Reagent Set for DNA•STRIP Kits

2022-05-24

Version A

Safety Data Sheet

according to Regulation (EC) No 1907/2006

HYB (GenoType, ThromboType, micro-IDent)

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,

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:

Poison Information Center Mainz, Germany, Tel: +49(0)6131/19240

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

Hazard categories:
Serious eye damage/eye irritation: Eye Irrit. 2
Hazard Statements:
Causes serious eye irritation.

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 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 do not meet the PBT/vPvB criteria according to REACH, annex XIII.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Hazardous components

CAS No	Chemical name			Quantity
	EC No	Index No	REACH No	
	GHS Classification			
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, Aquatic Chronic 3; H315 H318 H412			

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 = 4100 mg/kg Eye Dam. 1; H318: >= 10 - 100 Eye Irrit. 2; H319: >= 5 - < 10		

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. 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 information available.

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. Atomized water.

Unsuitable extinguishing media

High power water jet.

5.2. Special hazards arising from the substance or mixture

Can be released in case of fire: 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 measures

Safe handling: see section 7

For non-emergency personnel

Personal protection equipment: see 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

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, smoke, sniff. 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	Substance		
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	dermal	systemic	2750 mg/kg bw/day
Worker DNEL, long-term	inhalation	systemic	175 mg/m³
Consumer DNEL, long-term	dermal	systemic	1650 mg/kg bw/day
Consumer DNEL, long-term	inhalation	systemic	52 mg/m³
Consumer DNEL, long-term	oral	systemic	15 mg/kg bw/day

PNEC values

CAS No	Substance
Environmental compartment	Value
68891-38-3	Alcohols, C12-14(even numbered), ethoxylated < 2.5 EO, sulfates, sodium salts
Freshwater	0,24 mg/l
Freshwater (intermittent releases)	0,071 mg/l
Marine water	0,024 mg/l
Freshwater sediment	0,917 mg/kg
Marine sediment	0,092 mg/kg
Micro-organisms in sewage treatment plants (STP)	10000 mg/l
Soil	7,5 mg/kg

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 166

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
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 apron.
Minimum standard for preventive measures while handling with working materials are specified in the TRGS 500 (D).

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 protective equipment: particulates filter device (DIN EN 143). type: P1-3
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

Changes in the physical state

Melting point/freezing point:	not determined
Boiling point or initial boiling point and boiling range:	not determined
Sublimation point:	not determined
Softening point:	not determined
Pour point:	not determined
Flash point:	not determined

Explosive properties

none

Lower explosion limits:	not determined
Upper explosion limits:	not determined

Auto-ignition temperature:	not determined
Self-ignition temperature	
Gas:	not determined
Decomposition temperature:	not determined
Oxidizing properties	
none	
pH-Value:	7,0 - 7,5
Viscosity / dynamic:	< 20 mPa·s
Viscosity / kinematic:	not determined
Flow time:	not determined
Water solubility:	not determined
Solubility in other solvents	
not determined	
Partition coefficient n-octanol/water:	not determined
Vapour pressure:	not determined
Density:	1,1 g/cm³
Relative vapour density:	not determined

9.2. Other information

Sustaining combustion:	Not sustaining combustion
Solvent separation test:	not determined
Solvent content:	not determined
Solid content:	not determined
Evaporation rate:	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 chapter 10.5.

10.4. Conditions to avoid

Protect against: UV-radiation/sunlight. heat.

10.5. Incompatible materials

Materials to avoid: Oxidizing agents, strong. Reducing agents, strong.

10.6. Hazardous decomposition products

Does not decompose when used for intended uses.
Can be released in case of fire: Carbon monoxide. Carbon dioxide (CO2).

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.

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 4100 mg/kg	Rat	ECHA Dossier	OECD Guideline 401
	dermal	LD50 >= 2000 mg/kg	Rat	ECHA Dossier	OECD Guideline 402

Irritation and corrosivity

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

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

No data available.

SECTION 12: Ecological information

12.1. Toxicity

The product has not been tested.

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	ECHA Dossier	EG Guideline 92/69 C.1
	Acute algae toxicity	ErC50 27,7 mg/l	72 h	Desmodesmus subspicatus	ECHA Dossier	EU-Guideline 92/69 EWG
	Acute crustacea toxicity	EC50 7,4 mg/l	48 h	Daphnia magna	ECHA Dossier	EG Guideline 92/69/EWG
	Fish toxicity	NOEC 0,2 mg/l	28 d	Oncorhynchus mykiss	ECHA Dossier	OECD Guideline 204
	Crustacea toxicity	NOEC 0,27 mg/l	21 d	Daphnia magna	ECHA Dossier	OECD Guideline 211
	Acute bacteria toxicity	(>1000 mg/l)		Pseudomonas putida	ECHA Dossier	DIN 38412 T.8

12.2. Persistence and degradability

The product has not been tested.

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 301B/ ISO 9439/ EEC 92/69/V, C.4-C	100%	28	ECHA Dossier
	Readily biodegradable (according to OECD criteria).			

12.3. Bioaccumulative potential

No indication of bioaccumulation 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

12.4. Mobility in soil

No data available.

12.5. Results of PBT and vPvB assessment

The substances in the mixture do not meet the PBT/vPvB criteria according to REACH, annex XIII.

12.6. Endocrine disrupting properties

No data available.

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

Handle contaminated packages in the same way as the substance itself.

SECTION 14: Transport information

Land transport (ADR/RID)

14.1. UN 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:	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:	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:	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 chapter 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

2010/75/EU (VOC):	No information available.
2004/42/EC (VOC):	No information available.
Information according to 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

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

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

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)

H315 Causes skin irritation.
H318 Causes serious eye damage.

H319	Causes serious eye irritation.
H412	Harmful to aquatic life with long lasting effects.

Further Information

Classification according to Regulation (EC) No 1272/2008 [CLP] - Classification procedure:
Health hazards: Calculation method.
Environmental hazards: Calculation method.
Physical hazards: On basis of test data and / or calculated and / or estimated.

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 hazardous 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

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,

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:

Poison Information Center Mainz, Germany, Tel: +49(0)6131/19240

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

Special labelling of certain mixtures

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 do not meet the PBT/vPvB criteria according to REACH, annex XIII.
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

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. 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 information available.

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. Atomized water.

Unsuitable extinguishing media

High power water jet.

5.2. Special hazards arising from the substance or mixture

Can be released in case of fire: 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 measures

Safe handling: see section 7

For non-emergency personnel

Personal protection equipment: see 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

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, smoke, sniff. 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 166

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 apron.
Minimum standard for preventive measures while handling with working materials are specified in the TRGS 500 (D).

Respiratory protection

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

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

Changes in the physical state

Melting point/freezing point:	not determined
Boiling point or initial boiling point and boiling range:	not determined
Sublimation point:	not determined
Softening point:	not determined
Pour point:	not determined
Flash point:	not determined

Explosive properties

none

Lower explosion limits:	not determined
Upper explosion limits:	not determined
Auto-ignition temperature:	not determined

Self-ignition temperature

Gas:	not determined
Decomposition temperature:	not determined

Oxidizing properties

none

pH-Value:	not determined
Viscosity / dynamic:	not determined
Viscosity / kinematic:	not determined
Flow time:	not determined
Water solubility:	not determined

Solubility in other solvents

not determined

Partition coefficient n-octanol/water:	not determined
Vapour pressure:	not determined
Density:	not determined
Relative vapour density:	not determined

9.2. Other information

Sustaining combustion:	Not sustaining combustion
Solvent separation test:	not determined
Solvent content:	not determined
Solid content:	not determined
Evaporation rate:	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 chapter 10.5.

10.4. Conditions to avoid

Protect against: UV-radiation/sunlight. heat.

10.5. Incompatible materials

Materials to avoid: Oxidizing agents, strong. Reducing agents, strong.

10.6. Hazardous decomposition products

Does not decompose when used for intended uses.
Can be released in case of fire: Carbon monoxide. Carbon dioxide (CO2).

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.

Irritation and corrosivity

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

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

No data available.

SECTION 12: Ecological information

12.1. Toxicity

The product has not been tested.

12.2. Persistence and degradability

The product has not been tested.

12.3. Bioaccumulative potential

No indication of bioaccumulation potential.

12.4. Mobility in soil

No data available.

12.5. Results of PBT and vPvB assessment

The substances in the mixture do not meet the PBT/vPvB criteria according to REACH, annex XIII.

12.6. Endocrine disrupting properties

No data available.

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

Handle contaminated packages in the same way as the substance itself.

SECTION 14: Transport information

Land transport (ADR/RID)

14.1. UN 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:	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:	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.

Air transport (ICAO-TI/IATA-DGR)

14.1. UN 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.

14.5. Environmental hazards

ENVIRONMENTALLY HAZARDOUS: No

14.6. Special precautions for user

refer to chapter 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

2010/75/EU (VOC):	No information available.
2004/42/EC (VOC):	No information available.
Information according to 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 not hazardous according to regulation (EC) No 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

For the following substances of this mixture a chemical safety assessment has been carried out:

SECTION 16: Other information

Changes

Rev. 1.0; Initial release: 05.07.2021

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

Relevant H and EUH statements (number and full text)

EUH210 Safety data sheet available on request.

Further Information

Classification according to Regulation (EC) No 1272/2008 [CLP] - Classification procedure:
Health hazards: Calculation method.
Environmental hazards: Calculation method.
Physical hazards: On basis of test data and / or calculated and / or estimated.

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 hazardous 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,

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:

Poison Information Center Mainz, Germany, Tel: +49(0)6131/19240

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

Hazard categories:
Respiratory or skin sensitisation: Skin Sens. 1
Hazard Statements:
May cause an allergic skin reaction.

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 soap and water.
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 do not meet the PBT/vPvB criteria according to REACH, annex XIII.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Hazardous components

CAS No	Chemical name			Quantity
	EC No	Index No	REACH No	
	GHS Classification			
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			

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		

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. 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 information available.

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. Atomized water.

Unsuitable extinguishing media

High power water jet.

5.2. Special hazards arising from the substance or mixture

Can be released in case of fire: 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 measures

Safe handling: see section 7

For non-emergency personnel

Personal protection equipment: see 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

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, smoke, sniff. 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 166

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
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 apron.
Minimum standard for preventive measures while handling with working materials are specified in the TRGS 500 (D).

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 protective equipment: particulates filter device (DIN EN 143). type: P1-3

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

Changes in the physical state

Melting point/freezing point:	not determined
Boiling point or initial boiling point and boiling range:	not determined
Sublimation point:	not determined
Softening point:	not determined
Pour point:	not determined
Flash point:	not determined

Explosive properties

none

Lower explosion limits:	not determined
Upper explosion limits:	not determined
Auto-ignition temperature:	not determined

Self-ignition temperature

Gas:	not determined
Decomposition temperature:	not determined

Oxidizing properties

none

pH-Value:	7,5 - 8,0
Viscosity / dynamic:	not determined
Viscosity / kinematic:	not determined
Flow time:	not determined
Water solubility:	not determined

Solubility in other solvents

not determined

Partition coefficient n-octanol/water:	not determined
Vapour pressure:	not determined
Density:	1,005 g/cm³
Relative vapour density:	not determined

9.2. Other information

Sustaining combustion:	Not sustaining combustion
Solvent separation test:	not determined

Solvent content:	not determined
Solid content:	not determined
Evaporation rate:	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 chapter 10.5.

10.4. Conditions to avoid

Protect against: UV-radiation/sunlight. heat.

10.5. Incompatible materials

Materials to avoid: Oxidizing agents, strong. Reducing agents, strong.

10.6. Hazardous decomposition products

Does not decompose when used for intended uses.
Can be released in case of fire: Carbon monoxide. Carbon dioxide (CO2).

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.

CAS No	Chemical name				
	Exposure route	Dose	Species	Source	Method
371-47-1	Disodium maleate				
	oral	ATE 500 mg/kg			

Irritation and corrosivity

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

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

No data available.

SECTION 12: Ecological information

12.1. Toxicity

The product has not been tested.

12.2. Persistence and degradability

The product has not been tested.

12.3. Bioaccumulative potential

No indication of bioaccumulation potential.

12.4. Mobility in soil

No data available.

12.5. Results of PBT and vPvB assessment

The substances in the mixture do not meet the PBT/vPvB criteria according to REACH, annex XIII.

12.6. Endocrine disrupting properties

No data available.

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

Handle contaminated packages in the same way as the substance itself.

SECTION 14: Transport information

Land transport (ADR/RID)

14.1. UN 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:	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:	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:	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 chapter 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

2010/75/EU (VOC):	No information available.
2004/42/EC (VOC):	No information available.
Information according to 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):	- - non-hazardous to water

15.2. Chemical safety assessment

For the following substances of this mixture a chemical safety assessment has been carried out:

SECTION 16: Other information

Changes

Rev. 1.0; Initial release: 05.07.2021

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

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)

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.

Further Information

Classification according to Regulation (EC) No 1272/2008 [CLP] - Classification procedure:
Health hazards: Calculation method.
Environmental hazards: Calculation method.
Physical hazards: On basis of test data and / or calculated and / or estimated.

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 hazardous 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

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,

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:

Poison Information Center Mainz, Germany, Tel: +49(0)6131/19240

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

Hazard categories:
Skin corrosion/irritation: Skin Irrit. 2
Serious eye damage/eye irritation: Eye Irrit. 2
Hazard Statements:
Causes skin irritation.
Causes serious eye irritation.

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 soap and 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.

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 do not meet the PBT/vPvB criteria according to REACH, annex XIII.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

Hazardous components

CAS No	Chemical name			Quantity
	EC No	Index No	REACH No	
	GHS Classification			
6578-06-9	5-Bromo-4-chloro-3-indolyl hydrogen phosphate-p-toluidine			< 10 %
	229-506-1			
	Skin Irrit. 2, Eye Irrit. 2, STOT SE 3; H315 H319 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		
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. 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 information available.

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. Atomized water.

Unsuitable extinguishing media

High power water jet.

5.2. Special hazards arising from the substance or mixture

Can be released in case of fire: 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 measures

Safe handling: see section 7

For non-emergency personnel

Personal protection equipment: see 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

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, smoke, sniff. 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 166

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
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 apron.
Minimum standard for preventive measures while handling with working materials are specified in the TRGS 500 (D).

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 protective equipment: particulates filter device (DIN EN 143). type: P1-3
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

Changes in the physical state

Melting point/freezing point:	not determined
Boiling point or initial boiling point and boiling range:	not determined
Sublimation point:	not determined
Softening point:	not determined
Pour point:	not determined
Flash point:	not determined

Explosive properties

none

Lower explosion limits:	not determined
Upper explosion limits:	not determined
Auto-ignition temperature:	not determined

Self-ignition temperature

Gas:	not determined
Decomposition temperature:	not determined

Oxidizing properties

none

pH-Value:	9,2 - 9,4
Viscosity / dynamic:	not determined
Viscosity / kinematic:	not determined
Flow time:	not determined
Water solubility:	not determined

Solubility in other solvents

not determined

Partition coefficient n-octanol/water:	not determined
Vapour pressure:	not determined
Density:	1,1 g/cm³
Relative vapour density:	not determined

9.2. Other information

Sustaining combustion:	Not sustaining combustion

Solvent separation test:	not determined
Solvent content:	not determined
Solid content:	not determined
Evaporation rate:	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 chapter 10.5.

10.4. Conditions to avoid

Protect against: UV-radiation/sunlight. heat.

10.5. Incompatible materials

Materials to avoid: Oxidizing agents, strong. Reducing agents, strong.

10.6. Hazardous decomposition products

Does not decompose when used for intended uses.
Can be released in case of fire: Carbon monoxide. Carbon dioxide (CO_2).

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.

CAS No	Chemical name				
	Exposure route	Dose	Species	Source	Method
298-83-9	4-nitro blue tetrazolium chloride (NBT)				
	oral	ATE 500 mg/kg			

Irritation and corrosivity

Causes skin irritation.
Causes serious eye irritation.

Sensitising effects

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

Carcinogenic/mutagenic/toxic effects for reproduction

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

No data available.

SECTION 12: Ecological information

12.1. Toxicity

The product has not been tested.

12.2. Persistence and degradability

The product has not been tested.

12.3. Bioaccumulative potential

No indication of bioaccumulation potential.

12.4. Mobility in soil

No data available.

12.5. Results of PBT and vPvB assessment

The substances in the mixture do not meet the PBT/vPvB criteria according to REACH, annex XIII.

12.6. Endocrine disrupting properties

No data available.

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

Handle contaminated packages in the same way as the substance itself.

SECTION 14: Transport information

Land transport (ADR/RID)

14.1. UN 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:	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:	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:	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 chapter 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

2010/75/EU (VOC):	No information available.
2004/42/EC (VOC):	No information available.
Information according to 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

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:

SECTION 16: Other information

Changes

Rev. 1.0; Initial release: 05.07.2021, replaces version: 15.06.2021

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

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.

Further Information

Classification according to Regulation (EC) No 1272/2008 [CLP] - Classification procedure:
Health hazards: Calculation method.
Environmental hazards: Calculation method.
Physical hazards: On basis of test data and / or calculated and / or estimated.

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 hazardous ingredients were taken respectively from the last version of the sub-contractor's safety data sheet.)