

SAFETY DATA SHEET

according Regulation (EC) No 1907/2006

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY

1.1. Product identifier:

NM-Lyse® Solution

Product code: GAS-003

This Safety Data Sheet concerns all GAS-003 formulations (GAS-003, GAS-003-CE/IVD, GAS-003-1 and GAS-003-1-CE/IVD).

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

NM-Lyse® is a reagent for the fixation of white blood cells and lysis of red blood cells. It is used in the flow cytometric analysis of blood and bone marrow samples.

1.3. Particulars of supplier who prepared the safety datasheet

Producer:

Nordic Immunological Laboratories B.V., Tradename Nordic-MUBio

Rangerweg 5A

6114 BC Susteren, The Netherlands

www.nordicmubio.com

info@nordicmubio.com

Tel: +31 683611669

1.4. Emergency telephone number: Contact National Poison Information Center.

2. HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

Classification in accordance with GHS:

Carcinogenicity, Category 2, H351

Serious Eye Damage Category 1C, H318

Skin Irritant, Category 2, H312

Acute Oral Toxicity, Category 4, H302

For the full text of the H-statements mentioned in this Section, see Section 16.

Signal word: Danger

2.2. Label elements

Hazardous substance content: Formaldehyde



Corrosive



Irritant



Health hazard

Hazard statements:

H302 – Harmful if swallowed.
H312 – Harmful in contact with skin.
H318 – Causes serious eye damage
H351 – Suspected of causing cancer

Precautionary statements:

P280 – Wear protective gloves / protective clothing / eye protection / face protection.
P280A – Wear protective gloves
P285 In case of inadequate ventilation wear respiratory protection.
P301A – IF SWALLOWED do not induce vomiting. Do not give anything to drink. Obtain medical attention without delay.
P302+P352 – IF ON SKIN: Wash with plenty of soap and water.
P305 + P351 + P338 – IF IN EYES: Rinse cautiously with water for several minutes and remove contact lenses, if present and easy to do. Continue rinsing.
P315 – Get immediate medical advice / attention.
P340 – Remove victim to fresh air and keep at rest in a position comfortable for breathing.
P351 – Rinse cautiously with water for several minutes.
P361 – Remove / Take off immediately all contaminated clothing.

Reduced labeling (< 125ml):

Hazardous substance content: Formaldehyde



Corrosive



Irritant



Health hazard

Hazard statements:

H302 - Harmful if swallowed.
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Precautionary statements:

P280 – Wear protective gloves / protective clothing / eye protection / face protection.
P280A – Wear protective gloves
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P305 + P351 + P338 – IF IN EYES: Rinse cautiously with water for several minutes and remove contact lenses, if present and easy to do. Continue rinsing.
P315 – Get immediate medical advice / attention.
P340 – Remove victim to fresh air and keep at rest in a position comfortable for breathing.
P351 – Rinse cautiously with water for several minutes.
P361 – Remove / Take off immediately all contaminated clothing.

2.3. Other hazards
None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Mixture:

Chemical name	CAS No.:	EC no.:	REACH registration no.:	Conc. (%)
Formaldehyde	50-00-0	200-001-8	-	4-10

4. FIRST AID MEASURES

4.1. Description of first aid measures:

Contact medical personnel immediately.
Flush eyes with flowing water for at least 15 minutes.
If breathing is difficult, contact emergency personnel.
Remove contaminated clothing.
Remove to fresh air.

Separate eyelids with finger tips.

Wash skin with deluge of water for at least 15 minutes.

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

No data available.

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

Symptomatic treatment is needed.

5. FIREFIGHTING MEASURES

5.1. Extinguishing media:

5.1.1. Suitable extinguishing media:

CO₂, extinguishing powder, foam or water.

5.1.2. Unsuitable extinguishing media:

None known.

5.2. Special hazards arising from the substance or mixture:

Hazardous decomposition products: formaldehyde gas, carbon monoxide.

5.3. Advice for firefighters:

Wear full protective clothing and self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures:

6.1.1. For non-emergency personnel:

Keep unprotected people away, allow only well trained experts wearing suitable protective clothing to abide in the field of accident.

6.1.2. For emergency responders:

Wear appropriate protective equipments (see Section 8)!

Ensure adequate ventilation.

6.2. Environmental precautions:

Dispose of spillage and waste (product/packaging) in accordance with all applicable environmental laws. Do not allow to enter sewers/soil/surface or ground water. Notify the respective authorities in accordance with local law in the case of environmental pollution immediately.

6.3. Methods and material for containment and cleaning up:

Collect the spilled material with sand or vermiculite, then place into a suitable, closed, properly labelled chemical waste container for disposal. During disposal wear suitable personal protective equipment. Wash non-recoverable residues with large amounts of water.

6.4. Reference to other sections:

For further and detailed information see section 8 and 13.

7. HANDLING AND STORAGE

7.1. Precautions for safe handling:

Precautions for safe handling:

Observe conventional hygiene precautions.

Technical measures:

Ensure adequate ventilation!

Precautions against fire and explosion:

No specific prescription.

7.2. Conditions for safe storage, including any incompatibilities:

Technical measures and storage condition:

Keep in original, closed and labelled container.

The place of storage has to be properly ventilated and cleanable.
Store in cool and dry place.
Store at room temperature.
Follow all instructions on the label.
Incompatible materials: strong acids, strong bases, phenol, hydrochloric acid.
Packaging material: no special prescriptions.

7.3. Specific end use(s):
No specific instructions available.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.2. Exposure controls:
In case of a hazardous material with no controlled concentration limit it is the employer's duty to keep concentration levels down to a minimum achievable by existing scientific and technological means, where the hazardous substance poses no harm to workers.

8.2.1. Appropriate engineering controls
In pursuance of work is proper foresight needed to avoid spilling onto clothes and floors and to avoid contact with eyes and skin.
Ensure adequate ventilation.
In the vicinity of the workplace safety shower and eye washing fountain has to be installed.
Wash thoroughly after handling of the product.

8.2.2. Individual protection measures, such as personal protective equipment:

1. Eye/face protection: use appropriate protective goggles.
2. Skin protection:
 - a. Hand protection: use appropriate chemical resistant protective gloves.
 - b. Other: Use appropriate protective clothes.
3. Respiratory protection: use adequate respirator.
4. Thermal hazard: None known.

8.2.3. Environmental exposure controls:
No specific prescription.
The requirements detailed in Section 8 assume skilled work under normal conditions and usage of the product for appropriate aims. If conditions differ from normal or work is carried out under extreme conditions an expert's advice should be sought out before deciding upon further protective measures.

9. PHYSICAL AND CHEMICAL PROPERTIES:

9.1. Information on basic physical and chemical properties:

Parameter	Test method:	Remarks:
1. Appearance:		Colourless liquid
2. Odour:		pungent
3. Odour threshold:		no data available
4. pH value:		no data available
5. Melting point/ freezing point:		no data available
6. Initial boiling point/boiling range:		ca. 100 °C
7. Flash point:		no data available
8. Evaporation rate:		no data available
9. Flammability:		no data available
10. Upper/lower flammability or explosive limits:		no data available
11. Vapour pressure:		no data available
12. Relative density:		> 1,00
13. Solubility(ies):		Miscible with water. Not soluble in fats.
14. Partition coefficient: n-octanol/water:		no data available
15. Self-ignition temperature:		no data available
16. Degradation temperature:		no data available
17. Viscosity:		no data available
18. Explosive properties:		no data available
19. Oxidizing properties:		no data available

9.2. Other information:
No data available.

10. STABILITY AND REACTIVITY

10.1. Reactivity:
None known.

10.2. Chemical stability:
At normal temperature: stabile at general conditions of work.

10.3. Possibility of hazardous reactions:
oxidation may occur.

- 10.4. Conditions to avoid:
none known.
- 10.5. Incompatible materials:
strong acids, strong bases, phenol, hydrochloric acid.
- 10.6. Hazardous decomposition products:
formaldehyde gas, carbon monoxide.

11. TOXICOLOGICAL INFORMATION

Information applies only to „Formaldehyde” and not to the mixture!

This product has not been tested. Evaluation on the expected toxicity have been made upon application of the conventional method.

- 11.1. Information on toxicological effects:
Acute toxicity: Harmful by inhalation, in contact with skin and if swallowed.
Irritation: Irritates the skin and eyes, irritates the respiratory tract.
Sensitisation: May cause sensitization by skin contact
Repeated dose toxicity: none known.
Carcinogenicity: Limited evidence of a carcinogenic effect.
Mutagenicity: None known.
Reproduction toxicity: none known.
- 11.1.1. For substances subject to registration, brief summaries of the information derived from the test conducted:
No data available.
- 11.1.2. Relevant toxicological properties of the hazardous substances:
LD₅₀ (oral, rat): 100 mg/kg
LD₅₀ (dermal, rabbit): 270 µl/kg
LC₅₀ (inhalative, rat): 203 mg/m³
- 11.1.3. Information on likely routes of exposure:
ingestion, inhalation, skin and eye contact.
- 11.1.4. Symptoms related to the physical, chemical and toxicological characteristics:
No data available.
- 11.1.5. Delayed and immediate effects as well as chronic effects from short and long-term exposure:
Harmful by inhalation, in contact with skin and if swallowed.
Irritates the skin and eyes, irritates the respiratory tract.
Limited evidence of a carcinogenic effect.
May cause sensitization by skin contact
- 11.1.6. Interactive effects:
No data available.
- 11.1.7. Absence of specific data:
No information.
- 11.1.8. Other information:
No data available.

12. ECOLOGICAL INFORMATION

- 12.1. Toxicity:
Water hazard class (wgk, German regulation, self-classification): 2 (hazardous for the water)
- 12.2. Persistence and degradability:
No data available.
- 12.3. Bioaccumulation potential:
No data available.
- 12.4. Mobility in soil:
No data available.
- 12.5. Results of PBT and vPvB assessment:
No data available.
- 12.6. Other adverse effects:
No data available.

13. DISPOSAL CONSIDERATIONS

- 13.1. Waste treatment methods:
Disposal according to the local regulations.
- 13.1.1. Information regarding the disposal of the product:
In case of larger quantities: send the waste of the product to a licensed company dealing with disposal.
European Waste Code:
16 10 03* aqueous concentrates containing dangerous substances
- 13.1.2. Information regarding the disposal of the packaging:
Rinse the container thoroughly with water then re-use it.
- 13.1.3. Physical/chemical properties that may affect waste treatment options shall be specified:
None known.

- 13.1.4. Sewage disposal:
None known.
- 13.1.5. Special precautions for any recommended waste treatment:
No data available.

14. TRANSPORT INFORMATION

Not dangerous good in sense of the transport regulations!

- 14.1. UN Number: -
- 14.2. UN proper shipping name: -
- 14.3. Transport hazard class(es): -
- 14.4. Packing group: -
- 14.5. Environmental hazards: -
- 14.6. Special precautions for user: -
- 14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code: -

15. REGULATORY INFORMATION

- 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture:
REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC

DIRECTIVE 1999/45/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations

REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006

COMMISSION REGULATION (EU) No 453/2010 of 20 May 2010 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

- 15.2. Chemical safety assessment: has not been carried out for this product.

16. OTHER INFORMATION

Information regarding the revision of the safety data sheet: -

Full text of the abbreviations in the safety data sheet:

DNEL: Derived no effect level. PNEC: Predicted no effect concentration. CMR effects: carcinogenicity, mutagenicity and toxicity for reproduction: PBT: Persistent, bioaccumulative and toxic. . n.d.: not defined. . n.a.: Not applicable. .

Data sources: -

Relevant H-Phrases (number and full text) of Section 3:

H302 – Harmful if swallowed.

H312 – Harmful in contact with skin.

H318 – Causes serious eye damage.

H351 – Suspected of causing cancer

Training instructions: -

Recommended restrictions on use (non-statutory recommendations by supplier): -

This safety data sheet had been prepared on the basis of information provided by the manufacturer. The information, data and recommendations contained herein are provided in good faith, obtained from reliable sources and believed to be true and accurate as of the date issued; however, no representation is made as to the comprehensiveness of the information. The SDS shall be used only as a guide for handling the product; in the course of handling and using the product other considerations may arise or be required. Since the conditions or the handling, the storage and the disposal of this product are beyond the control of the manufacturer, the distributor or the preparer of this SDS, no warranty, expressed or implied, regarding the product described in this SDS shall be created or inferred by any statement in this SDS. No responsibility is assumed regarding the accuracy, completeness or suitability of all or any of the information contained herein or the results to be obtained from the use thereof at the time of use. In no way shall the manufacturer, the distributor or the preparer of the be liable for any claims, losses or damages of third parties, personal injury, property damage, lost profits or any special, direct, indirect, incidental, consequential or exemplary damages resulting from the use of or reliance upon such information. Users are cautioned to determine the appropriateness and applicability of the above information to their particular circumstances and purposes and assume all risk associated with the use of this product.

