

Safety data sheet

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

1.1. Product identifier

Product name **HEMOLYNAC-3N**
Product code **MEK-680 I**

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

Intended use **Reagent for hematology analyzer.**
Uses advised against **No use advised against.**

1.3. Details of the supplier of the safety data sheet

Name **NIHON KOHDEN FIRENZE S.r.l.**
Full address **Via Torta, 72/74**
District and Country **Osmannoro Sesto Fiorentino (FI)**
ITALY
Tel. 055/30.45.1
Fax. 055/30.85.48

e-mail address of the competent person

responsible for the Safety Data Sheet **e-mail: info.MSDS@nkf.it**
Product distribution by **NIHON KOHDEN FIRENZE S.r.l.**

1.4. Emergency telephone number

For urgent inquiries refer to **Company Emergency telephone number: +39(0)55 30451 (during working hours)**

SECTION 2. Hazards identification.

2.1. Classification of the substance or mixture.

The product is not classified as hazardous pursuant to the provisions set forth in EC Regulation 1272/2008 (CLP). However, since the product contains hazardous substances in concentrations such as to be declared in section no. 3, it requires a safety data sheet with appropriate information, compliant to EC Regulation 1907/2006 and subsequent amendments.

Hazard classification and indication:

2.2. Label elements.

Hazard pictograms: --

Signal words: --

Hazard statements:

EUH210 Safety data sheet available on request.

Precautionary statements: --

The product is in conformity with the requirements of in vitro diagnostic medical devices Directive 98/79/EC. Therefore, in accordance with art. 1, 5, d) of Regulation 1272/2008, CLP requirements of labelling do not apply to the product in the finished state, intended for the final user.

2.3. Other hazards.

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On the basis of available data, the product does not contain any PBT or vPvB in percentage greater than 0,1%.

SECTION 3. Composition/information on ingredients.

3.1. Substances.

Information not relevant.

3.2. Mixtures.

Contains:

Identification.	Conc. %.	Classification 1272/2008 (CLP).
DODECYLTRIMETHYLAMMONIUM CHLORIDE		
CAS. 112-00-5 EC. 203-927-0	3,5 - 4	Acute Tox. 4 H302, Eye Irrit. 2 H319, Skin Irrit. 2 H315, Aquatic Acute 1 H400 M=1
INDEX. - Reg. no. -		
OXALIC ACID, MONOPOTASSIUM SALT		
CAS. 6009-70-7 EC. 238-135-4	2 - 2,5	Acute Tox. 4 H302, Acute Tox. 4 H312, Note A
INDEX. 607-007-00-3 Reg. no. -		
CETRIMONIUM CHLORIDE		
CAS. 112-02-7 CE. 203-928-6	0,1 - 0,2	Acute Tox. 3 H311, Acute Tox. 4 H302, Skin Corr. 1C H314, Aquatic Acute 1 H400
INDEX. - Nr. Reg. -		

The full wording of hazard (H) phrases is given in section 16 of the sheet.

SECTION 4. First aid measures.

4.1. Description of first aid measures.

EYES: Remove contact lenses, if present. Wash immediately with plenty of water for at least 30-60 minutes, opening the eyelids fully. Get medical advice/attention.

SKIN: Remove contaminated clothing. Rinse skin with a shower immediately. Get medical advice/attention.

INGESTION: Have the subject drink as much water as possible. Get medical advice/attention. Do not induce vomiting unless explicitly authorised by a doctor.

INHALATION: Get medical advice/attention immediately. Remove victim to fresh air, away from the accident scene. If the subject stops breathing, administer artificial respiration. Take suitable precautions for rescue workers.

PROTECTIVE MEASURES FOR THE FIRST RESCUE WORKERS: for PPE (personal protection equipment) required for first aid refer to section 8.2 of this safety data sheet.

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

For symptoms and effects caused by the contained substances, see chap. 11.

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

Information not available.

SECTION 5. Firefighting measures.

5.1. Extinguishing media.

SUITABLE EXTINGUISHING EQUIPMENT

Extinguishing substances are: carbon dioxide, foam, chemical powder. For product loss or leakage that has not caught fire, water spray can be used to disperse flammable vapours and protect those trying to stem the leak.

UNSUITABLE EXTINGUISHING EQUIPMENT

Do not use jets of water. Water is not effective for putting out fires but can be used to cool containers exposed to flames to prevent explosions.

5.2. Special hazards arising from the substance or mixture.

HAZARDS CAUSED BY EXPOSURE IN THE EVENT OF FIRE

Excess pressure may form in containers exposed to fire at a risk of explosion. Do not breathe combustion products.

5.3. Advice for firefighters.

GENERAL INFORMATION

Use jets of water to cool the containers to prevent product decomposition and the development of substances potentially hazardous for health. Always wear full fire prevention gear. Collect extinguishing water to prevent it from draining into the sewer system. Dispose of contaminated water used for extinction and the remains of the fire according to applicable regulations.

SPECIAL PROTECTIVE EQUIPMENT FOR FIRE-FIGHTERS

Normal fire fighting clothing i.e. fire kit (BS EN 469), gloves (BS EN 659) and boots (HO specification A29 and A30) in combination with self-contained open circuit positive pressure compressed air breathing apparatus (BS EN 137).

SECTION 6. Accidental release measures.

6.1. Personal precautions, protective equipment and emergency procedures.

Block the leakage if there is no hazard.

Wear suitable protective equipment (including personal protective equipment referred to under Section 8 of the safety data sheet) to prevent any contamination of skin, eyes and personal clothing. These indications apply for both processing staff and those involved in emergency procedures.

6.2. Environmental precautions.

The product must not penetrate into the sewer system or come into contact with surface water or ground water.

6.3. Methods and material for containment and cleaning up.

Collect the leaked product into a suitable container. Evaluate the compatibility of the container to be used, by checking section 10. Absorb the remainder with inert absorbent material.

Make sure the leakage site is well aired. Check incompatibility for container material in section 7. Contaminated material should be disposed of in compliance with the provisions set forth in point 13.

6.4. Reference to other sections.

Any information on personal protection and disposal is given in sections 8 and 13.

SECTION 7. Handling and storage.

7.1. Precautions for safe handling.

Keep away from heat, sparks and naked flames; do not smoke or use matches or lighters. Vapours may catch fire and an explosion may occur; vapour

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accumulation is therefore to be avoided by leaving windows and doors open and ensuring good cross ventilation. Without adequate ventilation, vapours may accumulate at ground level and, if ignited, catch fire even at a distance, with the danger of backfire. Avoid bunching of electrostatic charges. When performing transfer operations involving large containers, connect to an earthing system and wear antistatic footwear. Vigorous stirring and flow through the tubes and equipment may cause the formation and accumulation of electrostatic charges. In order to avoid the risk of fires and explosions, never use compressed air when handling. Open containers with caution as they may be pressurised. Do not eat, drink or smoke during use. Avoid leakage of the product into the environment.

7.2. Conditions for safe storage, including any incompatibilities.

Store only in the original container. Store the containers sealed, in a well ventilated place, away from direct sunlight. Store in a well ventilated place, keep far away from sources of heat, naked flames and sparks and other sources of ignition. Keep containers away from any incompatible materials, see section 10 for details.

7.3. Specific end use(s).

No use other than specified in Section 1.2 of this safety data sheet.

SECTION 8. Exposure controls/personal protection.

8.1. Control parameters.

Regulatory References:

AUS	Österreich	Grenzwerteverordnung 2011 - GKV 2011
BEL	Belgique	AR du 11/3/2002. La liste est mise à jour pour 2010
BGR	България	МИНИСТЕРСТВО НА ТРУДА И СОЦИАЛНАТА ПОЛИТИКА МИНИСТЕРСТВО НА ЗДРАВЕОПАЗВАНЕТО НАРЕДБА No 13 от 30 декември 2003 г
CZE	Česká Republika	Nařízení vlády č. 361/2007 Sb. kterým se stanoví podmínky ochrany zdraví při práci
DEU	Deutschland	MAK-und BAT-Werte-Liste 2012
DNK	Danmark	Graensevaerdier per stoffer og materialer
ESP	España	INSHT - Límites de exposición profesional para agentes químicos en España 2015
EST	Eesti	Töökeskkonna keemiliste ohutegurite piinormid 1. Vastu võetud 18.09.2001 nr 293 RT I 2001, 77, 460 - Redaktsiooni jõustumise kp: 01.01.2008
FRA	France	JORF n°0109 du 10 mai 2012 page 8773 texte n° 102
GRB	United Kingdom	EH40/2005 Workplace exposure limits
GRC	Ελλάδα	ΕΦΗΜΕΡΙΣ ΤΗΣ ΚΥΒΕΡΝΗΣΕΩΣ -ΤΕΥΧΟΣ ΠΡΩΤΟ Αρ. Φύλλου 19 - 9 Φεβρουαρίου 2012
HRV	Hrvatska	NN13/09 - Ministarstvo gospodarstva, rada i poduzetništva
HUN	Magyarország	50/2011. (XII. 22.) NGM rendelet a munkahelyek kémiai biztonságáról
IRL	Éire	Code of Practice Chemical Agent Regulations 2011
LTU	Lietuva	DĖL LIETUVOS HIGIENOS NORMOS HN 23:2007 CHEMINIŲ MEDŽIAGŲ 2007 m. spalio 15 d. Nr. V-827/A1-287
LVA	Latvija	Ķīmisko vielu aroda ekspozīcijas robežvērtības (AER) darba vides gaisā 2012
NLD	Nederland	Databank of the social and Economic Council of Netherlands (SER) Values, AF 2011:18
NOR	Norge	Veiledning om Administrative normer for forurensning i arbeidsatmosfære
POL	Polska	ROZPORZĄDZENIE MINISTRA PRACY I POLITYKI SPOŁECZNEJ z dnia 16 grudnia 2011r
SVK	Slovensko	NARIADENIE VLÁDY Slovenskej republiky z 20. júna 2007
SVN	Slovenija	Uradni list Republike Slovenije 15. 6. 2007
SWE	Sverige	Occupational Exposure Limit Values, AF 2011:18
	TLV-ACGIH	ACGIH 2014

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Threshold Limit Value.

Type	Country	TWA/8h		STEL/15min	
		mg/m3	ppm	mg/m3	ppm
MAK	AUS	500	200	2000	800
VLEP	BEL	500	200	1000	400
TLV	BGR	980		1225	
TLV	CZE	500		1000	SKIN.
AGW	DEU	500	200	1000	400

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MAK	DEU	500	200	1000	400	
TLV	DNK	490	200			
VLA	ESP	500	200	1000	400	
TLV	EST	350	150	600	250	
VLEP	FRA			980	400	
WEL	GRB	999	400	1250	500	
TLV	GRC	980	400	1225	500	
GVI	HRV	999	400	1250	500	
AK	HUN	500		2000		
OEL	IRL		200		400	SKIN.
RD	LTU	350	150	600	250	
RV	LVA	350		600		
OEL	NLD	650				
TLV	NOR	245	100			
NDS	POL	900		1200		
NPHV	SVK	500	200	1000		
MV	SVN	500	200			
MAK	SWE	350	150	600	250	
TLV-ACGIH		492	200	983	400	

Legend:

(C) = CEILING ; INHAL = Inhalable Fraction ; RESP = Respirable Fraction ; THORA = Thoracic Fraction.

VND = hazard identified but no DNEL/PNEC available ; NEA = no exposure expected ; NPI = no hazard identified.

8.2. Exposure controls.

As the use of adequate technical equipment must always take priority over personal protective equipment, make sure that the workplace is well aired through effective local aspiration.

HAND PROTECTION

Protect hands with category III work gloves (see standard EN 374).

The following should be considered when choosing work glove material: compatibility, degradation, failure time and permeability.

The work gloves' resistance to chemical agents should be checked before use, as it can be unpredictable. The gloves' wear time depends on the duration and type of use.

SKIN PROTECTION

Wear category I professional long-sleeved overalls and safety footwear (see Directive 89/686/EEC and standard EN ISO 20344). Wash body with soap and water after removing protective clothing.

EYE PROTECTION

Wear airtight protective goggles (see standard EN 166).

RESPIRATORY PROTECTION

If the threshold value (e.g. TLV-TWA) is exceeded for the substance or one of the substances present in the product, use a mask with a type B filter whose class (1, 2 or 3) must be chosen according to the limit of use concentration. (see standard EN 14387). In the presence of gases or vapours of various kinds and/or gases or vapours containing particulate (aerosol sprays, fumes, mists, etc.) combined filters are required.

Respiratory protection devices must be used if the technical measures adopted are not suitable for restricting the worker's exposure to the threshold values considered. The protection provided by masks is in any case limited.

If the substance considered is odourless or its olfactory threshold is higher than the corresponding TLV-TWA and in the case of an emergency, wear open-circuit compressed air breathing apparatus (in compliance with standard EN 137) or external air-intake breathing apparatus (in compliance with standard EN 138). For a correct choice of respiratory protection device, see standard EN 529.

ENVIRONMENTAL EXPOSURE CONTROLS.

The emissions generated by manufacturing processes, including those generated by ventilation equipment, should be checked to ensure compliance with environmental standards.

SECTION 9. Physical and chemical properties.

9.1. Information on basic physical and chemical properties.

Appearance	liquid
Colour	colourless
Odour	characteristic
Odour threshold.	Not available.
pH.	4-7
Melting point / freezing point.	Not available.
Initial boiling point.	Not available.
Boiling range.	Not available.
Flash point.	> 60 °C.
Evaporation Rate	Not available.
Flammability of solids and gases	Not available.
Lower inflammability limit.	Not available.
Upper inflammability limit.	Not available.
Lower explosive limit.	Not available.
Upper explosive limit.	Not available.
Vapour pressure.	Not available.
Vapour density	Not available.
Relative density.	Not available.
Solubility	soluble in water
Partition coefficient: n-octanol/water	Not available.
Auto-ignition temperature.	Not available.
Decomposition temperature.	Not available.
Viscosity	Not available.
Explosive properties	Not available.
Oxidising properties	Not available.

9.2. Other information.

VOC (Directive 1999/13/EC) :	0,12 %
VOC (volatile carbon) :	0,07 %

SECTION 10. Stability and reactivity.

10.1. Reactivity.

There are no particular risks of reaction with other substances in normal conditions of use.

10.2. Chemical stability.

The product is stable in normal conditions of use and storage.

10.3. Possibility of hazardous reactions.

The vapours may also form explosive mixtures with the air.

10.4. Conditions to avoid.

Avoid overheating. Avoid bunching of electrostatic charges. Avoid all sources of ignition.

10.5. Incompatible materials.

Strong acids.

10.6. Hazardous decomposition products.

In the event of thermal decomposition or fire, gases and vapours that are potentially dangerous to health may be released.

SECTION 11. Toxicological information.

In the absence of experimental data for the product itself, health hazards are evaluated according to the properties of the substances it contains, using the criteria specified in the applicable regulation for classification. It is therefore necessary to take into account the concentration of the individual hazardous substances indicated in section 3, to evaluate the toxicological effects of exposure to the product.

11.1. Information on toxicological effects.

Data available for the mixture:

ACUTE TOXICITY: no data available.
SKIN CORROSION/IRRITATION: no data available.
SERIOUS EYE DAMAGE/IRRITATION: no data available.
RESPIRATORY OR SKIN SENSITISATION: no data available.
GERM CELL MUTAGENICITY: no data available.
CARCINOGENICITY: no data available.
REPRODUCTIVE TOXICITY: no data available.
STOT-SINGLE EXPOSURE: no data available.
STOT-REPEATED EXPOSURE: no data available.
ASPIRATION HAZARD: no data available.

Data available for the substances in the mixture:

DODECYLTRIMETHYLAMMONIUM CHLORIDE (Data available in the supplier safety data sheet)

ACUTE TOXICITY: Harmful if swallowed.; LDLo oral mouse 300 mg/kg
SKIN CORROSION/IRRITATION: Causes skin irritation.
SERIOUS EYE DAMAGE/IRRITATION: Causes serious eye irritation.

OXALIC ACID, MONOPOTASSIUM SALT

ACUTE TOXICITY: Harmful if swallowed and harmful in contact with skin, (Harmonised classification Annex VI Reg. CLP) (Data available in the supplier safety data sheet)

CETRIMONIUM CHLORIDE (ECHA website)

ACUTE TOXICITY
LD50 (Oral).450 mg/kg bw Rat – (OECD Guideline 401)
LD50 (dermal).528 mg/kg bw rabbit – (read across OECD Guideline 402 in GLP)
SKIN CORROSION/IRRITATION: corrosive (rabbit) read across (Method equivalent to OECD TG 404)
SERIOUS EYE DAMAGE/IRRITATION: Causes serious eye irritation. (rabbit) (Federal guideline: 16 CFR 1500.42)

SECTION 12. Ecological information.

No specific data are available for this product. Handle it according to good working practices. Avoid littering. Do not contaminate soil and waterways. Inform the competent authorities, should the product reach waterways or contaminate soil or vegetation. Please take all the proper measures to reduce harmful effects on aquifers.

12.1. Toxicity.

DODECYLTRIMETHYLAMMONIUM CHLORIDE

EC50 - for Algae / Aquatic 0,19 mg/l/96h *Selenastrum capricornutum*
Plants.

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CETRIMONIUM CHLORIDE

LC50 - Fish	0,21 mg/l/96h - OECD Guideline 203
EC50 - Crustaceans	0,09 mg/l/48h Daphnia magna (read across OECD 202)
EC50 - Algae / Aquatic plants.	0,05 mg/l/72h Selenastrum capricornutum (Read across - OECD 201)

12.2. Persistence and degradability.**CETRIMONIUM CHLORIDE**

Rapidly biodegradable

12.3. Bioaccumulative potential.**DODECYLTRIMETHYLAMMONIUM CHLORIDE**

Partition coefficient: n-octanol/water. 1,22 (Data available in the supplier safety data sheet)

12.4. Mobility in soil.

Information not available.

12.5. Results of PBT and vPvB assessment.

On the basis of available data, the product does not contain any PBT or vPvB in percentage greater than 0,1%.

12.6. Other adverse effects.

Information not available.

SECTION 13. Disposal considerations.**13.1. Waste treatment methods.**

Reuse, when possible. Neat product residues should be considered special non-hazardous waste.

Disposal must be performed through an authorised waste management firm, in compliance with national and local regulations.

CONTAMINATED PACKAGING

Contaminated packaging must be recovered or disposed of in compliance with national waste management regulations.

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.

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.

Information not relevant.

SECTION 15. Regulatory information.**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture.**

Seveso category. None.

Restrictions relating to the product or contained substances pursuant to Annex XVII to EC Regulation 1907/2006.

None.

Substances in Candidate List (Art. 59 REACH).

None.

Substances subject to authorisation (Annex XIV REACH).

None.

Substances subject to exportation reporting pursuant to (EC) Reg. 649/2012:

None.

Substances subject to the Rotterdam Convention:

None.

Substances subject to the Stockholm Convention:

None.

Healthcare controls.

Information not available.

German regulation on the classification of substances hazardous to water (VwVwS 2005).

WGK 3: Severe hazard to waters

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15.2. Chemical safety assessment.

No chemical safety assessment has been processed for the mixture and the substances it contains.

SECTION 16. Other information.

Text of hazard (H) indications mentioned in section 2-3 of the sheet:

Acute Tox. 4	Acute toxicity, category 4
Eye Irrit. 2	Eye irritation, category 2
Skin Irrit. 2	Skin irritation, category 2
Aquatic Acute 1	Hazardous to the aquatic environment, acute toxicity, category 1
H302	Harmful if swallowed.
H312	Harmful in contact with skin.
H314	Causes severe skin burns and eye damage.
H319	Causes serious eye irritation.
H315	Causes skin irritation.
H400	Very toxic to aquatic life.
EUH210	Safety data sheet available on request.

LEGEND:

- ADR: European Agreement concerning the carriage of Dangerous goods by Road
- CAS NUMBER: Chemical Abstract Service Number
- CE50: Effective concentration (required to induce a 50% effect)
- CE NUMBER: Identifier in ESIS (European archive of existing substances)
- CLP: EC Regulation 1272/2008
- DNEL: Derived No Effect Level
- EmS: Emergency Schedule
- GHS: Globally Harmonized System of classification and labeling of chemicals
- IATA DGR: International Air Transport Association Dangerous Goods Regulation
- IC50: Immobilization Concentration 50%
- IMDG: International Maritime Code for dangerous goods
- IMO: International Maritime Organization
- INDEX NUMBER: Identifier in Annex VI of CLP
- LC50: Lethal Concentration 50%
- LD50: Lethal dose 50%
- OEL: Occupational Exposure Level
- PBT: Persistent bioaccumulative and toxic as REACH Regulation
- PEC: Predicted environmental Concentration
- PEL: Predicted exposure level
- PNEC: Predicted no effect concentration
- REACH: EC Regulation 1907/2006
- RID: Regulation concerning the international transport of dangerous goods by train
- TLV: Threshold Limit Value
- TLV CEILING: Concentration that should not be exceeded during any time of occupational exposure.
- TWA STEL: Short-term exposure limit
- TWA: Time-weighted average exposure limit
- VOC: Volatile organic Compounds
- vPvB: Very Persistent and very Bioaccumulative as for REACH Regulation
- WGK: Water hazard classes (German).

GENERAL BIBLIOGRAPHY

1. Regulation (EU) 1907/2006 (REACH) of the European Parliament
2. Regulation (EU) 1272/2008 (CLP) of the European Parliament
3. Regulation (EU) 790/2009 (I Atp. CLP) of the European Parliament
4. Regulation (EU) 2015/830 of the European Parliament

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- 5. Regulation (EU) 286/2011 (II Atp. CLP) of the European Parliament
- 6. Regulation (EU) 618/2012 (III Atp. CLP) of the European Parliament
- 7. Regulation (EU) 487/2013 (IV Atp. CLP) of the European Parliament
- 8. Regulation (EU) 944/2013 (V Atp. CLP) of the European Parliament
- 9. Regulation (EU) 605/2014 (VI Atp. CLP) of the European Parliament
- The Merck Index. - 10th Edition
- Handling Chemical Safety
- INRS - Fiche Toxicologique (toxicological sheet)
- Patty - Industrial Hygiene and Toxicology
- N.I. Sax - Dangerous properties of Industrial Materials-7, 1989 Edition
- ECHA website

Note for users:

The information contained in the present sheet are based on our own knowledge on the date of the last version. Users must verify the suitability and thoroughness of provided information according to each specific use of the product.

This document must not be regarded as a guarantee on any specific product property.

The use of this product is not subject to our direct control; therefore, users must, under their own responsibility, comply with the current health and safety laws and regulations. The producer is relieved from any liability arising from improper uses.

Provide appointed staff with adequate training on how to use chemical products.

Changes to previous review:

The following sections were modified:

01/ 02 / 03 / 04 / 05 / 06 / 07 / 08 / 09/ 10 / 11 / 12 / 13 / 14 / 15 / 16.