2. Most important symptoms and effects, both acute and delayed

Symptoms/effects after skin contact	: May cause an allergic skin reaction.
-------------------------------------	----------------------------------------

#### 4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

### SECTION 5: Firefighting measures

#### 5.1. Extinguishing media

Suitable extinguishing media	: Use extinguishing media appropriate for surrounding fire. Water spray. Dry powder. Foam. Carbon dioxide.
Unsuitable extinguishing media	: Strong water jet.

#### 5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire	: Toxic fumes may be released. release of harmful/irritant gases/vapours. Carbon monoxide. Carbon dioxide. Nitrogen oxides.
--------------------------------------------------	-----------------------------------------------------------------------------------------------------------------------------

#### 5.3. Advice for firefighters

Protection during firefighting	: Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.
Other information	: Do not allow run-off from fire fighting to enter drains or water courses. Disposal must be done according to official regulations.

### SECTION 6: Accidental release measures

#### 6.1. Personal precautions, protective equipment and emergency procedures

##### 6.1.1. For non-emergency personnel

Emergency procedures	: Ventilate spillage area. Avoid contact with skin and eyes. Avoid breathing mist, vapours, spray.
----------------------	----------------------------------------------------------------------------------------------------

##### 6.1.2. For emergency responders

Protective equipment	: Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".
----------------------	-------------------------------------------------------------------------------------------------------------------------------------------------------------

#### 6.2. Environmental precautions

Prevent entry to sewers and public waters. Avoid sub-soil penetration. Notify authorities if product enters sewers or public waters.

#### 6.3. Methods and material for containment and cleaning up

Methods for cleaning up	: Take up liquid spill into absorbent material. Take up mechanically (sweeping, shovelling) and collect in suitable container for disposal.
Other information	: Disposal must be done according to official regulations.

#### 6.4. Reference to other sections

Information for safe handling. See section 7. Concerning personal protective equipment to use, see section 8. For further information refer to section 13.

# [CONJ D IgM]

## Safety Data Sheet

According to REACH Regulation (EC) No 1907/2006, as retained and amended in UK law

### SECTION 7: Handling and storage

#### 7.1. Precautions for safe handling

Precautions for safe handling : Ensure good ventilation of the work station. Wear personal protective equipment. Avoid contact with skin and eyes. Avoid breathing mist, vapours, spray.

Hygiene measures : Do not eat, drink or smoke when using this product. Always wash hands after handling the product. Contaminated work clothing should not be allowed out of the workplace. Wash contaminated clothing before reuse.

#### 7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in a well-ventilated place. Keep cool.

Information about storage in one common storage facility : Keep away from food, drink and animal feeding stuffs.

#### 7.3. Specific end use(s)

In vitro diagnostics.

### SECTION 8: Exposure controls/personal protection

#### 8.1. Control parameters

##### 8.1.1 National occupational exposure and biological limit values

No additional information available

##### 8.1.2. Recommended monitoring procedures

No additional information available

##### 8.1.3. Air contaminants formed

No additional information available

##### 8.1.4. DNEL and PNEC

reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) (55965-84-9)	
<b>DNEL/DMEL (Workers)</b>	
Acute - local effects, inhalation	0.04 mg/m <sup>3</sup>
Long-term - local effects, inhalation	0.02 mg/m <sup>3</sup>
<b>DNEL/DMEL (General population)</b>	
Acute - systemic effects, oral	0.11 mg/kg bodyweight
Acute - local effects, inhalation	0.04 mg/m <sup>3</sup>
Long-term - systemic effects, oral	0.09 mg/kg bodyweight/day
Long-term - local effects, inhalation	0.02 mg/m <sup>3</sup>
<b>PNEC (Water)</b>	
PNEC aqua (freshwater)	0.00339 mg/l
PNEC aqua (marine water)	0.00339 mg/l
PNEC aqua (intermittent, freshwater)	0.00339 mg/l
PNEC aqua (intermittent, marine water)	0.00339 mg/l
<b>PNEC (Sediment)</b>	
PNEC sediment (freshwater)	0.027 mg/kg dwt
PNEC sediment (marine water)	0.027 mg/kg dwt
<b>PNEC (Soil)</b>	
PNEC soil	0.01 mg/kg dwt



# [CONJ D IgM]

## Safety Data Sheet

According to REACH Regulation (EC) No 1907/2006, as retained and amended in UK law

PNEC (STP)	
PNEC sewage treatment plant	0.23 mg/l

### 8.1.5. Control banding

No additional information available

## 8.2. Exposure controls

### 8.2.1. Appropriate engineering controls

#### Appropriate engineering controls:

Ensure good ventilation of the work station.

### 8.2.2. Personal protection equipment

#### 8.2.2.1. Eye and face protection

##### Eye protection:

Use splash goggles when eye contact due to splashing is possible. ISO 16321-1

#### 8.2.2.2. Skin protection

##### Skin and body protection:

Wear suitable protective clothing. EN ISO 13688. EN 13034

##### Hand protection:

Chemically resistant protective gloves. ISO 374-1. Nitrile rubber. Choosing the proper glove is a decision that depends not only on the type of material, but also on other quality features, which differ for each manufacturer. Please follow the instructions related to the permeability and the penetration time provided by the manufacturer. Gloves must be replaced after each use and whenever signs of wear or perforation appear

#### 8.2.2.3. Respiratory protection

##### Respiratory protection:

In case of insufficient ventilation, wear suitable respiratory equipment. In case of unintended release: Breathing apparatus with filter. Particle filter. P2. EN 143. . Breathing equipment is only to be used in order to handle the residual risk of short term jobs if all other risk minimizing measures have been carried out e.g. retention and/or local exhaust

#### 8.2.2.4. Thermal hazards

No additional information available

## 8.2.3. Environmental exposure controls

### Environmental exposure controls:

Avoid release to the environment.

### Other information:

Do not eat, drink or smoke when using this product. Avoid contact with skin and eyes. Always wash hands after handling the product.

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Colour	: red.
Odour	: odourless.
Odour threshold	: Not available
Melting point	: Not available
Freezing point	: Not available
Boiling point	: Not available
Flammability	: Not applicable
Explosive properties	: Product is not explosive.
Oxidising properties	: Non oxidizing.
Explosive limits	: Not available
Lower explosion limit	: Not available
Upper explosion limit	: Not available
Flash point	: Not available
Auto-ignition temperature	: Not available

# [CONJ D IgM]

## Safety Data Sheet

According to REACH Regulation (EC) No 1907/2006, as retained and amended in UK law

Decomposition temperature	: Not available
pH	: 7.5 – 7.7 (20 °C)
Viscosity, kinematic	: Not available
Solubility	: Water: Soluble
Partition coefficient n-octanol/water (Log Kow)	: Not available
Vapour pressure	: Not available
Vapour pressure at 50°C	: Not available
Density	: Not available
Relative density	: Not available
Relative vapour density at 20°C	: Not available
Particle characteristics	: Not applicable

### 9.2. Other information

#### 9.2.1. Information with regard to physical hazard classes

No additional information available

#### 9.2.2. Other safety characteristics

No additional information available

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

### 10.2. Chemical stability

Stable under normal conditions.

### 10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

### 10.4. Conditions to avoid

No additional information available

### 10.5. Incompatible materials

No additional information available.

### 10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

## SECTION 11: Toxicological information

### 11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity (oral)	: Not classified (Based on available data, the classification criteria are not met)
Acute toxicity (dermal)	: Not classified (Based on available data, the classification criteria are not met)
Acute toxicity (inhalation)	: Not classified (Based on available data, the classification criteria are not met)

reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) (55965-84-9)	
LD50 oral rat	64 mg/kg bodyweight (male)
LD50 dermal rabbit	87.12 mg/kg bodyweight (Active substance; male)
LC50 Inhalation - Rat (Dust/Mist)	0.33 mg/l/4h (Active substance; (OECD 403 method))

Skin corrosion/irritation	: Not classified (Based on available data, the classification criteria are not met) pH: 7.5 – 7.7 (20 °C)
Serious eye damage/irritation	: Not classified (Based on available data, the classification criteria are not met) pH: 7.5 – 7.7 (20 °C)
Respiratory or skin sensitisation	: May cause an allergic skin reaction.

# [CONJ D IgM]

## Safety Data Sheet

According to REACH Regulation (EC) No 1907/2006, as retained and amended in UK law

Germ cell mutagenicity	: Not classified (Based on available data, the classification criteria are not met)
Carcinogenicity	: Not classified (Based on available data, the classification criteria are not met)
Reproductive toxicity	: Not classified (Based on available data, the classification criteria are not met)
STOT-single exposure	: Not classified (Based on available data, the classification criteria are not met)
STOT-repeated exposure	: Not classified (Based on available data, the classification criteria are not met)
Aspiration hazard	: Not classified (Based on available data, the classification criteria are not met)

### 11.2. Information on other hazards

No additional information available

## SECTION 12: Ecological information

### 12.1. Toxicity

Ecology - general	: The product has not been tested.
Hazardous to the aquatic environment, short-term (acute)	: Not classified (Based on available data, the classification criteria are not met)
Hazardous to the aquatic environment, long-term (chronic)	: Not classified (Based on available data, the classification criteria are not met)

#### reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) (55965-84-9)

LC50 - Fish [1]	0.19 mg/l (96 h; Oncorhynchus mykiss; EPA OPP 72-1)
EC50 - Crustacea [1]	0.18 mg/l (48 h; Daphnia magna; EPA OPP 72-2)
ErC50 algae	0.0063 mg/l (72 h; Skeletonema costatum (marine diatom); (OECD 201 method))
NOEC chronic fish	0.098 mg/l (28 d; Oncorhynchus mykiss; (OECD 215 method))
NOEC chronic crustacea	0.328 mg/l (21 d; Daphnia magna; (OECD 211 method))
NOEC chronic algae	0.0005 mg/l (48 h; Skeletonema costatum (marine diatom); (OECD 201 method))

### 12.2. Persistence and degradability

#### reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) (55965-84-9)

Persistence and degradability	Not readily biodegradable. Readily biodegradable, failing 10-d window.
Biodegradation	62 % (29 d; (OECD 301B method))

### 12.3. Bioaccumulative potential

#### Anti-dog IgM conjugate

Bioaccumulative potential	No additional information available.
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#### reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) (55965-84-9)

Bioconcentration factor (BCF REACH)	≈ 41 (20 °C; 0.12 mg/L; EPA OPP 165-4)
Partition coefficient n-octanol/water (Log Pow)	-0.32 – 0.7 (20 °C; (OECD 117 method))

### 12.4. Mobility in soil

#### Anti-dog IgM conjugate

Ecology - soil	No additional information available.
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# [CONJ D IgM]

## Safety Data Sheet

According to REACH Regulation (EC) No 1907/2006, as retained and amended in UK law

<b>reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) (55965-84-9)</b>	
Surface tension	73 mN/m (19.5 °C; 1 g/L; Test method EU A.5)
Ecology - soil	Low mobility (soil).

### 12.5. Results of PBT and vPvB assessment

<b>Anti-dog IgM conjugate</b>	
PBT: not relevant – no registration required	
vPvB: not relevant – no registration required	
<b>Component</b>	
reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) (55965-84-9)	This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

### 12.6. Endocrine disrupting properties

No additional information available

### 12.7. Other adverse effects

Other adverse effects : No additional information available.

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

Waste treatment methods : Disposal must be done according to official regulations. European waste catalogue. Do not discharge into drains or the environment. Do not dispose of with domestic waste.  
Product/Packaging disposal recommendations : Recycle or dispose of in compliance with current legislation.

## SECTION 14: Transport information

In accordance with ADR / IMDG / IATA / ADN / RID

ADR	IMDG	IATA	ADN	RID
<b>14.1. UN number or ID number</b>				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
<b>14.2. UN proper shipping name</b>				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
<b>14.3. Transport hazard class(es)</b>				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
<b>14.4. Packing group</b>				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
<b>14.5. Environmental hazards</b>				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
No supplementary information available				

### 14.6. Special precautions for user

#### Overland transport

Not regulated

# [CONJ D IgM]

## Safety Data Sheet

According to REACH Regulation (EC) No 1907/2006, as retained and amended in UK law

### Transport by sea

Not regulated

### Air transport

Not regulated

### Inland waterway transport

Not regulated

### Rail transport

Not regulated

### 14.7. Maritime transport in bulk according to IMO instruments

Not applicable

## SECTION 15: Regulatory information

### 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

#### 15.1.1. EU-Regulations

Other information, restriction and prohibition regulations : This product is a medical device and has not to be classified and labelled according to the current laws and regulations. Take note of Directive 94/33/EC on the protection of young people at work.

#### REACH Annex XVII (Restriction List)

EU restriction list (REACH Annex XVII)	
Reference code	Applicable on
3(b)	Anti-dog IgM conjugate ; reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)
3(c)	reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)

#### REACH Annex XIV (Authorisation List)

Contains no substance(s) listed on REACH Annex XIV (Authorisation List)

#### REACH Candidate List (SVHC)

Contains no substance(s) listed on the REACH Candidate List

#### PIC Regulation (Prior Informed Consent)

Contains no substance(s) listed on the PIC list (Regulation EU 649/2012 concerning the export and import of hazardous chemicals)

#### POP Regulation (Persistent Organic Pollutants)

Contains no substance(s) listed on the POP list (Regulation EU 2019/1021 on persistent organic pollutants)

#### Ozone Regulation (1005/2009)

Contains no substance(s) listed on the Ozone Depletion list (Regulation EU 1005/2009 on substances that deplete the ozone layer)

#### Explosives Precursors Regulation (2019/1148)

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

#### Drug Precursors Regulation (273/2004)

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

#### 15.1.2. National regulations

No additional information available

### 15.2. Chemical safety assessment

No chemical safety assessment has been carried out

# [CONJ D IgM]

## Safety Data Sheet

According to REACH Regulation (EC) No 1907/2006, as retained and amended in UK law

### SECTION 16: Other information

Indication of changes			
Section	Changed item	Change	Comments
	General revision		
2.1	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Modified	
2.2	Labelling according to Regulation (EC) No. 1272/2008 [CLP]	Modified	
11.1	Toxicological information	Modified	
15.1	REACH Annex XVII	Modified	

Abbreviations and acronyms:	
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
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DMEL	Derived Minimal Effect level
DNEL	Derived-No Effect Level
EC50	Median effective concentration
IARC	International Agency for Research on Cancer
IATA	International Air Transport Association
IMDG	International Maritime Dangerous Goods
LC50	Median lethal concentration
LD50	Median lethal dose
LOAEL	Lowest Observed Adverse Effect Level
NOAEC	No-Observed Adverse Effect Concentration
NOAEL	No-Observed Adverse Effect Level
NOEC	No-Observed Effect Concentration
OECD	Organisation for Economic Co-operation and Development
PBT	Persistent Bioaccumulative Toxic
PNEC	Predicted No-Effect Concentration
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
SDS	Safety Data Sheet
STP	Sewage treatment plant
TLM	Median Tolerance Limit
vPvB	Very Persistent and Very Bioaccumulative
CAS-No.	Chemical Abstract Service number

Data sources

: Information provided by the manufacturer. MSDS of the supplier. European Chemicals Agency, <http://echa.europa.eu/>.

# [CONJ D IgM]

## Safety Data Sheet

According to REACH Regulation (EC) No 1907/2006, as retained and amended in UK law

Department issuing data specification sheet: : KFT Chemieservice GmbH  
Im Leuschnerpark 3  
D-64347 Griesheim

Phone: +49 6155-8981-400  
Fax: +49 6155 8981-500  
SDS Service: +49 6155 8981-522

Contact person

: Dr. Andreas Kretzschmar

Other information

: This safety data sheet is for informational purposes only and does not comply with national legal requirements without reference to a national distributor. The national distributor is responsible for a legally compliant safety data sheet.

<b>Full text of H- and EUH-statements:</b>	
Acute Tox. 2 (Dermal)	Acute toxicity (dermal), Category 2
Acute Tox. 2 (Inhalation)	Acute toxicity (inhal.), Category 2
Acute Tox. 3 (Oral)	Acute toxicity (oral), Category 3
Aquatic Acute 1	Hazardous to the aquatic environment – Acute Hazard, Category 1
Aquatic Chronic 1	Hazardous to the aquatic environment – Chronic Hazard, Category 1
EUH071	Corrosive to the respiratory tract.
Eye Dam. 1	Serious eye damage/eye irritation, Category 1
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
H301	Toxic if swallowed.
H310	Fatal in contact with skin.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H330	Fatal if inhaled.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
Skin Corr. 1C	Skin corrosion/irritation, Category 1, Sub-Category 1C
Skin Irrit. 2	Skin corrosion/irritation, Category 2
Skin Sens. 1	Skin sensitisation, Category 1
Skin Sens. 1A	Skin sensitisation, category 1A

<b>Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:</b>		
Skin Sens. 1	H317	Calculation method

KFT SDS EU 00

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

### SECTION 1: Identification of the substance/mixture and of the company/undertaking

#### 1.1. Product identifier

Product form : Mixture  
Trade name : [CONJ H IgG]

#### 1.2. Relevant identified uses of the substance or mixture and uses advised against

##### 1.2.1. Relevant identified uses

Use of the substance/mixture : In vitro diagnostics

##### 1.2.2. Uses advised against

No additional information available

#### 1.3. Details of the supplier of the safety data sheet

##### Supplier

Virotech Diagnostics GmbH  
Waldstraße 23 A2  
DE- 63128 Dietzenbach  
Deutschland  
T +49 6074 236980

[qualitymanagement@virotechdiagnostics.com](mailto:qualitymanagement@virotechdiagnostics.com)

##### Email competent person

sds@kft.de

#### 1.4. Emergency telephone number

Country	Organisation/Company	Address	Emergency number	Comment
United Kingdom	National Health Service (NHS) England / Scotland / Wales / Northern Ireland	-	England / Scotland: 111 Wales: 111 or 0845 46 47 Northern Ireland: call your local General Practitioner. For life-threatening emergencies: call 999 for an ambulance.	24 h medical helpline for general public

### SECTION 2: Hazards identification

#### 2.1. Classification of the substance or mixture

##### Classification according to Regulation (EC) No. 1272/2008 [CLP]

Skin sensitisation, Category 1 H317  
Full text of H- and EUH-statements: see section 16

##### Adverse physicochemical, human health and environmental effects

May cause an allergic skin reaction.

#### 2.2. Label elements

##### Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP) :



GHS07

Signal word (CLP) :

Warning

Contains :

reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)

Hazard statements (CLP) :

H317 - May cause an allergic skin reaction.



# [CONJ H IgG]

## Safety Data Sheet

According to REACH Regulation (EC) No 1907/2006, as retained and amended in UK law

Precautionary statements (CLP) : P261 - Avoid breathing mist, vapours, spray.  
P280 - Wear protective gloves, protective clothing, eye protection.  
P333+P313 - If skin irritation or rash occurs: Get medical advice/attention.  
P362+P364 - Take off contaminated clothing and wash it before reuse.

### 2.3. Other hazards

Contains no PBT/vPvB substances  $\geq 0.1\%$  assessed in accordance with REACH Annex XIII

Component	
reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) (55965-84-9)	This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %

## SECTION 3: Composition/information on ingredients

### 3.1. Substances

Not applicable

### 3.2. Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) (Note B)	CAS-No.: 55965-84-9 EC Index-No.: 613-167-00-5	0.001 – 0.0025	Acute Tox. 2 (Inhalation), H330 (ATE=0.33 mg/l/4h) Acute Tox. 2 (Dermal), H310 (ATE=87.12 mg/kg bodyweight) Acute Tox. 3 (Oral), H301 (ATE=64 mg/kg bodyweight) Skin Corr. 1C, H314 Eye Dam. 1, H318 Skin Sens. 1A, H317 Aquatic Acute 1, H400 (M=100) Aquatic Chronic 1, H410 (M=100) EUH071

Specific concentration limits:		
Name	Product identifier	Specific concentration limits
reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)	CAS-No.: 55965-84-9 EC Index-No.: 613-167-00-5	( 0.0015 $\leq$ C $\leq$ 100) Skin Sens. 1A, H317 ( 0.06 $\leq$ C < 0.6) Eye Irrit. 2, H319 ( 0.06 $\leq$ C < 0.6) Skin Irrit. 2, H315 ( 0.6 $\leq$ C $\leq$ 100) Eye Dam. 1, H318 ( 0.6 $\leq$ C $\leq$ 100) Skin Corr. 1C, H314

Note B: Some substances (acids, bases, etc.) are placed on the market in aqueous solutions at various concentrations and, therefore, these solutions require different classification and labelling since the hazards vary at different concentrations. In Part 3 entries with Note B have a general designation of the following type: '... %'. In this case the supplier must state the percentage concentration of the solution on the label. Unless otherwise stated, it is assumed that the percentage concentration is calculated on a weight/weight basis.

Full text of H- and EUH-statements: see section 16

# [CONJ H IgG]

## Safety Data Sheet

According to REACH Regulation (EC) No 1907/2006, as retained and amended in UK law

### SECTION 4: First aid measures

#### 4.1. Description of first aid measures

First-aid measures general	: In all cases of doubt, or when symptoms persist, seek medical attention.
First-aid measures after inhalation	: Remove person to fresh air and keep comfortable for breathing.
First-aid measures after skin contact	: Wash skin with plenty of water. Take off contaminated clothing. If skin irritation or rash occurs: Get medical advice/attention.
First-aid measures after eye contact	: Rinse eyes with water as a precaution.
First-aid measures after ingestion	: Call a poison center or a doctor if you feel unwell.

#### 4.2. Most important symptoms and effects, both acute and delayed

Symptoms/effects after skin contact	: May cause an allergic skin reaction.
-------------------------------------	----------------------------------------

#### 4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

### SECTION 5: Firefighting measures

#### 5.1. Extinguishing media

Suitable extinguishing media	: Use extinguishing media appropriate for surrounding fire. Water spray. Dry powder. Foam. Carbon dioxide.
Unsuitable extinguishing media	: No information available. Strong water jet.

#### 5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire	: Toxic fumes may be released. release of harmful/irritant gases/vapours. Carbon monoxide. Carbon dioxide (CO <sub>2</sub> ). Nitrogen oxides. Sulphur oxides.
--------------------------------------------------	----------------------------------------------------------------------------------------------------------------------------------------------------------------

#### 5.3. Advice for firefighters

Protection during firefighting	: Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.
Other information	: Cool closed containers exposed to fire with water spray. Do not allow run-off from fire fighting to enter drains or water courses. Disposal must be done according to official regulations.

### SECTION 6: Accidental release measures

#### 6.1. Personal precautions, protective equipment and emergency procedures

##### 6.1.1. For non-emergency personnel

Emergency procedures	: Ventilate spillage area. Avoid contact with skin and eyes. Avoid breathing mist, vapours, spray.
----------------------	----------------------------------------------------------------------------------------------------

##### 6.1.2. For emergency responders

Protective equipment	: Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".
----------------------	-------------------------------------------------------------------------------------------------------------------------------------------------------------

#### 6.2. Environmental precautions

Prevent entry to sewers and public waters. Avoid sub-soil penetration. Notify authorities if product enters sewers or public waters.

#### 6.3. Methods and material for containment and cleaning up

Methods for cleaning up	: Take up liquid spill into absorbent material. Take up mechanically (sweeping, shovelling) and collect in suitable container for disposal.
Other information	: Disposal must be done according to official regulations.

# [CONJ H IgG]

## Safety Data Sheet

According to REACH Regulation (EC) No 1907/2006, as retained and amended in UK law

### 6.4. Reference to other sections

Information for safe handling. See section 7. Concerning personal protective equipment to use, see section 8. For further information refer to section 13.

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

Precautions for safe handling : Ensure good ventilation of the work station. Wear personal protective equipment. Avoid contact with skin and eyes. Avoid breathing mist, vapours, spray.

Hygiene measures : Do not eat, drink or smoke when using this product. Always wash hands after handling the product. Contaminated work clothing should not be allowed out of the workplace. Wash contaminated clothing before reuse.

### 7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in a well-ventilated place. Keep cool.

Information about storage in one common storage facility : Keep away from food, drink and animal feeding stuffs.

### 7.3. Specific end use(s)

In vitro diagnostics.

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

#### 8.1.1 National occupational exposure and biological limit values

No additional information available

#### 8.1.2. Recommended monitoring procedures

No additional information available

#### 8.1.3. Air contaminants formed

No additional information available

#### 8.1.4. DNEL and PNEC

reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) (55965-84-9)	
<b>DNEL/DMEL (Workers)</b>	
Acute - local effects, inhalation	0.04 mg/m <sup>3</sup>
Long-term - local effects, inhalation	0.02 mg/m <sup>3</sup>
<b>DNEL/DMEL (General population)</b>	
Acute - systemic effects, oral	0.11 mg/kg bodyweight
Acute - local effects, inhalation	0.04 mg/m <sup>3</sup>
Long-term - systemic effects, oral	0.09 mg/kg bodyweight/day
Long-term - local effects, inhalation	0.02 mg/m <sup>3</sup>
<b>PNEC (Water)</b>	
PNEC aqua (freshwater)	0.00339 mg/l
PNEC aqua (marine water)	0.00339 mg/l
PNEC aqua (intermittent, freshwater)	0.00339 mg/l
PNEC aqua (intermittent, marine water)	0.00339 mg/l

# [CONJ H IgG]

## Safety Data Sheet

According to REACH Regulation (EC) No 1907/2006, as retained and amended in UK law

<b>PNEC (Sediment)</b>	
PNEC sediment (freshwater)	0.027 mg/kg dwt
PNEC sediment (marine water)	0.027 mg/kg dwt
<b>PNEC (Soil)</b>	
PNEC soil	0.01 mg/kg dwt
<b>PNEC (STP)</b>	
PNEC sewage treatment plant	0.23 mg/l

### 8.1.5. Control banding

No additional information available

## 8.2. Exposure controls

### 8.2.1. Appropriate engineering controls

#### Appropriate engineering controls:

Ensure good ventilation of the work station.

### 8.2.2. Personal protection equipment

#### 8.2.2.1. Eye and face protection

##### Eye protection:

Use splash goggles when eye contact due to splashing is possible. ISO 16321-1

#### 8.2.2.2. Skin protection

##### Skin and body protection:

Wear suitable protective clothing. EN ISO 13688. EN 13034

##### Hand protection:

Chemically resistant protective gloves. ISO 374-1. Nitrile rubber. Choosing the proper glove is a decision that depends not only on the type of material, but also on other quality features, which differ for each manufacturer. Please follow the instructions related to the permeability and the penetration time provided by the manufacturer. Gloves must be replaced after each use and whenever signs of wear or perforation appear

#### 8.2.2.3. Respiratory protection

##### Respiratory protection:

In case of insufficient ventilation, wear suitable respiratory equipment. In case of unintended release: Breathing apparatus with filter. Particle filter. P2. EN 143. . Breathing equipment is only to be used in order to handle the residual risk of short term jobs if all other risk minimizing measures have been carried out e.g. retention and/or local exhaust

#### 8.2.2.4. Thermal hazards

No additional information available

### 8.2.3. Environmental exposure controls

#### Environmental exposure controls:

Avoid release to the environment.

#### Other information:

Do not eat, drink or smoke when using this product. Avoid contact with skin and eyes. Always wash hands after handling the product.

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Colour	: red.
Odour	: odourless.
Odour threshold	: Not available
Melting point	: Not available
Freezing point	: Not available
Boiling point	: Not available
Flammability	: Not applicable

# [CONJ H IgG]

## Safety Data Sheet

According to REACH Regulation (EC) No 1907/2006, as retained and amended in UK law

Explosive properties	: No data available. Product is not explosive.
Oxidising properties	: Non oxidizing.
Explosive limits	: Not available
Lower explosion limit	: Not available
Upper explosion limit	: Not available
Flash point	: Not available
Auto-ignition temperature	: Not available
Decomposition temperature	: Not available
pH	: 7.5 – 7.7 (20 °C)
Viscosity, kinematic	: Not available
Solubility	: Water: Soluble
Partition coefficient n-octanol/water (Log Kow)	: Not available
Vapour pressure	: Not available
Vapour pressure at 50°C	: Not available
Density	: Not available
Relative density	: Not available
Relative vapour density at 20°C	: Not available
Particle characteristics	: Not applicable

### 9.2. Other information

#### 9.2.1. Information with regard to physical hazard classes

No additional information available

#### 9.2.2. Other safety characteristics

No additional information available

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

### 10.2. Chemical stability

Stable under normal conditions.

### 10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

### 10.4. Conditions to avoid

No additional information available

### 10.5. Incompatible materials

No additional information available.

### 10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

## SECTION 11: Toxicological information

### 11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity (oral)	: Not classified (Based on available data, the classification criteria are not met)
Acute toxicity (dermal)	: Not classified (Based on available data, the classification criteria are not met)
Acute toxicity (inhalation)	: Not classified (Based on available data, the classification criteria are not met)

reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) (55965-84-9)	
LD50 oral rat	64 mg/kg bodyweight (male)
LD50 dermal rabbit	87.12 mg/kg bodyweight (Active substance; male)

# [CONJ H IgG]

## Safety Data Sheet

According to REACH Regulation (EC) No 1907/2006, as retained and amended in UK law

LC50 Inhalation - Rat (Dust/Mist)	0.33 mg/l/4h (Active substance; (OECD 403 method))
Skin corrosion/irritation	: Not classified (Based on available data, the classification criteria are not met) pH: 7.5 – 7.7 (20 °C)
Serious eye damage/irritation	: Not classified (Based on available data, the classification criteria are not met) pH: 7.5 – 7.7 (20 °C)
Respiratory or skin sensitisation	: May cause an allergic skin reaction.
Germ cell mutagenicity	: Not classified (Based on available data, the classification criteria are not met)
Carcinogenicity	: Not classified (No data available. Based on available data, the classification criteria are not met)
Reproductive toxicity	: Not classified (No data available. Based on available data, the classification criteria are not met)
STOT-single exposure	: Not classified (No data available. Based on available data, the classification criteria are not met)
STOT-repeated exposure	: Not classified (No data available. Based on available data, the classification criteria are not met)
Aspiration hazard	: Not classified (Based on available data, the classification criteria are not met)

### 11.2. Information on other hazards

No additional information available

## SECTION 12: Ecological information

### 12.1. Toxicity

Ecology - general	: The product has not been tested.
Hazardous to the aquatic environment, short-term (acute)	: Not classified (Based on available data, the classification criteria are not met)
Hazardous to the aquatic environment, long-term (chronic)	: Not classified (Based on available data, the classification criteria are not met)

<b>reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) (55965-84-9)</b>	
LC50 - Fish [1]	0.19 mg/l (96 h; Oncorhynchus mykiss; EPA OPP 72-1)
EC50 - Crustacea [1]	0.18 mg/l (48 h; Daphnia magna; EPA OPP 72-2)
ErC50 algae	0.0063 mg/l (72 h; Skeletonema costatum (marine diatom); (OECD 201 method))
NOEC chronic fish	0.098 mg/l (28 d; Oncorhynchus mykiss; (OECD 215 method))
NOEC chronic crustacea	0.328 mg/l (21 d; Daphnia magna; (OECD 211 method))
NOEC chronic algae	0.0005 mg/l (48 h; Skeletonema costatum (marine diatom); (OECD 201 method))

### 12.2. Persistence and degradability

<b>Anti-horse IgG conjugate</b>	
Persistence and degradability	No additional information available.
<b>reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) (55965-84-9)</b>	
Persistence and degradability	Not readily biodegradable. Readily biodegradable, failing 10-d window.
Biodegradation	62 % (29 d; (OECD 301B method))

### 12.3. Bioaccumulative potential

<b>Anti-horse IgG conjugate</b>	
Bioaccumulative potential	No additional information available.
<b>reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) (55965-84-9)</b>	
Bioconcentration factor (BCF REACH)	≈ 41 (20 °C; 0.12 mg/L; EPA OPP 165-4)

# [CONJ H IgG]

## Safety Data Sheet

According to REACH Regulation (EC) No 1907/2006, as retained and amended in UK law

Partition coefficient n-octanol/water (Log Pow)	-0.32 – 0.7 (20 °C; (OECD 117 method))
-------------------------------------------------	----------------------------------------

### 12.4. Mobility in soil

<b>Anti-horse IgG conjugate</b>	
Ecology - soil	No additional information available.
<b>reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) (55965-84-9)</b>	
Surface tension	73 mN/m (19.5 °C; 1 g/L; Test method EU A.5)
Ecology - soil	Low mobility (soil).

### 12.5. Results of PBT and vPvB assessment

<b>Component</b>	
reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) (55965-84-9)	This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

### 12.6. Endocrine disrupting properties

No additional information available

### 12.7. Other adverse effects

Other adverse effects : No additional information available.

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

Waste treatment methods : Disposal must be done according to official regulations. European waste catalogue. Do not discharge into drains or the environment. Do not dispose of with domestic waste.

Product/Packaging disposal recommendations : Comply with local regulations for disposal. Recycle or dispose of in compliance with current legislation.

## SECTION 14: Transport information

In accordance with ADR / IMDG / IATA / ADN / RID

# [CONJ H IgG]

## Safety Data Sheet

According to REACH Regulation (EC) No 1907/2006, as retained and amended in UK law

ADR	IMDG	IATA	ADN	RID
<b>14.1. UN number or ID number</b>				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
<b>14.2. UN proper shipping name</b>				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
<b>14.3. Transport hazard class(es)</b>				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
<b>14.4. Packing group</b>				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
<b>14.5. Environmental hazards</b>				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
No supplementary information available				

### 14.6. Special precautions for user

#### Overland transport

Not regulated

#### Transport by sea

Not regulated

#### Air transport

Not regulated

#### Inland waterway transport

Not regulated

#### Rail transport

Not regulated

### 14.7. Maritime transport in bulk according to IMO instruments

Not applicable

## SECTION 15: Regulatory information

### 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

#### 15.1.1. EU-Regulations

Other information, restriction and prohibition regulations

: This product is a medical device and has not to be classified and labelled according to the current laws and regulations. Take note of Directive 94/33/EC on the protection of young people at work.

#### REACH Annex XVII (Restriction List)

##### EU restriction list (REACH Annex XVII)

Reference code	Applicable on
3(b)	Anti-horse IgG conjugate ; reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)
3(c)	reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)

#### REACH Annex XIV (Authorisation List)

Contains no substance(s) listed on REACH Annex XIV (Authorisation List)



# [CONJ H IgG]

## Safety Data Sheet

According to REACH Regulation (EC) No 1907/2006, as retained and amended in UK law

### REACH Candidate List (SVHC)

Contains no substance(s) listed on the REACH Candidate List

### PIC Regulation (Prior Informed Consent)

Contains no substance(s) listed on the PIC list (Regulation EU 649/2012 concerning the export and import of hazardous chemicals)

### POP Regulation (Persistent Organic Pollutants)

Contains no substance(s) listed on the POP list (Regulation EU 2019/1021 on persistent organic pollutants)

### Ozone Regulation (1005/2009)

Contains no substance(s) listed on the Ozone Depletion list (Regulation EU 1005/2009 on substances that deplete the ozone layer)

### Explosives Precursors Regulation (2019/1148)

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

### Drug Precursors Regulation (273/2004)

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

#### 15.1.2. National regulations

No additional information available

#### 15.2. Chemical safety assessment

No chemical safety assessment has been carried out

## SECTION 16: Other information

### Indication of changes

Section	Changed item	Change	Comments
	General revision		
2.1	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Modified	
2.2	Labelling according to Regulation (EC) No. 1272/2008 [CLP]	Modified	
11.1	Toxicological information	Modified	

### Abbreviations and acronyms:

ADN	Accord européen relatif au transport international des marchandises dangereuses par voie de navigation intérieure (European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways)
ADR	Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
BCF	Bioconcentration factor
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008
DNEL	Derived-No Effect Level
EC50	Median effective concentration
IATA	International Air Transport Association
IMDG	International Maritime Code for Dangerous Goods
LC50	Median lethal concentration
LOAEL	Lowest Observed Adverse Effect Level
NOAEC	No-Observed Adverse Effect Concentration
NOAEL	No-Observed Adverse Effect Level

# [CONJ H IgG]

## Safety Data Sheet

According to REACH Regulation (EC) No 1907/2006, as retained and amended in UK law

NOEC	No-Observed Effect Concentration
PBT	Persistent Bioaccumulative Toxic
PNEC	Predicted No-Effect Concentration
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
STP	Sewage treatment plant
vPvB	Very Persistent and Very Bioaccumulative
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
ATE	Acute Toxicity Estimate
DMEL	Derived Minimal Effect level
IARC	International Agency for Research on Cancer
IATA	International Air Transport Association
IMDG	International Maritime Dangerous Goods
LD50	Median lethal dose
OECD	Organisation for Economic Co-operation and Development
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
SDS	Safety Data Sheet
TLM	Median Tolerance Limit
CAS-No.	Chemical Abstract Service number

Data sources : Information provided by the manufacturer. MSDS of the supplier. European Chemicals Agency, <http://echa.europa.eu/>.

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SDS Service: +49 6155 8981-522

Contact person : Dr. Andreas Kretzschmar

Other information : This safety data sheet is for informational purposes only and does not comply with national legal requirements without reference to a national distributor. The national distributor is responsible for a legally compliant safety data sheet.

<b>Full text of H- and EUH-statements:</b>	
Acute Tox. 2 (Dermal)	Acute toxicity (dermal), Category 2
Acute Tox. 2 (Inhalation)	Acute toxicity (inhal.), Category 2
Acute Tox. 3 (Oral)	Acute toxicity (oral), Category 3
Aquatic Acute 1	Hazardous to the aquatic environment – Acute Hazard, Category 1
Aquatic Chronic 1	Hazardous to the aquatic environment – Chronic Hazard, Category 1
EUH071	Corrosive to the respiratory tract.
Eye Dam. 1	Serious eye damage/eye irritation, Category 1
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
H301	Toxic if swallowed.
H310	Fatal in contact with skin.
H314	Causes severe skin burns and eye damage.

# [CONJ H IgG]

## Safety Data Sheet

According to REACH Regulation (EC) No 1907/2006, as retained and amended in UK law

H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H330	Fatal if inhaled.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
Skin Corr. 1C	Skin corrosion/irritation, Category 1, Sub-Category 1C
Skin Irrit. 2	Skin corrosion/irritation, Category 2
Skin Sens. 1	Skin sensitisation, Category 1
Skin Sens. 1A	Skin sensitisation, category 1A

<b>Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:</b>		
Skin Sens. 1	H317	Calculation method

KFT SDS EU 00

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

### SECTION 1: Identification of the substance/mixture and of the company/undertaking

#### 1.1. Product identifier

Product form : Mixture  
Trade name : [STOP RTU]

#### 1.2. Relevant identified uses of the substance or mixture and uses advised against

##### 1.2.1. Relevant identified uses

Use of the substance/mixture : In vitro diagnostics

##### 1.2.2. Uses advised against

No additional information available

#### 1.3. Details of the supplier of the safety data sheet

##### Supplier

Virotech Diagnostics GmbH  
Waldstraße 23 A2  
DE- 63128 Dietzenbach  
Deutschland  
T +49 6074 236980  
[qualitymanagement@virotechdiagnostics.com](mailto:qualitymanagement@virotechdiagnostics.com)

##### Email competent person

sds@kft.de

#### 1.4. Emergency telephone number

Emergency number : National Health Service (NHS)  
24 hour national number consumer  
England and Scotland: 111  
Wales: 0845 46 47  
Northern Ireland: call your local General Practitioner  
  
Call 999 if there is a life-threatening incident.

### SECTION 2: Hazards identification

#### 2.1. Classification of the substance or mixture

##### Classification according to Regulation (EC) No. 1272/2008 [CLP]

Corrosive to metals, Category 1	H290
Serious eye damage/eye irritation, Category 2	H319
Specific target organ toxicity – Single exposure, Category 3, Respiratory tract irritation	H335

Full text of H- and EUH-statements: see section 16

##### Adverse physicochemical, human health and environmental effects

May be corrosive to metals. Causes serious eye damage. May cause respiratory irritation.

#### 2.2. Label elements

##### Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP) :



GHS05

GHS07

Signal word (CLP) : Warning

Contains : citric acid, monohydrate

# [STOP RTU]

## Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

Hazard statements (CLP)	: H290 - May be corrosive to metals. H319 - Causes serious eye irritation. H335 - May cause respiratory irritation.
Precautionary statements (CLP)	: P261 - Avoid breathing vapours, mist. P280 - Wear face protection, eye protection. P312 - Call a POISON CENTER, doctor if you feel unwell. P337+P313 - If eye irritation persists: Get medical advice/attention. P390 - Absorb spillage to prevent material damage.

### 2.3. Other hazards

Contains no PBT/vPvB substances  $\geq 0.1\%$  assessed in accordance with REACH Annex XIII

Component	
citric acid, monohydrate (5949-29-1)	This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII
sulphuric acid (7664-93-9)	This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII
Hydrochloric acid (7647-01-0)	This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %

## SECTION 3: Composition/information on ingredients

### 3.1. Substances

Not applicable

### 3.2. Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
citric acid, monohydrate	CAS-No.: 5949-29-1 EC-No.: 201-069-1	$\geq 20 - < 25$	Eye Irrit. 2, H319 STOT SE 3, H335
sulphuric acid substance with national workplace exposure limit(s) (GB); substance with a Community workplace exposure limit	CAS-No.: 7664-93-9 EC-No.: 231-639-5 EC Index-No.: 016-020-00-8 REACH-no: 01-2119458838-20-xxxx	$\geq 1 - < 2.5$	Skin Corr. 1A, H314
Hydrochloric acid (Note B)	CAS-No.: 7647-01-0 EC-No.: 231-595-7 EC Index-No.: 017-002-01-X REACH-no: 01-2119484862-27-xxxx	$\geq 0.1 - < 0.25$	Met. Corr. 1, H290 Skin Corr. 1B, H314 STOT SE 3, H335

### Specific concentration limits:

Name	Product identifier	Specific concentration limits
sulphuric acid	CAS-No.: 7664-93-9 EC-No.: 231-639-5 EC Index-No.: 016-020-00-8 REACH-no: 01-2119458838-20-xxxx	( $5 \leq C < 15$ ) Eye Irrit. 2, H319 ( $5 \leq C < 15$ ) Skin Irrit. 2, H315 ( $15 \leq C < 100$ ) Skin Corr. 1A, H314

# [STOP RTU]

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according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

Hydrochloric acid	CAS-No.: 7647-01-0 EC-No.: 231-595-7 EC Index-No.: 017-002-01-X REACH-no: 01-2119484862-27-xxxx	( 0.1 ≤C < 100) Met. Corr. 1, H290 ( 10 ≤C < 100) STOT SE 3, H335 ( 10 ≤C < 25) Eye Irrit. 2, H319 ( 10 ≤C < 25) Skin Irrit. 2, H315 ( 25 ≤C < 100) Skin Corr. 1B, H314
-------------------	----------------------------------------------------------------------------------------------------------	-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

Note B : Some substances (acids, bases, etc.) are placed on the market in aqueous solutions at various concentrations and, therefore, these solutions require different classification and labelling since the hazards vary at different concentrations. In Part 3 entries with Note B have a general designation of the following type: 'nitric acid ... %'. In this case the supplier must state the percentage concentration of the solution on the label. Unless otherwise stated, it is assumed that the percentage concentration is calculated on a weight/weight basis.

Full text of H- and EUH-statements: see section 16

### SECTION 4: First aid measures

#### 4.1. Description of first aid measures

- First-aid measures after inhalation : Remove person to fresh air and keep comfortable for breathing. Call a poison center or a doctor if you feel unwell.
- First-aid measures after skin contact : Rinse skin with water/shower.
- First-aid measures after eye contact : Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.
- First-aid measures after ingestion : Rinse mouth. Do not induce vomiting. If symptoms persist, call a physician.

#### 4.2. Most important symptoms and effects, both acute and delayed

- Symptoms/effects after inhalation : May cause respiratory irritation.
- Symptoms/effects after eye contact : Serious damage to eyes.

#### 4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

### SECTION 5: Firefighting measures

#### 5.1. Extinguishing media

- Suitable extinguishing media : Use extinguishing media appropriate for surrounding fire. Water spray. Dry powder. Foam. Carbon dioxide.
- Unsuitable extinguishing media : Strong water jet.

#### 5.2. Special hazards arising from the substance or mixture

- Hazardous decomposition products in case of fire : Toxic fumes may be released. release of harmful/irritant gases/vapours. Carbon dioxide (CO<sub>2</sub>). Hydrogen chloride. Sulphur oxides.

#### 5.3. Advice for firefighters

- Protection during firefighting : Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.
- Other information : Do not allow run-off from fire fighting to enter drains or water courses. Disposal must be done according to official regulations.

### SECTION 6: Accidental release measures

#### 6.1. Personal precautions, protective equipment and emergency procedures

##### 6.1.1. For non-emergency personnel

- Emergency procedures : Ventilate spillage area. Avoid contact with skin and eyes. Do not breathe spray, vapours, mist.

# [STOP RTU]

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according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

### 6.1.2. For emergency responders

Protective equipment : Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

### 6.2. Environmental precautions

Avoid sub-soil penetration. Prevent entry to sewers and public waters.

### 6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Take up liquid spill into absorbent material. Take up mechanically (sweeping, shovelling) and collect in suitable container for disposal.

Other information : Dispose of materials or solid residues at an authorized site. Disposal must be done according to official regulations.

### 6.4. Reference to other sections

Information for safe handling. See section 7. Concerning personal protective equipment to use, see section 8. For further information refer to section 13.

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

Precautions for safe handling : Ensure good ventilation of the work station. Avoid contact with skin and eyes. Do not breathe spray, vapours, mist. Wear personal protective equipment. Use only outdoors or in a well-ventilated area.

Hygiene measures : Wash contaminated clothing before reuse. Do not eat, drink or smoke when using this product. Always wash hands after handling the product.

### 7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store locked up. Store in a well-ventilated place. Keep cool. Store in corrosive resistant container with a resistant inner liner. Keep only in original container. Keep container tightly closed.

Incompatible materials : Metals.

Information about storage in one common storage facility : Keep away from food, drink and animal feeding stuffs.

### 7.3. Specific end use(s)

No additional information available

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

#### 8.1.1 National occupational exposure and biological limit values

sulphuric acid (7664-93-9)	
<b>EU - Indicative Occupational Exposure Limit (IOEL)</b>	
Local name	Sulphuric acid (mist)
IOEL TWA	0.05 mg/m <sup>3</sup>
Regulatory reference	COMMISSION DIRECTIVE 2009/161/EU
<b>United Kingdom - Occupational Exposure Limits</b>	
Local name	Sulphuric acid
WEL TWA (OEL TWA) [1]	0.05 mg/m <sup>3</sup> mist
Remark	The mist is defined as the thoracic fraction
Regulatory reference	EH40/2005 (Fourth edition, 2020). HSE

# [STOP RTU]

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according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

<b>Hydrochloric acid (7647-01-0)</b>	
<b>United Kingdom - Occupational Exposure Limits</b>	
Local name	Hydrogen chloride
WEL TWA (OEL TWA) [1]	2 mg/m <sup>3</sup> gas and aerosol mists
WEL TWA (OEL TWA) [2]	1 ppm gas and aerosol mists
WEL STEL (OEL STEL)	8 mg/m <sup>3</sup> gas and aerosol mists
WEL STEL (OEL STEL) [ppm]	5 ppm gas and aerosol mists
Regulatory reference	EH40/2005 (Fourth edition, 2020). HSE

### 8.1.2. Recommended monitoring procedures

No additional information available

### 8.1.3. Air contaminants formed

No additional information available

### 8.1.4. DNEL and PNEC

<b>sulphuric acid (7664-93-9)</b>	
<b>DNEL/DMEL (Workers)</b>	
Acute - local effects, inhalation	0.1 mg/m <sup>3</sup>
Long-term - local effects, inhalation	0.05 mg/m <sup>3</sup>

<b>Hydrochloric acid (7647-01-0)</b>	
<b>DNEL/DMEL (Workers)</b>	
Acute - local effects, inhalation	15 mg/m <sup>3</sup>
Long-term - local effects, inhalation	8 mg/m <sup>3</sup>
<b>DNEL/DMEL (General population)</b>	
Acute - local effects, inhalation	15 mg/m <sup>3</sup>
Long-term - local effects, inhalation	8 mg/m <sup>3</sup>

### 8.1.5. Control banding

No additional information available

## 8.2. Exposure controls

### 8.2.1. Appropriate engineering controls

#### Appropriate engineering controls:

Ensure good ventilation of the work station. Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure.

### 8.2.2. Personal protection equipment

#### 8.2.2.1. Eye and face protection

##### Eye protection:

ISO 16321-1. Wear closed safety glasses

#### 8.2.2.2. Skin protection

##### Skin and body protection:

Wear suitable protective clothing. EN ISO 13688. EN 13034

##### Hand protection:

Chemically resistant protective gloves. Nitrile rubber. ISO 374-1. Choosing the proper glove is a decision that depends not only on the type of material, but also on other quality features, which differ for each manufacturer. Please follow the instructions related to the permeability and the penetration time provided by the manufacturer. Gloves must be replaced after each use and whenever signs of wear or perforation appear



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### Other skin protection

#### Materials for protective clothing:

Use protective clothing

### 8.2.2.3. Respiratory protection

#### Respiratory protection:

In case of insufficient ventilation, wear suitable respiratory equipment. Breathing apparatus with filter. A-P2. EN 143. . Breathing equipment is only to be used in order to handle the residual risk of short term jobs if all other risk minimizing measures have been carried out e.g. retention and/or local exhaust

### 8.2.2.4. Thermal hazards

No additional information available

### 8.2.3. Environmental exposure controls

#### Environmental exposure controls:

Avoid release to the environment.

#### Other information:

Do not eat, drink or smoke when using this product. Avoid contact with skin and eyes. Always wash hands after handling the product.

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Colour	: colourless.
Odour	: Not available
Odour threshold	: Not available
Melting point	: Not available
Freezing point	: Not available
Boiling point	: Not available
Flammability	: Not applicable
Explosive properties	: Product is not explosive.
Oxidising properties	: Non oxidizing.
Explosive limits	: Not available
Lower explosion limit	: Not available
Upper explosion limit	: Not available
Flash point	: Not available
Auto-ignition temperature	: Not available
Decomposition temperature	: Not available
pH	: < 1.2 (20 °C)
pH solution concentration	: 100 %
Viscosity, kinematic	: Not available
Solubility	: Water: Soluble
Partition coefficient n-octanol/water (Log Kow)	: Not available
Vapour pressure	: Not available
Vapour pressure at 50°C	: Not available
Density	: Not available
Relative density	: Not available
Relative vapour density at 20°C	: Not available
Particle characteristics	: Not applicable

### 9.2. Other information

#### 9.2.1. Information with regard to physical hazard classes

No additional information available

#### 9.2.2. Other safety characteristics

Other properties : This product is corrosive to metals

# [STOP RTU]

## Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

### SECTION 10: Stability and reactivity

#### 10.1. Reactivity

May be corrosive to metals.

#### 10.2. Chemical stability

Stable under normal conditions.

#### 10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

#### 10.4. Conditions to avoid

None under recommended storage and handling conditions (see section 7).

#### 10.5. Incompatible materials

Strong bases. May be corrosive to metals. metals.

#### 10.6. Hazardous decomposition products

Hydrogen chloride.

### SECTION 11: Toxicological information

#### 11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity (oral)	: Not classified (No data available. Based on available data, the classification criteria are not met)
Acute toxicity (dermal)	: Not classified (No data available. Based on available data, the classification criteria are not met)
Acute toxicity (inhalation)	: Not classified (Based on available data, the classification criteria are not met)
Skin corrosion/irritation	: Not classified. (Based on available data, the classification criteria are not met) pH: < 1.2 (20 °C)
Serious eye damage/irritation	: Causes serious eye irritation. pH: < 1.2 (20 °C)
Respiratory or skin sensitisation	: Not classified (Based on available data, the classification criteria are not met)
Germ cell mutagenicity	: Not classified (Based on available data, the classification criteria are not met)
Carcinogenicity	: Not classified (Based on available data, the classification criteria are not met)
Reproductive toxicity	: Not classified (Based on available data, the classification criteria are not met)
STOT-single exposure	: May cause respiratory irritation.

#### citric acid, monohydrate (5949-29-1)

STOT-single exposure	May cause respiratory irritation.
----------------------	-----------------------------------

#### Hydrochloric acid (7647-01-0)

STOT-single exposure	May cause respiratory irritation.
----------------------	-----------------------------------

STOT-repeated exposure	: Not classified (Based on available data, the classification criteria are not met)
Aspiration hazard	: Not classified (Based on available data, the classification criteria are not met)

#### 11.2. Information on other hazards

No additional information available

### SECTION 12: Ecological information

#### 12.1. Toxicity

Ecology - general : Before neutralisation, the product may represent a danger to aquatic organisms.

# [STOP RTU]

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Hazardous to the aquatic environment, short-term (acute) : Not classified (Based on available data, the classification criteria are not met)

Hazardous to the aquatic environment, long-term (chronic) : Not classified (Based on available data, the classification criteria are not met)

### 12.2. Persistence and degradability

<b>citric acid, monohydrate</b>	
Persistence and degradability	Readily biodegradable.
Biodegradation	97 % (OECD 301B method)
<b>Hydrochloric acid</b>	
Persistence and degradability	Not applicable for inorganic substances.

### 12.3. Bioaccumulative potential

<b>Citrate-Stopping Solution</b>	
Bioaccumulative potential	No additional information available.
<b>citric acid, monohydrate (5949-29-1)</b>	
Partition coefficient n-octanol/water (Log Kow)	-1.61
<b>Hydrochloric acid</b>	
Bioaccumulative potential	Not applicable for inorganic substances.

### 12.4. Mobility in soil

<b>Citrate-Stopping Solution</b>	
Ecology - soil	No additional information available.

### 12.5. Results of PBT and vPvB assessment

No additional information available

### 12.6. Endocrine disrupting properties

No additional information available

### 12.7. Other adverse effects

Other adverse effects : No additional information available

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

Waste treatment methods : Disposal must be done according to official regulations. European waste catalogue. Do not discharge into drains or the environment. Do not dispose of with domestic waste.

Product/Packaging disposal recommendations : Recycle or dispose of in compliance with current legislation.

HP Code : HP5 - "Specific Target Organ Toxicity (STOT)/Aspiration Toxicity:" waste which can cause specific target organ toxicity either from a single or repeated exposure, or which cause acute toxic effects following aspiration.

HP4 - "Irritant – skin irritation and eye damage:" waste which on application can cause skin irritation or damage to the eye.






## SECTION 14: Transport information

In accordance with ADR / IMDG / IATA / ADN / RID

# [STOP RTU]

## Safety Data Sheet

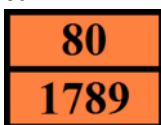
according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

ADR	IMDG	IATA	ADN	RID
<b>14.1. UN number or ID number</b>				
UN 1789	UN 1789	UN 1789	UN 1789	UN 1789
<b>14.2. UN proper shipping name</b>				
HYDROCHLORIC ACID	HYDROCHLORIC ACID	Hydrochloric acid	HYDROCHLORIC ACID	HYDROCHLORIC ACID
<b>Transport document description</b>				
UN 1789 HYDROCHLORIC ACID, 8, III, (E)	UN 1789 HYDROCHLORIC ACID, 8, III	UN 1789 Hydrochloric acid, 8, III	UN 1789 HYDROCHLORIC ACID, 8, III	UN 1789 HYDROCHLORIC ACID, 8, III
<b>14.3. Transport hazard class(es)</b>				
8	8	8	8	8
				
<b>14.4. Packing group</b>				
III	III	III	III	III
<b>14.5. Environmental hazards</b>				
Dangerous for the environment: No	Dangerous for the environment: No Marine pollutant: No	Dangerous for the environment: No	Dangerous for the environment: No	Dangerous for the environment: No
No supplementary information available				

### 14.6. Special precautions for user

#### Overland transport

Classification code (ADR) : C1  
Special provisions (ADR) : 520  
Limited quantities (ADR) : 5I  
Excepted quantities (ADR) : E1  
Transport category (ADR) : 3  
Hazard identification number (Kemler No.) : 80  
Orange plates :



Tunnel restriction code (ADR) : E  
EAC code : 2R

#### Transport by sea

Special provisions (IMDG) : 223  
Limited quantities (IMDG) : 5 L  
Excepted quantities (IMDG) : E1  
EmS-No. (Fire) : F-A  
EmS-No. (Spillage) : S-B

#### Air transport

PCA Excepted quantities (IATA) : E1  
PCA Limited quantities (IATA) : Y841  
PCA limited quantity max net quantity (IATA) : 1L  
PCA packing instructions (IATA) : 852  
PCA max net quantity (IATA) : 5L  
CAO max net quantity (IATA) : 60L  
Special provisions (IATA) : A3

# [STOP RTU]

## Safety Data Sheet

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### Inland waterway transport

Classification code (ADN) : C1  
Special provisions (ADN) : 520  
Limited quantities (ADN) : 5 L  
Excepted quantities (ADN) : E1  
Carriage permitted (ADN) : T

### Rail transport

Classification code (RID) : C1  
Special provisions (RID) : 520  
Limited quantities (RID) : 5L  
Excepted quantities (RID) : E1  
Transport category (RID) : 3  
Hazard identification number (RID) : 80

### 14.7. Maritime transport in bulk according to IMO instruments

Not applicable

## SECTION 15: Regulatory information

### 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

#### 15.1.1. EU-Regulations

Other information, restriction and prohibition regulations : Take note of Directive 94/33/EC on the protection of young people at work. This product is a medical device and has not to be classified and labelled according to the current laws and regulations.

#### REACH Annex XVII (Restriction List)

EU restriction list (REACH Annex XVII)	
Reference code	Applicable on
3(b)	Citrate-Stopping Solution ; sulphuric acid ; Hydrochloric acid

#### REACH Annex XIV (Authorisation List)

Contains no substance(s) listed on REACH Annex XIV (Authorisation List)

#### REACH Candidate List (SVHC)

Contains no substance(s) listed on the REACH Candidate List

#### PIC Regulation (Prior Informed Consent)

Contains no substance(s) listed on the PIC list (Regulation EU 649/2012 concerning the export and import of hazardous chemicals)

#### POP Regulation (Persistent Organic Pollutants)

Contains no substance(s) listed on the POP list (Regulation EU 2019/1021 on persistent organic pollutants)

#### Ozone Regulation (1005/2009)

Contains no substance(s) listed on the Ozone Depletion list (Regulation EU 1005/2009 on substances that deplete the ozone layer)

#### Explosives Precursors Regulation (2019/1148)

Contains substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

### ANNEX I RESTRICTED EXPLOSIVES PRECURSORS

List of substances which shall not be made available to, or introduced, possessed or used by, members of the general public, whether on their own or in mixtures or substances that include those substances, unless the concentration is equal to or lower than the limit values set out in column 2, and for which suspicious transactions and significant disappearances and thefts are to be reported to the relevant national contact point within 24 hours.

# [STOP RTU]

## Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

Name	CAS-No.	Limit value	Upper limit value for licensing under Article 5(3)	Combined Nomenclature (CN) code for a separate chemically defined compound meeting the requirements of Note 1 to Chapter 28 or 29 of the CN, respectively	Combined Nomenclature code for mixture without constituents which would determine classification under another CN code
Sulphuric acid	7664-93-9	15 % w/w	40 % w/w	ex 2807 00 00	ex 3824 99 96

Please see [https://ec.europa.eu/home-affairs/system/files/2021-11/list\\_of\\_competent\\_authorities\\_and\\_national\\_contact\\_points\\_en.pdf](https://ec.europa.eu/home-affairs/system/files/2021-11/list_of_competent_authorities_and_national_contact_points_en.pdf)

### Drug Precursors Regulation (273/2004)

Contains substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

Name	CN designation	CAS-No.	CN code	Category	Threshold	Annex
Sulphuric acid		7664-93-9	2807 00 00	Category 3		Annex I
Hydrochloric acid	Hydrogen chloride	7647-01-0	2806 10 00	Category 3		Annex I

### 15.1.2. National regulations

No additional information available

### 15.2. Chemical safety assessment

No chemical safety assessment has been carried out

## SECTION 16: Other information

Indication of changes			
Section	Changed item	Change	Comments
	General revision		
1.1	Trade name	Modified	
1.3	SDS EU addresses	Modified	
2.1	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Modified	
2.2	Labelling according to Regulation (EC) No. 1272/2008 [CLP]	Modified	

### Abbreviations and acronyms:

ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
ATE	Acute Toxicity Estimate
BCF	Bioconcentration factor
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008
DMEL	Derived Minimal Effect level

# [STOP RTU]

## Safety Data Sheet

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DNEL	Derived-No Effect Level
EC50	Median effective concentration
IARC	International Agency for Research on Cancer
IATA	International Air Transport Association
IMDG	International Maritime Dangerous Goods
LC50	Median lethal concentration
LD50	Median lethal dose
LOAEL	Lowest Observed Adverse Effect Level
NOAEC	No-Observed Adverse Effect Concentration
NOAEL	No-Observed Adverse Effect Level
NOEC	No-Observed Effect Concentration
OECD	Organisation for Economic Co-operation and Development
PBT	Persistent Bioaccumulative Toxic
PNEC	Predicted No-Effect Concentration
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
SDS	Safety Data Sheet
STP	Sewage treatment plant
TLM	Median Tolerance Limit
vPvB	Very Persistent and Very Bioaccumulative
CAS-No.	Chemical Abstract Service number

Data sources : Information provided by the manufacturer. MSDS of the supplier. European Chemicals Agency, <http://echa.europa.eu/>.

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Other information : This safety data sheet is for informational purposes only and does not fully comply with national legal requirements. The national distributor is responsible for a legally compliant safety data sheet.

Full text of H- and EUH-statements:	
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
H290	May be corrosive to metals.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
Met. Corr. 1	Corrosive to metals, Category 1
Skin Corr. 1A	Skin corrosion/irritation, Category 1, Sub-Category 1A

# [STOP RTU]

## Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

Skin Corr. 1B	Skin corrosion/irritation, Category 1, Sub-Category 1B
Skin Irrit. 2	Skin corrosion/irritation, Category 2
STOT SE 3	Specific target organ toxicity – Single exposure, Category 3, Respiratory tract irritation

### Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:

Met. Corr. 1	H290	Calculation method
Eye Irrit. 2	H319	Expert judgement
STOT SE 3	H335	Calculation method

KFT SDS EU 00

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.