

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

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

1.1. Product identifier

Product form : Mixture

Product name : Alere NMP22™ Sample Diluent

Alere NMP22™ Test Controls Alere NMP22™ Calibrators

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 : For professional use only

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Abbott Diagnostics Scarborough, Inc.

10 Southgate Road

Scarborough, Maine 04074 - United States

T+1 (207) 730-5750

ts.scr@abbott.com

1.4. Emergency telephone number

Emergency number : +1-703-741-5970

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

May cause an allergic skin reaction.

2.2. Label elements

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

No labeling applicable

2.3. Other hazards

No additional information available

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]
Urea	(CAS-No.) 57-13-6	2.47	Not classified

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Gentamicin sulfate	(CAS-No.) 1405-41-0	0.2	Not classified
uric acid	(CAS-No.) 69-93-2 (EC-No.) 200-720-7	0.05	Not classified

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures after inhalation : Remove person to fresh air and keep comfortable for breathing.

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/doctor/physician if you feel unwell.

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

Symptoms/effects : Not expected to present a significant hazard under anticipated conditions of normal use.

Symptoms/effects after inhalation : None under normal use.

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

Symptoms/effects after eye contact : None under normal use. Symptoms/effects after ingestion : None under normal use. Symptoms/effects upon intravenous administration : None under normal use. Chronic symptoms : None under normal use.

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 : Water spray. Dry powder. Foam.

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.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Emergency procedures : Evacuate 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".

Emergency procedures : Containment as appropriate.

6.2. Environmental precautions

Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Mechanically recover the product.

Other information : Dispose of materials or solid residues at an authorized site.

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6.4. Reference to other sections

For further information refer to section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Additional hazards when processed

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

contact with skin and eyes.

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.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Comply with instructions for use (refer to technical sheet). Store in a well-ventilated place.

Keep cool.

: None known.

Incompatible products : None known.

Incompatible materials : Store away from direct sunlight or other heat sources.

Heat-ignition : None known. Information on mixed storage : None known.

Storage area : Keep only in the original container.

7.3. Specific end use(s)

For professional use only.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No additional information available

8.2. Exposure controls

Appropriate engineering controls:

Ensure good ventilation of the work station.

Personal protective equipment:

Protective clothing. Gloves.

Hand	pro	tecti	on:

Protective gloves

Eye protection:

Safety glasses

Skin and body protection:

Wear suitable protective clothing

Respiratory protection:

A risk assessment is required

No data availableNot applicable

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Personal protective equipment symbol(s):







Environmental exposure controls:

Avoid release to the environment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Solid Color : white.

Odor : No data available Odor threshold : No data available : No data available рΗ Relative evaporation rate (butyl acetate=1) : No data available Melting point : No data available Freezing point Not applicable Boiling point : No data available Flash point : Not applicable Auto-ignition temperature : Not applicable : No data available Decomposition temperature Flammability (solid, gas) : Non flammable. Vapor pressure : No data available Relative vapor density at 20 °C : No data available Relative density : No data available Solubility : No data available Partition coefficient n-octanol/water (Log Pow) : No data available Viscosity, kinematic : No data available Viscosity, dynamic : No data available Explosive properties : No data available

9.2. Other information

Oxidizing properties

Explosion limits

Minimum ignition energy : No data 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

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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 toxicological effects

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

Gentamicin sulfate (1405-41-0)

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LD50 oral rat	> 5000 mg/kg
EBOO CIGITAL	> 0000 mg/kg

 Skin corrosion/irritation
 : Not classified

 Serious eye damage/irritation
 : Not classified

 Respiratory or skin sensitization
 : Not classified

 Germ cell mutagenicity
 : Not classified

 Carcinogenicity
 : Not classified

Reproductive toxicity : Not classified

STOT-single exposure : Not classified

STOT-repeated exposure : Not classified

Aspiration hazard : Not classified

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general : The product is not considered harmful to aquatic organisms or to cause long-term adverse

effects in the environment.

Aquatic acute : Not classified Aquatic chronic : Not classified

12.2. Persistence and degradability

ıric acid (69-93-2)	
Persistence and degradability	Not readily biodegradable in water.
BOD (% of ThOD)	0.45 (5 day(s), Literature study)

12.3. Bioaccumulative potential

uric acid (69-93-2)		
Partition coefficient n-octanol/water (Log Pow)	-1.149 (Experimental value, 20 °C)	
Bioaccumulative potential	Not bioaccumulative.	

12.4. Mobility in soil

ric acid (69-93-2)	
Partition coefficient n-octanol/water (Log Koc)	1 (log Koc, SRC PCKOCWIN v2.0, Calculated value)
Ecology - soil	Highly mobile in soil.

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12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Regional legislation (waste) : Disposal must be done according to official regulations.

Waste treatment methods : Dispose of contents/container in accordance with licensed collector's sorting instructions.

Sewage disposal recommendations : Disposal must be done according to official regulations.

Product/Packaging disposal recommendations : Dispose of contents/container: Dispose in a safe manner in accordance with local/national

regulations.

Ecology - waste materials : Avoid release to the environment.

SECTION 14: Transport information

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

14.1. UN number

UN-No. (ADR) : Not applicable UN-No. (IMDG) : Not applicable UN-No. (IATA) : Not applicable UN-No. (ADN) : Not applicable UN-No. (RID) : Not applicable

14.2. UN proper shipping name

Proper Shipping Name (ADR) : Not applicable
Proper Shipping Name (IMDG) : Not applicable
Proper Shipping Name (IATA) : Not applicable
Proper Shipping Name (ADN) : Not applicable
Proper Shipping Name (RID) : Not applicable

14.3. Transport hazard class(es)

ADR

Transport hazard class(es) (ADR) : Not applicable

IMDG

Transport hazard class(es) (IMDG) : Not applicable

IATA

Transport hazard class(es) (IATA) : Not applicable

ADN

Transport hazard class(es) (ADN) : Not applicable

RID

Transport hazard class(es) (RID) : Not applicable

14.4. Packing group

Packing group (ADR): Not applicablePacking group (IMDG): Not applicablePacking group (IATA): Not applicablePacking group (ADN): Not applicablePacking group (RID): Not applicable

14.5. Environmental hazards

Dangerous for the environment : No

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Marine pollutant : No

Other information : No supplementary information available

14.6. Special precautions for user

Overland transport

No data available

Transport by sea

No data available

Air transport

No data available

Inland waterway transport

No data available

Rail transport

No data available

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

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

Contains no REACH substances with Annex XVII restrictions

Contains no REACH candidate substance

Contains no REACH Annex XIV substances.

Contains no substance subject to Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals.

Contains no substance(s) subject to Regulation (EU) No 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants

15.1.2. National regulations

Germany

Water hazard class (WGK) : WGK 2, significant hazardous to water (Classification according to AwSV, Annex 1)

Hazardous Incident Ordinance (12. BImSchV) : Is not subject of the Hazardous Incident Ordinance (12. BImSchV)

Netherlands

SZW-lijst van kankerverwekkende stoffen

SZW-lijst van mutagene stoffen

NIET-limitatieve lijst van voor de voortplanting

giftige stoffen - Borstvoeding

NIET-limitatieve lijst van voor de voortplanting

giftige stoffen - Vruchtbaarheid

NIET-limitatieve lijst van voor de voortplanting

giftige stoffen – Ontwikkeling

None of the components are listedNone of the components are listed

: None of the components are listed

: None of the components are listed

: None of the components are listed

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Data sources : REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16

December 2008 on classification, labeling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Other information : Date of issue.

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SDS EU (REACH Annex II)

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.

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