

# Safety data sheet

acc. to Regulation (EC) No. 1907/2006 (REACH)



## ROTI®Cell Trypsin/EDTA solution (10x) CELLPURE® 0.5 % in DPBS, ready-to-use, sterile

article number: **1Y19**  
Version: **1.0 en**

date of compilation: 2022-10-17

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

#### 1.1 Product identifier

Identification of the substance

**ROTI®Cell Trypsin/EDTA solution (10x) CELL-PURE® 0.5 % in DPBS, ready-to-use, sterile**

Article number

1Y19

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

Relevant identified uses:

Laboratory and analytical use  
Laboratory chemical

Uses advised against:

Do not use for products which come into contact with foodstuffs. Do not use for private purposes (household).

#### 1.3 Details of the supplier of the safety data sheet

Carl Roth GmbH + Co KG  
Schoemperlenstr. 3-5  
D-76185 Karlsruhe  
Germany

**Telephone:**+49 (0) 721 - 56 06 0

**Telefax:** +49 (0) 721 - 56 06 149

**e-mail:** [sicherheit@carlroth.de](mailto:sicherheit@carlroth.de)

**Website:** [www.carlroth.de](http://www.carlroth.de)

Competent person responsible for the safety data sheet: :Department Health, Safety and Environment

**e-mail (competent person):**

**[sicherheit@carlroth.de](mailto:sicherheit@carlroth.de)**

#### 1.4 Emergency telephone number

Name	Street	Postal code/city	Telephone	Website
National Poisons Information Service City Hospital	Dudley Rd	B187QH Birmingham	844 892 0111	

### SECTION 2: Hazards identification

#### 2.1 Classification of the substance or mixture

##### Classification acc. to GHS

This mixture does not meet the criteria for classification.

##### Supplemental hazard information

Code	Supplemental hazard information
EUH208	contains Trypsin. May produce an allergic reaction

#### 2.2 Label elements

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### Labelling

**Signal word** Not required

Not required

### Pictograms

### Supplemental hazard information

EUH208 Contains Trypsin. May produce an allergic reaction.

### 2.3 Other hazards

### Results of PBT and vPvB assessment

This mixture does not contain any substances that are assessed to be a PBT or a vPvB.

## SECTION 3: Composition/information on ingredients

### 3.1 Substances

not relevant (mixture)

### 3.2 Mixtures

#### Description of the mixture

Name of substance	Identifier	Wt%	Classification acc. to GHS	Pictograms	Notes
Trypsin	CAS No 9002-07-7  EC No 232-650-8  Index No 647-010-00-7	< 1	Skin Irrit. 2 / H315 Eye Irrit. 2 / H319 Resp. Sens. 1 / H334 STOT SE 3 / H335		GHS-HC
Ethylenediamine tetraacetic acid tetrasodium salt tetrahydrate	CAS No 13235-36-4  EC No 603-569-9	< 1	Acute Tox. 4 / H302 Eye Dam. 1 / H318		GHS-HC

#### Notes

GHS-HC: Harmonised classification (the classification of the substance corresponds to the entry in the list according to 1272/2008/EC, Annex VI)

Name of substance	Identifier	Specific Conc. Limits	M-Factors	ATE	Exposure route
Ethylenediamine tetraacetic acid tetrasodium salt tetrahydrate	CAS No 13235-36-4  EC No 603-569-9	-	-	>1.780 mg/kg	oral

For full text of abbreviations: see SECTION 16

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## SECTION 4: First aid measures

### 4.1 Description of first aid measures



#### General notes

Take off contaminated clothing.

#### Following inhalation

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

#### Following skin contact

Rinse skin with water/shower. In all cases of doubt, or when symptoms persist, seek medical advice.

#### Following eye contact

Rinse cautiously with water for several minutes. In all cases of doubt, or when symptoms persist, seek medical advice.

#### Following ingestion

Rinse mouth. Call a doctor if you feel unwell.

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

Allergic reactions

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

none

## SECTION 5: Firefighting measures

### 5.1 Extinguishing media



#### Suitable extinguishing media

co-ordinate firefighting measures to the fire surroundings  
water spray, dry extinguishing powder, BC-powder, carbon dioxide (CO<sub>2</sub>)

#### Unsuitable extinguishing media

water jet

### 5.2 Special hazards arising from the substance or mixture

Combustible.

#### Hazardous combustion products

In case of fire may be liberated: Nitrogen oxides (NO<sub>x</sub>), May produce toxic fumes of carbon monoxide if burning.

### 5.3 Advice for firefighters

In case of fire and/or explosion do not breathe fumes. Fight fire with normal precautions from a reasonable distance. Wear self-contained breathing apparatus.

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## SECTION 6: Accidental release measures

### 6.1 Personal precautions, protective equipment and emergency procedures



#### For non-emergency personnel

No special measures are necessary.

### 6.2 Environmental precautions

Keep away from drains, surface and ground water.

### 6.3 Methods and material for containment and cleaning up

#### Advice on how to contain a spill

Covering of drains.

#### Advice on how to clean up a spill

Wipe up with absorbent material (e.g. cloth, fleece).

#### Other information relating to spills and releases

Place in appropriate containers for disposal.

### 6.4 Reference to other sections

Hazardous combustion products: see section 5. Personal protective equipment: see section 8. Incompatible materials: see section 10. Disposal considerations: see section 13.

## SECTION 7: Handling and storage

### 7.1 Precautions for safe handling

No special measures are necessary.

#### Advice on general occupational hygiene

Keep away from food, drink and animal feedingstuffs.

### 7.2 Conditions for safe storage, including any incompatibilities

Keep in a cool place.

#### Incompatible substances or mixtures

Observe hints for combined storage.

#### Consideration of other advice:

#### Specific designs for storage rooms or vessels

Recommended storage temperature: -20 °C

### 7.3 Specific end use(s)

No information available.

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### SECTION 8: Exposure controls/personal protection

#### 8.1 Control parameters

##### National limit values

##### Occupational exposure limit values (Workplace Exposure Limits)

This information is not available.

Relevant DNELs of components of the mixture						
Name of substance	CAS No	End-point	Threshold level	Protection goal, route of exposure	Used in	Exposure time
Ethylenediamine tetraacetic acid tetrasodium salt tetrahydrate	13235-36-4	DNEL	1,5 mg/m <sup>3</sup>	human, inhalatory	worker (industry)	chronic - systemic effects
Ethylenediamine tetraacetic acid tetrasodium salt tetrahydrate	13235-36-4	DNEL	3 mg/m <sup>3</sup>	human, inhalatory	worker (industry)	acute - systemic effects
Ethylenediamine tetraacetic acid tetrasodium salt tetrahydrate	13235-36-4	DNEL	1,5 mg/m <sup>3</sup>	human, inhalatory	worker (industry)	chronic - local effects
Ethylenediamine tetraacetic acid tetrasodium salt tetrahydrate	13235-36-4	DNEL	3 mg/m <sup>3</sup>	human, inhalatory	worker (industry)	acute - local effects

Relevant PNECs of components of the mixture						
Name of substance	CAS No	End-point	Threshold level	Organism	Environmental compartment	Exposure time
Trypsin	9002-07-7	PNEC	2,5 µg/l	aquatic organisms	freshwater	short-term (single instance)
Trypsin	9002-07-7	PNEC	0,25 µg/l	aquatic organisms	marine water	short-term (single instance)
Trypsin	9002-07-7	PNEC	65.000 µg/l	aquatic organisms	sewage treatment plant (STP)	short-term (single instance)
Ethylenediamine tetraacetic acid tetrasodium salt tetrahydrate	13235-36-4	PNEC	2,83 mg/l	aquatic organisms	freshwater	short-term (single instance)
Ethylenediamine tetraacetic acid tetrasodium salt tetrahydrate	13235-36-4	PNEC	0,283 mg/l	aquatic organisms	marine water	short-term (single instance)
Ethylenediamine tetraacetic acid tetrasodium salt tetrahydrate	13235-36-4	PNEC	50 mg/l	aquatic organisms	sewage treatment plant (STP)	short-term (single instance)
Ethylenediamine tetraacetic acid tetrasodium salt tetrahydrate	13235-36-4	PNEC	1,1 mg/kg	terrestrial organisms	soil	short-term (single instance)

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### 8.2 Exposure controls

#### Individual protection measures (personal protective equipment)

##### Eye/face protection



Use safety goggle with side protection.

##### Skin protection



- **hand protection**

Wear suitable gloves. Chemical protection gloves are suitable, which are tested according to EN 374. The times are approximate values from measurements at 22 ° C and permanent contact. Increased temperatures due to heated substances, body heat etc. and a reduction of the effective layer thickness by stretching can lead to a considerable reduction of the breakthrough time. If in doubt, contact manufacturer. At an approx. 1.5 times larger / smaller layer thickness, the respective breakthrough time is doubled / halved. The data apply only to the pure substance. When transferred to substance mixtures, they may only be considered as a guide.

- **type of material**

NBR (Nitrile rubber)

- **material thickness**

>0,11 mm

- **breakthrough times of the glove material**

>480 minutes (permeation: level 6)

- **other protection measures**

Take recovery periods for skin regeneration. Preventive skin protection (barrier creams/ointments) is recommended.

##### Respiratory protection



Respiratory protection necessary at: Aerosol or mist formation.

##### Environmental exposure controls

Keep away from drains, surface and ground water.

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### SECTION 9: Physical and chemical properties

#### 9.1 Information on basic physical and chemical properties

Physical state	liquid
Colour	acc. to product description
Odour	odourless
Melting point/freezing point	not determined
Boiling point or initial boiling point and boiling range	not determined
Flammability	this material is combustible, but will not ignite readily
Lower and upper explosion limit	not determined
Flash point	not determined
Auto-ignition temperature	not determined
Decomposition temperature	not relevant
pH (value)	not determined
Kinematic viscosity	not determined
<u>Solubility(ies)</u>	
Water solubility	not determined
<u>Partition coefficient</u>	
Partition coefficient n-octanol/water (log value):	this information is not available
Vapour pressure	not determined
<u>Density and/or relative density</u>	
Density	~ 1 g/cm <sup>3</sup> at 20 °C
Relative vapour density	information on this property is not available
Particle characteristics	not relevant (liquid)
<u>Other safety parameters</u>	
Oxidising properties	none

#### 9.2 Other information

Information with regard to physical hazard classes:	hazard classes acc. to GHS (physical hazards): not relevant
Other safety characteristics:	There is no additional information.

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## SECTION 10: Stability and reactivity

### 10.1 Reactivity

This material is not reactive under normal ambient conditions.

### 10.2 Chemical stability

The material is stable under normal ambient and anticipated storage and handling conditions of temperature and pressure.

### 10.3 Possibility of hazardous reactions

**Violent reaction with:** strong oxidiser

### 10.4 Conditions to avoid

There are no specific conditions known which have to be avoided.

### 10.5 Incompatible materials

There is no additional information.

### 10.6 Hazardous decomposition products

Hazardous combustion products: see section 5.

## SECTION 11: Toxicological information

### 11.1 Information on toxicological effects

Test data are not available for the complete mixture.

#### Classification procedure

The method for classification of the mixture is based on ingredients of the mixture (additivity formula).

#### Classification acc. to GHS

This mixture does not meet the criteria for classification.

#### Acute toxicity

Shall not be classified as acutely toxic.

Acute toxicity estimate (ATE) of components of the mixture			
Name of substance	CAS No	Exposure route	ATE
Ethylenediamine tetraacetic acid tetrasodium salt tetrahydrate	13235-36-4	oral	>1.780 mg/kg

Acute toxicity of components of the mixture					
Name of substance	CAS No	Exposure route	Endpoint	Value	Species
Trypsin	9002-07-7	oral	LD50	>5.000 mg/kg	rat
Ethylenediamine tetraacetic acid tetrasodium salt tetrahydrate	13235-36-4	oral	LD50	>1.780 - <2.000 mg/kg	rat

#### Skin corrosion/irritation

Shall not be classified as corrosive/irritant to skin.



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### **Serious eye damage/eye irritation**

Shall not be classified as seriously damaging to the eye or eye irritant.

### **Respiratory or skin sensitisation**

Contains Trypsin. May produce an allergic reaction.

### **Germ cell mutagenicity**

Shall not be classified as germ cell mutagenic.

### **Carcinogenicity**

Shall not be classified as carcinogenic.

### **Reproductive toxicity**

Shall not be classified as a reproductive toxicant.

### **Specific target organ toxicity - single exposure**

Shall not be classified as a specific target organ toxicant (single exposure).

### **Specific target organ toxicity - repeated exposure**

Shall not be classified as a specific target organ toxicant (repeated exposure).

### **Aspiration hazard**

Shall not be classified as presenting an aspiration hazard.

### **Symptoms related to the physical, chemical and toxicological characteristics**

#### **• If swallowed**

Data are not available.

#### **• If in eyes**

Data are not available.

#### **• If inhaled**

Data are not available.

#### **• If on skin**

May produce an allergic reaction, pruritis, localised redness

#### **• Other information**

none

### **11.2 Endocrine disrupting properties**

None of the ingredients are listed.

### **11.3 Information on other hazards**

There is no additional information.

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## SECTION 12: Ecological information

### 12.1 Toxicity

Shall not be classified as hazardous to the aquatic environment.

Aquatic toxicity (acute) of components of the mixture					
Name of substance	CAS No	Endpoint	Value	Species	Exposure time
Trypsin	9002-07-7	EC50	>24,7 mg/l	aquatic invertebrates	48 h
Trypsin	9002-07-7	ErC50	>24,7 mg/l	algae	72 h
Ethylenediamine tetraacetic acid tetrasodium salt tetrahydrate	13235-36-4	LC50	>100 mg/l	fish	96 h
Ethylenediamine tetraacetic acid tetrasodium salt tetrahydrate	13235-36-4	EC50	>114 mg/l	aquatic invertebrates	48 h
Ethylenediamine tetraacetic acid tetrasodium salt tetrahydrate	13235-36-4	ErC50	>60 mg/l	algae	72 h

### Biodegradation

Data are not available.

### 12.2 Process of degradability

Degradability of components of the mixture						
Name of substance	CAS No	Process	Degradation rate	Time	Method	Source
Trypsin	9002-07-7	carbon dioxide generation	10 %	2 d		ECHA
Ethylenediamine tetraacetic acid tetrasodium salt tetrahydrate	13235-36-4	oxygen depletion	78 %	56 d		ECHA

### 12.3 Bioaccumulative potential

Data are not available.

Bioaccumulative potential of components of the mixture				
Name of substance	CAS No	BCF	Log KOW	BOD5/COD
Trypsin	9002-07-7		-1,3 (20 °C)	
Ethylenediamine tetraacetic acid tetrasodium salt tetrahydrate	13235-36-4	1,8	-13,17 (25 °C)	

### 12.4 Mobility in soil

Data are not available.

### 12.5 Results of PBT and vPvB assessment

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Data are not available.

## 12.6 Endocrine disrupting properties

None of the ingredients are listed.

## 12.7 Other adverse effects

Data are not available.

## SECTION 13: Disposal considerations

### 13.1 Waste treatment methods



This material and its container must be disposed of as hazardous waste.

#### Sewage disposal-relevant information

Do not empty into drains.

### 13.2 Relevant provisions relating to waste

The allocation of waste identity numbers/waste descriptions must be carried out according to the EEC, specific to the industry and process.

### 13.3 Remarks

Waste shall be separated into the categories that can be handled separately by the local or national waste management facilities. Please consider the relevant national or regional provisions.

## SECTION 14: Transport information

- |  |   |
|--|---|
| 14.1 UN number or ID number  | not subject to transport regulations                                  |
| 14.2 UN proper shipping name   | not assigned  |
| 14.3 Transport hazard class(es)  | none  |
| 14.4 Packing group   | not assigned  |
| 14.5 Environmental hazards   | non-environmentally hazardous acc. to the dangerous goods regulations |
| 14.6 Special precautions for user  | There is no additional information.                                   |
| 14.7 Maritime transport in bulk according to IMO instruments   | The cargo is not intended to be carried in bulk.                      |
| 14.8 <u>Information for each of the UN Model Regulations</u>   |   |
| <b>Transport of dangerous goods by road, rail and inland waterway (ADR/RID/ADN) - Additional information</b> | Not subject to ADR, RID and ADN.                                      |
| <b>International Maritime Dangerous Goods Code (IMDG) - Additional information</b>                           | Not subject to IMDG.  |
| <b>International Civil Aviation Organization (ICAO-IATA/DGR) - Additional information</b>                    | Not subject to ICAO-IATA.   |

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## SECTION 15: Regulatory information

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

#### Relevant provisions of the European Union (EU)

##### Seveso Directive

2012/18/EU (Seveso III)			
No	Dangerous substance/hazard categories	Qualifying quantity (tonnes) for the application of lower and upper-tier requirements	Notes
	not assigned		

##### Deco-Paint Directive

VOC content	0 % 0 g/l
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##### Industrial Emissions Directive (IED)

VOC content	0 %
VOC content (Water content was discounted)	0 g/l

##### Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS)

none of the ingredients are listed

##### Regulation concerning the establishment of a European Pollutant Release and Transfer Register (PRTR)

none of the ingredients are listed

##### Water Framework Directive (WFD)

List of pollutants (WFD)				
Name of substance	Name acc. to inventory	CAS No	Listed in	Remarks
Ethylenediamine tetraacetic acid tetrasodium salt tetrahydrate	Metals and their compounds		a)	

##### Legend

A) Indicative list of the main pollutants

##### Regulation on the marketing and use of explosives precursors

none of the ingredients are listed

##### Regulation on drug precursors

none of the ingredients are listed

##### Regulation on substances that deplete the ozone layer (ODS)

none of the ingredients are listed

##### Regulation concerning the export and import of hazardous chemicals (PIC)

none of the ingredients are listed

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### Regulation on persistent organic pollutants (POP)

none of the ingredients are listed

### National regulations(GB)

#### List of substances subject to authorisation (GB REACH, Annex 14) / SVHC - candidate list

none of the ingredients are listed

#### Restrictions according to GB REACH, Annex 17

none of the ingredients are listed

### Other information

Directive 94/33/EC on the protection of young people at work. Observe employment restrictions under the Maternity Protection Directive (92/85/EEC) for expectant or nursing mothers.

### National inventories

Country	Inventory	Status
AU	AIIC	all ingredients are listed
CA	DSL	not all ingredients are listed
CN	IECSC	all ingredients are listed
EU	ECSI	all ingredients are listed
EU	REACH Reg.	all ingredients are listed
JP	CSCL-ENCS	not all ingredients are listed
JP	ISHA-ENCS	not all ingredients are listed
KR	KECI	all ingredients are listed
MX	INSQ	not all ingredients are listed
NZ	NZIoC	all ingredients are listed
PH	PICCS	all ingredients are listed
TR	CICR	not all ingredients are listed
TW	TCSI	all ingredients are listed
US	TSCA	all ingredients are listed

#### Legend

AIIC	Australian Inventory of Industrial Chemicals
CICR	Chemical Inventory and Control Regulation
CSCL-ENCS	List of Existing and New Chemical Substances (CSCL-ENCS)
DSL	Domestic Substances List (DSL)
ECSI	EC Substance Inventory (EINECS, ELINCS, NLP)
IECSC	Inventory of Existing Chemical Substances Produced or Imported in China
INSQ	National Inventory of Chemical Substances
ISHA-ENCS	Inventory of Existing and New Chemical Substances (ISHA-ENCS)
KECI	Korea Existing Chemicals Inventory
NZIoC	New Zealand Inventory of Chemicals
PICCS	Philippine Inventory of Chemicals and Chemical Substances (PICCS)
REACH Reg.	REACH registered substances
TCSI	Taiwan Chemical Substance Inventory
TSCA	Toxic Substance Control Act

## 15.2 Chemical Safety Assessment

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

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### SECTION 16: Other information

#### Abbreviations and acronyms

Abbr.	Descriptions of used abbreviations
Acute Tox.	Acute toxicity
ADN	Accord européen relatif au transport international des marchandises dangereuses par voies de navigation intérieures (European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways)
ADR	Accord relatif au transport international des marchandises dangereuses par route (Agreement concerning the International Carriage of Dangerous Goods by Road)
ATE	Acute Toxicity Estimate
BCF	Bioconcentration factor
BOD	Biochemical Oxygen Demand
CAS	Chemical Abstracts Service (service that maintains the most comprehensive list of chemical substances)
COD	Chemical oxygen demand
DGR	Dangerous Goods Regulations (see IATA/DGR)
DNEL	Derived No-Effect Level
EC50	Effective Concentration 50 %. The EC50 corresponds to the concentration of a tested substance causing 50 % changes in response (e.g. on growth) during a specified time interval
EC No	The EC Inventory (EINECS, ELINCS and the NLP-list) is the source for the seven-digit EC number, an identifier of substances commercially available within the EU (European Union)
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances
ErC50	≡ EC50: in this method, that concentration of test substance which results in a 50 % reduction in either growth (EbC50) or growth rate (ErC50) relative to the control
Eye Dam.	Seriously damaging to the eye
Eye Irrit.	Irritant to the eye
GB REACH	The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019, SI 2019/758 (as amended)
GHS	"Globally Harmonized System of Classification and Labelling of Chemicals" developed by the United Nations
IATA	International Air Transport Association
IATA/DGR	Dangerous Goods Regulations (DGR) for the air transport (IATA)
ICAO	International Civil Aviation Organization
IMDG	International Maritime Dangerous Goods Code
index No	The Index number is the identification code given to the substance in Part 3 of Annex VI to Regulation (EC) No 1272/2008
LC50	Lethal Concentration 50%: the LC50 corresponds to the concentration of a tested substance causing 50 % lethality during a specified time interval
LD50	Lethal Dose 50 %: the LD50 corresponds to the dose of a tested substance causing 50 % lethality during a specified time interval
log KOW	n-Octanol/water

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Abbr.	Descriptions of used abbreviations
NLP	No-Longer Polymer
PBT	Persistent, Bioaccumulative and Toxic
PNEC	Predicted No-Effect Concentration
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
Resp. Sens.	Respiratory sensitisation
RID	Règlement concernant le transport International ferroviaire des marchandises Dangereuses (Regulations concerning the International carriage of Dangerous goods by Rail)
Skin Corr.	Corrosive to skin
Skin Irrit.	Irritant to skin
STOT SE	Specific target organ toxicity - single exposure
VOC	Volatile Organic Compounds
vPvB	Very Persistent and very Bioaccumulative

### Key literature references and sources for data

Agreement concerning the International Carriage of Dangerous Goods by Road (ADR). Regulations concerning the International Carriage of Dangerous Goods by Rail (RID). International Maritime Dangerous Goods Code (IMDG). Dangerous Goods Regulations (DGR) for the air transport (IATA).

### Classification procedure

Physical and chemical properties. The classification is based on tested mixture. Health hazards. Environmental hazards. The method for classification of the mixture is based on ingredients of the mixture (additivity formula).

### List of relevant phrases (code and full text as stated in section 2 and 3)

Code	Text
H302	Harmful if swallowed.
H315	Causes skin irritation.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H335	May cause respiratory irritation.

### Disclaimer

This information is based upon the present state of our knowledge. This SDS has been compiled and is solely intended for this product.