



SAFETY DATA SHEET

According to Regulation (EC) No. 1907/2006 (REACH), Annex II

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

- 1.1 Product identifier**
Trade name NMP22[®] Urine Stabilizer
- 1.2 Relevant identified uses of the substance or mixture and uses advised against**
Identified use(s) *In vitro* diagnostic reagent.
- 1.3 Details of the supplier of the safety data sheet**
Company Identification Alere Scarborough Inc.,
10 Southgate Road,
Scarborough,
Maine 04074, USA.
Telephone +1 207-730-5750
E-Mail (competent person) ts.scr@alere.com
- 1.4 Emergency telephone number**
Emergency Phone No. +1 207-730-5750

SECTION 2: HAZARDS IDENTIFICATION

- 2.1 Classification of the substance or mixture**
Regulation (EC) No. 1272/2008 (CLP) Not classified as hazardous.

Directive 67/548/EEC & Directive 1999/45/EC
Risk Phrases Not classified as dangerous for supply/use.
- 2.2 Label elements**
Special labelling phrase: According to Regulation (EC) No. 1272/2008 (CLP)
Safety data sheet available on request
- 2.3 Other hazards** None anticipated.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

- 3.2 Mixtures**
Description: *In vitro* diagnostic reagent. Aqueous solution.

Dangerous components:

EC Classification No. 1272/2008

Hazardous ingredient(s)	CAS No.	EC No.	REACH Registration No.	Classification code: Hazard statement(s)	%W/W
Na ₂ EDTA	139-33-3	205-358-3	Not available	Acute Tox. 4; H332	2 - 5

EC Classification No. 67/548/EEC

Hazardous ingredient(s)	CAS No.	EC No.	REACH Registration No.	EC Classification and Risk Phrases	%W/W
Na ₂ EDTA	139-33-3	205-358-3	Not available	Xn; R20	2 - 5

- 3.3 Additional Information** For full text of R/H phrases see section 16.

SECTION 4: FIRST AID MEASURES



4.1 Description of first aid measures



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Inhalation	Supply fresh air; consult doctor in case of complaint.
Skin Contact	Wash skin with soap and water. Remove contaminated clothing and wash clothing before reuse.
Eye Contact	Rinse cautiously with water for several minutes. Consult a doctor in case of complaint.
Ingestion	Wash out mouth with water. Consult a doctor in case of complaint.
4.2 Most important symptoms and effects, both acute and delayed	Respiratory tract disorders. Note: Inhalation = Unlikely route of exposure.
4.3 Indication of the immediate medical attention and special treatment needed	None.

SECTION 5: FIRE-FIGHTING MEASURES

5.1 Extinguishing media Suitable Extinguishing Media	CO ₂ , powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
5.2 Special hazards arising from the substance or mixture	In case of fire, the following can be released: Carbon oxides (CO _x), nitrogen oxides (NO _x), phosphorous oxides (P _x O _y) .
5.3 Advice for fire-fighters	Use fire-extinguishing methods suitable to surrounding conditions. Wear full protective suit and self-contained breathing apparatus (SCBA) when extinguishing fires.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures	Refer to Section 8 for protective measures when handling the spillage.
6.2 Environmental precautions	Do not allow the undiluted product to enter sewers/surface or ground water.
6.3 Methods and material for containment and cleaning up	Absorb with liquid-binding material (paper towelling, sand, diatomite, acid binders, universal binders, sawdust) Dispose of contaminated material as waste according to Section 13. Rinse off area with water.
6.4 Reference to other sections	8, 13

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling	Avoid contact with skin and eyes. Keep out of reach of children. Wash hands and exposed skin after use.
7.2 Conditions for safe storage, including any incompatibilities	Store in the original container at 2 to 8°C.
7.3 Specific end use(s)	Use as per instructions for use.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters	
8.1.1 Occupational Exposure Limits	The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
8.2 Exposure controls	
8.2.1 Appropriate engineering controls	Not relevant for this material.
8.2.2 Personal protection equipment Eye/face protection	Not normally required.

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Hand protection (Hygiene Measures)

Disposable gloves. (EN374) -



Material of gloves:

Latex / natural rubber, Nitrile rubber.

Penetration time of glove material:

Gloves resistance is not critical when the product is handled according to the instructions for use.

Body protection

Not applicable.

Respiratory protection

Not normally required.

8.2.3 Environmental Exposure Controls

No special measures are required.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance	Clear liquid
Colour	Blue
Odour	No odour.
Odour Threshold (ppm)	Not applicable
pH (Value)	7.0
Melting Point (°C) / Freezing Point (°C)	Similar to water, approximately 0°C.
Boiling point/boiling range (°C):	Similar to water, approximately 100°C.
Flash Point (°C)	Not applicable
Evaporation rate (BA = 1)	Not determined
Flammability (solid, gas)	Not applicable
Explosive limit ranges	Not applicable
Vapour Pressure (Pascal)	Similar to water, approximately 23 hPa.
Vapour Density (Air=1)	Not determined
Density (g/ml)	~1.0
Solubility (Water)	Soluble.
Solubility (Other)	Not determined
Partition Coefficient (n-Octanol/water)	Not determined
Auto Ignition Temperature (°C)	Not determined
Decomposition Temperature (°C)	Not determined
Viscosity (mPa.s)	Not determined
Explosive properties	Not explosive.
Oxidising properties	Not oxidising

9.2 Other information

Not available

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity	None known.
10.2 Chemical stability	The product is stable in accordance with the recommended storage conditions.
10.3 Possibility of hazardous reactions	None known. Hazardous polymerisation will not occur.
10.4 Conditions to avoid	None
10.5 Incompatible materials	None known.
10.6 Hazardous Decomposition Product(s)	None known.

▶ SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects



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11.1.2 Mixtures

Acute toxicity	Based upon the available data, the classification criteria are not met. ATE (Inhalation) = 16 mg/l
Skin corrosion/irritation	Based upon the available data, the classification criteria are not met.
Serious eye damage/irritation	Based upon the available data, the classification criteria are not met.
Respiratory/skin sensitization	Based upon the available data, the classification criteria are not met.
Germ cell mutagenicity	Based upon the available data, the classification criteria are not met.
Carcinogenicity	Based upon the available data, the classification criteria are not met.
Reproductive toxicity	Based upon the available data, the classification criteria are not met.
STOT-single exposure	Based upon the available data, the classification criteria are not met.
STOT-repeated exposure	Based upon the available data, the classification criteria are not met.
Aspiration hazard	Based upon the available data, the classification criteria are not met.

Health Effects and Symptoms

Skin Contact	No significant harmful effects anticipated
Eye Contact (Sensitised individual)	No significant harmful effects anticipated
Ingestion	No significant harmful effects anticipated
Inhalation	Increased difficulty in breathing. Lung damage. Note: Unlikely route of exposure.

11.2 Other information Not applicable

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity	The product does not contain significant quantities of ingredients that are environmentally toxic.
12.2 Persistence and degradability	The product is biodegradable.
12.3 Bioaccumulative potential	The product has low potential for bioaccumulation.
12.4 Mobility in soil	No data. The product is predicted to have high mobility in soil.
12.5 Results of PBT and vPvB assessment	Not applicable
12.6 Other adverse effects	Not applicable

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods	
Product:	Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.
European waste catalogue:	18 01 07.
Packaging:	Disposal should be in accordance with local, state or national legislation. Contaminated packaging must be disposed of in the same manner as the product. Non-contaminated packaging materials may be recycled. Contact your local service providers for further information.



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SECTION 14: TRANSPORT INFORMATION

14.1	UN number	Not applicable
14.2	Proper Shipping Name	Not applicable
14.3	Transport hazard class(es)	Not classified as dangerous for transport.
14.4	Packing Group	Not applicable
14.5	Environmental hazards	Not applicable
14.6	Special precautions for user	Not applicable
14.7	Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not applicable

SECTION 15: REGULATORY INFORMATION

15.1	Safety, health and environmental regulations/legislation specific for the substance or mixture	<i>In Vitro</i> diagnostics medical devices directive 98/79/EC. Water hazard class:(Germany): WGK 1
15.2	Chemical Safety Assessment	Not applicable.

▶ SECTION 16: OTHER INFORMATION

LEGEND

STOT	Specific Target Organ Toxicity
ATE	Acute toxicity estimate

Classification code:

Acute Tox. 4	Acute toxicity, Category 4
Xn	Harmful.

Hazard statement(s)

H332: Harmful if inhaled.

Risk Phrases

R20: Harmful by inhalation.

References:

Raw material safety data sheets.

Additional Information

Reason for update: Regulation (EC) No. 1272/2008 (CLP), SECTION 2:
SECTION 3: SECTION 11: SECTION 16:

Supersedes: Version: 1

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