

## SAFETY DATA SHEET

**PRODUCT NAME: HEMOLYNAC.3N**  
**PRODUCT CODE: MEK-680D**

**SDS NUMBER: SDS/ MEK-680D-00**  
**ISSUANCE DATE: 09/04/2020**

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### Section 1 – Identification of the Substance/Mixture and of the Company/Undertaking

Product name: HEMOLYNAC.3N  
Product code: MEK-680 I  
Supplier: Nihon Kohden Middle East (Branch)  
Address: QC-4, QC-5, QC-6, QC-7  
DAFZA Industrial Park. Al Qusais, Dubai U.A.E  
Telephone number: +971 4-239-9911  
Fax: +971 4-880-0122  
Website for contact:  
Emergency telephone number: +971 4-239-9911 (during working hours)  
Recommended use and restrictions on use: Reagent for hematology analyzer

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### 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) (and subsequent amendments and supplements).

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: --

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 labeling do not apply to the product in the finished state, intended for the final user.

## SAFETY DATA SHEET

**PRODUCT NAME: HEMOLYNAC.3N**  
**PRODUCT CODE: MEK-680D**

**SDS NUMBER: SDS/ MEK-680D-00**  
**ISSUANCE DATE: 09/04/2020**

### 2.3. Other hazards.

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).
<b>DODECYLTRIMETHYLAMMONIUM CHLORIDE</b> CAS. 112-00-5 EC. 203-927-0 INDEX. - Reg. no. -	3,5 - 4	Acute Tox. 4 H302, Eye Irrit. 2 H319, Skin Irrit. 2 H315, Aquatic Acute 1 H400 M=1
<b>OXALIC ACID, MONOPOTASSIUM SALT</b> CAS. 6009-70-7 EC. 238-135-4 INDEX. 607-007-00- 3 Reg. no. -	2 - 2,5	Acute Tox. 4 H302, Acute Tox. 4 H312, Note A
<b>CETRIMONIUM CHLORIDE</b> CAS. 112-02-7  EC. 203-928-6 INDEX. - Reg. no. -	0,1 - 0,2	Muta. 2 H341, Repr. 1A H360FD, Acute Tox. 3 H311, Acute Tox. 4 H302, STOT RE 1 H372, Skin Corr. 1B H314, STOT SE 3 H335, STOT SE 3 H336, Aquatic Acute 1 H400 M=10, Aquatic Chronic 1 H410

Note: Upper limit is not included into the range.

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

## SAFETY DATA SHEET

**PRODUCT NAME: HEMOLYNAC.3N**  
**PRODUCT CODE: MEK-680D**

**SDS NUMBER: SDS/ MEK-680D-00**  
**ISSUANCE DATE: 09/04/2020**

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### 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

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### Section 5 – Fire-fighting 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.

## SAFETY DATA SHEET

**PRODUCT NAME: HEMOLYNAC.3N**  
**PRODUCT CODE: MEK-680D**

**SDS NUMBER: SDS/ MEK-680D-00**  
**ISSUANCE DATE: 09/04/2020**

### **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 firefighting 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).

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## 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.

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## 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.

## SAFETY DATA SHEET

**PRODUCT NAME: HEMOLYNAC.3N**  
**PRODUCT CODE: MEK-680D**

**SDS NUMBER: SDS/ MEK-680D-00**  
**ISSUANCE DATE: 09/04/2020**

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.

Storage class TRGS 510 (Germany):10

### **7.3. Specific end use(s).**

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

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## Section 8 – Exposure Controls/Personal Protection

### **8.1. Control parameters.**

Information not available.

### **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

## SAFETY DATA SHEET

**PRODUCT NAME: HEMOLYNAC.3N**
**SDS NUMBER: SDS/ MEK-680D-00**
**PRODUCT CODE: MEK-680D**
**ISSUANCE DATE: 09/04/2020**

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.

## SAFETY DATA SHEET

**PRODUCT NAME: HEMOLYNAC.3N**  
**PRODUCT CODE: MEK-680D**

**SDS NUMBER: SDS/ MEK-680D-00**  
**ISSUANCE DATE: 09/04/2020**

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 (volatile carbon) :	0,05 %
VOC (Directive 2010/75/EC) :	0,10 %

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### Section 10 – Stability and Reactivity

#### 10.1. Reactivity.

In contact with acids releases toxic gases.

#### 10.2. Chemical stability.

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

#### 10.3. Possibility of hazardous reactions.

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

#### 10.4. Conditions to avoid.

None in particular. However the usual precautions used for chemical products should be respected.

#### 10.5. Incompatible materials.

Strong acids. Strong oxidizing agents.

#### 10.6. Hazardous decomposition products.

When heated or in case of fire can be released vapors potentially dangerous to health

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### 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

## SAFETY DATA SHEET

**PRODUCT NAME: HEMOLYNAC.3N**  
**PRODUCT CODE: MEK-680D**

**SDS NUMBER: SDS/ MEK-680D-00**  
**ISSUANCE DATE: 09/04/2020**

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 refers to the mix:

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 relating to substances hazardous mixture:

##### CETRIMONIUM CHLORIDE:

ACUTE TOXICITY: Harmful if swallowed (Rat; method in accord to OECD Guideline 401, in GLP)  
 LD50 (Oral).450 mg/kg bw (Rat; method in accord to OECD Guideline 401, in GLP)  
 ACUTE TOXICITY: Toxic in contact with skin (Rabbit; read across (CAS 61789-18-2), method in accord to OECD Guideline 402, in GLP)  
 LD50 (Dermal).528 mg/kg bw (Rabbit; read across (CAS 61789-18-2), method in accord to OECD Guideline 402, in GLP)  
 SKIN CORROSION/IRRITATION: It causes severe skin burns (In vivo rabbit test; read across (CAS 68002-61-9), method equivalent to OECD Guideline 404)  
 SERIOUS EYE DAMAGE/IRRITATION: It causes serious eye damage (In vivo rabbit test; method in accord to Federal guidelines 16 CFR 1500.42)  
 GERM CELL MUTAGENICITY: Suspected of causing genetic defects (Source: Information available in the supplier's SDS)  
 REPRODUCTIVE TOXICITY: It may damage fertility or the unborn child (Source: Information available in the supplier's SDS)  
 STOT-SINGLE EXPOSURE: It can irritate the respiratory tract and can cause drowsiness or dizziness (Source: Information available in the supplier's SDS)  
 STOT-REPEATED EXPOSURE: It causes damage to organs through prolonged or repeated exposure (Source: Information available in the supplier's SDS)



## SAFETY DATA SHEET

**PRODUCT NAME: HEMOLYNAC.3N**  
**PRODUCT CODE: MEK-680D**

**SDS NUMBER: SDS/ MEK-680D-00**  
**ISSUANCE DATE: 09/04/2020**

DODECYLTRIMETHYLAMMONIUM CHLORIDE:

ACUTE TOXICITY: Harmful if swallowed (Source: Information available in the SDS of the supplier and in the ECHA's Inventory Classification and Labelling)

SKIN CORROSION/IRRITATION: It causes skin irritation (Source: Information available in the SDS of the supplier and in the ECHA's Inventory Classification and Labelling)

SERIOUS EYE DAMAGE/IRRITATION: It causes serious eye irritation (Source: Information available in the SDS of the supplier and in the ECHA's Inventory Classification and Labelling)

OXALIC ACID, MONOPOTASSIUM SALT:

ACUTE TOXICITY: Harmful if swallowed (Source: Information available in the SDS of the supplier and in the ECHA's Inventory Classification and Labelling)

ACUTE TOXICITY: Harmful in contact with skin (Source: Information available in the SDS of the supplier and in the ECHA's Inventory Classification and Labelling)

### 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.

#### 1.2. Toxicity

CETRIMONIUM CHLORIDE

LC50 - for Fish. 0,21 mg/l/96h Fish - OECD Guideline 203

EC50 - for Crustacea. 0,09 mg/l/48h Daphnia magna (read across from similar substance OECD 202)

EC50 - for Algae / Aquatic Plants. 0,05 mg/l/72h Selenastrum capricornutum (Read across - OECD 201)

DODECYLTRIMETHYLAMMONIUM CHLORIDE:

EC50 - for Algae / Aquatic Plants. 0,19 mg/l/96h Selenastrum capricornutum (Source: supplier's SDS)

#### 12.2. Persistence and degradability.

CETRIMONIUM CHLORIDE: Rapidly biodegradable, 93,5% in 28 days (method in accord to OECD Guideline 301 B, in GLP) OXALIC ACID, MONOPOTASSIUM SALT: Rapidly

biodegradable

## SAFETY DATA SHEET

**PRODUCT NAME: HEMOLYNAC.3N**  
**PRODUCT CODE: MEK-680D**

**SDS NUMBER: SDS/ MEK-680D-00**  
**ISSUANCE DATE: 09/04/2020**

### **12.3. Bioaccumulative potential.**

#### DODECYLTRIMETHYLAMMONIUM CHLORIDE

Partition coefficient: n-octanol/water. 1,22 (Source: supplier's SDS)

### **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.

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## **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

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## **Section 14 – Transport Information**

The product is not dangerous under current provisions for transport of dangerous goods by road (ADR) and by Rail (RID), by sea (IMDG Code) and by air (IATA).

### **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.

## SAFETY DATA SHEET

**PRODUCT NAME: HEMOLYNAC.3N**  
**PRODUCT CODE: MEK-680D**

**SDS NUMBER: SDS/ MEK-680D-00**  
**ISSUANCE DATE: 09/04/2020**

**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.

Skin Corr. 1B	
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## SAFETY DATA SHEET

**PRODUCT NAME: HEMOLYNAC.3N**  
**PRODUCT CODE: MEK-680D**

**SDS NUMBER: SDS/ MEK-680D-00**  
**ISSUANCE DATE: 09/04/2020**

Eye Irrit. 2	
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None

Repr. 1A	Reproductive toxicity, category 1A
Acute Tox. 3	Acute toxicity, category 3
Acute Tox. 4	Acute toxicity, category 4
STOT RE 1	Specific target organ toxicity - repeated exposure, category 1
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
Aquatic Acute 1	Hazardous to the aquatic environment, acute toxicity, category 1
Aquatic Chronic 1	Hazardous to the aquatic environment, chronic toxicity, category 1
H341	Suspected of causing genetic defects.
H360FD	May damage fertility. Suspected of damaging the unborn child.
H311	Toxic in contact with skin.
H302	Harmful if swallowed.
H312	Harmful in contact with skin.
H372	Causes damage to organs through prolonged or repeated exposure.
H314	Causes severe skin burns and eye damage.
H319	Causes serious eye irritation.
H315	Causes skin irritation.
H335	May cause respiratory irritation.
H336	May cause drowsiness or dizziness.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
EUH210	Safety data sheet available on request.

### Section 16 – Other Information

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

#### 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

## SAFETY DATA SHEET

**PRODUCT NAME: HEMOLYNAC.3N**
**SDS NUMBER: SDS/ MEK-680D-00**
**PRODUCT CODE: MEK-680D**
**ISSUANCE DATE: 09/04/2020**

- 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
  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

## SAFETY DATA SHEET

**PRODUCT NAME: HEMOLYNAC.3N**  
**PRODUCT CODE: MEK-680D**

**SDS NUMBER: SDS/ MEK-680D-00**  
**ISSUANCE DATE: 09/04/2020**

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: NA

This data sheet is complete and accurate to the best of our knowledge, but all information may not be covered. Any product may contain unknown harmful substances. This product must be handled carefully and used under the responsibility of the user, taking appropriate safety measures.