

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

1.1. Product identifier

Product form : Mixture
Trade name : [CONJ 100x 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

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]

Specific target organ toxicity – Repeated exposure, Category 2 H373
Full text of H- and EUH-statements: see section 16

Adverse physicochemical, human health and environmental effects

May cause damage to organs through prolonged or repeated exposure.

2.2. Label elements

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

Hazard pictograms (CLP) :



GHS08

Signal word (CLP) : Warning
Contains : Thiomersal
Hazard statements (CLP) : H373 - May cause damage to organs (central nervous system) through prolonged or repeated exposure.
Precautionary statements (CLP) : P314 - Get medical advice/attention if you feel unwell.
P260 - Do not breathe vapours, mist, spray.

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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

Other hazards which do not result in classification : Contains : Mercury (Hg).

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	
Glycerol (56-81-5)	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
Thiomersal (54-64-8)	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]
Glycerol substance with national workplace exposure limit(s) (GB)	CAS-No.: 56-81-5 EC-No.: 200-289-5	$\geq 10 - < 20$	Not classified
Thiomersal (Note A)(Note 1)	CAS-No.: 54-64-8 EC-No.: 200-210-4 EC Index-No.: 080-004-00-7	$\geq 0.1 - < 0.25$	Acute Tox. 2 (Inhalation), H330 Acute Tox. 1 (Dermal), H310 Acute Tox. 2 (Oral), H300 STOT RE 2, H373 Aquatic Acute 1, H400 Aquatic Chronic 1, H410

Specific concentration limits:

Name	Product identifier	Specific concentration limits
Thiomersal	CAS-No.: 54-64-8 EC-No.: 200-210-4 EC Index-No.: 080-004-00-7	(0.1 \leq C < 100) STOT RE 2, H373

Note 1 : The concentration stated or, in the absence of such concentrations, the generic concentrations set out in this Regulation are the percentages by weight of the metallic element calculated with reference to the total weight of the mixture.

Note A : Without prejudice to Article 17(2), the name of the substance must appear on the label in the form of one of the designations given in Part 3. In Part 3, use is sometimes made of a general description such as '... compounds' or '... salts'. In this case, the supplier is required to state on the label the correct name, due account being taken of section 1.1.1.4.

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

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

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. Get medical advice/attention if you feel unwell.
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	: 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 ₂). Nitrogen oxides. Sulphur oxides. Mercury compounds.
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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. Do not breathe vapours, mist, 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.

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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. Wear personal protective equipment. Do not breathe vapours, mist, spray.

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.

Storage temperature : 2 – 8 °C

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

Glycerol (56-81-5)	
United Kingdom - Occupational Exposure Limits	
Local name	Glycerol
WEL TWA (OEL TWA) [1]	10 mg/m ³ mist
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

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 eye protection according to EN 166, designed to protect against liquid splashes.

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:

In case of repeated or prolonged contact wear gloves. Chemically resistant protective gloves. Nitrile rubber. ISO 374-1. 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: Breathing apparatus with filter. Filter A (colour code: brown). 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	: 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	: 7.8 – 8.2 (20 °C)
Viscosity, kinematic	:
Viscosity, dynamic	:
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. Contact with acids liberates very toxic gas.

10.4. Conditions to avoid

Protect from light.

10.5. Incompatible materials

Strong oxidizing agent. Strong acids. Strong bases. 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
Acute toxicity (dermal)	: Not classified
Acute toxicity (inhalation)	: Not classified

IgM-Conjugate (anti-human,100x conc.)	
ATE CLP (oral)	> 2000 mg/kg bodyweight
Skin corrosion/irritation	: Not classified (No data available. Based on available data, the classification criteria are not met) pH: 7.8 – 8.2 (20 °C)
Serious eye damage/irritation	: Not classified (No data available. Based on available data, the classification criteria are not met) pH: 7.8 – 8.2 (20 °C)
Respiratory or skin sensitisation	: Not classified (No data available. 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 (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	: May cause damage to organs (central nervous system) through prolonged or repeated exposure.

Thiomersal (54-64-8)	
STOT-repeated exposure	May cause damage to organs (central nervous system) through prolonged or repeated exposure.
Aspiration hazard	: Not classified (Based on available data, the classification criteria are not met)

IgM-Conjugate (anti-human,100x conc.)	
Viscosity, kinematic	

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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.
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

IgM-Conjugate (anti-human,100x conc.)

Persistence and degradability	No additional information available.
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Glycerol (56-81-5)

Persistence and degradability	Readily biodegradable.
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Biodegradation	94 % (24 h)
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12.3. Bioaccumulative potential

IgM-Conjugate (anti-human,100x conc.)

Bioaccumulative potential	No additional information available.
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Glycerol (56-81-5)

Partition coefficient n-octanol/water (Log Kow)	-1.75 (25 °C; pH 7.4)
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Bioaccumulative potential	Bioaccumulation unlikely.
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12.4. Mobility in soil

IgM-Conjugate (anti-human,100x conc.)

Ecology - soil	No additional information available.
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Glycerol (56-81-5)

Surface tension	≈ 63.4 mN/m (20 °C)
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12.5. Results of PBT and vPvB assessment

IgM-Conjugate (anti-human,100x conc.)

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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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.
- 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.

SECTION 14: Transport information

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

ADR	IMDG	IATA	ADN	RID
14.1. UN number or ID number				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.2. UN proper shipping name				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.3. Transport hazard class(es)				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.4. Packing group				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.5. Environmental hazards				
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

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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 : 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
18.	Thiomersal
3(b)	IgM-Conjugate (anti-human,100x conc.)

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 substance(s) listed on the PIC list (Regulation EU 649/2012 concerning the export and import of hazardous chemicals): Thiomersal (54-64-8)

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		SDS EU format according to COMMISSION REGULATION (EU) 2020/878
1.1	Trade name	Modified	
1.3	Address	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)
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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
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.

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Full text of H- and EUH-statements:	
Acute Tox. 1 (Dermal)	Acute toxicity (dermal), Category 1
Acute Tox. 2 (Inhalation)	Acute toxicity (inhal.), Category 2
Acute Tox. 2 (Oral)	Acute toxicity (oral), Category 2
Aquatic Acute 1	Hazardous to the aquatic environment – Acute Hazard, Category 1
Aquatic Chronic 1	Hazardous to the aquatic environment – Chronic Hazard, Category 1
H300	Fatal if swallowed.
H310	Fatal in contact with skin.
H330	Fatal if inhaled.
H373	May cause damage to organs through prolonged or repeated exposure.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
STOT RE 2	Specific target organ toxicity – Repeated exposure, Category 2

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:		
STOT RE 2	H373	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 : [NC]

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

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]

Flammable solids, Category 1 H228
Full text of H- and EUH-statements: see section 16

Adverse physicochemical, human health and environmental effects

Flammable solid.

2.2. Label elements

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

Hazard pictograms (CLP) :



GHS02

Signal word (CLP) : Danger
Hazard statements (CLP) : H228 - Flammable solid.
Precautionary statements (CLP) : P210 - Keep away from heat, hot surfaces, sparks, open flames and other ignition sources.
No smoking.

[NC]

Safety Data Sheet

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

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	
nitrocellulose (9004-70-0)	PBT: not yet assessed vPvB: not yet assessed

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]
nitrocellulose (Note T)	CAS-No.: 9004-70-0 EC Index-No.: 603-037-00-6	($\leq 12.6\%$ N)	Expl. 1.1, H201

Note T : This substance may be marketed in a form which does not have the physical hazards as indicated by the classification in the entry in Part 3. If the results of the relevant method or methods in accordance with Part 2 of Annex I of this Regulation show that the specific form of substance marketed does not exhibit this physical property or these physical hazards, the substance shall be classified in accordance with the result or results of this test or these tests. Relevant information, including reference to the relevant test method(s) shall be included in the safety data sheet.
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 : 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. Use fire fighting measures suiting the environment. Water spray. Dry powder. Foam.
Unsuitable extinguishing media : Strong water jet.

[NC]

Safety Data Sheet

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

5.2. Special hazards arising from the substance or mixture

- Fire hazard : Flammable solid.
- Explosion hazard : Dust may form explosive mixture in air.
- Hazardous decomposition products in case of fire : Toxic fumes may be released. release of harmful/irritant gases/vapours. Carbon monoxide. Carbon dioxide (CO₂). Nitrogen oxides. Sulphur oxides. Nitrous fumes.

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. No open flames, no sparks, and no smoking.

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 mechanically (sweeping, shovelling) and collect in suitable container for disposal. Notify authorities if product enters sewers or public waters.
- 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

- Additional hazards when processed : Dust may form flammable and explosive mixture with air.
- Precautions for safe handling : Ensure good ventilation of the work station. Wear personal protective equipment. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
- 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. Protect from sunlight. Keep away from ignition sources.
- Heat and ignition sources : Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Keep away from heat and direct sunlight.
- 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.

[NC]

Safety Data Sheet

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

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 13034. EN ISO 13688

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 formation: dust mask. 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.

[NC]

Safety Data Sheet

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

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Solid
Colour	: white.
Odour	: odourless.
Odour threshold	: Not available
Melting point	: Not available
Freezing point	: Not applicable
Boiling point	: Not available
Flammability	: Flammable solid.
Explosive properties	: Product is not explosive. Dust may form explosive mixture in air. Dust may form flammable and explosive mixture with 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	: 185 °C
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

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. Flammable solid.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

[NC]

Safety Data Sheet

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

10.4. Conditions to avoid

Avoid contact with hot surfaces. Heat. No flames, no sparks. Eliminate all sources of ignition.

10.5. Incompatible materials

Strong oxidizing agent. Strong acids. Strong bases. Amines.

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)

Nitrocellulose test strips with sprayed antigen, (solid strips stabilised on a plastic foil)

ATE CLP (oral)	> 2000 mg/kg bodyweight
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)

Nitrocellulose test strips with sprayed antigen, (solid strips stabilised on a plastic foil)

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.
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

Nitrocellulose test strips with sprayed antigen, (solid strips stabilised on a plastic foil)

Persistence and degradability	No additional information available.
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12.3. Bioaccumulative potential

Nitrocellulose test strips with sprayed antigen, (solid strips stabilised on a plastic foil)

Bioaccumulative potential	No additional information available.
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[NC]

Safety Data Sheet

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

12.4. Mobility in soil

Nitrocellulose test strips with sprayed antigen, (solid strips stabilised on a plastic foil)	
Ecology - soil	No additional information available.

12.5. Results of PBT and vPvB assessment

Nitrocellulose test strips with sprayed antigen, (solid strips stabilised on a plastic foil)	
PBT: not relevant – no registration required	
vPvB: not relevant – no registration required	

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.
HP Code	: HP3 - "Flammable:" – flammable liquid waste: liquid waste having a flash point below 60 °C or waste gas oil, diesel and light heating oils having a flash point > 55 °C and ≤ 75 °C; – flammable pyrophoric liquid and solid waste: solid or liquid waste which, even in small quantities, is liable to ignite within five minutes after coming into contact with air; – flammable solid waste: solid waste which is readily combustible or may cause or contribute to fire through friction; – flammable gaseous waste: gaseous waste which is flammable in air at 20 °C and a standard pressure of 101.3 kPa; – water reactive waste: waste which, in contact with water, emits flammable gases in dangerous quantities; – other flammable waste: flammable aerosols, flammable self-heating waste, flammable organic peroxides and flammable self-reactive waste.

SECTION 14: Transport information






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

ADR	IMDG	IATA	ADN	RID
14.1. UN number or ID number				
UN 3270	UN 3270	UN 3270	UN 3270	UN 3270
14.2. UN proper shipping name				
NITROCELLULOSE MEMBRANE FILTERS	NITROCELLULOSE MEMBRANE FILTERS	Nitrocellulose membrane filters	NITROCELLULOSE MEMBRANE FILTERS	NITROCELLULOSE MEMBRANE FILTERS
Transport document description				
UN 3270 NITROCELLULOSE MEMBRANE FILTERS, 4.1, II, (E)	UN 3270 NITROCELLULOSE MEMBRANE FILTERS, 4.1, II	UN 3270 Nitrocellulose membrane filters, 4.1, II	UN 3270 NITROCELLULOSE MEMBRANE FILTERS, 4.1, II	UN 3270 NITROCELLULOSE MEMBRANE FILTERS, 4.1, II

[NC]

Safety Data Sheet

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

14.3. Transport hazard class(es)				
4.1	4.1	4.1	4.1	4.1
				
14.4. Packing group				
II	II	II	II	II
14.5. Environmental hazards				
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) : F1
Special provisions (ADR) : 237, 286
Limited quantities (ADR) : 1kg
Excepted quantities (ADR) : E2
Transport category (ADR) : 2
Tunnel restriction code (ADR) : E
EAC code : 1Z

Transport by sea

Special provisions (IMDG) : 237, 286
Limited quantities (IMDG) : 1 kg
Excepted quantities (IMDG) : E2
EmS-No. (Fire) : F-A
EmS-No. (Spillage) : S-I

Air transport

PCA Excepted quantities (IATA) : E2
PCA Limited quantities (IATA) : Y458
PCA limited quantity max net quantity (IATA) : 1kg
PCA packing instructions (IATA) : 458
PCA max net quantity (IATA) : 1kg
CAO max net quantity (IATA) : 15kg
Special provisions (IATA) : A57, A73, A122

Inland waterway transport

Classification code (ADN) : F1
Special provisions (ADN) : 237, 286
Limited quantities (ADN) : 1 kg
Excepted quantities (ADN) : E2

Rail transport

Classification code (RID) : F1
Special provisions (RID) : 237, 286
Limited quantities (RID) : 1kg
Excepted quantities (RID) : E2
Transport category (RID) : 2
Hazard identification number (RID) : 40

14.7. Maritime transport in bulk according to IMO instruments

Not applicable

[NC]

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		SDS EU format according to COMMISSION REGULATION (EU) 2020/878
1.1	Trade name	Modified	
1.3	Address	Modified	
2.2	Precautionary statements (CLP)	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

[NC]**Safety Data Sheet**

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

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 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:	
Expl. 1.1	Explosives, Division 1.1
Flam. Sol. 1	Flammable solids, Category 1

[NC]

Safety Data Sheet

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

H201	Explosive; mass explosion hazard.
H228	Flammable solid.

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

Flam. Sol. 1	H228	Expert judgment
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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.



[SUBS RTU]

Safety Data Sheet

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
Issue date: 27/01/2023 Revision date: 27/01/2023 Supersedes version of: 15/03/2017 Version: 2.00

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

1.1. Product identifier

Product form : Mixture
Trade name : [SUBS 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 product safety information sheet

Supplier

Virotech Diagnostics GmbH
Waldstraße 23 A2
DE- 63128 Dietzenbach
Deutschland
T +49 6074 236980
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

No additional information available

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 %

[SUBS RTU]

Safety Data Sheet

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

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 ₂). 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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[SUBS RTU]

Safety Data Sheet

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

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. 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.

[SUBS RTU]

Safety Data Sheet

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

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

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	: 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	: 9.5 – 9.6 (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

[SUBS RTU]

Safety Data Sheet

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

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
Acute toxicity (inhalation)	: Not classified
Skin corrosion/irritation	: Not classified (Based on available data, the classification criteria are not met) pH: 9.5 – 9.6 (20 °C)
Serious eye damage/irritation	: Not classified (Based on available data, the classification criteria are not met) pH: 9.5 – 9.6 (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.

[SUBS RTU]

Safety Data Sheet

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

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

Substrate (BCIP/NBT), ready to use	
Persistence and degradability	No additional information available.

12.3. Bioaccumulative potential

Substrate (BCIP/NBT), ready to use	
Bioaccumulative potential	No additional information available.

12.4. Mobility in soil

Substrate (BCIP/NBT), ready to use	
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
14.1. UN number or ID number				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.2. UN proper shipping name				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.3. Transport hazard class(es)				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.4. Packing group				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable

[SUBS RTU]

Safety Data Sheet

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

14.5. Environmental hazards

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

: 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

[SUBS RTU]

Safety Data Sheet

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

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

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

Indication of changes			
Section	Changed item	Change	Comments
	General revision		SDS EU format according to COMMISSION REGULATION (EU) 2020/878
1.1	Trade name	Modified	
1.3	Address	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

[SUBS RTU]

Safety Data Sheet

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

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/>.

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

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

1.1. Product identifier

Product form : Mixture
Trade name : [CONJ D 100x 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

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]

Specific target organ toxicity – Repeated exposure, Category 2 H373
Full text of H- and EUH-statements: see section 16

Adverse physicochemical, human health and environmental effects

May cause damage to organs through prolonged or repeated exposure.

2.2. Label elements

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

Hazard pictograms (CLP) :



GHS08

Signal word (CLP) : Warning
Contains : Thiomersal
Hazard statements (CLP) : H373 - May cause damage to organs (central nervous system) through prolonged or repeated exposure.
Precautionary statements (CLP) : P314 - Get medical advice/attention if you feel unwell.
P260 - Do not breathe mist, vapours, spray.

[CONJ D 100x IgG]

Safety Data Sheet

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

2.3. Other hazards

Other hazards which do not result in classification : Contains : Mercury (Hg).

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	
Glycerol (56-81-5)	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
Thiomersal (54-64-8)	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]
Glycerol substance with national workplace exposure limit(s) (GB)	CAS-No.: 56-81-5 EC-No.: 200-289-5	$\geq 10 - < 20$	Not classified
Thiomersal (Note A)(Note 1)	CAS-No.: 54-64-8 EC-No.: 200-210-4 EC Index-No.: 080-004-00-7	$\geq 0.1 - < 0.25$	Acute Tox. 2 (Inhalation), H330 Acute Tox. 1 (Dermal), H310 Acute Tox. 2 (Oral), H300 STOT RE 2, H373 Aquatic Acute 1, H400 Aquatic Chronic 1, H410

Specific concentration limits:

Name	Product identifier	Specific concentration limits
Thiomersal	CAS-No.: 54-64-8 EC-No.: 200-210-4 EC Index-No.: 080-004-00-7	(0.1 \leq C < 100) STOT RE 2, H373

Note 1 : The concentration stated or, in the absence of such concentrations, the generic concentrations set out in this Regulation are the percentages by weight of the metallic element calculated with reference to the total weight of the mixture.

Note A : Without prejudice to Article 17(2), the name of the substance must appear on the label in the form of one of the designations given in Part 3. In Part 3, use is sometimes made of a general description such as '... compounds' or '... salts'. In this case, the supplier is required to state on the label the correct name, due account being taken of section 1.1.1.4.

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

[CONJ D 100x IgG]

Safety Data Sheet

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

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. Get medical advice/attention if you feel unwell.
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	: 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 ₂). Nitrogen oxides. Sulphur oxides. Mercury compounds.
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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. Do not breathe vapours, mist, 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 100x IgG]

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. Do not breathe vapours, mist, spray.

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.

Storage temperature : 2 – 8 °C

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

Glycerol (56-81-5)	
United Kingdom - Occupational Exposure Limits	
Local name	Glycerol
WEL TWA (OEL TWA) [1]	10 mg/m ³ mist
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

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 D 100x IgG]

Safety Data Sheet

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

Hand protection:

In case of repeated or prolonged contact wear gloves. Chemically resistant protective gloves. Nitrile rubber. ISO 374-1. 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: Filter A (colour code: brown). . 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	: colourless.
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	: 7.8 – 8.2 (20 °C)
Viscosity, kinematic	:
Viscosity, dynamic	:
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

[CONJ D 100x IgG]

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

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

Protect from light.

10.5. Incompatible materials

Strong oxidizing agent. Strong acids. Strong bases.

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)

Anti-dog IgG conjugate (100x conc.)

ATE CLP (oral)	> 2000 mg/kg bodyweight
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Glycerol

LD50 oral	≈ 23000 mg/kg bodyweight (mouse, male)
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Skin corrosion/irritation : Not classified (No data available. Based on available data, the classification criteria are not met)
pH: 7.8 – 8.2 (20 °C)

Serious eye damage/irritation : Not classified (No data available. Based on available data, the classification criteria are not met)
pH: 7.8 – 8.2 (20 °C)

Respiratory or skin sensitisation : Not classified (No data available. 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 (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 : May cause damage to organs (central nervous system) through prolonged or repeated exposure.

Thiomersal (54-64-8)

STOT-repeated exposure	May cause damage to organs (central nervous system) through prolonged or repeated exposure.
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Aspiration hazard : Not classified (Based on available data, the classification criteria are not met)

[CONJ D 100x IgG]

Safety Data Sheet

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

Anti-dog IgG conjugate (100x conc.)	
Viscosity, kinematic	

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

Anti-dog IgG conjugate (100x conc.)	
Persistence and degradability	No additional information available.

Glycerol (56-81-5)	
Persistence and degradability	Readily biodegradable.
Biodegradation	94 % (24 h)

12.3. Bioaccumulative potential

Anti-dog IgG conjugate (100x conc.)	
Bioaccumulative potential	No additional information available.

Glycerol (56-81-5)	
Partition coefficient n-octanol/water (Log Kow)	-1.75 (25 °C; pH 7.4)
Bioaccumulative potential	Bioaccumulation unlikely.

12.4. Mobility in soil

Anti-dog IgG conjugate (100x conc.)	
Ecology - soil	No additional information available.

Glycerol (56-81-5)	
Surface tension	≈ 63.4 mN/m (20 °C)

12.5. Results of PBT and vPvB assessment

Anti-dog IgG conjugate (100x conc.)	
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 D 100x IgG]

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	: Comply with local regulations for disposal. 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.

SECTION 14: Transport information

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

ADR	IMDG	IATA	ADN	RID
14.1. UN number or ID number				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.2. UN proper shipping name				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.3. Transport hazard class(es)				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.4. Packing group				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.5. Environmental hazards				
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

[CONJ D 100x IgG]

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 : 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
18.	Thiomersal
3(b)	Anti-dog IgG conjugate (100x conc.)

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 substance(s) listed on the PIC list (Regulation EU 649/2012 concerning the export and import of hazardous chemicals): Thiomersal (54-64-8)

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		SDS EU format according to COMMISSION REGULATION (EU) 2020/878
1.1	Trade name	Modified	
1.3	Address	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)
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[CONJ D 100x IgG]

Safety Data Sheet

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

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
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.

[CONJ D 100x IgG]

Safety Data Sheet

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

Full text of H- and EUH-statements:	
Acute Tox. 1 (Dermal)	Acute toxicity (dermal), Category 1
Acute Tox. 2 (Inhalation)	Acute toxicity (inhal.), Category 2
Acute Tox. 2 (Oral)	Acute toxicity (oral), Category 2
Aquatic Acute 1	Hazardous to the aquatic environment – Acute Hazard, Category 1
Aquatic Chronic 1	Hazardous to the aquatic environment – Chronic Hazard, Category 1
H300	Fatal if swallowed.
H310	Fatal in contact with skin.
H330	Fatal if inhaled.
H373	May cause damage to organs through prolonged or repeated exposure.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
STOT RE 2	Specific target organ toxicity – Repeated exposure, Category 2

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:		
STOT RE 2	H373	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

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

[CONJ H IgG]

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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.
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.
-------------------------------------	--

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

Treat symptomatically.

[CONJ H IgG]

Safety Data Sheet

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

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.

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

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 : 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.

[CONJ H IgG]

Safety Data Sheet

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

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)	
DNEL/DMEL (Workers)	
Acute - local effects, inhalation	0.04 mg/m ³
Long-term - local effects, inhalation	0.02 mg/m ³
DNEL/DMEL (General population)	
Acute - systemic effects, oral	0.11 mg/kg bodyweight
Acute - local effects, inhalation	0.04 mg/m ³
Long-term - systemic effects, oral	0.09 mg/kg bodyweight/day
Long-term - local effects, inhalation	0.02 mg/m ³
PNEC (Water)	
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
PNEC (Sediment)	
PNEC sediment (freshwater)	0.027 mg/kg dwt
PNEC sediment (marine water)	0.027 mg/kg dwt
PNEC (Soil)	
PNEC soil	0.01 mg/kg dwt
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. EN 166

[CONJ H IgG]

Safety Data Sheet

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

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. EN 374. 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 insufficient ventilation, wear suitable respiratory equipment. 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.

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	: 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	: (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
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

[CONJ H IgG]

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

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 : Not classified
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)

Anti-horse IgG conjugate	
Viscosity, kinematic	(No available data)

11.2. Information on other hazards

No additional information available

[CONJ H IgG]

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

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	0.0273 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

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

Anti-horse 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-horse IgG conjugate

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

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

[CONJ H IgG]

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
14.1. UN number or ID number				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.2. UN proper shipping name				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.3. Transport hazard class(es)				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.4. Packing group				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.5. Environmental hazards				
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.

[CONJ H IgG]

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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		SDS EU format according to COMMISSION REGULATION (EU) 2020/878
1.1	Trade name	Modified	
1.3	Address	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	
3.2	Hazardous ingredients	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

[CONJ H IgG]

Safety Data Sheet

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

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 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.

[CONJ H IgG]

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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
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 : [DWBUF 10x]

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

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
Hazardous to the aquatic environment – Chronic Hazard, Category 3 H412
Full text of H- and EUH-statements: see section 16

Adverse physicochemical, human health and environmental effects

May cause an allergic skin reaction. Harmful to aquatic life with long lasting effects.

2.2. Label elements

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

Hazard pictograms (CLP) :



GHS07

Signal word (CLP) :

Warning

Contains :

2-methyl-2H-isothiazol-3-one, 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.
H412 - Harmful to aquatic life with long lasting effects.

[DWBUF 10x]

Safety Data Sheet

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

Precautionary statements (CLP)	: P261 - Avoid breathing vapours, mist, spray. P273 - Avoid release to the environment. P280 - Wear protective gloves. P333+P313 - If skin irritation or rash occurs: Get medical advice/attention. P362+P364 - Take off contaminated clothing and wash it before reuse.
EUH-statements	: EUH032 - Contact with acids liberates very toxic gas.

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	
2-methyl-2H-isothiazol-3-one (2682-20-4)	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

3.2. Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Potassium thiocyanate (Note A)	CAS-No.: 333-20-0 EC-No.: 206-370-1 EC Index-No.: 615-004-00-3	$\geq 2.5 - < 5$	Acute Tox. 4 (Inhalation), H332 (ATE=1.5 mg/l/4h) Acute Tox. 4 (Dermal), H312 (ATE=1100 mg/kg bodyweight) Acute Tox. 4 (Oral), H302 (ATE=500 mg/kg bodyweight) Aquatic Chronic 3, H412 EUH032
2-methyl-2H-isothiazol-3-one	CAS-No.: 2682-20-4 EC-No.: 220-239-6 EC Index-No.: 613-326-00-9	< 0.1	Acute Tox. 2 (Inhalation), H330 (ATE=0.1 mg/l/4h) Acute Tox. 3 (Dermal), H311 (ATE=242 mg/kg bodyweight) Acute Tox. 3 (Oral), H301 (ATE=120 mg/kg bodyweight) Skin Corr. 1B, H314 Eye Dam. 1, H318 Skin Sens. 1A, H317 Aquatic Acute 1, H400 (M=10) Aquatic Chronic 1, H410 EUH071

[DWBUF 10x]

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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
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Specific concentration limits:		
Name	Product identifier	Specific concentration limits
2-methyl-2H-isothiazol-3-one	CAS-No.: 2682-20-4 EC-No.: 220-239-6 EC Index-No.: 613-326-00-9	(0.0015 ≤ C ≤ 100) Skin Sens. 1A, H317
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 A : Without prejudice to Article 17(2), the name of the substance must appear on the label in the form of one of the designations given in Part 3. In Part 3, use is sometimes made of a general description such as '... compounds' or '... salts'. In this case, the supplier is required to state on the label the correct name, due account being taken of section 1.1.1.4.

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. 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.
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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 (CO₂). Nitrogen oxides. Sulphur oxides. Potassium oxide.

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.

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 : 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 vapours, mist, 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.

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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

2-methyl-2H-isothiazol-3-one (2682-20-4)	
DNEL/DMEL (Workers)	
Acute - local effects, inhalation	0.043 mg/m ³
Long-term - local effects, inhalation	0.021 mg/m ³
DNEL/DMEL (General population)	
Acute - systemic effects, oral	0.053 mg/kg bodyweight/day
Acute - local effects, inhalation	0.043 mg/m ³
Long-term - systemic effects,oral	0.027 mg/kg bodyweight/day
Long-term - local effects, inhalation	0.021 mg/m ³
PNEC (Water)	
PNEC aqua (freshwater)	3.39 µg/L
PNEC aqua (marine water)	3.39 µg/L
PNEC aqua (intermittent, freshwater)	3.39 µg/L
PNEC aqua (intermittent, marine water)	3.39 µg/L
PNEC (Soil)	
PNEC soil	0.047 mg/kg dwt
PNEC (STP)	
PNEC sewage treatment plant	0.23 mg/l
reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) (55965-84-9)	
DNEL/DMEL (Workers)	
Acute - local effects, inhalation	0.04 mg/m ³
Long-term - local effects, inhalation	0.02 mg/m ³
DNEL/DMEL (General population)	
Acute - systemic effects, oral	0.11 mg/kg bodyweight
Acute - local effects, inhalation	0.04 mg/m ³
Long-term - systemic effects,oral	0.09 mg/kg bodyweight/day
Long-term - local effects, inhalation	0.02 mg/m ³
PNEC (Water)	
PNEC aqua (freshwater)	0.00339 mg/l
PNEC aqua (marine water)	0.00339 mg/l
PNEC aqua (intermittent, freshwater)	0.00339 mg/l

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PNEC aqua (intermittent, marine water)	0.00339 mg/l
PNEC (Sediment)	
PNEC sediment (freshwater)	0.027 mg/kg dwt
PNEC sediment (marine water)	0.027 mg/kg dwt
PNEC (Soil)	
PNEC soil	0.01 mg/kg dwt
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 13034. EN ISO 13688

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

8.2.2.3. Respiratory protection

Respiratory protection:

In case of inadequate ventilation wear respiratory protection. In case of unintended release: Breathing apparatus with 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	: colourless.
Odour	: odourless.
Odour threshold	: Not available
Melting point	: Not applicable
Freezing point	: Not available

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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 – 7.6 (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. Contact with acids liberates very toxic gas.

10.4. Conditions to avoid

No additional information available

10.5. Incompatible materials

Strong oxidizing agent. Reducing agents. 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)

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Dilution-/ washbuffer (10x conc.)	
ATE CLP (oral)	> 2000 mg/kg bodyweight
Potassium thiocyanate (333-20-0)	
LD50 oral rat	508 mg/kg (OECD Guideline 401)
2-methyl-2H-isothiazol-3-one (2682-20-4)	
LD50 oral rat	120 mg/kg bodyweight (EPA OPPTS 870.1100)
LD50 dermal rat	242 mg/kg bodyweight (OECD 402 method)
LC50 Inhalation - Rat (Dust/Mist)	0.1 mg/l/4h (OECD 403 method)
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 – 7.6 (20 °C)
reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) (55965-84-9)	
pH	3.43 (20 °C; 10 g/L; CIPAC MT 75)
Serious eye damage/irritation	: Not classified (Based on available data, the classification criteria are not met) pH: 7 – 7.6 (20 °C)
reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) (55965-84-9)	
pH	3.43 (20 °C; 10 g/L; CIPAC MT 75)
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)
2-methyl-2H-isothiazol-3-one (2682-20-4)	
NOAEL (chronic, oral, animal/male, 2 years)	> 400 ppm (mouse)
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)
reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1) (55965-84-9)	
Viscosity, kinematic	11.4 mm ² /s (25 °C; (OECD 114 method))

11.2. Information on other hazards

No additional information available

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general	: Harmful to aquatic life with long lasting effects.
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)	: Harmful to aquatic life with long lasting effects.

2-methyl-2H-isothiazol-3-one (2682-20-4)	
LC50 - Fish [1]	4.77 mg/l (96 h; Oncorhynchus mykiss; (OECD 203 method))

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EC50 - Crustacea [1]	0.934 mg/l (48 h; Daphnia magna; (OECD 202 method))
EC50 72h algae	0.103 mg/l (72 h, Pseudokirchneriella Subcapita; (OECD 201 method))
ErC50 algae	0.072 mg/l (OECD 201 method)
NOEC chronic fish	4.93 mg/l (98 d; Oncorhynchus mykiss; (OECD 210 method))
NOEC chronic crustacea	0.044 mg/l (21 d; Daphnia magna; (OECD 211 method))
NOEC chronic algae	0.05 mg/l (5 d; Pseudokirchneriella subcapitata; (OECD 201 method))

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

2-methyl-2H-isothiazol-3-one (2682-20-4)

Persistence and degradability	Not readily biodegradable. (OECD 301B method). (OECD 301D method).
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

Dilution-/ washbuffer (10x conc.)

Bioaccumulative potential	No additional information available.
2-methyl-2H-isothiazol-3-one (2682-20-4)	
Partition coefficient n-octanol/water (Log Pow)	-0.486 (25 °C; (OECD 107 method))
Bioaccumulative potential	Bioaccumulation unlikely.
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

Dilution-/ washbuffer (10x conc.)

Ecology - soil	No additional information available.
2-methyl-2H-isothiazol-3-one (2682-20-4)	
Surface tension	68.8 mN/m (19 °C, EEC Method A5)
Ecology - soil	Low mobility (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).

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12.5. Results of PBT and vPvB assessment

Dilution-/ washbuffer (10x conc.)

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.

HP Code : HP12 - "Release of an acute toxic gas:" waste which releases acute toxic gases (Acute Tox. 1, 2 or 3) in contact with water or an acid
HP13 - "Sensitising:" waste which contains one or more substances known to cause sensitising effects to the skin or the respiratory organs.
HP14 - "Ecotoxic:" waste which presents or may present immediate or delayed risks for one or more sectors of the environment

SECTION 14: Transport information

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

ADR	IMDG	IATA	ADN	RID
14.1. UN number or ID number				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.2. UN proper shipping name				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.3. Transport hazard class(es)				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.4. Packing group				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.5. Environmental hazards				
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

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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. 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)	Dilution-/ washbuffer (10x conc.) ; Potassium thiocyanate ; reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)
3(c)	Dilution-/ washbuffer (10x conc.) ; Potassium thiocyanate ; 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

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SECTION 16: Other information

Indication of changes			
Section	Changed item	Change	Comments
	General revision		SDS EU format according to COMMISSION REGULATION (EU) 2020/878
1.1	Trade name	Modified	
1.3	Address	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	
3.2	Labelling of contents	Modified	
8.1	DNEL and PNEC	Added	
8.2	Personal protective equipment	Modified	
10.3	Possibility of hazardous reactions	Modified	
10.5	Incompatible materials	Modified	
11	Toxicological information	Modified	
12.	Ecotoxicity	Modified	
15.1	Water hazard class (WGK)	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

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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.

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 (Dermal)	Acute toxicity (dermal), Category 3
Acute Tox. 3 (Oral)	Acute toxicity (oral), Category 3
Acute Tox. 4 (Dermal)	Acute toxicity (dermal), Category 4
Acute Tox. 4 (Inhalation)	Acute toxicity (inhal.), Category 4
Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Aquatic Acute 1	Hazardous to the aquatic environment – Acute Hazard, Category 1
Aquatic Chronic 1	Hazardous to the aquatic environment – Chronic Hazard, Category 1
Aquatic Chronic 3	Hazardous to the aquatic environment – Chronic Hazard, Category 3
EUH032	Contact with acids liberates very toxic gas.
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.
H302	Harmful if swallowed.

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H310	Fatal in contact with skin.
H311	Toxic in contact with skin.
H312	Harmful 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.
H332	Harmful if inhaled.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
H412	Harmful to aquatic life with long lasting effects.
Skin Corr. 1B	Skin corrosion/irritation, Category 1, Sub-Category 1B
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
Aquatic Chronic 3	H412	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 100x IgA]

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

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]

Specific target organ toxicity – Repeated exposure, Category 2 H373
Full text of H- and EUH-statements: see section 16

Adverse physicochemical, human health and environmental effects

May cause damage to organs through prolonged or repeated exposure.

2.2. Label elements

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

Hazard pictograms (CLP) :



GHS08

Signal word (CLP) : Warning
Contains : Thiomersal
Hazard statements (CLP) : H373 - May cause damage to organs (central nervous system) through prolonged or repeated exposure.
Precautionary statements (CLP) : P314 - Get medical advice/attention if you feel unwell.
P260 - Do not breathe vapours, mist, spray.

[CONJ 100x IgA]

Safety Data Sheet

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

2.3. Other hazards

Other hazards which do not result in classification : Contains : Mercury (Hg).

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	
Glycerol (56-81-5)	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
Thiomersal (54-64-8)	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]
Glycerol substance with national workplace exposure limit(s) (GB)	CAS-No.: 56-81-5 EC-No.: 200-289-5	$\geq 10 - < 20$	Not classified
Thiomersal (Note A)(Note 1)	CAS-No.: 54-64-8 EC-No.: 200-210-4 EC Index-No.: 080-004-00-7	$\geq 0.1 - < 0.25$	Acute Tox. 2 (Inhalation), H330 Acute Tox. 1 (Dermal), H310 Acute Tox. 2 (Oral), H300 STOT RE 2, H373 Aquatic Acute 1, H400 Aquatic Chronic 1, H410

Specific concentration limits:

Name	Product identifier	Specific concentration limits
Thiomersal	CAS-No.: 54-64-8 EC-No.: 200-210-4 EC Index-No.: 080-004-00-7	(0.1 \leq C < 100) STOT RE 2, H373

Note 1 : The concentration stated or, in the absence of such concentrations, the generic concentrations set out in this Regulation are the percentages by weight of the metallic element calculated with reference to the total weight of the mixture.

Note A : Without prejudice to Article 17(2), the name of the substance must appear on the label in the form of one of the designations given in Part 3. In Part 3, use is sometimes made of a general description such as '... compounds' or '... salts'. In this case, the supplier is required to state on the label the correct name, due account being taken of section 1.1.1.4.

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

[CONJ 100x IgA]

Safety Data Sheet

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

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. Get medical advice/attention if you feel unwell.
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	: 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 ₂). Nitrogen oxides. Sulphur oxides. Mercury compounds.
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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. Do not breathe vapours, mist, 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 100x IgA]

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. Do not breathe vapours, mist, spray.

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.

Storage temperature : 2 – 8 °C

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

Glycerol (56-81-5)	
United Kingdom - Occupational Exposure Limits	
Local name	Glycerol
WEL TWA (OEL TWA) [1]	10 mg/m ³ mist
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

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 eye protection according to EN 166, designed to protect against liquid splashes.

8.2.2.2. Skin protection

Skin and body protection:

Wear suitable protective clothing. EN ISO 13688. EN 13034

[CONJ 100x IgA]

Safety Data Sheet

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

Hand protection:

In case of repeated or prolonged contact wear gloves. Chemically resistant protective gloves. Nitrile rubber. ISO 374-1. 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: Breathing apparatus with filter. Filter A (colour code: brown). 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	: 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	: 7.8 – 8.2 (20 °C)
Viscosity, kinematic	:
Viscosity, dynamic	:
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

[CONJ 100x IgA]

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

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. Contact with acids liberates very toxic gas.

10.4. Conditions to avoid

Protect from light.

10.5. Incompatible materials

Strong oxidizing agent. Strong acids. Strong bases. 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)

IgA-Conjugate (anti-human, 100x conc.)

ATE CLP (oral)	> 2000 mg/kg bodyweight
Skin corrosion/irritation	: Not classified (No data available. Based on available data, the classification criteria are not met) pH: 7.8 – 8.2 (20 °C)
Serious eye damage/irritation	: Not classified (No data available. Based on available data, the classification criteria are not met) pH: 7.8 – 8.2 (20 °C)
Respiratory or skin sensitisation	: Not classified (No data available. 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 (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	: May cause damage to organs (central nervous system) through prolonged or repeated exposure.

Thiomersal (54-64-8)

STOT-repeated exposure	May cause damage to organs (central nervous system) through prolonged or repeated exposure.
Aspiration hazard	: Not classified (Based on available data, the classification criteria are not met)

IgA-Conjugate (anti-human, 100x conc.)

Viscosity, kinematic	
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[CONJ 100x IgA]

Safety Data Sheet

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

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

IgA-Conjugate (anti-human, 100x conc.)	
Persistence and degradability	No additional information available.
Glycerol (56-81-5)	
Persistence and degradability	Readily biodegradable.
Biodegradation	94 % (24 h)

12.3. Bioaccumulative potential

IgA-Conjugate (anti-human, 100x conc.)	
Bioaccumulative potential	No additional information available.
Glycerol (56-81-5)	
Partition coefficient n-octanol/water (Log Kow)	-1.75 (25 °C; pH 7.4)
Bioaccumulative potential	Bioaccumulation unlikely.

12.4. Mobility in soil

IgA-Conjugate (anti-human, 100x conc.)	
Ecology - soil	No additional information available.
Glycerol (56-81-5)	
Surface tension	≈ 63.4 mN/m (20 °C)

12.5. Results of PBT and vPvB assessment

IgA-Conjugate (anti-human, 100x conc.)	
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 100x IgA]

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	: Comply with local regulations for disposal. 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.

SECTION 14: Transport information

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

ADR	IMDG	IATA	ADN	RID
14.1. UN number or ID number				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.2. UN proper shipping name				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.3. Transport hazard class(es)				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.4. Packing group				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.5. Environmental hazards				
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

[CONJ 100x IgA]

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 : 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
18.	Thiomersal
3(b)	IgA-Conjugate (anti-human, 100x conc.)

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 substance(s) listed on the PIC list (Regulation EU 649/2012 concerning the export and import of hazardous chemicals): Thiomersal (54-64-8)

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		SDS EU format according to COMMISSION REGULATION (EU) 2020/878
1.1	Trade name	Modified	
1.3	Address	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)
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[CONJ 100x IgA]

Safety Data Sheet

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

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
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.

[CONJ 100x IgA]

Safety Data Sheet

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

Full text of H- and EUH-statements:	
Acute Tox. 1 (Dermal)	Acute toxicity (dermal), Category 1
Acute Tox. 2 (Inhalation)	Acute toxicity (inhal.), Category 2
Acute Tox. 2 (Oral)	Acute toxicity (oral), Category 2
Aquatic Acute 1	Hazardous to the aquatic environment – Acute Hazard, Category 1
Aquatic Chronic 1	Hazardous to the aquatic environment – Chronic Hazard, Category 1
H300	Fatal if swallowed.
H310	Fatal in contact with skin.
H330	Fatal if inhaled.
H373	May cause damage to organs through prolonged or repeated exposure.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
STOT RE 2	Specific target organ toxicity – Repeated exposure, Category 2

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:		
STOT RE 2	H373	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 5 +/- IgX]

Safety Data Sheet

A safety data sheet is not required for this product. This document was created on a voluntary basis
Issue date: 27/01/2023 Revision date: 27/01/2023 Supersedes version of: 16/03/2017 Version: 2.00

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

1.1. Product identifier

Product form : Mixture
Trade name : [CONTROL 5 +/- IgX]

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

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

No additional information available

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

Component

Glycerol (56-81-5)	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
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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 %

[CONTROL 5 +/- IgX]

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

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Glycerol substance with national workplace exposure limit(s) (GB)	CAS-No.: 56-81-5 EC-No.: 200-289-5	≥ 10 – < 20	Not classified

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 ₂). 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.

[CONTROL 5 +/- IgX]

Safety Data Sheet

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

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.

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 : 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. 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

Glycerol (56-81-5)	
United Kingdom - Occupational Exposure Limits	
Local name	Glycerol
WEL TWA (OEL TWA) [1]	10 mg/m ³ mist
Regulatory reference	EH40/2005 (Fourth edition, 2020). HSE

8.1.2. Recommended monitoring procedures

No additional information available

[CONTROL 5 +/- IgX]

Safety Data Sheet

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

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 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

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
Explosive properties	: Product is not explosive.
Oxidising properties	: Non oxidizing.
Explosive limits	: Not available
Lower explosion limit	: Not available
Upper explosion limit	: Not available

[CONTROL 5 +/- IgX]

Safety Data Sheet

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

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

Strong oxidizing agent.

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
Acute toxicity (dermal)	: Not classified
Acute toxicity (inhalation)	: Not classified

IgG / IgM / IgA Cut off Control (human serum, prediluted) in buffer ZWB12205	
ATE CLP (oral)	> 2000 mg/kg bodyweight
Glycerol (56-81-5)	
LD50 oral rat	27200 mg/kg bodyweight
LD50 oral	≈ 23000 mg/kg bodyweight (mouse, male)
LC50 Inhalation - Rat (Vapours)	> 2.75 mg/l/4h

[CONTROL 5 +/- IgX]

Safety Data Sheet

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

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 (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)

Glycerol (56-81-5)

LC50 - Fish [1]	54000 mg/l (96 h; Oncorhynchus mykiss)
EC50 - Crustacea [1]	1955 mg/l (48 h; Daphnia magna)

12.2. Persistence and degradability

IgG / IgM / IgA Cut off Control (human serum, prediluted) in buffer ZWB12205

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

Glycerol (56-81-5)

Persistence and degradability	Readily biodegradable.
Biodegradation	94 % (24 h)

12.3. Bioaccumulative potential

IgG / IgM / IgA Cut off Control (human serum, prediluted) in buffer ZWB12205

Bioaccumulative potential	No additional information available.
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Glycerol (56-81-5)

Partition coefficient n-octanol/water (Log Kow)	-1.75 (25 °C; pH 7.4)
Bioaccumulative potential	Bioaccumulation unlikely.

12.4. Mobility in soil

IgG / IgM / IgA Cut off Control (human serum, prediluted) in buffer ZWB12205

Ecology - soil	No additional information available.
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Glycerol (56-81-5)

Surface tension	≈ 63.4 mN/m (20 °C)
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[CONTROL 5 +/- IgX]

Safety Data Sheet

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

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
14.1. UN number or ID number				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.2. UN proper shipping name				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.3. Transport hazard class(es)				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.4. Packing group				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.5. Environmental hazards				
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

[CONTROL 5 +/- IgX]

Safety Data Sheet

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

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

SECTION 16: Other information

Indication of changes

Section	Changed item	Change	Comments
	General revision		SDS EU format according to COMMISSION REGULATION (EU) 2020/878
1.1	Trade name	Modified	
1.3	Address	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)
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[CONTROL 5 +/- IgX]

Safety Data Sheet

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

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
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.

[CONTROL 5 +/- IgX]

Safety Data Sheet

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

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 100x 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

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]

Specific target organ toxicity – Repeated exposure, Category 2 H373
Full text of H- and EUH-statements: see section 16

Adverse physicochemical, human health and environmental effects

May cause damage to organs through prolonged or repeated exposure.

2.2. Label elements

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

Hazard pictograms (CLP) :



GHS08

Signal word (CLP) : Warning
Contains : Thiomersal
Hazard statements (CLP) : H373 - May cause damage to organs (central nervous system) through prolonged or repeated exposure.
Precautionary statements (CLP) : P314 - Get medical advice/attention if you feel unwell.
P260 - Do not breathe vapours, mist, spray.

[CONJ 100x IgG]

Safety Data Sheet

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

2.3. Other hazards

Other hazards which do not result in classification : Contains : Mercury (Hg).

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	
Glycerol (56-81-5)	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
Thiomersal (54-64-8)	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]
Glycerol substance with national workplace exposure limit(s) (GB)	CAS-No.: 56-81-5 EC-No.: 200-289-5	$\geq 10 - < 20$	Not classified
Thiomersal (Note A)(Note 1)	CAS-No.: 54-64-8 EC-No.: 200-210-4 EC Index-No.: 080-004-00-7	$\geq 0.1 - < 0.25$	Acute Tox. 2 (Inhalation), H330 Acute Tox. 1 (Dermal), H310 Acute Tox. 2 (Oral), H300 STOT RE 2, H373 Aquatic Acute 1, H400 Aquatic Chronic 1, H410

Specific concentration limits:

Name	Product identifier	Specific concentration limits
Thiomersal	CAS-No.: 54-64-8 EC-No.: 200-210-4 EC Index-No.: 080-004-00-7	(0.1 \leq C < 100) STOT RE 2, H373

Note 1 : The concentration stated or, in the absence of such concentrations, the generic concentrations set out in this Regulation are the percentages by weight of the metallic element calculated with reference to the total weight of the mixture.

Note A : Without prejudice to Article 17(2), the name of the substance must appear on the label in the form of one of the designations given in Part 3. In Part 3, use is sometimes made of a general description such as '... compounds' or '... salts'. In this case, the supplier is required to state on the label the correct name, due account being taken of section 1.1.1.4.

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

[CONJ 100x IgG]

Safety Data Sheet

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

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. Get medical advice/attention if you feel unwell.
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	: 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 ₂). Nitrogen oxides. Sulphur oxides. Mercury compounds.
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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. Do not breathe vapours, mist, 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 100x IgG]

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. Do not breathe vapours, mist, spray.

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.

Storage temperature : 2 – 8 °C

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

Glycerol (56-81-5)	
United Kingdom - Occupational Exposure Limits	
Local name	Glycerol
WEL TWA (OEL TWA) [1]	10 mg/m ³ mist
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

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 eye protection according to EN 166, designed to protect against liquid splashes.

8.2.2.2. Skin protection

Skin and body protection:

Wear suitable protective clothing. EN ISO 13688. EN 13034

[CONJ 100x IgG]

Safety Data Sheet

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

Hand protection:

In case of repeated or prolonged contact wear gloves. Chemically resistant protective gloves. Nitrile rubber. ISO 374-1. 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: Breathing apparatus with filter. Filter A (colour code: brown). 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	: 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	: 7.8 – 8.2 (20 °C)
Viscosity, kinematic	:
Viscosity, dynamic	:
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

[CONJ 100x IgG]

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

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. Contact with acids liberates very toxic gas.

10.4. Conditions to avoid

Protect from light.

10.5. Incompatible materials

Strong oxidizing agent. Strong acids. Strong bases. 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)

IgG-Conjugate (anti-human,100x conc.)

ATE CLP (oral)	> 2000 mg/kg bodyweight
Skin corrosion/irritation	: Not classified (No data available. Based on available data, the classification criteria are not met) pH: 7.8 – 8.2 (20 °C)
Serious eye damage/irritation	: Not classified (No data available. Based on available data, the classification criteria are not met) pH: 7.8 – 8.2 (20 °C)
Respiratory or skin sensitisation	: Not classified (No data available. 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 (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	: May cause damage to organs (central nervous system) through prolonged or repeated exposure.

Thiomersal (54-64-8)

STOT-repeated exposure	May cause damage to organs (central nervous system) through prolonged or repeated exposure.
Aspiration hazard	: Not classified (Based on available data, the classification criteria are not met)

IgG-Conjugate (anti-human,100x conc.)

Viscosity, kinematic	
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[CONJ 100x IgG]

Safety Data Sheet

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

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

IgG-Conjugate (anti-human,100x conc.)	
Persistence and degradability	No additional information available.
Glycerol (56-81-5)	
Persistence and degradability	Readily biodegradable.
Biodegradation	94 % (24 h)

12.3. Bioaccumulative potential

IgG-Conjugate (anti-human,100x conc.)	
Bioaccumulative potential	No additional information available.
Glycerol (56-81-5)	
Partition coefficient n-octanol/water (Log Kow)	-1.75 (25 °C; pH 7.4)
Bioaccumulative potential	Bioaccumulation unlikely.

12.4. Mobility in soil

IgG-Conjugate (anti-human,100x conc.)	
Ecology - soil	No additional information available.
Glycerol (56-81-5)	
Surface tension	≈ 63.4 mN/m (20 °C)

12.5. Results of PBT and vPvB assessment

IgG-Conjugate (anti-human,100x conc.)	
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

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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	: Comply with local regulations for disposal. 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.

SECTION 14: Transport information

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

ADR	IMDG	IATA	ADN	RID
14.1. UN number or ID number				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.2. UN proper shipping name				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.3. Transport hazard class(es)				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.4. Packing group				
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.5. Environmental hazards				
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

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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
18.	Thiomersal
3(b)	IgG-Conjugate (anti-human,100x conc.)

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 substance(s) listed on the PIC list (Regulation EU 649/2012 concerning the export and import of hazardous chemicals): Thiomersal (54-64-8)

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		SDS EU format according to COMMISSION REGULATION (EU) 2020/878
1.1	Trade name	Modified	
1.3	Address	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)
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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
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 comply with national legal requirements without reference to a national distributor. The national distributor is responsible for a legally compliant safety data sheet.

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Full text of H- and EUH-statements:	
Acute Tox. 1 (Dermal)	Acute toxicity (dermal), Category 1
Acute Tox. 2 (Inhalation)	Acute toxicity (inhal.), Category 2
Acute Tox. 2 (Oral)	Acute toxicity (oral), Category 2
Aquatic Acute 1	Hazardous to the aquatic environment – Acute Hazard, Category 1
Aquatic Chronic 1	Hazardous to the aquatic environment – Chronic Hazard, Category 1
H300	Fatal if swallowed.
H310	Fatal in contact with skin.
H330	Fatal if inhaled.
H373	May cause damage to organs through prolonged or repeated exposure.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
STOT RE 2	Specific target organ toxicity – Repeated exposure, Category 2

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:		
STOT RE 2	H373	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.