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Name and version of the MSDS: NG-Test Blood Culture Prep - version 1 - 04/2019

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

1.1. Product identifier

Product

NG-Test Blood Culture Prep (Ref. NGP-BCU-S73)

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

NG-Test Blood Culture Prep is intended for preparing a bacterial extract from positive blood culture samples. It is an in vitro diagnostic kit for professional use only. NG-Test Blood Culture Prep should be used in conjunction with NG-Test CARBA 5.

1.3. Details of the supplier of the safety data sheet

Manufacturer

NG Biotech

Z.A. Courbouton Secteur 1, 35480 Guipry, FRANCE info@ngbiotech.com

1.4. Emergency telephone number

Emergency telephone

Phone: +33 (0)2 23 30 17 83 (during normal business hours only)

+33 (0)1 45 42 59 59 (Poisons Information Service in France)

Other countries: Contact local authorities

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification of the substances according to Regulation (EC) No. 1272/2008, and (EC) No. 1907/2006

H315: Causes skin irritation/ skin corrosion (category 2)

H318: Causes serious eye damage/ eye irritation (category 1)

2.2. Label elements

Label according to Regulation (EC) No. 1272/2008.

Signal Word

Corrosive



Hazard Statements

H315: Causes skin irritation/ skin corrosion (category 2)

H318: Causes serious eye damage/ eye irritation (category 1)

Precautionary Statements

P302+P352: IF ON SKIN: Wash with soap and water

P332+P313 If skin irritation occurs: Get medical advice/attention

P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if

present and easy to do. continue rinsing

P310: Immediately call a POISON CENTER or doctor/physician

P280: Wear protective gloves/protective clothing/eye protection/face protection

2.3. Other hazards

Not applicable.



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SECTION 3: Composition/information on ingredients

3.1. Substances

This product is a mixture.

3.2. Mixtures

This product is constituted of two solutions (R1 and R2). The solution R2 does not contain substance to be mentioned according the EU regulation No.1272/2008.

Component	No. CAS	No. CE	Percent (by weight)	Classification according to EU regulation 1272/2008		
R1 (anionic surfactant)	151-21-3	7732-18-5	20%	DANGER H315, 318		

SECTION 4: First aid measures

The following first aid measures are only relevant in the event of serious misuse, whereby the device is disassembled and there is exposure to the chemicals in the strip.

R1 (anionic surfactant)

4.1. Description of first aid measures

After skin contact: Wash with soap and plenty of water at least 15 minutes. Consult a doctor.

After eye contact: Rinse eyes with water for at least 15 minutes. Remove contact lenses, if present. Consult a doctor and call a poison center.

After ingestion: Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a doctor.

After inhalation: In case of inhalation, remove the person from the contaminated area. In case of respiratory arrest, give artificial respiration. Consult a doctor.

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

Causes severe eye damage.

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

Notes to Doctor: Treat symptomatically

SECTION 5: Firefighting measures

5.1. Extinguishing media

Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide

5.2. Special hazards arising from the substance or mixture

Keep product and empty container away from heat and sources of ignition

5.3. Advice for firefighters

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.



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SECTION 6: Accidental release measures

Information are pertinent only with an abusive use of the device (exposition with chemical products)

6.1. Personal precautions, protective equipment and emergency procedures

Ensure adequate ventilation. Avoid direct contact with skin, eyes, mucous membranes, and clothing with appropriate personal protective equipment (PPE) including gloves and lab coat.

6.2. Environmental precautions

Do not flush into surface water or sanitary sewer system.

6.3. Methods and material for containment and cleaning up

Soak up with inert absorbent material. Keep in suitable, closed containers for disposal.

6.4. Reference to other sections

Not applicable

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Ensure adequate ventilation. Wear individual equipment is recommended. Avoid contact with aye, skin, or cloth. Avoid ingestion or inhalation.

7.2. Conditions for safe storage, including any incompatibilities

Store between 20-30°C. Keep containers tightly closed in a dry, cool and well-ventilated place.

7.3. Specific end use(s)

see section 1.2

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

The product does not contain any relevant quantities of materials with critical values that have to be monitored in the workplace.

8.2. Exposure controls

Ensure that eyewash stations and safety showers are close to the workstation location. Ensure adequate ventilation, especially in confined areas.

Eye/face Protection: Tightly fitting safety goggles. Face-shield. (EN 166)

Skin and body protection: Long sleeved clothing.

Respiratory Protection: Follow the OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149.

Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced.

Hygiene Measures: Handle in accordance with good industrial hygiene and safety practice.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Form: Liquid

Color: Clear/Colorless

Odor: N/A

Boiling point: $> 100^{\circ}\text{C} / 212^{\circ}\text{F} @760 \text{ mmHg}$



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Specific gravity: 1.01

No other data available

9.2. Other information

No data available

SECTION 10: Stability and reactivity

10.1. Reactivity

No dangerous reactions known if handled under normal conditions of use

10.2. Chemical stability

Any chemical component is stable under recommended stockage temperature.

10.3. Possibility of hazardous reactions

None if used for the intended purpose

10.4. Conditions to avoid

It is recommended to avoid high temperature.

10.5. Incompatible materials

Strong oxidizing agents

10.6. Hazardous decomposition products

Sulfur oxides, Carbon monoxide (CO), Carbon dioxide (CO2)

SECTION 11: Toxicological information

Information are pertinent only with an abusive use of the device (exposition with chemical products)

11.1. Information on toxicological effects

Product information

Component	LD50 oral	LD50 dermal	LC50 inhalation		
Anionic surfactant	1288 mg/kg (rat)	> 2000 mg/kg (rabbit)	> 3900 mg/m³ (rat) 1h		

See sections 2 and 4.

SECTION 12: Ecological information

Information are pertinent only with an abusive use of the device (exposition with chemical products)

12.1. Toxicity

Contains a substance which is toxic to aquatic organisms.

12.2. Persistence and degradability

Persistence is unlikely based on information available.

12.3. Bioaccumulative potential

No data available



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12.4. Mobility in soil

Will likely be mobile in the environment due to its water solubility.

12.5. Results of PBT and vPvB assessment

No data available

12.6. Other adverse effects

No data available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Dispose the device and/or the packing of in a biological and risk of infection bin in compliance with national rules

SECTION 14: Transport information

14.1. UN number

Not applicable

14.2. UN proper shipping name

Not applicable

14.3. Transport hazard class(es)

Not applicable

14.4. Packing group

Not applicable

14.5. Environmental hazards

See section 12

14.6. Special precautions for user

See section 6

14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

Delivery will only be made in an approved and regulated packaging.

SECTION 15: Regulatory information

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

Classified as dangerous according to EU regulation (EC) No. 1272/2008, and (EC) No. 1907/2006

Component	TSCA	DSL	NDSL	EINECS	ELINCS	NLP	PICCS	ENCS	AICS	IECSC	KECL
Anionic	×	х		205-		V	V		V	V	
surfactant			_	788-1	_	-	^	X	^	_ X	Х

15.2. Chemical safety assessment

The mixture has not been subject to a safety assessment



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SECTION 16: Other information

Warranty

The above information is believed to be correct but is all inclusive and should only be used as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not present any guarantee of the properties of the product. NG Biotech shall not be liable for any damage resulting from handling or contact with the above product

Written by: Francius Laura - Project manager

Date: April 2, 2019

Signature:

Approved by: Marie SUET, Quality Assurance Manager

Date: April 2, 2019

Signature: