

Safety Data Sheet

According to Annex II to REACH - Regulation 2020/878 and to Annex II to UK REACH

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

1.1. Product identifier

Code: MK310
Product name: Hemolynac-310

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

Intended use: Reagent for professional hematology analyzers
Uses advised against: Uses other than those indicated above

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. +39 055/30.45.1

Fax. +39 055/30.85.48

e-mail address of the competent person
responsible for the Safety Data Sheet

e-mail: info.MSDS@nkf.it

1.4. Emergency telephone number

For urgent inquiries refer to

Malta 112
United Kingdom NHS 111
Ireland Members of Public: +353 (01) 809 2166. (8.00 a.m. to 10.00 p.m. 7 days a week)
NIHON KOHDEN FIRENZE S.r.l. Tel. +39 055 / 30.45.1 (technical support - office 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 (EU) Regulation 2020/878.
Hazard classification and indication:

2.2. Label elements

Hazard labelling pursuant to EC Regulation 1272/2008 (CLP) and subsequent amendments and supplements.

Hazard pictograms: --

Signal words: --

Hazard statements:

EUH210 Safety data sheet available on request.

Precautionary statements:

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2.3. Other hazards

On the basis of available data, the product does not contain any PBT or vPvB in percentage $\geq$ than 0,1%.
The product does not contain substances with endocrine disrupting properties in concentration $\geq$ 0.1%.

SECTION 3. Composition/information on ingredients

3.2. Mixtures

Contains:

Identification	x = Conc. %	Classification (EC) 1272/2008 (CLP)
DODECYLTRIMETHYLAMMONIUM CHLORIDE INDEX - EC 203-927-0 CAS 112-00-5 REACH Reg. 01-2120766653-46-0010	$2,5 \leq x < 3$	Acute Tox. 4 H302, Eye Irrit. 2 H319, Skin Irrit. 2 H315, Aquatic Acute 1 H400 M=1 DL50 Oral: 800 mg/kg
CITRIC ACID MONOHYDRATE INDEX - EC 201-069-1 CAS 5949-29-1 REACH Reg. 01-2119457026-42	$1 \leq x < 1,5$	Eye Irrit. 2 H319, STOT SE 3 H335
FORMALDEHYDE INDEX 605-001-00-5 CE 200-001-8 CAS 50-00-0	$0 \leq x < 0,1$	Carc. 1B H350, Muta. 2 H341, Acute Tox. 3 H301, Acute Tox. 3 H311, Acute Tox. 3 H331, Skin Corr. 1B H314, Eye Dam. 1 H318, STOT SE 3 H335, Skin Sens. 1 H317, Classification note according to Annex VI of the Regulation CLP: B, D <u>Specific concentration limits (Annex VI Reg. 1272/2008)</u> Skin Corr. 1B H314: $\geq$ 25%, Skin Irrit. 2 H315: $\geq$ 5%, Skin Sens. 1 H317: $\geq$ 0,2%, Eye Dam. 1 H318: $\geq$ 25%, Eye Irrit. 2 H319: $\geq$ 5%, STOT SE 3 H335: $\geq$ 5% <u>Values used for the calculation of the Acute Toxicity Estimate (ATE) of the mixture</u> STA Oral: 100 mg/kg, STA Dermal: 300 mg/kg, STA Inhalation of vapors: 3 mg/l

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 15 minutes, opening the eyelids fully. If problem persists, seek medical advice.
SKIN: Remove contaminated clothing. Wash immediately with plenty of water. If irritation persists, get medical advice. Wash contaminated clothing before using it again.
INHALATION: Remove to open air. In the event of breathing difficulties, get medical attention immediately.
INGESTION: Get medical advice. Induce vomiting only if indicated by the doctor. Never give anything by mouth to an unconscious person, unless authorised by a doctor.
PROTECTIVE MEASURES FOR THE FIRST RESCUE WORKERS: for PPE (personal protection equipment) required for first aid refer to section 8.2 of

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this safety data sheet.

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

Specific information on symptoms and effects caused by the product are unknown.

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

Treat symptomatically.

In case of accident or if you feel unwell, seek medical advice immediately (show directions for use or safety data sheet if possible).

SECTION 5. Firefighting measures**5.1. Extinguishing media****SUITABLE EXTINGUISHING EQUIPMENT**

The extinguishing equipment should be of the conventional kind: carbon dioxide, foam, powder and water spray.

UNSUITABLE EXTINGUISHING EQUIPMENT

None in particular.

5.2. Special hazards arising from the substance or mixture**HAZARDS CAUSED BY EXPOSURE IN THE EVENT OF FIRE**

Do not breathe combustion products.

CITRIC ACID MONOHYDRATE

In the event of a fire, carbon oxides can be released.

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****For non-emergency personnel**

Evacuate unprotected and untrained personnel from hazard area. Do not breathe smoke/vapour. Avoid leakage of the product into the environment. Non-emergency personnel must follow the appropriate internal procedures in case of accidental release.

For emergency responders

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. Follow the appropriate internal procedures in case of accidental release. Control smoke/vapour. Evacuate unprotected and untrained personnel. Eliminate all sources of ignition (cigarettes, flames, sparks, etc.) from the leakage site.

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. 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

Before handling the product, consult all the other sections of this material safety data sheet. Avoid leakage of the product into the environment. Do not eat, drink or smoke during use. Remove any contaminated clothes and personal protective equipment before entering places in which people eat.

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. Keep containers away from any incompatible materials, see section 10 for details.

7.3. Specific end use(s)

No use other than as indicated in section 1.2 of this safety data sheet

SECTION 8. Exposure controls/personal protection

8.1. Control parameters

Regulatory References:

GBR	United Kingdom	EH40/2005 Workplace exposure limits (Fourth Edition 2020) 2020 Code of Practice for the Safety, Health and Welfare at Work (Chemical Agents) Regulations (2001-2015) and the Safety, Health and Welfare at Work (Carcinogens) Regulations (2001-2019) Directive (EU) 2022/431; Directive (EU) 2019/1831; Directive (EU) 2019/130; Directive (EU) 2019/983; Directive (EU) 2017/2398; Directive (EU) 2017/164; Directive 2009/161/EU; Directive 2006/15/EC; Directive 2004/37/EC; Directive 2000/39/EC; Directive 98/24/EC; Directive 91/322/EEC. ACGIH 2021
IRL	Éire	
EU	OEL EU	
	TLV-ACGIH	

Although it is not mandatory to declare the following substance in Section 3.2 of this Safety Data Sheet (since the requirements referred to in paragraph 3.2.1 of the Annex to Reg. (EU) 878/2020 do not exist), it is nevertheless mentioned in this section as the substance has a threshold limit value described in ACGIH 2021

ETHANOL					
Threshold Limit Value					
Type	Country	TWA/8h		STEL/15min	
		mg/m3	ppm	mg/m3	ppm
TLV-ACGIH				1884	1000

CITRIC ACID MONOHYDRATE		
Predicted no-effect concentration - PNEC		
Normal value in fresh water	0,44	mg/l
Normal value in marine water	0,044	mg/l
Normal value for fresh water sediment	34,6	mg/kg/d
Normal value for marine water sediment	3,46	mg/kg/d

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Normal value of STP microorganisms	1000	mg/l
Normal value for the terrestrial compartment	33,1	mg/kg/d

FORMALDEHYDE**Threshold Limit Value**

Type	Country	TWA/8h		STEL/15min		Remarks / Observations
		mg/m3	ppm	mg/m3	ppm	
WEL	GBR	2,5	2	2,5	2	
OELV	IRL	0,37	0,3	0,738	0,6	
OEL	EU	0,37	0,3	0,74	0,6	
TLV-ACGIH				1884	1000	

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 ; LOW = low hazard ; MED = medium hazard ; HIGH = high hazard.

Recommended monitoring procedures

This product contains substances with exposure limits, for which personal, workplace atmosphere and biological monitoring may be required to determine the effectiveness of ventilation or other control measures and / or the need to use protective equipment respiratory.

The European Standards of reference are:

- UNI EN 689: 2018 "Guide to the assessment of exposure by inhalation to chemical compounds for the purpose of comparison with the limit values and measurement strategy";
- UNI EN 482: 2015 "general requirements for the performance of chemical agent measurement procedures".

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.

When choosing personal protective equipment, ask your chemical substance supplier for advice.

Personal protective equipment must be CE marked, showing that it complies with applicable standards.

HAND PROTECTION

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

Recommended materials:

Natural rubber, Nitrile / butadiene rubber (nitrile or NBR), Neoprene, Polyvinyl chloride (PVC or vinyl).

Protection class: 6 (permeation time greater than 480 minutes according to EN 374).

Thickness of the recommended material: When identifying the relevant material and its thickness to be used, it is highly recommended to discuss directly with the manufacturer of the PPE to assess the actual protection in this regard based on use and duration of use.

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 Regulation 2016/425 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

It is recommended to wear a mask with a type A 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.

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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**

Properties	Value
Appearance	liquid
Colour	colorless
Odour	not available
Melting point / freezing point	not available
Initial boiling point	not available
Flammability	not available
Lower explosive limit	Not explosive due to the absence in the components of reactive groups associated with explosive properties (Annex I, Part 2.1.4.2 and 2, 1.4.3 Reg. CLP)
Upper explosive limit	Not explosive due to the absence in the components of reactive groups associated with explosive properties (Annex I, Part 2.1.4.2 and 2, 1.4.3 Reg. CLP)
Flash point	> 60 °C
Auto-ignition temperature	not available
Decomposition temperature	not available
pH	7,1 – 7,6
Kinematic viscosity	not available
Solubility	not available
Partition coefficient: n-octanol/water	not available for the mixture, see sect. 12 for the individual substances contained
Vapour pressure	not available
Density and/or relative density	not available
Relative vapour density	not available
Particle characteristics	not applicable based on physical state

9.2. Other information

9.2.1. Information with regard to physical hazard classes

Information not available

9.2.2. Other safety characteristics

Information not available

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

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No hazardous reactions are foreseeable in normal conditions of use and storage.

10.4. Conditions to avoid

Keep away from incompatible materials, direct sunlight. However the usual precautions used for chemical products should be respected.

10.5. Incompatible materials

Oxidizing agents. Strong bases. Amines. Heavy metals.

10.6. Hazardous decomposition products

In the event of a fire, carbon oxides can 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 hazard classes as defined in Regulation (EC) No 1272/2008ACUTE TOXICITY

ATE (Inhalation) of the mixture:	Not classified (no significant component)
ATE (Oral) of the mixture:	>2000 mg/kg
ATE (Dermal) of the mixture:	Not classified (no significant component)

DODECYLTRIMETHYLAMMONIUM CHLORIDE

Method: equivalent or similar to OECD 401

Reliability (Klimisch score): 1

Species: rat (male/female wistar)

Exposure: oral

Results DL50: 800 mg/kg (data used for the calculation of the estimate of the acute toxicity of the mixture)

The substance is classified as acute toxic orally cat. 4.

CITRIC ACID MONOHYDRATE

Method: OECD 401

Reliability (Klimisch score): 2

Species: mouse

Exposure: oral

Results: LD50 5400 mg/kg

Method: OECD 402

Reliability (Klimisch score): 1

Species: rat

Exposure: dermal

Results: LD50 5400 mg/kg

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Routes of exposure: cutaneous. Not determined

Toxic in contact with the skin. Harmonized classification data (Annex VI CLP Reg.).

STA (dermal):	300 mg / kg estimate from table 3.1.2 of Annex I of CLP (data used for the calculation of the estimate of the acute toxicity of the mixture)
LD50 (Oral):	640 mg / kg Rat, equivalent or similar to OECD TG 401
STA (Oral):	100 mg / kg estimate from table 3.1.2 of Annex I of CLP (data used for the calculation of the estimate of the acute toxicity of the mixture)

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LC50 (inhalation of vapors):
STA (inhalation of vapors):

mixture)
< 463 ppm/4h Rat, OECD TG 403
3 mg / l estimate from table 3.1.2 of Annex I of CLP
(data used for the calculation of the estimate of the acute toxicity of the mixture)

SKIN CORROSION / IRRITATION

Does not meet the classification criteria for this hazard class

SERIOUS EYE DAMAGE / IRRITATION

Does not meet the classification criteria for this hazard class

RESPIRATORY OR SKIN SENSITISATION

Does not meet the classification criteria for this hazard class

GERM CELL MUTAGENICITY

Does not meet the classification criteria for this hazard class

CARCINOGENICITY

Does not meet the classification criteria for this hazard class

REPRODUCTIVE TOXICITY

Does not meet the classification criteria for this hazard class

STOT - SINGLE EXPOSURE

Does not meet the classification criteria for this hazard class

STOT - REPEATED EXPOSURE

Does not meet the classification criteria for this hazard class

ASPIRATION HAZARD

Does not meet the classification criteria for this hazard class

11.2. Information on other hazards

Based on the available data, the product does not contain substances listed in the main European lists of potential or suspected endocrine disruptors with human health effects under evaluation.

SECTION 12. Ecological information

Use this product according to good working practices. Avoid littering. Inform the competent authorities, should the product reach waterways or contaminate soil or vegetation.

12.1. Toxicity

CITRIC ACID MONOHYDRATE

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Chronic NOEC for Algae / Aquatic Plants

425 mg/l/8d *Scenedesmus quadricauda*; pubblic. Bringmann G and Kuhn R 1980Acute toxicity (fish): *Leuciscus idus* - LC50: 440-760 mg/l/96h (Method: equivalent or similar to OECD TG 203)Acute toxicity (crustaceans): *Daphnia magna* - LC50: 1535 mg/l/24 h (Bibliography: Z. Wasser Abwasser Forsch. 15(1): 1977))

DODECYLTRIMETHYLAMMONIUM CHLORIDE

EC50 - Crustaceans

0,46 mg/l/48h *D. magna* U.S. EPA, 1975

NOEC Algae / Aquatic Plants:

0,01 mg/l/72h *Selenastrum capricornutum*; OECD Guideline 201 (Algae, Growth Inhibition Test)

ACIDO CITRICO MONOIDRATO

LC50 - Fish

440 mg/l/48h *Leuciscus idus melanotus* (equivalent or similar to OECD 203)

FORMALDEHYDE

LC50 - Fish

6,7 mg/l/96h *Morone saxatilis* (publication, dissemination site ECHA).

EC50 - Crustacea

5,8 mg/l/48h *Daphnia pulex*, OECD Guideline 202.

EC50 - Algae / Aquatic Plants

4,89 mg/l/72h *Scenedesmus subspicatus*, OECD Guideline 201.**12.2. Persistence and degradability**

DODECYLTRIMETHYLAMMONIUM CHLORIDE

Rapidly degradable

> 60% in 28d (OECD TG 301F)

CITRIC ACID MONOHYDRATE

Rapidly degradable

OECD 301 B - 97% in 28 days

FORMALDEHYDE

90% biodegradation was observed in one test [OECD TG 301D] (HSDB, 2017; INERIS, 2011; OECD, 2002).

12.3. Bioaccumulative potential

CITRIC ACID MONOHYDRATE

Partition coefficient: n-octanol/water

-1,72 Log Pow a 20°C; Verschueren: Handbook of Environmental Data of Organic Chemicals, 3

BCF

3,2 l/kg Calculated value (EPA 2009)

DODECYLTRIMETHYLAMMONIUM CHLORIDE

Partition coefficient: n-octanol/water

log Pow 1.22 - 25 °C KowWin

FORMALDEIDE

Partition coefficient: n-octanol/water

0,35 Log Kow 25°C - KOWWIN v1.68

BCF

3 HSDB, 2017; INERIS, 2011; OECD, 2002 (calculated value)

12.4. Mobility in soil

Information not available

12.5. Results of PBT and vPvB assessmentOn the basis of available data, the product does not contain any PBT or vPvB in percentage $\geq$ than 0,1%.

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12.6. Endocrine disrupting properties

Based on the available data, the product does not contain substances listed in the main European lists of potential or suspected endocrine disruptors with environmental effects under evaluation.

12.7. Other adverse effects

Information not available

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

Reuse if possible. The residues of the product as such are to be considered special non-hazardous waste.

Disposal must be entrusted to an authorized waste management company, in compliance with national and possibly local regulations.

The legal responsibility for disposal lies with the producer / holder of the waste.

Different EWC (European Waste Code) codes could be applied to this mixture according to the specific circumstances that generated the waste, any alterations and contaminations.

Disposal via the wastewater drain is not permitted

CONTAMINATED PACKAGING

Contaminated packaging must be sent, properly labeled, for recovery or disposal in compliance with national regulations on waste management and must be classified with the following EWC:

15 01 01	: paper and cardboard packaging
15 01 02	: plastic packaging
15 01 03	: wooden packaging
15 01 04	: metal packaging
15 01 05	: composite material packaging
15 01 06	: mixed material packaging
15 01 07	: glass packaging
15 01 09	: textile packaging

SECTION 14. Transport information

The product is not dangerous under current provisions of the Code of International Carriage of Dangerous Goods by Road (ADR) and by Rail (RID), of the International Maritime Dangerous Goods Code (IMDG), and of the International Air Transport Association (IATA) regulations.

14.1. UN number or ID 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

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14.6. Special precautions for user

not applicable

14.7. Maritime transport in bulk according to IMO instruments

Information not relevant

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

Seveso Category - Directive 2012/18/EU: None

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

Product

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Substances classified as flammable gases category 1 or 2, flammable liquids categories 1, 2 or 3, flammable solids category 1 or 2, substances and mixtures which, in contact with water, emit flammable gases, category 1, 2 or 3, pyrophoric liquids category 1 or pyrophoric solids category 1, regardless of whether they appear in Part 3 of Annex VI to Regulation (EC) No 1272/2008

Contained substance

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Substances falling within one or more of the following points:
(a) substances classified as any of the following in Part 3 of Annex VI to Regulation (EC) No 1272/2008:
— carcinogen category 1A, 1B or 2, or germ cell mutagen category 1A, 1B or 2, but excluding any such substances classified due to effects only following exposure by inhalation
— reproductive toxicant category 1A, 1B or 2 but excluding any such substances classified due to effects only following exposure by inhalation — skin sensitiser category 1, 1A or 1B
— skin corrosive category 1, 1A, 1B or 1C or skin irritant category 2
— serious eye damage category 1 or eye irritant category 2 (b) substances listed in Annex II to Regulation (EC) No 1223/2009 of the European Parliament and of the Council ()*
(c) substances listed in Annex IV to Regulation (EC) No 1223/2009 for which a condition is specified in at least one of the columns g, h and i of the table in that Annex
(d) substances listed in Appendix 13 to this Annex. The ancillary requirements in paragraphs 7 and 8 of column 2 of this entry apply to all mixtures for use for tattooing purposes, whether or not they contain a substance falling within points (a) to (d) of this column of this entry

Point 72 FORMALDEHYDE

Regulation (EU) 2019/1148 - on the marketing and use of explosives precursors

not applicable

Substances in Candidate List (Art. 59 REACH)

On the basis of available data, the product does not contain any SVHC in percentage $\geq$ than 0,1%.

Substances subject to authorisation (Annex XIV REACH)

None

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Substances subject to exportation reporting pursuant to Regulation (EU) 649/2012:

None

Substances subject to the Rotterdam Convention:

None

Substances subject to the Stockholm Convention:

None

Healthcare controls

Information not available

15.2. Chemical safety assessment

A chemical safety assessment has not been developed for the mixture. For the substance dodecyltrimethylammonium chloride

CAS 112-00-5

CE 203-927-0

a chemical safety assessment was not carried out as the substance was registered in the tonnage band below 10 tons / year (Art. 14 paragraph 1 of the REACH Reg.).

SECTION 16. Other information

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

Carc. 1B	Carcinogenicity, category 1B
Muta. 2	Germ cell mutagenicity, category 2
Acute Tox. 3	Acute toxicity, category 3
Acute Tox. 4	Acute toxicity, category 4
Skin Corr. 1B	Skin corrosion, category 1B
Eye Irrit. 2	Eye irritation, category 2
Skin Irrit. 2	Skin irritation, category 2
STOT SE 3	Specific target organ toxicity - single exposure, category 3
Skin Sens. 1	Skin sensitization, category 1
Aquatic Acute 1	Hazardous to the aquatic environment, acute toxicity, category 1
H350	May cause cancer.
H341	Suspected of causing genetic defects.
H301	Toxic if swallowed.
H311	Toxic in contact with skin.
H331	Toxic if inhaled.
H302	Harmful if swallowed.
H314	Causes severe skin burns and eye damage.
H319	Causes serious eye irritation.
H315	Causes skin irritation.

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H335	May cause respiratory irritation.
H317	May cause an allergic skin reaction.
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
- ATE: Acute Toxicity Estimate
- CAS: Chemical Abstract Service Number
- CE50: Effective concentration (required to induce a 50% effect)
- CE: Identifier in ESIS (European archive of existing substances)
- CLP: Regulation (EC) 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: 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: Regulation (EC) 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: Time-weighted average exposure limit
- TWA STEL: Short-term 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 (EC) 1907/2006 (REACH) of the European Parliament
 2. Regulation (EC) 1272/2008 (CLP) of the European Parliament
 3. Regulation (EU) 2020/878 (II Annex of REACH Regulation)
 4. Regulation (EC) 790/2009 (I Atp. CLP) of the European Parliament
 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
 10. Regulation (EU) 2015/1221 (VII Atp. CLP) of the European Parliament
 11. Regulation (EU) 2016/918 (VIII Atp. CLP) of the European Parliament
 12. Regulation (EU) 2016/1179 (IX Atp. CLP)
 13. Regulation (EU) 2017/776 (X Atp. CLP)
 14. Regulation (EU) 2018/669 (XI Atp. CLP)
 15. Regulation (EU) 2019/521 (XII Atp. CLP)
 16. Delegated Regulation (UE) 2018/1480 (XIII Atp. CLP)
 17. Regulation (EU) 2019/1148
 18. Delegated Regulation (UE) 2020/217 (XIV Atp. CLP)
 19. Delegated Regulation (UE) 2020/1182 (XV Atp. CLP)
 20. Delegated Regulation (UE) 2021/643 (XVI Atp. CLP)
 21. Delegated Regulation (UE) 2021/849 (XVII Atp. CLP)
 22. Delegated Regulation (UE) 2022/692 (XVIII Atp. CLP)
- The Merck Index. - 10th Edition

Hemolynac-310

- Handling Chemical Safety
- INRS - Fiche Toxicologique (toxicological sheet)
- Patty - Industrial Hygiene and Toxicology
- N.I. Sax - Dangerous properties of Industrial Materials-7, 1989 Edition
- IFA GESTIS website
- ECHA website
- Database of SDS models for chemicals - Ministry of Health and ISS (Istituto Superiore di Sanità) - Italy

Note for the recipient of the Safety Data Sheet (SDS):

It is the recipient of this SDS who must ensure that the information contained is read and understood by all persons who handle, store, use, or otherwise come into contact in any way with the substance or mixture to which this sheet refers. In particular, the recipient must provide adequate training to personnel assigned to the use of dangerous substances or mixtures. The recipient must ensure the suitability and completeness of the information in relation to the specific use of the substance or mixture.

However, the substance or mixture to which this SDS refers must not be used for uses other than those specified in section 1. No responsibility is assumed for improper uses. Since the use of the product does not fall under the direct control of the Supplier, it is the user's obligation to observe, under his own responsibility, the laws and regulations in force regarding national and Community hygiene and safety.

The information contained in this SDS is provided in good faith and is based on the current state of scientific and technical knowledge, at the revision date indicated, available from the Supplier indicated in section 1 of this sheet. The SDS should not be interpreted as a guarantee of any specific property of the substance or mixture. The information refers only to the substance or mixture specifically designated in section 1 and may not be valid for the substance or mixture used in combination with other materials or in other processes not specifically indicated in the text.

This version of the SDS supersedes all previous versions.

Changes to previous review:

The following sections were modified:

all