Safety Data Sheet

GenoType Mycobacterium AS RUO

VER 1.0

CON-C

CON-D

DEN

HYB

SUB-C

Safety Data Sheet

according to Regulation (EC) No 1907/2006

CON-C (GenoType, ThromboType, micro-IDent)

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

1.1. Product identifier

CON-C (GenoType, ThromboType, micro-IDent)

Further trade names

Article No.: 003-001-12 (120 µl)
Article No.: 003-001-96 (960 µl)

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

Use of the substance/mixture

Scientific research and development, in vitro diagnostic medical devices

Uses advised against

Any non-intended use.

1.3. Details of the supplier of the safety data sheet

Company name:	Hain Lifescience GmbH	
Street:	Hardwiesenstrasse 1	
Place:	D-72147 Nehren	
Telephone:	+49 (0) 74 73- 94 51- 0	Telefax: +49 (0) 74 73- 94 51- 31
Responsible Department:	msds.mdx.de@bruker.com	

1.4. Emergency telephone number:

Only from Malta: 112

Further Information

The product falls under the regulation (EU) 2017/746 on in-vitro diagnostics.

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Regulation (EC) No 1272/2008

This mixture is not classified as hazardous in accordance with Regulation (EC) No 1272/2008.

2.2. Label elements

Regulation (EC) No 1272/2008

Hazard statements

EUH210 Safety data sheet available on request.

Additional advice on labelling

Labelling according to national medical devices regulations.

2.3. Other hazards

The substances in the mixture (>0,1%) do not meet the PBT/vPvB criteria according to REACH, annex XIII. This product does not contain a substance (> 0,1%) that has endocrine disrupting properties with respect to humans as no components meets the criteria. This product does not contain a substance (> 0,1 %) that has endocrine disrupting properties with respect to non-target organisms as no components meets the criteria. No risks worthy of mention. Please observe the information on the safety data sheet at all times.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Chemical characterization

The product does not contain dangerous substances according to REGULATION (EU) No. 2020/878, Annex II, Part A , 3.1/3.2. that must be mentioned in Chapter 3.

Relevant ingredients

none (according to Regulation (EC) No 1907/2006 (REACH))

Further Information

Product does not contain listed SVHC substances > 0,1 % according to Regulation (EC) No. 1907/2006 Article 59 (REACH)

SECTION 4: First aid measures

4.1. Description of first aid measures

General information

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

After inhalation

In case of accident by inhalation: remove casualty to fresh air and keep at rest. In case of respiratory tract irritation, consult a physician.

After contact with skin

Gently wash with plenty of soap and water. In case of skin irritation, seek medical treatment.

After contact with eyes

Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. In case of troubles or persistent symptoms, consult an ophthalmologist.

After ingestion

Rinse mouth thoroughly with water. Let water be drunken in little sips (dilution effect). Do NOT induce vomiting. In all cases of doubt, or when symptoms persist, seek medical advice.

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

No known symptoms to date.

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

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media

Carbon dioxide (CO_2). Dry extinguishing powder. Alcohol resistant foam. Water spray

Unsuitable extinguishing media

High power water jet.

5.2. Special hazards arising from the substance or mixture

In case of fire may be liberated: Carbon monoxide. Carbon dioxide (CO_2).

5.3. Advice for firefighters

In case of fire: Wear self-contained breathing apparatus.

Additional information

Collect contaminated fire extinguishing water separately. Do not allow entering drains or surface water. Co-ordinate fire-fighting measures to the fire surroundings.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General advice

Safe handling: see section 7

For non-emergency personnel

Wear personal protection equipment (refer to section 8).

For emergency responders

No special measures are necessary.

6.2. Environmental precautions

Discharge into the environment must be avoided.

6.3. Methods and material for containment and cleaning up

For containment

Absorb with liquid-binding material (e.g. sand, diatomaceous earth, acid- or universal binding agents).
Treat the recovered material as prescribed in the section on waste disposal .

For cleaning up

Clean contaminated objects and areas thoroughly observing environmental regulations.

6.4. Reference to other sections

Safe handling: see section 7
Personal protection equipment: see section 8
Disposal: see section 13

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Advice on safe handling

Wear suitable protective clothing. (See section 8.)

Advice on protection against fire and explosion

Usual measures for fire prevention.

Advice on general occupational hygiene

Always close containers tightly after the removal of product. When using do not eat, drink or smoke. Wash hands before breaks and after work.

Further information on handling

General protection and hygiene measures: See section 8.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

Keep container tightly closed in a cool, well-ventilated place.

Hints on joint storage

Do not store together with: Explosives. Oxidizing solids. Oxidizing liquids. Radioactive substances. Infectious substances. Food and animal feedingstuff.

Further information on storage conditions

Keep the packing dry and well sealed to prevent contamination and absorbtion of humidity.
Recommended storage temperature: 2 - 8°C
Protect against: frost. UV-radiation/sunlight. heat. Humidity

7.3. Specific end use(s)

See section 1.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Additional advice on limit values

To date, no national critical limit values exist.

8.2. Exposure controls

Appropriate engineering controls

Technical measures and the application of suitable work processes have priority over personal protection equipment.
Provide adequate ventilation.

Individual protection measures, such as personal protective equipment

Eye/face protection

Wear safety glasses; chemical goggles (if splashing is possible). EN ISO 16321-1:2022

Hand protection

In case of prolonged or frequently repeated skin contact:
Wear suitable gloves.
Suitable material:
FKM (fluororubber). - Thickness of glove material: 0,4 mm
Breakthrough time >= 8 h
Butyl rubber. - Thickness of glove material: 0,5 mm
Breakthrough time >= 8 h
CR (polychloroprenes, Chloroprene rubber). - Thickness of glove material: 0,5 mm
Breakthrough time >= 8 h
NBR (Nitrile rubber). - Thickness of glove material: 0,35 mm
Breakthrough time >= 8 h
PVC (Polyvinyl chloride). - Thickness of glove material: 0,5 mm
Breakthrough time >= 8 h
The selected protective gloves have to satisfy the specifications of EU Directive EC/ 2016/425 and the standard EN 374 derived from it.
Before using check leak tightness / impermeability. In the case of wanting to use the gloves again, clean them before taking off and air them well.

Skin protection

Suitable protective clothing: Lab coat.

Respiratory protection

With correct and proper use, and under normal conditions, breathing protection is not required.

Thermal hazards

No special precautionary measures are necessary.

Environmental exposure controls

No special precautionary measures are necessary.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state:	liquid
Colour:	orange
Odour:	characteristic
Odour threshold:	not determined

Melting point/freezing point:	not determined
Boiling point or initial boiling point and boiling range:	not determined
Flammability:	not determined
Lower explosion limits:	not determined
Upper explosion limits:	not determined
Flash point:	not determined
Auto-ignition temperature:	not determined
Decomposition temperature:	not relevant
pH-Value:	not determined
Viscosity / kinematic:	not determined
Water solubility:	not determined

Solubility in other solvents

not determined

Dissolution rate:	not relevant
Partition coefficient n-octanol/water:	not relevant

Dispersion stability:	not relevant
Vapour pressure:	not determined
Density:	not determined
Bulk density:	not relevant
Relative vapour density:	not determined
Particle characteristics:	not relevant

9.2. Other information

Information with regard to physical hazard classes

Explosive properties

none

Sustained combustibility:	No sustained combustibility

Self-ignition temperature

Solid:	not relevant
Gas:	not relevant

Oxidizing properties

none

Other safety characteristics

Evaporation rate:	not determined
Solvent separation test:	not determined
Solvent content:	not determined
Solid content:	not determined
Sublimation point:	not relevant
Softening point:	not relevant
Pour point:	not relevant
Viscosity / dynamic:	not determined
Flow time:	not determined

Further Information

No information available.

SECTION 10: Stability and reactivity

10.1. Reactivity

No information available.

10.2. Chemical stability

The product is chemically stable under recommended conditions of storage, use and temperature.

10.3. Possibility of hazardous reactions

No hazardous reaction when handled and stored according to provisions.
Refer to section 10.5.

10.4. Conditions to avoid

Protect against: UV-radiation/sunlight. heat.

10.5. Incompatible materials

Materials to avoid: Oxidising agent, strong. Reducing agents, strong.

10.6. Hazardous decomposition products

Does not decompose when used for intended uses.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Toxicocinetics, metabolism and distribution

No data available.

Acute toxicity

Based on available data, the classification criteria are not met.

ATEmix calculated

ATE (oral) > 2000 mg/kg; ATE (dermal) > 2000 mg/kg; ATE (inhalation vapour) > 20 mg/l; ATE (inhalation dust/mist) > 5 mg/l

Irritation and corrosivity

Skin corrosion/irritation: Based on available data, the classification criteria are not met.
Serious eye damage/eye irritation: Based on available data, the classification criteria are not met.

Sensitising effects

Based on available data, the classification criteria are not met.

Carcinogenic/mutagenic/toxic effects for reproduction

Germ cell mutagenicity: Based on available data, the classification criteria are not met.
Carcinogenicity: Based on available data, the classification criteria are not met.
Reproductive toxicity: Based on available data, the classification criteria are not met.

STOT-single exposure

Based on available data, the classification criteria are not met.

STOT-repeated exposure

Based on available data, the classification criteria are not met.

Aspiration hazard

Based on available data, the classification criteria are not met.

Specific effects in experiment on an animal

No data available.

11.2. Information on other hazards

Endocrine disrupting properties

Based on available data, the classification criteria are not met.
This product does not contain a substance (> 0,1%) that has endocrine disrupting properties with respect to humans as no components meets the criteria.

Other information

No data available.

SECTION 12: Ecological information

12.1. Toxicity

Based on available data, the classification criteria are not met.

12.2. Persistence and degradability

The product has not been tested.

12.3. Bioaccumulative potential

The product has not been tested.

12.4. Mobility in soil

No data available.

12.5. Results of PBT and vPvB assessment

Based on available data, the classification criteria are not met.
The aforementioned statement applies to substances contained in the product with a minimum content of 0.1%.

12.6. Endocrine disrupting properties

Based on available data, the classification criteria are not met.
The aforementioned statement applies to substances contained in the product with a minimum content of 0.1%.

12.7. Other adverse effects

No data available.

Further information

Do not allow to enter into surface water or drains.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Disposal recommendations

Observe in addition any national regulations! Consult the local waste disposal expert about waste disposal.
Non-contaminated packages may be recycled.
According to (EWC) European Waste Catalogue, allocation of waste identity numbers/waste descriptions must be carried out in a specific way for every industry and process.
Control report for waste code/ waste marking according to (EWC) European Waste Catalogue:

List of Wastes Code - residues/unused products

160509 WASTES NOT OTHERWISE SPECIFIED IN THE LIST; gases in pressure containers and discarded chemicals; discarded chemicals other than those mentioned in 16 05 06, 16 05 07 or 16 05 08

List of Wastes Code - used product

160509 WASTES NOT OTHERWISE SPECIFIED IN THE LIST; gases in pressure containers and discarded chemicals; discarded chemicals other than those mentioned in 16 05 06, 16 05 07 or 16 05 08

List of Wastes Code - contaminated packaging

150106 WASTE PACKAGING; ABSORBENTS, WIPING CLOTHS, FILTER MATERIALS AND PROTECTIVE CLOTHING NOT OTHERWISE SPECIFIED; packaging (including separately collected municipal packaging waste); mixed packaging

Contaminated packaging

Contaminated packages must be completely emptied and can be re-used following proper cleaning.

SECTION 14: Transport information

Land transport (ADR/RID)

14.1. UN number or ID number:	No dangerous good in sense of these transport regulations.
14.2. UN proper shipping name:	No dangerous good in sense of these transport regulations.
14.3. Transport hazard class(es):	No dangerous good in sense of these transport regulations.
14.4. Packing group:	No dangerous good in sense of these transport regulations.

Inland waterways transport (ADN)

14.1. UN number or ID number:	No dangerous good in sense of these transport regulations.
14.2. UN proper shipping name:	No dangerous good in sense of these transport regulations.
14.3. Transport hazard class(es):	No dangerous good in sense of these transport regulations.
14.4. Packing group:	No dangerous good in sense of these transport regulations.

Marine transport (IMDG)

14.1. UN number or ID number:	No dangerous good in sense of these transport regulations.
14.2. UN proper shipping name:	No dangerous good in sense of these transport regulations.
14.3. Transport hazard class(es):	No dangerous good in sense of these transport regulations.
14.4. Packing group:	No dangerous good in sense of this transport regulation.
Marine pollutant:	NO

Air transport (ICAO-TI/IATA-DGR)

14.1. UN number or ID number:	No dangerous good in sense of these transport regulations.
14.2. UN proper shipping name:	No dangerous good in sense of these transport regulations.
14.3. Transport hazard class(es):	No dangerous good in sense of these transport regulations.
14.4. Packing group:	No dangerous good in sense of this transport regulation.

14.5. Environmental hazards

ENVIRONMENTALLY HAZARDOUS: No

14.6. Special precautions for user

refer to section 6 - 8

14.7. Maritime transport in bulk according to IMO instruments

not relevant

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

EU regulatory information

Directive 2010/75/EU on industrial emissions:	not determined
Directive 2004/42/EC on VOC in paints and varnishes:	not determined
Information according to Directive 2012/18/EU (SEVESO III):	Not subject to 2012/18/EU (SEVESO III)

Additional information

Safety Data Sheet according to Regulation (EC) No. 1907/2006 (amended by Regulation (EU) No 2020/878)
This mixture is classified as not hazardous according to Regulation (EC) 1272/2008 [CLP].
REACH 1907/2006 Appendix XVII, No (mixture): not relevant

National regulatory information

Water hazard class (D):	1 - slightly hazardous to water

15.2. Chemical safety assessment

Chemical safety assessments for substances in this mixture were not carried out.

SECTION 16: Other information

Changes

Rev. 1,0; Initial release: 05,07.2021
Rev. 2,0; Revision: 27.05.2026; Changes in section: 1 - 16

Abbreviations and acronyms

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
AGW: Arbeitsplatzgrenzwert
CAS: Chemical Abstracts Service
CLP: Classification, Labelling and Packaging of substances and mixtures
DNEL: Derived No Effect Level
d: day(s)
EINECS: European INventory of Existing Commercial chemical Substances
ELINCS: European LIst of Notified Chemical Substances
ECHA: European Chemicals Agency
EWC: European Waste Catalogue
IARC: INTERNATIONAL AGENCY FOR RESEARCH ON CANCER
IMDG: International Maritime Code for Dangerous Goods
IATA: International Air Transport Association
IATA-DGR: Dangerous Goods Regulations by the "International Air Transport Association" (IATA)
ICAO: International Civil Aviation Organization
ICAO-TI: Technical Instructions by the "International Civil Aviation Organization" (ICAO)
GHS: Globally Harmonized System of Classification and Labelling of Chemicals
GefStoffV: Gefahrstoffverordnung (Ordinance on Hazardous Substances, Germany)
h: hour
LOAEL: Lowest observed adverse effect level
LOAEC: Lowest observed adverse effect concentration
LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent
NOAEL: No observed adverse effect level
NOAEC: No observed adverse effect concentration
NLP: No-Longer Polymers
N/A: not applicable
OECD: Organisation for Economic Co-operation and Development
PNEC: predicted no effect concentration
PBT: Persistent bioaccumulative toxic
RID: Reglement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)
REACH: Registration, Evaluation, Authorisation of Chemicals
SVHC: substance of very high concern
TRGS: Technische Regeln für Gefahrstoffe
UN: United Nations
VOC: Volatile Organic Compounds
WGK: Water Hazard Class (Germany)

Relevant H and EUH statements (number and full text)

EUH210 Safety data sheet available on request.

Further Information

The above information describes exclusively the safety requirements of the product and is based on our present-day knowledge. The information is intended to give you advice about the safe handling of the product named in this safety data sheet, for storage, processing, transport and disposal. The information cannot be transferred to other products. In the case of mixing the product with other products or in the case of processing, the information on this safety data sheet is not necessarily valid for the new made-up material.

(The data for the relevant ingredients were taken respectively from the last version of the sub-contractor's safety data sheet.)

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

1.1. Product identifier

CON-D (GenoType, ThromboType, micro-IDent)

Further trade names

Article No.: 004-010-12 (12 ml)
Article No.: 004-010-96 (96 ml)

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

Use of the substance/mixture

Scientific research and development, in vitro diagnostic medical devices

Uses advised against

Any non-intended use.

1.3. Details of the supplier of the safety data sheet

Company name:	Hain Lifescience GmbH	
Street:	Hardwiesenstrasse 1	
Place:	D-72147 Nehren	
Telephone:	+49 (0) 74 73- 94 51- 0	Telefax: +49 (0) 74 73- 94 51- 31
Responsible Department:	msds.mdx.de@bruker.com	

1.4. Emergency telephone number:

Only from Malta: 112

Further Information

The product falls under the regulation (EU) 2017/746 on in-vitro diagnostics.

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Regulation (EC) No 1272/2008

Skin Sens. 1; H317

Full text of hazard statements: see SECTION 16.

2.2. Label elements

Regulation (EC) No 1272/2008

Hazard components for labelling

Disodium maleate

Signal word: Warning

Pictograms:

Hazard statements

H317	May cause an allergic skin reaction.

Precautionary statements

P261	Avoid breathing dust/fume/gas/mist/vapours/spray.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P302+P352	IF ON SKIN: Wash with plenty of water and soap.
P333+P313	If skin irritation or rash occurs: Get medical advice/attention.
P362+P364	Take off contaminated clothing and wash it before reuse.
P501	Dispose of contents/container to local/regional/national/international regulations.

Additional advice on labelling

Labelling according to national medical devices regulations.

2.3. Other hazards

The substances in the mixture (>0,1%) do not meet the PBT/vPvB criteria according to REACH, annex XIII. This product does not contain a substance (> 0,1%) that has endocrine disrupting properties with respect to humans as no components meets the criteria. This product does not contain a substance (> 0,1 %) that has endocrine disrupting properties with respect to non-target organisms as no components meets the criteria.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Relevant ingredients

CAS No	Chemical name			Quantity
	EC No	Index No	REACH No	
	Classification (Regulation (EC) No 1272/2008)			
371-47-1	Disodium maleate			1 - < 3 %
	206-738-1			
	Acute Tox. 4, Skin Irrit. 2, Eye Irrit. 2, Skin Sens. 1, STOT SE 3; H302 H315 H319 H317 H335			
26628-22-8	sodium azide			< 0.1 %
	247-852-1	011-004-00-7		
	Acute Tox. 2, Aquatic Acute 1, Aquatic Chronic 1; H300 H400 H410 EUH032			

Full text of H and EUH statements: see section 16.

Specific Conc. Limits, M-factors and ATE

CAS No	EC No	Chemical name	Quantity
	Specific Conc. Limits, M-factors and ATE		
371-47-1	206-738-1	Disodium maleate	1 - < 3 %
	oral: ATE = 500 mg/kg		
26628-22-8	247-852-1	sodium azide	< 0.1 %
	oral: ATE = 5 mg/kg		

Further Information

Product does not contain listed SVHC substances > 0,1 % according to Regulation (EC) No. 1907/2006 Article 59 (REACH)

SECTION 4: First aid measures

4.1. Description of first aid measures

General information

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

After inhalation

In case of accident by inhalation: remove casualty to fresh air and keep at rest. In case of respiratory tract irritation, consult a physician.

After contact with skin

Gently wash with plenty of soap and water. In case of skin irritation, seek medical treatment.

After contact with eyes

Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. In case of troubles or persistent symptoms, consult an ophthalmologist.

After ingestion

Rinse mouth thoroughly with water. Let water be drunken in little sips (dilution effect). Do NOT induce vomiting.

In all cases of doubt, or when symptoms persist, seek medical advice.

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

See sections 2 and 11

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

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media

Carbon dioxide (CO2). Dry extinguishing powder. Alcohol resistant foam. Water spray

Unsuitable extinguishing media

High power water jet.

5.2. Special hazards arising from the substance or mixture

In case of fire may be liberated: Carbon monoxide. Carbon dioxide (CO2).

5.3. Advice for firefighters

In case of fire: Wear self-contained breathing apparatus.

Additional information

Collect contaminated fire extinguishing water separately. Do not allow entering drains or surface water.
Co-ordinate fire-fighting measures to the fire surroundings.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General advice

Safe handling: see section 7

For non-emergency personnel

Wear personal protection equipment (refer to section 8).

For emergency responders

No special measures are necessary.

6.2. Environmental precautions

Discharge into the environment must be avoided.

6.3. Methods and material for containment and cleaning up

For containment

Absorb with liquid-binding material (e.g. sand, diatomaceous earth, acid- or universal binding agents).
Treat the recovered material as prescribed in the section on waste disposal .

For cleaning up

Clean contaminated objects and areas thoroughly observing environmental regulations.

6.4. Reference to other sections

Safe handling: see section 7
Personal protection equipment: see section 8
Disposal: see section 13

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Advice on safe handling

Wear suitable protective clothing. See section 8.

Advice on protection against fire and explosion

Usual measures for fire prevention.

Advice on general occupational hygiene

Always close containers tightly after the removal of product. When using do not eat, drink or smoke. Wash hands before breaks and after work.

Further information on handling

General protection and hygiene measures: See section 8.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

Keep container tightly closed in a cool, well-ventilated place.

Hints on joint storage

Do not store together with: Explosives. Oxidizing solids. Oxidizing liquids. Radioactive substances. Infectious substances. Food and animal feedingstuff.

Further information on storage conditions

Keep the packing dry and well sealed to prevent contamination and absorbtion of humidity.
Recommended storage temperature: 2 - 8°C
Protect against: frost. UV-radiation/sunlight. heat. Humidity

7.3. Specific end use(s)

See section 1.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Occupational exposure limit values

CAS No	Name of agent	ppm	mg/m³	fib/cm³	Category	Origin
26628-22-8	Sodium azide	-	0.1		TWA (8 h)	
		-	0.3		STEL (15 min)	

8.2. Exposure controls

Appropriate engineering controls

Technical measures and the application of suitable work processes have priority over personal protection equipment.
Provide adequate ventilation.

Individual protection measures, such as personal protective equipment

Eye/face protection

Wear safety glasses; chemical goggles (if splashing is possible). EN ISO 16321-1:2022

Hand protection

Wear suitable gloves.
Suitable material:
FKM (fluororubber). - Thickness of glove material: 0,4 mm
Breakthrough time >= 8 h
Butyl rubber. - Thickness of glove material: 0,5 mm
Breakthrough time >= 8 h
CR (polychloroprenes, Chloroprene rubber). - Thickness of glove material: 0,5 mm
Breakthrough time >= 8 h
NBR (Nitrile rubber). - Thickness of glove material: 0,35 mm
Breakthrough time >= 8 h

PVC (Polyvinyl chloride). - Thickness of glove material: 0,5 mm
Breakthrough time >= 8 h
For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves.
The selected protective gloves have to satisfy the specifications of EU Directive EC/ 2016/425 and the standard EN 374 derived from it.
Check leak tightness/impermeability prior to use. In the case of wanting to use the gloves again, clean them before taking off and air them well.

Skin protection

Suitable protective clothing: Lab coat.

Respiratory protection

With correct and proper use, and under normal conditions, breathing protection is not required.
Respiratory protection necessary at:
-Exceeding exposure limit values
-Insufficient ventilation and aerosol or mist formation
Suitable respiratory protection apparatus: particulates filter device (DIN EN 143). Filter type: P1-3
Half-face mask or quarter facepiece: maximum use concentration for substances with exposure limits: P1 filter: up to a max. of 4 times the exposure limit. P2 filter: up to a max. of 10 times the exposure limit. P3 filter: up to a max. of 30 times the expo.
The filter class must be suitable for the maximum contaminant concentration (gas/vapour/aerosol/particulates) that may arise when handling the product. If the concentration is exceeded, self-contained breathing apparatus must be used.

Environmental exposure controls

Do not allow uncontrolled discharge of product into the environment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state:	liquid
Colour:	opaque
Odour:	characteristic
Odour threshold:	not determined

Melting point/freezing point:	not determined
Boiling point or initial boiling point and boiling range:	not determined
Flammability:	not determined
Lower explosion limits:	not determined
Upper explosion limits:	not determined
Flash point:	not determined
Auto-ignition temperature:	not determined
Decomposition temperature:	not relevant
pH-Value:	7,5 - 8,0
Viscosity / kinematic:	not determined
Water solubility:	not determined

Solubility in other solvents
not determined

Dissolution rate:	not relevant
Partition coefficient n-octanol/water:	not relevant
Dispersion stability:	not relevant
Vapour pressure:	not determined
Density:	1,005 g/cm³
Bulk density:	not relevant
Relative vapour density:	not determined

Particle characteristics: not relevant

9.2. Other information

Information with regard to physical hazard classes

Explosive properties

none

Sustained combustibility: No sustained combustibility

Self-ignition temperature

Solid: not relevant

Gas: not relevant

Oxidizing properties

none

Other safety characteristics

Evaporation rate:	not determined
Solvent separation test:	not determined
Solvent content:	not determined
Solid content:	not determined
Sublimation point:	not relevant
Softening point:	not relevant
Pour point:	not relevant
Viscosity / dynamic:	not determined
Flow time:	not determined

Further Information

No information available.

SECTION 10: Stability and reactivity

10.1. Reactivity

No information available.

10.2. Chemical stability

The product is chemically stable under recommended conditions of storage, use and temperature.

10.3. Possibility of hazardous reactions

Refer to section 10.5.

10.4. Conditions to avoid

Protect against: UV-radiation/sunlight. heat.

10.5. Incompatible materials

Materials to avoid: Oxidising agent, strong. Reducing agents, strong.

10.6. Hazardous decomposition products

Does not decompose when used for intended uses.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Toxicocinetics, metabolism and distribution

No data available.

Acute toxicity

Based on available data, the classification criteria are not met.

ATEmix calculated

ATE (oral) > 5000 mg/kg; ATE (dermal) > 2000 mg/kg; ATE (inhalation vapour) > 20 mg/l; ATE (inhalation dust/mist) > 5 mg/l

CAS No	Chemical name

	Exposure route	Dose	Species	Source	Method
371-47-1	Disodium maleate				
	oral	ATE 500 mg/kg			
26628-22-8	sodium azide				
	oral	ATE 5 mg/kg			

Irritation and corrosivity

Skin corrosion/irritation: Based on available data, the classification criteria are not met.
Serious eye damage/eye irritation: Based on available data, the classification criteria are not met.

Sensitising effects

May cause an allergic skin reaction. (Disodium maleate)

Carcinogenic/mutagenic/toxic effects for reproduction

Germ cell mutagenicity: Based on available data, the classification criteria are not met.
Carcinogenicity: Based on available data, the classification criteria are not met.
Reproductive toxicity: Based on available data, the classification criteria are not met.

STOT-single exposure

Based on available data, the classification criteria are not met.

STOT-repeated exposure

Based on available data, the classification criteria are not met.

Aspiration hazard

Based on available data, the classification criteria are not met.

Specific effects in experiment on an animal

No data available.

11.2. Information on other hazards

Endocrine disrupting properties

Based on available data, the classification criteria are not met.
This product does not contain a substance (> 0,1%) that has endocrine disrupting properties with respect to humans as no components meets the criteria.

Other information

No data available.

SECTION 12: Ecological information

12.1. Toxicity

Based on available data, the classification criteria are not met.

12.2. Persistence and degradability

The product has not been tested.

12.3. Bioaccumulative potential

The product has not been tested.

12.4. Mobility in soil

No data available.

12.5. Results of PBT and vPvB assessment

Based on available data, the classification criteria are not met.
The aforementioned statement applies to substances contained in the product with a minimum content of 0.1%.

12.6. Endocrine disrupting properties

Based on available data, the classification criteria are not met.
The aforementioned statement applies to substances contained in the product with a minimum content of 0.1%.

12.7. Other adverse effects

No data available.

Further information

Do not allow to enter into surface water or drains.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Disposal recommendations

Observe in addition any national regulations! Consult the local waste disposal expert about waste disposal.
Non-contaminated packages may be recycled.
According to (EWC) European Waste Catalogue, allocation of waste identity numbers/waste descriptions must be carried out in a specific way for every industry and process.
Control report for waste code/ waste marking according to (EWC) European Waste Catalogue:

List of Wastes Code - residues/unused products

160509 WASTES NOT OTHERWISE SPECIFIED IN THE LIST; gases in pressure containers and discarded chemicals; discarded chemicals other than those mentioned in 16 05 06, 16 05 07 or 16 05 08

List of Wastes Code - used product

160509 WASTES NOT OTHERWISE SPECIFIED IN THE LIST; gases in pressure containers and discarded chemicals; discarded chemicals other than those mentioned in 16 05 06, 16 05 07 or 16 05 08

List of Wastes Code - contaminated packaging

150110 WASTE PACKAGING; ABSORBENTS, WIPING CLOTHS, FILTER MATERIALS AND PROTECTIVE CLOTHING NOT OTHERWISE SPECIFIED; packaging (including separately collected municipal packaging waste); packaging containing residues of or contaminated by hazardous substances; hazardous waste

Contaminated packaging

Contaminated packages must be completely emptied and can be re-used following proper cleaning.

SECTION 14: Transport information

Land transport (ADR/RID)

14.1. UN number or ID number:	No dangerous good in sense of this transport regulation.
14.2. UN proper shipping name:	No dangerous good in sense of this transport regulation.
14.3. Transport hazard class(es):	No dangerous good in sense of this transport regulation.
14.4. Packing group:	No dangerous good in sense of this transport regulation.

Inland waterways transport (ADN)

14.1. UN number or ID number:	No dangerous good in sense of this transport regulation.
14.2. UN proper shipping name:	No dangerous good in sense of this transport regulation.
14.3. Transport hazard class(es):	No dangerous good in sense of this transport regulation.
14.4. Packing group:	No dangerous good in sense of this transport regulation.

Marine transport (IMDG)

14.1. UN number or ID number:	No dangerous good in sense of this transport regulation.
14.2. UN proper shipping name:	No dangerous good in sense of this transport regulation.
14.3. Transport hazard class(es):	No dangerous good in sense of this transport regulation.
14.4. Packing group:	No dangerous good in sense of this transport regulation.
Marine pollutant:	NO

Air transport (ICAO-TI/IATA-DGR)

14.1. UN number or ID number:	No dangerous good in sense of this transport regulation.
14.2. UN proper shipping name:	No dangerous good in sense of this transport regulation.
14.3. Transport hazard class(es):	No dangerous good in sense of this transport regulation.

14.4. Packing group: No dangerous good in sense of this transport regulation.

14.5. Environmental hazards

ENVIRONMENTALLY HAZARDOUS: No

14.6. Special precautions for user

refer to section 6 - 8

14.7. Maritime transport in bulk according to IMO instruments

not relevant

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

EU regulatory information

Restrictions on use (REACH, annex XVII):

Entry 3

Directive 2010/75/EU on industrial emissions:	not determined
Directive 2004/42/EC on VOC in paints and varnishes:	not determined
Information according to Directive 2012/18/EU (SEVESO III):	Not subject to 2012/18/EU (SEVESO III)

Additional information

Safety Data Sheet according to Regulation (EC) No. 1907/2006 (amended by Regulation (EU) No 2020/878)
The mixture is classified as hazardous according to regulation (EC) No 1272/2008 [CLP].
REACH 1907/2006 Appendix XVII, No (mixture): 3

National regulatory information

Employment restrictions:	Observe restrictions to employment for juveniles according to the 'juvenile work protection guideline' (94/33/EC).
Water hazard class (D):	1 - slightly hazardous to water

15.2. Chemical safety assessment

Chemical safety assessments for substances in this mixture were not carried out.

SECTION 16: Other information

Changes

Rev. 1,0; Initial release: 05,07.2021
Rev. 2,0; Revision: 27.05.2026; Changes in section: 1 - 16

Abbreviations and acronyms

Acute Tox. 2: Acute toxicity, hazard category 2
Acute Tox. 4: Acute toxicity, hazard category 4
Skin Irrit. 2: Skin irritation, hazard category 2
Eye Irrit. 2: Eye irritation, hazard category 2
Skin Sens. 1: Skin sensitisation, hazard category 1
STOT SE 3: Specific target organ toxicity - single exposure, hazard category 3
Aquatic Acute 1: Hazardous to the aquatic environment, hazard category: Acute 1
Aquatic Chronic 1: Hazardous to the aquatic environment, long-term hazard category: Chronic 1
ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
AGW: Arbeitsplatzgrenzwert
CAS: Chemical Abstracts Service
CLP: Classification, Labelling and Packaging of substances and mixtures
DNEL: Derived No Effect Level
d: day(s)

EINECS: European INventory of Existing Commercial chemical Substances
ELINCS: European LIst of Notified Chemical Substances
ECHA: European Chemicals Agency
EWC: European Waste Catalogue
IARC: INTERNATIONAL AGENCY FOR RESEARCH ON CANCER
IMDG: International Maritime Code for Dangerous Goods
IATA: International Air Transport Association
IATA-DGR: Dangerous Goods Regulations by the "International Air Transport Association" (IATA)
ICAO: International Civil Aviation Organization
ICAO-TI: Technical Instructions by the "International Civil Aviation Organization" (ICAO)
GHS: Globally Harmonized System of Classification and Labelling of Chemicals
GefStoffV: Gefahrstoffverordnung (Ordinance on Hazardous Substances, Germany)
h: hour
LOAEL: Lowest observed adverse effect level
LOAEC: Lowest observed adverse effect concentration
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
NOAEL: No observed adverse effect level
NOAEC: No observed adverse effect concentration
NLP: No-Longer Polymers
N/A: not applicable
OECD: Organisation for Economic Co-operation and Development
PNEC: predicted no effect concentration
PBT: Persistent bioaccumulative toxic
RID: Regulation Concerning the International Transport of Dangerous Goods by Rail
REACH: Registration, Evaluation, Authorisation of Chemicals
SVHC: substance of very high concern
TRGS: Technische Regeln für Gefahrstoffe
UN: United Nations
VOC: Volatile Organic Compounds
WGK: Water Hazard Class (Germany)

Classification for mixtures and used evaluation method according to Regulation (EC) No 1272/2008 [CLP]

Classification	Classification procedure
Skin Sens. 1; H317	Calculation method

Relevant H and EUH statements (number and full text)

H300	Fatal if swallowed.
H302	Harmful if swallowed.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
EUH032	Contact with acids liberates very toxic gas.

Further Information

The above information describes exclusively the safety requirements of the product and is based on our present-day knowledge. The information is intended to give you advice about the safe handling of the product named in this safety data sheet, for storage, processing, transport and disposal. The information cannot be transferred to other products. In the case of mixing the product with other products or in the case of processing, the information on this safety data sheet is not necessarily valid for the new made-up material.

(The data for the relevant ingredients were taken respectively from the last version of the sub-contractor's safety data sheet.)

Safety Data Sheet

according to Regulation (EC) No 1907/2006

DEN (GenoType, ThromboType, micro-IDent)

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

1.1. Product identifier

DEN (GenoType, ThromboType, micro-IDent)

Further trade names

Article No.: 004-001-12 (240 µl)
Article No.: 004-001-96 (960 µl)

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

Use of the substance/mixture

Scientific research and development

Uses advised against

Any non-intended use.

1.3. Details of the supplier of the safety data sheet

Company name:	Hain Lifescience GmbH	
Street:	Hardwiesenstrasse 1	
Place:	D-72147 Nehren	
Telephone:	+49 (0) 74 73- 94 51- 0	Telefax: +49 (0) 74 73- 94 51- 31
Responsible Department:	msds.mdx.de@bruker.com	

1.4. Emergency telephone number:

+49 (0) 74 73- 94 51- 0 (Mo–Fr: 08:00–17:00)
Only from Malta: 112

Further Information

The product falls under the regulation (EU) 2017/746 on in-vitro diagnostics.

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Regulation (EC) No 1272/2008

Skin Irrit. 2; H315
Eye Irrit. 2; H319

Full text of hazard statements: see SECTION 16.

2.2. Label elements

Regulation (EC) No 1272/2008

Signal word: Warning

Pictograms:

Hazard statements

H315	Causes skin irritation.
H319	Causes serious eye irritation.

Precautionary statements

P280	Wear protective gloves/protective clothing/eye protection/face protection.
P302+P352	IF ON SKIN: Wash with plenty of water.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P337+P313	If eye irritation persists: Get medical advice/attention.

Additional advice on labelling

Labelling according to national medical devices regulations.

2.3. Other hazards

The substances in the mixture (>0,1%) do not meet the PBT/vPvB criteria according to REACH, annex XIII. This product does not contain a substance (> 0,1%) that has endocrine disrupting properties with respect to humans as no components meets the criteria. This product does not contain a substance (> 0,1 %) that has endocrine disrupting properties with respect to non-target organisms as no components meets the criteria.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Chemical characterization

aqueous solution (alkaline)

Relevant ingredients

CAS No	Chemical name			Quantity
	EC No	Index No	REACH No	
	Classification (Regulation (EC) No 1272/2008)			
1310-73-2	sodium hydroxide; caustic soda			< 2 %
	215-185-5	011-002-00-6	01-2119457892-27	
	Met. Corr. 1, Skin Corr. 1A, Eye Dam. 1; H290 H314 H318			

Full text of H and EUH statements: see section 16.

Specific Conc. Limits, M-factors and ATE

CAS No	EC No	Chemical name	Quantity
	Specific Conc. Limits, M-factors and ATE		
1310-73-2	215-185-5	sodium hydroxide; caustic soda	< 2 %
	Skin Corr. 1A; H314: >= 5 - 100 Skin Corr. 1B; H314: >= 2 - < 5 Skin Irrit. 2; H315: >= 0,5 - < 2 Eye Irrit. 2; H319: >= 0,5 - < 2		

Further Information

Product does not contain listed SVHC substances > 0,1 % according to Regulation (EC) No. 1907/2006 Article 59 (REACH)

SECTION 4: First aid measures

4.1. Description of first aid measures

General information

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

After inhalation

In case of accident by inhalation: remove casualty to fresh air and keep at rest. In case of respiratory tract irritation, consult a physician.

After contact with skin

Gently wash with plenty of soap and water. In case of skin irritation, seek medical treatment.

After contact with eyes

Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. In case of troubles or persistent symptoms, consult an ophthalmologist.

After ingestion

Rinse mouth thoroughly with water. Let water be drunken in little sips (dilution effect). Do NOT induce vomiting. In all cases of doubt, or when symptoms persist, seek medical advice.

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

See sections 2 and 11

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

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media

Carbon dioxide (CO2). Dry extinguishing powder. Alcohol resistant foam. Water spray

Unsuitable extinguishing media

High power water jet.

5.2. Special hazards arising from the substance or mixture

In case of fire may be liberated: Carbon monoxide. Carbon dioxide (CO2).

5.3. Advice for firefighters

In case of fire: Wear self-contained breathing apparatus.

Additional information

Collect contaminated fire extinguishing water separately. Do not allow entering drains or surface water.
Co-ordinate fire-fighting measures to the fire surroundings.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General advice

Safe handling: see section 7

For non-emergency personnel

Wear personal protection equipment (refer to section 8).

For emergency responders

No special measures are necessary.

6.2. Environmental precautions

Discharge into the environment must be avoided.

6.3. Methods and material for containment and cleaning up

For containment

Absorb with liquid-binding material (e.g. sand, diatomaceous earth, acid- or universal binding agents).
Treat the recovered material as prescribed in the section on waste disposal .

For cleaning up

Clean contaminated objects and areas thoroughly observing environmental regulations.

6.4. Reference to other sections

Safe handling: see section 7
Personal protection equipment: see section 8
Disposal: see section 13

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Advice on safe handling

Wear suitable protective clothing. See section 8.

Advice on protection against fire and explosion

Usual measures for fire prevention.

Advice on general occupational hygiene

Always close containers tightly after the removal of product. When using do not eat, drink or smoke. Wash hands before breaks and after work.

Further information on handling

General protection and hygiene measures: See section 8.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

Keep container tightly closed in a cool, well-ventilated place.

Hints on joint storage

Do not store together with: Explosives. Oxidizing solids. Oxidizing liquids. Radioactive substances. Infectious substances. Food and animal feedingstuff.

Further information on storage conditions

Keep the packing dry and well sealed to prevent contamination and absorbtion of humidity.
Recommended storage temperature: 2 - 8°C
Protect against: frost. UV-radiation/sunlight. heat. Humidity

7.3. Specific end use(s)

See section 1.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

DNEL/DMEL values

CAS No	Name of agent			
DNEL type		Exposure route	Effect	Value
1310-73-2	sodium hydroxide; caustic soda			
Worker DNEL, long-term		inhalation	local	1 mg/m³
Consumer DNEL, long-term		inhalation	local	1 mg/m³

Additional advice on limit values

To date, no national critical limit values exist.

8.2. Exposure controls

Appropriate engineering controls

Technical measures and the application of suitable work processes have priority over personal protection equipment.
Provide adequate ventilation.

Individual protection measures, such as personal protective equipment

Eye/face protection

Wear safety glasses; chemical goggles (if splashing is possible). EN ISO 16321-1:2022

Hand protection

Wear suitable gloves.
Suitable material:
FKM (fluororubber). - Thickness of glove material: 0,4 mm
Breakthrough time >= 8 h
Butyl rubber. - Thickness of glove material: 0,5 mm
Breakthrough time >= 8 h
CR (polychloroprenes, Chloroprene rubber). - Thickness of glove material: 0,5 mm
Breakthrough time >= 8 h
NBR (Nitrile rubber). - Thickness of glove material: 0,35 mm
Breakthrough time >= 8 h
PVC (Polyvinyl chloride). - Thickness of glove material: 0,5 mm
Breakthrough time >= 8 h
For special purposes, it is recommended to check the resistance to chemicals of the protective gloves

mentioned above together with the supplier of these gloves.
The selected protective gloves have to satisfy the specifications of EU Directive EC/ 2016/425 and the standard EN 374 derived from it.
Check leak tightness/impermeability prior to use. In the case of wanting to use the gloves again, clean them before taking off and air them well.

Skin protection

Suitable protective clothing: Lab coat.

Respiratory protection

With correct and proper use, and under normal conditions, breathing protection is not required.
Respiratory protection necessary at:
-Exceeding exposure limit values
-Insufficient ventilation and aerosol or mist formation
Suitable respiratory protection apparatus: particulates filter device (DIN EN 143). Filter type: P1-3
Half-face mask or quarter facepiece: maximum use concentration for substances with exposure limits: P1 filter: up to a max. of 4 times the exposure limit. P2 filter: up to a max. of 10 times the exposure limit. P3 filter: up to a max. of 30 times the expo.
The filter class must be suitable for the maximum contaminant concentration (gas/vapour/aerosol/particulates) that may arise when handling the product. If the concentration is exceeded, self-contained breathing apparatus must be used.

Environmental exposure controls

Do not allow uncontrolled discharge of product into the environment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state:	liquid
Colour:	blue
Odour:	characteristic
Odour threshold:	not determined

Melting point/freezing point:	not determined
Boiling point or initial boiling point and boiling range:	not determined
Flammability:	not determined
Lower explosion limits:	not determined
Upper explosion limits:	not determined
Flash point:	not determined
Auto-ignition temperature:	not determined
Decomposition temperature:	not relevant
pH-Value:	13,5 - 13,6
Viscosity / kinematic:	not determined
Water solubility:	Soluble in water.

Solubility in other solvents

not determined

Dissolution rate:	not relevant
Partition coefficient n-octanol/water:	not relevant
Dispersion stability:	not relevant
Vapour pressure:	not determined
Density:	1 g/cm³
Bulk density:	not relevant
Relative vapour density:	not determined
Particle characteristics:	not relevant

9.2. Other information

Information with regard to physical hazard classes

Explosive properties
none
Sustained combustibility: No sustained combustibility
Self-ignition temperature
Solid: not relevant
Gas: not relevant
Oxidizing properties
none

Other safety characteristics

Evaporation rate:	not determined
Solvent separation test:	not determined
Solvent content:	not determined
Solid content:	not determined
Sublimation point:	not relevant
Softening point:	not relevant
Pour point:	not relevant
Viscosity / dynamic:	not determined
Flow time:	not determined

Further Information

No information available.

SECTION 10: Stability and reactivity

10.1. Reactivity

No information available.

10.2. Chemical stability

The product is chemically stable under recommended conditions of storage, use and temperature.

10.3. Possibility of hazardous reactions

Refer to section 10.5.

10.4. Conditions to avoid

Protect against: UV-radiation/sunlight. heat.

10.5. Incompatible materials

Materials to avoid: Oxidising agent, strong. Reducing agents, strong. Strong acids. May corrode copper, lead, and silicon alloys.

10.6. Hazardous decomposition products

Does not decompose when used for intended uses.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Toxicocinetics, metabolism and distribution

No data available.

Acute toxicity

Based on available data, the classification criteria are not met.

ATEmix calculated

ATE (oral) > 2000 mg/kg; ATE (dermal) > 2000 mg/kg; ATE (inhalation vapour) > 20 mg/l; ATE (inhalation dust/mist) > 5 mg/l

Irritation and corrosivity

Skin corrosion/irritation: Causes skin irritation.
Serious eye damage/eye irritation: Causes serious eye irritation.

Sensitising effects

Based on available data, the classification criteria are not met.

Carcinogenic/mutagenic/toxic effects for reproduction

Germ cell mutagenicity: Based on available data, the classification criteria are not met.
Carcinogenicity: Based on available data, the classification criteria are not met.
Reproductive toxicity: Based on available data, the classification criteria are not met.

STOT-single exposure

Based on available data, the classification criteria are not met.

STOT-repeated exposure

Based on available data, the classification criteria are not met.

Aspiration hazard

Based on available data, the classification criteria are not met.

Specific effects in experiment on an animal

No data available.

11.2. Information on other hazards

Endocrine disrupting properties

Based on available data, the classification criteria are not met.
This product does not contain a substance (> 0,1%) that has endocrine disrupting properties with respect to humans as no components meets the criteria.

Other information

No data available.

SECTION 12: Ecological information

12.1. Toxicity

Based on available data, the classification criteria are not met.

CAS No	Chemical name					
	Aquatic toxicity	Dose	[h] | [d]	Species	Source	Method
1310-73-2	sodium hydroxide; caustic soda					
	Acute crustacea toxicity	EC50 40,4 mg/l	48 h	Ceriodaphnia sp.	ECHA Dossier	Ecotoxicol. Environ. Saf. 1999, 44

12.2. Persistence and degradability

The product has not been tested.

12.3. Bioaccumulative potential

The product has not been tested.

12.4. Mobility in soil

No data available.

12.5. Results of PBT and vPvB assessment

Based on available data, the classification criteria are not met.
The aforementioned statement applies to substances contained in the product with a minimum content of 0.1%.

12.6. Endocrine disrupting properties

Based on available data, the classification criteria are not met.
The aforementioned statement applies to substances contained in the product with a minimum content of 0.1%.

12.7. Other adverse effects

No data available.

Further information

Do not allow to enter into surface water or drains.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Disposal recommendations

Observe in addition any national regulations! Consult the local waste disposal expert about waste disposal.
Non-contaminated packages may be recycled.
According to (EWC) European Waste Catalogue, allocation of waste identity numbers/waste descriptions must be carried out in a specific way for every industry and process.
Control report for waste code/ waste marking according to (EWC) European Waste Catalogue:

List of Wastes Code - residues/unused products

160506 WASTES NOT OTHERWISE SPECIFIED IN THE LIST; gases in pressure containers and discarded chemicals; laboratory chemicals, consisting of or containing hazardous substances, including mixtures of laboratory chemicals; hazardous waste

List of Wastes Code - used product

160506 WASTES NOT OTHERWISE SPECIFIED IN THE LIST; gases in pressure containers and discarded chemicals; laboratory chemicals, consisting of or containing hazardous substances, including mixtures of laboratory chemicals; hazardous waste

List of Wastes Code - contaminated packaging

150110 WASTE PACKAGING; ABSORBENTS, WIPING CLOTHS, FILTER MATERIALS AND PROTECTIVE CLOTHING NOT OTHERWISE SPECIFIED; packaging (including separately collected municipal packaging waste); packaging containing residues of or contaminated by hazardous substances; hazardous waste

Contaminated packaging

Contaminated packages must be completely emptied and can be re-used following proper cleaning.

SECTION 14: Transport information

Land transport (ADR/RID)

14.1. UN number or ID number:	No dangerous good in sense of this transport regulation.
14.2. UN proper shipping name:	No dangerous good in sense of this transport regulation.
14.3. Transport hazard class(es):	No dangerous good in sense of this transport regulation.
14.4. Packing group:	No dangerous good in sense of this transport regulation.

Inland waterways transport (ADN)

14.1. UN number or ID number:	No dangerous good in sense of this transport regulation.
14.2. UN proper shipping name:	No dangerous good in sense of this transport regulation.
14.3. Transport hazard class(es):	No dangerous good in sense of this transport regulation.
14.4. Packing group:	No dangerous good in sense of this transport regulation.

Marine transport (IMDG)

14.1. UN number or ID number:	No dangerous good in sense of this transport regulation.
14.2. UN proper shipping name:	No dangerous good in sense of this transport regulation.
14.3. Transport hazard class(es):	No dangerous good in sense of this transport regulation.
14.4. Packing group:	No dangerous good in sense of this transport regulation.

Air transport (ICAO-TI/IATA-DGR)

14.1. UN number or ID number:	No dangerous good in sense of this transport regulation.
14.2. UN proper shipping name:	No dangerous good in sense of this transport regulation.
14.3. Transport hazard class(es):	No dangerous good in sense of this transport regulation.
14.4. Packing group:	No dangerous good in sense of this transport regulation.

14.5. Environmental hazards

ENVIRONMENTALLY HAZARDOUS: No

Marine pollutant: NO

14.6. Special precautions for user

refer to section 6 - 8

14.7. Maritime transport in bulk according to IMO instruments

not relevant

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

EU regulatory information

Restrictions on use (REACH, annex XVII):

Entry 3, Entry 75

Directive 2010/75/EU on industrial emissions:	not determined
Directive 2004/42/EC on VOC in paints and varnishes:	not determined
Information according to Directive 2012/18/EU (SEVESO III):	Not subject to 2012/18/EU (SEVESO III)

Additional information

Safety Data Sheet according to Regulation (EC) No. 1907/2006 (amended by Regulation (EU) No 2020/878)
The mixture is classified as hazardous according to regulation (EC) No 1272/2008 [CLP].
REACH 1907/2006 Appendix XVII, No (mixture): 3

National regulatory information

Employment restrictions:	Observe restrictions to employment for juveniles according to the 'juvenile work protection guideline' (94/33/EC).
Water hazard class (D):	1 - slightly hazardous to water

15.2. Chemical safety assessment

For this substance a chemical safety assessment has been carried out.

SECTION 16: Other information

Changes

Rev. 1,00; Initial release: 01,07.2021, replaces version: 04. 11.2019
Rev. 2,0; Revision: 27.05.2026; Changes in section: 1 - 16
Rev. 2,1; Changes in section: 2: 11.06.2026

Abbreviations and acronyms

Met. Corr. 1: Corrosive to metals, hazard category 1
Skin Corr. 1A: Skin corrosion, sub-category 1A
Skin Irrit. 2: Skin irritation, hazard category 2
Eye Dam. 1: Serious eye damage, hazard category 1
Eye Irrit. 2: Eye irritation, hazard category 2
ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
AGW: Arbeitsplatzgrenzwert
CAS: Chemical Abstracts Service
CLP: Classification, Labelling and Packaging of substances and mixtures
DNEL: Derived No Effect Level
d: day(s)
EINECS: European INventory of Existing Commercial chemical Substances
ELINCS: European LIst of Notified Chemical Substances
ECHA: European Chemicals Agency
EWC: European Waste Catalogue

IARC: INTERNATIONAL AGENCY FOR RESEARCH ON CANCER
IMDG: International Maritime Code for Dangerous Goods
IATA: International Air Transport Association
IATA-DGR: Dangerous Goods Regulations by the "International Air Transport Association" (IATA)
ICAO: International Civil Aviation Organization
ICAO-TI: Technical Instructions by the "International Civil Aviation Organization" (ICAO)
GHS: Globally Harmonized System of Classification and Labelling of Chemicals
GefStoffV: Gefahrstoffverordnung (Ordinance on Hazardous Substances, Germany)
h: hour
LOAEL: Lowest observed adverse effect level
LOAEC: Lowest observed adverse effect concentration
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
NOAEL: No observed adverse effect level
NOAEC: No observed adverse effect concentration
NLP: No-Longer Polymers
N/A: not applicable
OECD: Organisation for Economic Co-operation and Development
PNEC: predicted no effect concentration
PBT: Persistent bioaccumulative toxic
RID: Regulation Concerning the International Transport of Dangerous Goods by Rail
REACH: Registration, Evaluation, Authorisation of Chemicals
SVHC: substance of very high concern
TRGS: Technische Regeln für Gefahrstoffe
UN: United Nations
VOC: Volatile Organic Compounds
WGK: Water Hazard Class (Germany)

Classification for mixtures and used evaluation method according to Regulation (EC) No 1272/2008 [CLP]

Classification	Classification procedure
Skin Irrit. 2; H315	Calculation method
Eye Irrit. 2; H319	Calculation method

Relevant H and EUH statements (number and full text)

H290	May be corrosive to metals.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.

Further Information

The above information describes exclusively the safety requirements of the product and is based on our present-day knowledge. The information is intended to give you advice about the safe handling of the product named in this safety data sheet, for storage, processing, transport and disposal. The information cannot be transferred to other products. In the case of mixing the product with other products or in the case of processing, the information on this safety data sheet is not necessarily valid for the new made-up material.

(The data for the relevant ingredients were taken respectively from the last version of the sub-contractor's safety data sheet.)

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

1.1. Product identifier

HYB (GenoType, ThromboType, micro-IDent)

Further trade names

Article No.: 004-005-12 (12 ml)
Article No.: 004-005-96 (96 ml)

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

Use of the substance/mixture

Scientific research and development, in vitro diagnostic medical devices

Uses advised against

Any non-intended use.

1.3. Details of the supplier of the safety data sheet

Company name:	Hain Lifescience GmbH	
Street:	Hardwiesenstrasse 1	
Place:	D-72147 Nehren	
Telephone:	+49 (0) 74 73- 94 51- 0	Telefax: +49 (0) 74 73- 94 51- 31
Responsible Department:	msds.mdx.de@bruker.com	

1.4. Emergency telephone number:

Only from Malta: 112

Further Information

The product falls under the regulation (EU) 2017/746 on in-vitro diagnostics.

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Regulation (EC) No 1272/2008

Eye Irrit. 2; H319

Full text of hazard statements: see SECTION 16.

2.2. Label elements

Regulation (EC) No 1272/2008

Signal word: Warning

Pictograms:

Hazard statements

H319	Causes serious eye irritation.

Precautionary statements

P264	Wash hands and face thoroughly after handling.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P337+P313	If eye irritation persists: Get medical advice/attention.

Additional advice on labelling

Labelling according to national medical devices regulations.

2.3. Other hazards

The substances in the mixture (>0,1%) do not meet the PBT/vPvB criteria according to REACH, annex XIII. This product does not contain a substance (> 0,1%) that has endocrine disrupting properties with respect to humans as no components meets the criteria. This product does not contain a substance (> 0,1 %) that has endocrine disrupting properties with respect to non-target organisms as no components meets the criteria.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Relevant ingredients

CAS No	Chemical name			Quantity
	EC No	Index No	REACH No	
	Classification (Regulation (EC) No 1272/2008)			
68891-38-3	Alcohols, C12-14(even numbered), ethoxylated < 2.5 EO, sulfates, sodium salts			7 - < 10 %
	500-234-8		01-2119488639-16	
	Skin Irrit. 2, Eye Dam. 1; H315 H318			
26628-22-8	sodium azide			< 0.1 %
	247-852-1	011-004-00-7		
	Acute Tox. 2, Aquatic Acute 1, Aquatic Chronic 1; H300 H400 H410 EUH032			

Full text of H and EUH statements: see section 16.

Specific Conc. Limits, M-factors and ATE

CAS No	EC No	Chemical name	Quantity
	Specific Conc. Limits, M-factors and ATE		
68891-38-3	500-234-8	Alcohols, C12-14(even numbered), ethoxylated < 2.5 EO, sulfates, sodium salts	7 - < 10 %
	dermal: LD50 = > 2000 mg/kg; oral: LD50 = > 2000 mg/kg Eye Dam. 1; H318: >= 10 - 100 Eye Irrit. 2; H319: >= 5 - < 10		
26628-22-8	247-852-1	sodium azide	< 0.1 %
	oral: ATE = 5 mg/kg		

Further Information

Product does not contain listed SVHC substances > 0,1 % according to Regulation (EC) No. 1907/2006 Article 59 (REACH)

SECTION 4: First aid measures

4.1. Description of first aid measures

General information

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

After inhalation

In case of accident by inhalation: remove casualty to fresh air and keep at rest. In case of respiratory tract irritation, consult a physician.

After contact with skin

Gently wash with plenty of soap and water. In case of skin irritation, seek medical treatment.

After contact with eyes

Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. In case of troubles or persistent symptoms, consult an ophthalmologist.

After ingestion

Rinse mouth thoroughly with water. Let water be drunken in little sips (dilution effect). Do NOT induce vomiting. In all cases of doubt, or when symptoms persist, seek medical advice.

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

See sections 2 and 11

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

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media

Carbon dioxide (CO2). Dry extinguishing powder. Alcohol resistant foam. Water spray

Unsuitable extinguishing media

High power water jet.

5.2. Special hazards arising from the substance or mixture

In case of fire may be liberated: Carbon monoxide. Carbon dioxide (CO2).

5.3. Advice for firefighters

In case of fire: Wear self-contained breathing apparatus.

Additional information

Collect contaminated fire extinguishing water separately. Do not allow entering drains or surface water.
Co-ordinate fire-fighting measures to the fire surroundings.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General advice

Safe handling: see section 7

For non-emergency personnel

Wear personal protection equipment (refer to section 8).

For emergency responders

No special measures are necessary.

6.2. Environmental precautions

Discharge into the environment must be avoided.

6.3. Methods and material for containment and cleaning up

For containment

Absorb with liquid-binding material (e.g. sand, diatomaceous earth, acid- or universal binding agents).
Treat the recovered material as prescribed in the section on waste disposal .

For cleaning up

Clean contaminated objects and areas thoroughly observing environmental regulations.

6.4. Reference to other sections

Safe handling: see section 7
Personal protection equipment: see section 8
Disposal: see section 13

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Advice on safe handling

Wear suitable protective clothing. See section 8.

Advice on protection against fire and explosion

Usual measures for fire prevention.

Advice on general occupational hygiene

Always close containers tightly after the removal of product. When using do not eat, drink or smoke. Wash

hands before breaks and after work.

Further information on handling

General protection and hygiene measures: See section 8.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

Keep container tightly closed in a cool, well-ventilated place.

Hints on joint storage

Do not store together with: Explosives. Oxidizing solids. Oxidizing liquids. Radioactive substances. Infectious substances. Food and animal feedingstuff.

Further information on storage conditions

Keep the packing dry and well sealed to prevent contamination and absorbtion of humidity.
Recommended storage temperature: 2 - 8°C
Protect against: frost. UV-radiation/sunlight. heat. Humidity

7.3. Specific end use(s)

See section 1.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Occupational exposure limit values

CAS No	Name of agent	ppm	mg/m³	fib/cm³	Category	Origin
26628-22-8	Sodium azide	-	0.1		TWA (8 h)	
		-	0.3		STEL (15 min)	

DNEL/DMEL values

CAS No	Name of agent			
DNEL type		Exposure route	Effect	Value
68891-38-3	Alcohols, C12-14(even numbered), ethoxylated < 2.5 EO, sulfates, sodium salts			
Worker DNEL, long-term		inhalation	systemic	411 mg/m³
Worker DNEL, long-term		dermal	systemic	5830 mg/kg bw/day
Consumer DNEL, long-term		inhalation	systemic	87,1 mg/m³
Consumer DNEL, long-term		dermal	systemic	2500 mg/kg bw/day
Consumer DNEL, long-term		oral	systemic	25 mg/kg bw/day

PNEC values

CAS No	Name of agent	
Environmental compartment		Value
68891-38-3	Alcohols, C12-14(even numbered), ethoxylated < 2.5 EO, sulfates, sodium salts	
Freshwater		0,129 mg/l
Freshwater (intermittent releases)		0,71 mg/l
Marine water		0,013 mg/l
Marine water (intermittent releases)		0,071 mg/l
Freshwater sediment		4,835 mg/kg
Marine sediment		0,483 mg/kg
Microorganisms in sewage treatment plants (STP)		10000 mg/l

Soil	7,5 mg/kg

8.2. Exposure controls

Appropriate engineering controls

Technical measures and the application of suitable work processes have priority over personal protection equipment.

Provide adequate ventilation.

Individual protection measures, such as personal protective equipment

Eye/face protection

Wear safety glasses; chemical goggles (if splashing is possible). EN ISO 16321-1:2022

Hand protection

Wear suitable gloves.
Suitable material:
FKM (fluororubber). - Thickness of glove material: 0,4 mm
Breakthrough time >= 8 h
Butyl rubber. - Thickness of glove material: 0,5 mm
Breakthrough time >= 8 h
CR (polychloroprenes, Chloroprene rubber). - Thickness of glove material: 0,5 mm
Breakthrough time >= 8 h
NBR (Nitrile rubber). - Thickness of glove material: 0,35 mm
Breakthrough time >= 8 h
PVC (Polyvinyl chloride). - Thickness of glove material: 0,5 mm
Breakthrough time >= 8 h
For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves.
The selected protective gloves have to satisfy the specifications of EU Directive EC/ 2016/425 and the standard EN 374 derived from it.
Check leak tightness/impermeability prior to use. In the case of wanting to use the gloves again, clean them before taking off and air them well.

Skin protection

Suitable protective clothing: Lab coat.

Respiratory protection

With correct and proper use, and under normal conditions, breathing protection is not required.
Respiratory protection necessary at:
-Exceeding exposure limit values
-Insufficient ventilation and aerosol or mist formation
Suitable respiratory protection apparatus: particulates filter device (DIN EN 143). Filter type: P1-3
Half-face mask or quarter facepiece: maximum use concentration for substances with exposure limits: P1 filter: up to a max. of 4 times the exposure limit. P2 filter: up to a max. of 10 times the exposure limit. P3 filter: up to a max. of 30 times the expo.
The filter class must be suitable for the maximum contaminant concentration (gas/vapour/aerosol/particulates) that may arise when handling the product. If the concentration is exceeded, self-contained breathing apparatus must be used.

Environmental exposure controls

Do not allow uncontrolled discharge of product into the environment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state:	liquid
Colour:	green
Odour:	characteristic
Odour threshold:	not determined

Melting point/freezing point:	not determined
Boiling point or initial boiling point and boiling range:	not determined
Flammability:	not determined
Lower explosion limits:	not determined
Upper explosion limits:	not determined
Flash point:	not determined
Auto-ignition temperature:	not determined
Decomposition temperature:	not relevant
pH-Value:	7,0 - 7,5
Viscosity / kinematic:	not determined
Water solubility:	not determined

Solubility in other solvents

not determined

Dissolution rate:	not relevant
Partition coefficient n-octanol/water:	not relevant
Dispersion stability:	not relevant
Vapour pressure:	not determined
Density:	1,1 g/cm³
Bulk density:	not relevant
Relative vapour density:	not determined
Particle characteristics:	not relevant

9.2. Other information

Information with regard to physical hazard classes

Explosive properties

none

Sustained combustibility:	No sustained combustibility

Self-ignition temperature

Solid:	not relevant
Gas:	not relevant

Oxidizing properties

none

Other safety characteristics

Evaporation rate:	not determined
Solvent separation test:	not determined
Solvent content:	not determined
Solid content:	not determined
Sublimation point:	not relevant
Softening point:	not relevant
Pour point:	not relevant
Viscosity / dynamic:	< 20 mPa·s
Flow time:	not determined

Further Information

No information available.

SECTION 10: Stability and reactivity

10.1. Reactivity

No information available.

10.2. Chemical stability

The product is chemically stable under recommended conditions of storage, use and temperature.

10.3. Possibility of hazardous reactions

Refer to section 10.5.

10.4. Conditions to avoid

Protect against: UV-radiation/sunlight. heat.

10.5. Incompatible materials

Materials to avoid: Oxidising agent, strong. Reducing agents, strong.

10.6. Hazardous decomposition products

Does not decompose when used for intended uses.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Toxicocinetics, metabolism and distribution

No data available.

Acute toxicity

Based on available data, the classification criteria are not met.

ATEmix calculated

ATE (oral) > 2000 mg/kg; ATE (dermal) > 2000 mg/kg; ATE (inhalation vapour) > 20 mg/l; ATE (inhalation dust/mist) > 5 mg/l

CAS No	Chemical name				
	Exposure route	Dose	Species	Source	Method
68891-38-3	Alcohols, C12-14(even numbered), ethoxylated < 2.5 EO, sulfates, sodium salts				
	oral	LD50 > 2000 mg/kg	Rat	ECHA Dossier	OECD Guideline 401
	dermal	LD50 > 2000 mg/kg	Rat	ECHA Dossier	WoE
26628-22-8	sodium azide				
	oral	ATE 5 mg/kg			

Irritation and corrosivity

Serious eye damage/eye irritation: Causes serious eye irritation.
Skin corrosion/irritation: Based on available data, the classification criteria are not met.

Sensitising effects

Based on available data, the classification criteria are not met.

Carcinogenic/mutagenic/toxic effects for reproduction

Germ cell mutagenicity: Based on available data, the classification criteria are not met.
Carcinogenicity: Based on available data, the classification criteria are not met.
Reproductive toxicity: Based on available data, the classification criteria are not met.

STOT-single exposure

Based on available data, the classification criteria are not met.

STOT-repeated exposure

Based on available data, the classification criteria are not met.

Aspiration hazard

Based on available data, the classification criteria are not met.

Specific effects in experiment on an animal

No data available.

11.2. Information on other hazards

Endocrine disrupting properties

Based on available data, the classification criteria are not met.

This product does not contain a substance (> 0,1%) that has endocrine disrupting properties with respect to humans as no components meets the criteria.

Other information

No data available.

SECTION 12: Ecological information

12.1. Toxicity

Based on available data, the classification criteria are not met.

CAS No	Chemical name						
	Aquatic toxicity	Dose		[h] | [d]	Species	Source	Method
68891-38-3	Alcohols, C12-14(even numbered), ethoxylated < 2.5 EO, sulfates, sodium salts						
	Acute fish toxicity	LC50	7,1 mg/l	96 h	Danio rerio (zebra-fish)	ECHA Dossier	OECD Guideline 203
	Acute algae toxicity	ErC50	27,7 mg/l	72 h	Desmodesmus subspicatus (previous name: Scenedesmu	ECHA Dossier	EU-Guideline 92/69 EWG
	Acute crustacea toxicity	EC50	7,4 mg/l	48 h	Daphnia magna	ECHA Dossier	OECD Guideline 202
	Acute bacteria toxicity	EC50	> 10000 mg/l ( )	0 h	Pseudomonas putida (16h)	ECHA Dossier	DIN 38412 / part 8

12.2. Persistence and degradability

CAS No	Chemical name			
	Method	Value	d	Source
	Evaluation			
68891-38-3	Alcohols, C12-14(even numbered), ethoxylated < 2.5 EO, sulfates, sodium salts			
	OECD 301D / EEC 92/69 annex V, C.4-E	>= 77 %	28	ECHA Dossier
	Readily biodegradable (according to OECD criteria).			

12.3. Bioaccumulative potential

Partition coefficient n-octanol/water

CAS No	Chemical name	Log Pow
68891-38-3	Alcohols, C12-14(even numbered), ethoxylated < 2.5 EO, sulfates, sodium salts	0,3

BCF

CAS No	Chemical name	BCF	Species	Source
68891-38-3	Alcohols, C12-14(even numbered), ethoxylated < 2.5 EO, sulfates, sodium salts	4,7	Cyprinus carpio	ECHA Dossier

12.4. Mobility in soil

No data available.

12.5. Results of PBT and vPvB assessment

Based on available data, the classification criteria are not met.
The aforementioned statement applies to substances contained in the product with a minimum content of 0.1%.

12.6. Endocrine disrupting properties

Based on available data, the classification criteria are not met.
The aforementioned statement applies to substances contained in the product with a minimum content of 0.1%.

12.7. Other adverse effects

No data available.

Further information

Do not allow to enter into surface water or drains.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Disposal recommendations

Observe in addition any national regulations! Consult the local waste disposal expert about waste disposal.
Non-contaminated packages may be recycled.
According to (EWC) European Waste Catalogue, allocation of waste identity numbers/waste descriptions must be carried out in a specific way for every industry and process.
Control report for waste code/ waste marking according to (EWC) European Waste Catalogue:

List of Wastes Code - residues/unused products

160509 WASTES NOT OTHERWISE SPECIFIED IN THE LIST; gases in pressure containers and discarded chemicals; discarded chemicals other than those mentioned in 16 05 06, 16 05 07 or 16 05 08

List of Wastes Code - used product

160509 WASTES NOT OTHERWISE SPECIFIED IN THE LIST; gases in pressure containers and discarded chemicals; discarded chemicals other than those mentioned in 16 05 06, 16 05 07 or 16 05 08

List of Wastes Code - contaminated packaging

150110 WASTE PACKAGING; ABSORBENTS, WIPING CLOTHS, FILTER MATERIALS AND PROTECTIVE CLOTHING NOT OTHERWISE SPECIFIED; packaging (including separately collected municipal packaging waste); packaging containing residues of or contaminated by hazardous substances; hazardous waste

Contaminated packaging

Contaminated packages must be completely emptied and can be re-used following proper cleaning.

SECTION 14: Transport information

Land transport (ADR/RID)

14.1. UN number or ID number:	No dangerous good in sense of this transport regulation.
14.2. UN proper shipping name:	No dangerous good in sense of this transport regulation.
14.3. Transport hazard class(es):	No dangerous good in sense of this transport regulation.
14.4. Packing group:	No dangerous good in sense of this transport regulation.

Inland waterways transport (ADN)

14.1. UN number or ID number:	No dangerous good in sense of this transport regulation.
14.2. UN proper shipping name:	No dangerous good in sense of this transport regulation.
14.3. Transport hazard class(es):	No dangerous good in sense of this transport regulation.
14.4. Packing group:	No dangerous good in sense of this transport regulation.

Marine transport (IMDG)

14.1. UN number or ID number:	No dangerous good in sense of this transport regulation.
14.2. UN proper shipping name:	No dangerous good in sense of this transport regulation.

14.3. Transport hazard class(es):	No dangerous good in sense of this transport regulation.
14.4. Packing group:	No dangerous good in sense of this transport regulation.
Marine pollutant:	NO

Air transport (ICAO-TI/IATA-DGR)

14.1. UN number or ID number:	No dangerous good in sense of this transport regulation.
14.2. UN proper shipping name:	No dangerous good in sense of this transport regulation.
14.3. Transport hazard class(es):	No dangerous good in sense of this transport regulation.
14.4. Packing group:	No dangerous good in sense of this transport regulation.

14.5. Environmental hazards

ENVIRONMENTALLY HAZARDOUS: No

14.6. Special precautions for user

refer to section 6 - 8

14.7. Maritime transport in bulk according to IMO instruments

not relevant

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

EU regulatory information

Restrictions on use (REACH, annex XVII):

Entry 3

Directive 2010/75/EU on industrial emissions:	not determined
Directive 2004/42/EC on VOC in paints and varnishes:	not determined
Information according to Directive 2012/18/EU (SEVESO III):	Not subject to 2012/18/EU (SEVESO III)

Additional information

Safety Data Sheet according to Regulation (EC) No. 1907/2006 (amended by Regulation (EU) No 2020/878)
The mixture is classified as hazardous according to regulation (EC) No 1272/2008 [CLP].
REACH 1907/2006 Appendix XVII, No (mixture): 3

National regulatory information

Employment restrictions:	Observe restrictions to employment for juveniles according to the 'juvenile work protection guideline' (94/33/EC).
Water hazard class (D):	1 - slightly hazardous to water

15.2. Chemical safety assessment

For the following substances of this mixture a chemical safety assessment has been carried out:
Alcohols, C12-14(even numbered), ethoxylated < 2.5 EO, sulfates, sodium salts

SECTION 16: Other information

Changes

Rev. 1,0; Initial release: 02.07.2021, replaces version: 15.06.2021
Rev. 2,0; Revision: 22.05.2026; Changes in section: 1 - 16

Abbreviations and acronyms

Acute Tox. 2: Acute toxicity, hazard category 2
Skin Irrit. 2: Skin irritation, hazard category 2
Eye Dam. 1: Serious eye damage, hazard category 1
Eye Irrit. 2: Eye irritation, hazard category 2
Aquatic Acute 1: Hazardous to the aquatic environment, hazard category: Acute 1
Aquatic Chronic 1: Hazardous to the aquatic environment, long-term hazard category: Chronic 1

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
AGW: Arbeitsplatzgrenzwert
CAS: Chemical Abstracts Service
CLP: Classification, Labelling and Packaging of substances and mixtures
DNEL: Derived No Effect Level
d: day(s)
EINECS: European INventory of Existing Commercial chemical Substances
ELINCS: European LIst of Notified Chemical Substances
ECHA: European Chemicals Agency
EWC: European Waste Catalogue
IARC: INTERNATIONAL AGENCY FOR RESEARCH ON CANCER
IMDG: International Maritime Code for Dangerous Goods
IATA: International Air Transport Association
IATA-DGR: Dangerous Goods Regulations by the "International Air Transport Association" (IATA)
ICAO: International Civil Aviation Organization
ICAO-TI: Technical Instructions by the "International Civil Aviation Organization" (ICAO)
GHS: Globally Harmonized System of Classification and Labelling of Chemicals
GefStoffV: Gefahrstoffverordnung (Ordinance on Hazardous Substances, Germany)
h: hour
LOAEL: Lowest observed adverse effect level
LOAEC: Lowest observed adverse effect concentration
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
NOAEL: No observed adverse effect level
NOAEC: No observed adverse effect concentration
NLP: No-Longer Polymers
N/A: not applicable
OECD: Organisation for Economic Co-operation and Development
PNEC: predicted no effect concentration
PBT: Persistent bioaccumulative toxic
RID: Regulation Concerning the International Transport of Dangerous Goods by Rail
REACH: Registration, Evaluation, Authorisation of Chemicals
SVHC: substance of very high concern
TRGS: Technische Regeln für Gefahrstoffe
UN: United Nations
VOC: Volatile Organic Compounds
WGK: Water Hazard Class (Germany)

Classification for mixtures and used evaluation method according to Regulation (EC) No 1272/2008 [CLP]

Classification	Classification procedure
Eye Irrit. 2; H319	Calculation method

Relevant H and EUH statements (number and full text)

H300	Fatal if swallowed.
H315	Causes skin irritation.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
EUH032	Contact with acids liberates very toxic gas.

Further Information

The above information describes exclusively the safety requirements of the product and is based on our present-day knowledge. The information is intended to give you advice about the safe handling of the product named in this safety data sheet, for storage, processing, transport and disposal. The information cannot be transferred to other products. In the case of mixing the product with other products or in the case of

processing, the information on this safety data sheet is not necessarily valid for the new made-up material.

(The data for the relevant ingredients were taken respectively from the last version of the sub-contractor's safety data sheet.)

Safety Data Sheet

according to Regulation (EC) No 1907/2006

SUB-C (GenoType, ThromboType, micro-IDent)

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

1.1. Product identifier

SUB-C (GenoType, ThromboType, micro-IDent)

Further trade names

Article No.: 003-002-12 (120 µl)
Article No.: 003-002-96 (960 µl)

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

Use of the substance/mixture

Scientific research and development, in vitro diagnostic medical devices

Uses advised against

Any non-intended use.

1.3. Details of the supplier of the safety data sheet

Company name:	Hain Lifescience GmbH	
Street:	Hardwiesenstrasse 1	
Place:	D-72147 Nehren	
Telephone:	+49 (0) 74 73- 94 51- 0	Telefax: +49 (0) 74 73- 94 51- 31
Responsible Department:	msds.mdx.de@bruker.com	

1.4. Emergency telephone number:

Only from Malta: 112

Further Information

The product falls under the regulation (EU) 2017/746 on in-vitro diagnostics.

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Regulation (EC) No 1272/2008

Skin Irrit. 2; H315
Eye Irrit. 2; H319

Full text of hazard statements: see SECTION 16.

2.2. Label elements

Regulation (EC) No 1272/2008

Signal word: Warning

Pictograms:

Hazard statements

H315	Causes skin irritation.
H319	Causes serious eye irritation.

Precautionary statements

P264	Wash hands thoroughly after handling.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P302+P352	IF ON SKIN: Wash with plenty of water and soap.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P332+P313	If skin irritation occurs: Get medical advice/attention.
P337+P313	If eye irritation persists: Get medical advice/attention.

Additional advice on labelling

Labelling according to national medical devices regulations.

2.3. Other hazards

The substances in the mixture (>0,1%) do not meet the PBT/vPvB criteria according to REACH, annex XIII. This product does not contain a substance (> 0,1%) that has endocrine disrupting properties with respect to humans as no components meets the criteria. This product does not contain a substance (> 0,1 %) that has endocrine disrupting properties with respect to non-target organisms as no components meets the criteria.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Relevant ingredients

CAS No	Chemical name			Quantity
	EC No	Index No	REACH No	
	Classification (Regulation (EC) No 1272/2008)			
6578-06-9	5-Bromo-4-chloro-3-indolyl hydrogen phosphate-p-toluidine			< 10 %
	229-506-1			
	Acute Tox. 4, Skin Irrit. 2, Eye Irrit. 2, STOT SE 2, STOT SE 3; H302 H315 H319 H371 H335			
298-83-9	4-nitro blue tetrazolium chloride (NBT)			< 10 %
	206-067-4			
	Acute Tox. 4, Skin Irrit. 2, Eye Irrit. 2, STOT SE 3; H302 H315 H319 H335			

Full text of H and EUH statements: see section 16.

Specific Conc. Limits, M-factors and ATE

CAS No	EC No	Chemical name	Quantity
	Specific Conc. Limits, M-factors and ATE		
6578-06-9	229-506-1	5-Bromo-4-chloro-3-indolyl hydrogen phosphate-p-toluidine	< 10 %
	oral: ATE = 500 mg/kg		
298-83-9	206-067-4	4-nitro blue tetrazolium chloride (NBT)	< 10 %
	oral: ATE = 500 mg/kg		

Further Information

Product does not contain listed SVHC substances > 0,1 % according to Regulation (EC) No. 1907/2006 Article 59 (REACH)

SECTION 4: First aid measures

4.1. Description of first aid measures

General information

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

After inhalation

In case of accident by inhalation: remove casualty to fresh air and keep at rest. In case of respiratory tract irritation, consult a physician.

After contact with skin

Gently wash with plenty of soap and water. In case of skin irritation, seek medical treatment.

After contact with eyes

Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. In case of troubles or persistent symptoms, consult an ophthalmologist.

After ingestion

Rinse mouth thoroughly with water. Let water be drunken in little sips (dilution effect). Do NOT induce vomiting.

In all cases of doubt, or when symptoms persist, seek medical advice.

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

See sections 2 and 11

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

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media

Carbon dioxide (CO2). Dry extinguishing powder. Alcohol resistant foam. Water spray

Unsuitable extinguishing media

High power water jet.

5.2. Special hazards arising from the substance or mixture

In case of fire may be liberated: Carbon monoxide. Carbon dioxide (CO2).

5.3. Advice for firefighters

In case of fire: Wear self-contained breathing apparatus.

Additional information

Collect contaminated fire extinguishing water separately. Do not allow entering drains or surface water.
Co-ordinate fire-fighting measures to the fire surroundings.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General advice

Safe handling: see section 7

For non-emergency personnel

Wear personal protection equipment (refer to section 8).

For emergency responders

No special measures are necessary.

6.2. Environmental precautions

Discharge into the environment must be avoided.

6.3. Methods and material for containment and cleaning up

For containment

Absorb with liquid-binding material (e.g. sand, diatomaceous earth, acid- or universal binding agents).
Treat the recovered material as prescribed in the section on waste disposal .

For cleaning up

Clean contaminated objects and areas thoroughly observing environmental regulations.

6.4. Reference to other sections

Safe handling: see section 7
Personal protection equipment: see section 8
Disposal: see section 13

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Advice on safe handling

Wear suitable protective clothing. See section 8.

Advice on protection against fire and explosion

Usual measures for fire prevention.

Advice on general occupational hygiene

Always close containers tightly after the removal of product. When using do not eat, drink or smoke. Wash hands before breaks and after work.

Further information on handling

General protection and hygiene measures: See section 8.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels

Keep container tightly closed in a cool, well-ventilated place.

Hints on joint storage

Do not store together with: Explosives. Oxidizing solids. Oxidizing liquids. Radioactive substances. Infectious substances. Food and animal feedingstuff.

Further information on storage conditions

Keep the packing dry and well sealed to prevent contamination and absorbtion of humidity.
Recommended storage temperature: 2 - 8°C
Protect against: frost. UV-radiation/sunlight. heat. Humidity

7.3. Specific end use(s)

See section 1.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Additional advice on limit values

To date, no national critical limit values exist.

8.2. Exposure controls

Appropriate engineering controls

Technical measures and the application of suitable work processes have priority over personal protection equipment.
Provide adequate ventilation.

Individual protection measures, such as personal protective equipment

Eye/face protection

Wear safety glasses; chemical goggles (if splashing is possible). EN ISO 16321-1:2022

Hand protection

Wear suitable gloves.
Suitable material:
FKM (fluororubber). - Thickness of glove material: 0,4 mm
Breakthrough time >= 8 h
Butyl rubber. - Thickness of glove material: 0,5 mm
Breakthrough time >= 8 h
CR (polychloroprenes, Chloroprene rubber). - Thickness of glove material: 0,5 mm
Breakthrough time >= 8 h
NBR (Nitrile rubber). - Thickness of glove material: 0,35 mm
Breakthrough time >= 8 h
PVC (Polyvinyl chloride). - Thickness of glove material: 0,5 mm
Breakthrough time >= 8 h
For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves.

The selected protective gloves have to satisfy the specifications of EU Directive EC/ 2016/425 and the standard EN 374 derived from it.
Check leak tightness/impermeability prior to use. In the case of wanting to use the gloves again, clean them before taking off and air them well.

Skin protection

Suitable protective clothing: Lab coat.

Respiratory protection

With correct and proper use, and under normal conditions, breathing protection is not required.
Respiratory protection necessary at:
-Exceeding exposure limit values
-Insufficient ventilation and aerosol or mist formation
Suitable respiratory protection apparatus: particulates filter device (DIN EN 143). Filter type: P1-3
Half-face mask or quarter facepiece: maximum use concentration for substances with exposure limits: P1 filter: up to a max. of 4 times the exposure limit. P2 filter: up to a max. of 10 times the exposure limit. P3 filter: up to a max. of 30 times the expo.
The filter class must be suitable for the maximum contaminant concentration (gas/vapour/aerosol/particulates) that may arise when handling the product. If the concentration is exceeded, self-contained breathing apparatus must be used.

Environmental exposure controls

Do not allow uncontrolled discharge of product into the environment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state:	liquid	
Colour:	yellow	
Odour:	characteristic	
Odour threshold:	not determined	
Melting point/freezing point:		not determined
Boiling point or initial boiling point and boiling range:		not determined
Flammability:		not determined
Lower explosion limits:		not determined
Upper explosion limits:		not determined
Flash point:		not determined
Auto-ignition temperature:		not determined
Decomposition temperature:		not relevant
pH-Value:		9,2 - 9,4
Viscosity / kinematic:		not determined
Water solubility:		not determined
Solubility in other solvents		
not determined		
Dissolution rate:		not relevant
Partition coefficient n-octanol/water:		not relevant
Dispersion stability:		not relevant
Vapour pressure:		not determined
Density:		1,1 g/cm³
Bulk density:		not relevant
Relative vapour density:		not determined
Particle characteristics:		not relevant

9.2. Other information

Information with regard to physical hazard classes

Explosive properties
none
Sustained combustibility: No sustained combustibility
Self-ignition temperature
Solid: not relevant
Gas: not relevant
Oxidizing properties
none

Other safety characteristics

Evaporation rate: not determined
Solvent separation test: not determined
Solvent content: not determined
Solid content: not determined
Sublimation point: not relevant
Softening point: not relevant
Pour point: not relevant
Viscosity / dynamic: not determined
Flow time: not determined

Further Information

No information available.

SECTION 10: Stability and reactivity

10.1. Reactivity

No information available.

10.2. Chemical stability

The product is chemically stable under recommended conditions of storage, use and temperature.

10.3. Possibility of hazardous reactions

Refer to section 10.5.

10.4. Conditions to avoid

Protect against: UV-radiation/sunlight. heat.

10.5. Incompatible materials

Materials to avoid: Oxidising agent, strong. Reducing agents, strong.

10.6. Hazardous decomposition products

Does not decompose when used for intended uses.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Toxicocinetics, metabolism and distribution

No data available.

Acute toxicity

Based on available data, the classification criteria are not met.

ATEmix calculated

ATE (oral) > 2000 mg/kg; ATE (dermal) > 2000 mg/kg; ATE (inhalation vapour) > 20 mg/l; ATE (inhalation dust/mist) > 5 mg/l

CAS No	Chemical name				
	Exposure route	Dose	Species	Source	Method
6578-06-9	5-Bromo-4-chloro-3-indolyl hydrogen phosphate-p-toluidine				

	oral	ATE 500 mg/kg			
298-83-9	4-nitro blue tetrazolium chloride (NBT)				
	oral	ATE 500 mg/kg			

Irritation and corrosivity

Skin corrosion/irritation: Causes skin irritation.
Serious eye damage/eye irritation: Causes serious eye irritation.

Sensitising effects

Based on available data, the classification criteria are not met.

Carcinogenic/mutagenic/toxic effects for reproduction

Germ cell mutagenicity: Based on available data, the classification criteria are not met.
Carcinogenicity: Based on available data, the classification criteria are not met.
Reproductive toxicity: Based on available data, the classification criteria are not met.

STOT-single exposure

Based on available data, the classification criteria are not met.

STOT-repeated exposure

Based on available data, the classification criteria are not met.

Aspiration hazard

Based on available data, the classification criteria are not met.

Specific effects in experiment on an animal

No data available.

11.2. Information on other hazards

Endocrine disrupting properties

Based on available data, the classification criteria are not met.
This product does not contain a substance (> 0,1%) that has endocrine disrupting properties with respect to humans as no components meets the criteria.

Other information

No data available.

SECTION 12: Ecological information

12.1. Toxicity

Based on available data, the classification criteria are not met.

12.2. Persistence and degradability

The product has not been tested.

12.3. Bioaccumulative potential

The product has not been tested.

12.4. Mobility in soil

No data available.

12.5. Results of PBT and vPvB assessment

Based on available data, the classification criteria are not met.
The aforementioned statement applies to substances contained in the product with a minimum content of 0.1%.

12.6. Endocrine disrupting properties

Based on available data, the classification criteria are not met.
The aforementioned statement applies to substances contained in the product with a minimum content of 0.1%.

12.7. Other adverse effects

No data available.

Further information

Do not allow to enter into surface water or drains.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Disposal recommendations

Observe in addition any national regulations! Consult the local waste disposal expert about waste disposal.
Non-contaminated packages may be recycled.
According to (EWC) European Waste Catalogue, allocation of waste identity numbers/waste descriptions must be carried out in a specific way for every industry and process.
Control report for waste code/ waste marking according to (EWC) European Waste Catalogue:

List of Wastes Code - residues/unused products

160509 WASTES NOT OTHERWISE SPECIFIED IN THE LIST; gases in pressure containers and discarded chemicals; discarded chemicals other than those mentioned in 16 05 06, 16 05 07 or 16 05 08

List of Wastes Code - used product

160509 WASTES NOT OTHERWISE SPECIFIED IN THE LIST; gases in pressure containers and discarded chemicals; discarded chemicals other than those mentioned in 16 05 06, 16 05 07 or 16 05 08

List of Wastes Code - contaminated packaging

150106 WASTE PACKAGING; ABSORBENTS, WIPING CLOTHS, FILTER MATERIALS AND PROTECTIVE CLOTHING NOT OTHERWISE SPECIFIED; packaging (including separately collected municipal packaging waste); mixed packaging

Contaminated packaging

Contaminated packages must be completely emptied and can be re-used following proper cleaning.

SECTION 14: Transport information

Land transport (ADR/RID)

14.1. UN number or ID number:	No dangerous good in sense of this transport regulation.
14.2. UN proper shipping name:	No dangerous good in sense of this transport regulation.
14.3. Transport hazard class(es):	No dangerous good in sense of this transport regulation.
14.4. Packing group:	No dangerous good in sense of this transport regulation.

Inland waterways transport (ADN)

14.1. UN number or ID number:	No dangerous good in sense of this transport regulation.
14.2. UN proper shipping name:	No dangerous good in sense of this transport regulation.
14.3. Transport hazard class(es):	No dangerous good in sense of this transport regulation.
14.4. Packing group:	No dangerous good in sense of this transport regulation.

Marine transport (IMDG)

14.1. UN number or ID number:	No dangerous good in sense of this transport regulation.
14.2. UN proper shipping name:	No dangerous good in sense of this transport regulation.
14.3. Transport hazard class(es):	No dangerous good in sense of this transport regulation.
14.4. Packing group:	No dangerous good in sense of this transport regulation.
Marine pollutant:	NO

Air transport (ICAO-TI/IATA-DGR)

14.1. UN number or ID number:	No dangerous good in sense of this transport regulation.
14.2. UN proper shipping name:	No dangerous good in sense of this transport regulation.
14.3. Transport hazard class(es):	No dangerous good in sense of this transport regulation.
14.4. Packing group:	No dangerous good in sense of this transport regulation.

14.5. Environmental hazards

ENVIRONMENTALLY HAZARDOUS: No

14.6. Special precautions for user

refer to section 6 - 8

14.7. Maritime transport in bulk according to IMO instruments

not relevant

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

EU regulatory information

Restrictions on use (REACH, annex XVII):

Entry 3, Entry 43, Entry 75

Directive 2010/75/EU on industrial emissions:	not determined
Directive 2004/42/EC on VOC in paints and varnishes:	not determined
Information according to Directive 2012/18/EU (SEVESO III):	Not subject to 2012/18/EU (SEVESO III)

Additional information

Safety Data Sheet according to Regulation (EC) No. 1907/2006 (amended by Regulation (EU) No 2020/878)
The mixture is classified as hazardous according to regulation (EC) No 1272/2008 [CLP].
REACH 1907/2006 Appendix XVII, No (mixture): 3, 43, 75

National regulatory information

Employment restrictions:	Observe restrictions to employment for juveniles according to the 'juvenile work protection guideline' (94/33/EC).
Water hazard class (D):	1 - slightly hazardous to water

15.2. Chemical safety assessment

Chemical safety assessments for substances in this mixture were not carried out.

SECTION 16: Other information

Changes

Rev. 1,0; Initial release: 05.07.2021, replaces version: 15.06.2021
Rev. 2,0; Revision: 27.05.2026; Changes in section: 1 - 16

Abbreviations and acronyms

Acute Tox. 4: Acute toxicity, hazard category 4
Skin Irrit. 2: Skin irritation, hazard category 2
Eye Irrit. 2: Eye irritation, hazard category 2
STOT SE 2: Specific target organ toxicity - single exposure, hazard category 2
STOT SE 3: Specific target organ toxicity - single exposure, hazard category 3
ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
AGW: Arbeitsplatzgrenzwert
CAS: Chemical Abstracts Service
CLP: Classification, Labelling and Packaging of substances and mixtures
DNEL: Derived No Effect Level
d: day(s)
EINECS: European INventory of Existing Commercial chemical Substances
ELINCS: European LIst of Notified Chemical Substances
ECHA: European Chemicals Agency
EWC: European Waste Catalogue
IARC: INTERNATIONAL AGENCY FOR RESEARCH ON CANCER
IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association
IATA-DGR: Dangerous Goods Regulations by the "International Air Transport Association" (IATA)
ICAO: International Civil Aviation Organization
ICAO-TI: Technical Instructions by the "International Civil Aviation Organization" (ICAO)
GHS: Globally Harmonized System of Classification and Labelling of Chemicals
GefStoffV: Gefahrstoffverordnung (Ordinance on Hazardous Substances, Germany)
h: hour
LOAEL: Lowest observed adverse effect level
LOAEC: Lowest observed adverse effect concentration
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
NOAEL: No observed adverse effect level
NOAEC: No observed adverse effect concentration
NLP: No-Longer Polymers
N/A: not applicable
OECD: Organisation for Economic Co-operation and Development
PNEC: predicted no effect concentration
PBT: Persistent bioaccumulative toxic
RID: Regulation Concerning the International Transport of Dangerous Goods by Rail
REACH: Registration, Evaluation, Authorisation of Chemicals
SVHC: substance of very high concern
TRGS: Technische Regeln für Gefahrstoffe
UN: United Nations
VOC: Volatile Organic Compounds
WGK: Water Hazard Class (Germany)

Classification for mixtures and used evaluation method according to Regulation (EC) No 1272/2008 [CLP]

Classification	Classification procedure
Skin Irrit. 2; H315	Calculation method
Eye Irrit. 2; H319	Calculation method

Relevant H and EUH statements (number and full text)

H302	Harmful if swallowed.
H315	Causes skin irritation.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
H371	May cause damage to organs.

Further Information

The above information describes exclusively the safety requirements of the product and is based on our present-day knowledge. The information is intended to give you advice about the safe handling of the product named in this safety data sheet, for storage, processing, transport and disposal. The information cannot be transferred to other products. In the case of mixing the product with other products or in the case of processing, the information on this safety data sheet is not necessarily valid for the new made-up material.

(The data for the relevant ingredients were taken respectively from the last version of the sub-contractor's safety data sheet.)