

# Safety data sheet

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



## ROTI®Histofix 10 % formaldehyde, phosphate buffered, pH 7, ready-to-use

article number: **A146**  
Version: **2.0 en**  
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Version: (1)

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

### 1.1 Product identifier

Identification of the substance **ROTI®Histofix 10 % formaldehyde, phosphate buffered, pH 7, ready-to-use**

Article number A146

Registration number (REACH) not relevant (mixture)

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

Relevant identified uses: Laboratory chemical  
Laboratory and analytical use

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  
**Website:** www.carlroth.de

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

**e-mail (competent person):** **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 according to Regulation (EC) No 1272/2008 (CLP)

Section	Hazard class	Cat-egory	Hazard class and category	Hazard statement
3.10	Acute toxicity (oral)	4	Acute Tox. 4	H302
3.1D	Acute toxicity (dermal)	4	Acute Tox. 4	H312
3.2	Skin corrosion/irritation	2	Skin Irrit. 2	H315
3.3	Serious eye damage/eye irritation	2	Eye Irrit. 2	H319

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Section	Hazard class	Cat-egory	Hazard class and category	Hazard statement
3.4S	Skin sensitisation	1	Skin Sens. 1	H317
3.5	Germ cell mutagenicity	2	Muta. 2	H341
3.6	Carcinogenicity	1B	Carc. 1B	H350
3.8	Specific target organ toxicity - single exposure	2	STOT SE 2	H371
3.8R	Specific target organ toxicity - single exposure (respiratory tract irritation)	3	STOT SE 3	H335

For full text of abbreviations: see SECTION 16

### The most important adverse physicochemical, human health and environmental effects

Immediate effects can be expected after short-term exposure.

## 2.2 Label elements

### Labelling according to Regulation (EC) No 1272/2008 (CLP)

#### Signal word

**Danger**

#### Pictograms

GHS07, GHS08



#### Hazard statements

H302+H312	Harmful if swallowed or in contact with skin
H315	Causes skin irritation
H317	May cause an allergic skin reaction
H319	Causes serious eye irritation
H335	May cause respiratory irritation
H341	Suspected of causing genetic defects
H350	May cause cancer
H371	May cause damage to organs (eye)

#### Precautionary statements

##### **Precautionary statements - prevention**

P260	Do not breathe mist/vapours/spray
P280	Wear protective gloves/protective clothing/eye protection/face protection

##### **Precautionary statements - response**

P302+P352	IF ON SKIN: Wash with plenty of water
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P308+P313	IF exposed or concerned: Get medical advice/attention

For professional users only

#### **Hazardous ingredients for labelling:**

Formaldehyde ... %, Methanol

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### Labelling of packages where the contents do not exceed 125 ml

Signal word: **Danger**

Symbol(s)



H317 May cause an allergic skin reaction.  
H341 Suspected of causing genetic defects.  
H350 May cause cancer.  
P280 Wear protective gloves/protective clothing/eye protection/face protection.  
P302+P352 IF ON SKIN: Wash with plenty of water.  
P308+P313 IF exposed or concerned: Get medical advice/attention.  
contains: Formaldehyde ... %, Methanol

### 2.3 Other hazards

This material is combustible, but will not ignite readily.

### 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
Formaldehyde ... %	CAS No 50-00-0  EC No 200-001-8  Index No 605-001-00-5  REACH Reg. No 01-2119488953- 20-xxxx	5 - 10	Acute Tox. 3 / H301 Acute Tox. 3 / H311 Acute Tox. 3 / H331 Skin Corr. 1B / H314 Eye Dam. 1 / H318 Skin Sens. 1 / H317 Muta. 2 / H341 Carc. 1B / H350 STOT SE 3 / H335		B D GHS-HC IARC: 1 IOELV RoC "Known"
Methanol	CAS No 67-56-1  EC No 200-659-6  Index No 603-001-00-X  REACH Reg. No 01-2119433307- 44-xxxx	3 - < 10	Flam. Liq. 2 / H225 Acute Tox. 3 / H301 Acute Tox. 3 / H311 Acute Tox. 3 / H331 STOT SE 1 / H370		GHS-HC IOELV

#### Notes

- B: Some substances (acids, bases, etc.) are placed on the market in aqueous solutions at various concentrations and, therefore, these solutions require different classification and labelling since the hazards vary at different concentrations. In Part 3 entries with Note B have a general designation of the following type: 'nitric acid ... %'. In this case the supplier must state the percentage concentration of the solution on the label. Unless otherwise stated, it is assumed that the percentage concentration is calculated on a weight/weight basis.
- D: Certain substances which are susceptible to spontaneous polymerisation or decomposition are generally placed on the market in a stabilised form. It is in this form that they are listed in Part 3. However, such substances are sometimes placed on the market in a non-stabilised form. In this case, the supplier must state on the label the name of the substance followed by the words 'non-stabilised'.

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### Notes

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

IARC: 1: IARC group 1: carcinogenic to humans (International Agency for Research on Cancer)

IOELV: Substance with a community indicative occupational exposure limit value

RoC NTP-RoC: Known To Be A Human Carcinogen

"Known"

:

Name of substance	Identifier	Specific Conc. Limits	M-Factors	ATE	Exposure route
Formaldehyde ... %	CAS No 50-00-0  EC No 200-001-8  Index No 605-001-00-5	Skin Corr. 1B; H314: C ≥ 25 % Skin Irrit. 2; H315: 5 % ≤ C < 25 % Eye Dam. 1; H318: C ≥ 25 % Eye Irrit. 2; H319: 5 % ≤ C < 25 % Skin Sens. 1; H317: C ≥ 0,2 % STOT SE 3; H335: C ≥ 5 %	-	100 mg/kg 300 mg/kg 3 mg/l/4h	oral dermal inhalation: va- pour
Methanol	CAS No 67-56-1  EC No 200-659-6  Index No 603-001-00-X	STOT SE 1; H370: C ≥ 10 % STOT SE 2; H371: 3 % ≤ C < 10 %	-	100 mg/kg 300 mg/kg 3 mg/l/4h	oral dermal inhalation: va- pour

For full text of abbreviations: see SECTION 16

## 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. After contact with skin, wash immediately with plenty of water. In case of skin reactions, consult a physician. In case of skin irritation, consult a physician.

#### Following eye contact

Irrigate copiously with clean, fresh water for at least 10 minutes, holding the eyelids apart. In case of eye irritation consult an ophthalmologist.

#### Following ingestion

Rinse mouth with water (only if the person is conscious). In case of accident or unwellness, seek medical advice immediately (show directions for use or safety data sheet if possible). Call a doctor.

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

Vomiting, Allergic reactions, Irritation, Cough, Dyspnoea, Headache, Vertigo, Dizziness, Unconsciousness, Spasms

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

none

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## SECTION 5: Firefighting measures

### 5.1 Extinguishing media



#### Suitable extinguishing media

co-ordinate firefighting measures to the fire surroundings  
water spray, alcohol resistant foam, 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

Ingredients of the mixture combustible. The product itself does not burn. Vapours may form explosive mixtures with air.

#### Hazardous combustion products

Carbon monoxide (CO), Carbon dioxide (CO<sub>2</sub>)

### 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.

## SECTION 6: Accidental release measures

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



#### For non-emergency personnel

Use personal protective equipment as required. Avoid contact with skin, eyes and clothes. Do not breathe vapour/spray.

### 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

Absorb with liquid-binding material (sand, diatomaceous earth, acid- or universal binding agents).

#### Other information relating to spills and releases

Place in appropriate containers for disposal. Ventilate affected area.

### 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.

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## SECTION 7: Handling and storage

### 7.1 Precautions for safe handling

Provision of sufficient ventilation. Use extractor hood (laboratory). Avoid exposure.

#### Measures to prevent fire as well as aerosol and dust generation



Keep away from sources of ignition - No smoking.

#### Advice on general occupational hygiene

Wash hands before breaks and after work. Keep away from food, drink and animal feedingstuffs.

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

Store in a well-ventilated place. Keep container tightly closed. May cause decomposition by long-term light influence.

#### Incompatible substances or mixtures

Observe hints for combined storage.

#### Protect against external exposure, such as

high temperatures, direct light irradiation

#### Consideration of other advice:

#### Specific designs for storage rooms or vessels

Recommended storage temperature: 15 – 25 °C

### 7.3 Specific end use(s)

No information available.

## SECTION 8: Exposure controls/personal protection

### 8.1 Control parameters

#### National limit values

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

Country	Name of agent	CAS No	Identifier	TWA [ppm]	TWA [mg/m <sup>3</sup> ]	STEL [ppm]	STEL [mg/m <sup>3</sup> ]	Ceiling-C [ppm]	Ceiling-C [mg/m <sup>3</sup> ]	Notation	Source
EU	formaldehyde	50-00-0	IOELV	0,3	0,37	0,74	0,6			sect	2019/983/EU
EU	methanol	67-56-1	IOELV	200	260						2006/15/EC
GB	formaldehyde	50-00-0	WEL	2	2,5	2	2,5				EH40/2005
GB	methanol	67-56-1	WEL	200	266	250	333				EH40/2005

#### Notation

Ceiling-C

Ceiling value is a limit value above which exposure should not occur

sect

Limit value of 0,62 mg/m<sup>3</sup> or 0,5 ppm for the health care, funeral and embalming sectors until 11 July 2024

STEL

Short-term exposure limit: a limit value above which exposure should not occur and which is related to a 15-minute period (unless otherwise specified)

TWA

Time-weighted average (long-term exposure limit): measured or calculated in relation to a reference period of 8 hours time-weighted average (unless otherwise specified)

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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
Formaldehyde ... %	50-00-0	DNEL	9 mg/m <sup>3</sup>	human, inhalatory	worker (industry)	chronic - systemic effects
Formaldehyde ... %	50-00-0	DNEL	0,375 mg/m <sup>3</sup>	human, inhalatory	worker (industry)	chronic - local effects
Formaldehyde ... %	50-00-0	DNEL	0,75 mg/m <sup>3</sup>	human, inhalatory	worker (industry)	acute - local effects
Formaldehyde ... %	50-00-0	DNEL	240 mg/kg bw/day	human, dermal	worker (industry)	chronic - systemic effects
Formaldehyde ... %	50-00-0	DNEL	37 µg/cm <sup>2</sup>	human, dermal	worker (industry)	chronic - local effects
Methanol	67-56-1	DNEL	130 mg/m <sup>3</sup>	human, inhalatory	worker (industry)	chronic - systemic effects
Methanol	67-56-1	DNEL	130 mg/m <sup>3</sup>	human, inhalatory	worker (industry)	acute - systemic effects
Methanol	67-56-1	DNEL	130 mg/m <sup>3</sup>	human, inhalatory	worker (industry)	chronic - local effects
Methanol	67-56-1	DNEL	130 mg/m <sup>3</sup>	human, inhalatory	worker (industry)	acute - local effects
Methanol	67-56-1	DNEL	20 mg/kg bw/day	human, dermal	worker (industry)	chronic - systemic effects
Methanol	67-56-1	DNEL	20 mg/kg bw/day	human, dermal	worker (industry)	acute - systemic effects

Relevant PNECs of components of the mixture						
Name of substance	CAS No	End-point	Threshold level	Organism	Environmental compartment	Exposure time
Formaldehyde ... %	50-00-0	PNEC	0,44 mg/l	aquatic organisms	freshwater	short-term (single instance)
Formaldehyde ... %	50-00-0	PNEC	0,44 mg/l	aquatic organisms	marine water	short-term (single instance)
Formaldehyde ... %	50-00-0	PNEC	0,19 mg/l	aquatic organisms	sewage treatment plant (STP)	short-term (single instance)
Formaldehyde ... %	50-00-0	PNEC	2,3 mg/kg	aquatic organisms	freshwater sediment	short-term (single instance)
Formaldehyde ... %	50-00-0	PNEC	2,3 mg/kg	aquatic organisms	marine sediment	short-term (single instance)
Formaldehyde ... %	50-00-0	PNEC	0,2 mg/kg	terrestrial organisms	soil	short-term (single instance)
Methanol	67-56-1	PNEC	20,8 mg/l	aquatic organisms	freshwater	short-term (single instance)
Methanol	67-56-1	PNEC	2,08 mg/l	aquatic organisms	marine water	short-term (single instance)
Methanol	67-56-1	PNEC	100 mg/l	aquatic organisms	sewage treatment plant (STP)	short-term (single instance)

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Relevant PNECs of components of the mixture						
Name of substance	CAS No	End-point	Threshold level	Organism	Environmental compartment	Exposure time
Methanol	67-56-1	PNEC	77 mg/kg	aquatic organisms	freshwater sediment	short-term (single instance)
Methanol	67-56-1	PNEC	7,7 mg/kg	aquatic organisms	marine sediment	short-term (single instance)
Methanol	67-56-1	PNEC	100 mg/kg	terrestrial organisms	soil	short-term (single instance)

## 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. For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves. The 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

Butyl caoutchouc (butyl rubber)

##### • material thickness

0,4 mm

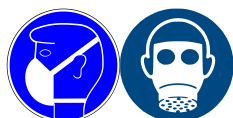
##### • breakthrough times of the glove material

>480 minutes (permeation: level 6)

##### • other protection measures

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

#### Respiratory protection





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Respiratory protection necessary at: Aerosol or mist formation. Type: ABEK (combined filters against gases and vapours, colour code: Brown/Grey/Yellow/Green).

### Environmental exposure controls

Keep away from drains, surface and ground water.

## SECTION 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

Physical state	liquid
Colour	colourless
Odour	stinging
Melting point/freezing point	-15 °C
Boiling point or initial boiling point and boiling range	97 °C
Flammability	non-combustible
Lower and upper explosion limit	7 vol% - 72 vol% (anhydrous)
Flash point	79 – 85 °C
Auto-ignition temperature	not determined
Decomposition temperature	not relevant
pH (value)	6,8 – 7,2 (20 °C)
Kinematic viscosity	not determined
<u>Solubility(ies)</u>	
Water solubility	miscible in any proportion
<u>Partition coefficient</u>	
Partition coefficient n-octanol/water (log value):	this information is not available
Vapour pressure	not determined
Density	1,042 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

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Other safety characteristics:

Miscibility

completely miscible with water

## SECTION 10: Stability and reactivity

### 10.1 Reactivity

Danger of polymerisation.

#### If heated

Vapours may form explosive mixtures with air.

### 10.2 Chemical stability

May cause decomposition by long-term light influence.

To stabilise: Methanol.

### 10.3 Possibility of hazardous reactions

**Exothermic reaction with:** Alkalis, Permanganates, strong oxidiser, Aniline,

**Violent reaction with:** Acids, Phenol, Nitric acid, Hydrogen peroxide,

=> Explosive properties

### 10.4 Conditions to avoid

Direct light irradiation. Keep away from heat.

### 10.5 Incompatible materials

different metals

### 10.6 Hazardous decomposition products

Hazardous combustion products: see section 5.

## SECTION 11: Toxicological information

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

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 according to GHS (1272/2008/EC, CLP)

#### Acute toxicity

Harmful if swallowed. Harmful in contact with skin.

Acute toxicity estimate (ATE) of components of the mixture			
Name of substance	CAS No	Exposure route	ATE
Formaldehyde ... %	50-00-0	oral	100 mg/kg
Formaldehyde ... %	50-00-0	dermal	300 mg/kg
Formaldehyde ... %	50-00-0	inhalation: vapour	3 mg/l/4h
Methanol	67-56-1	oral	100 mg/kg
Methanol	67-56-1	dermal	300 mg/kg
Methanol	67-56-1	inhalation: vapour	3 mg/l/4h

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Acute toxicity of components of the mixture					
Name of substance	CAS No	Exposure route	Endpoint	Value	Species
Methanol	67-56-1	inhalation: vapour	LC50	131 mg/l/4h	rat
Methanol	67-56-1	oral	LD50	5.628 mg/kg	rat
Methanol	67-56-1	oral	LDLo	143 mg/kg	human
Methanol	67-56-1	dermal	LD50	15.800 mg/kg	rabbit

### Skin corrosion/irritation

Causes skin irritation.

### Serious eye damage/eye irritation

Causes serious eye irritation.

### Respiratory or skin sensitisation

May cause an allergic skin reaction.

### Germ cell mutagenicity

Suspected of causing genetic defects.

### Carcinogenicity

May cause cancer.

### Reproductive toxicity

Shall not be classified as a reproductive toxicant.

### Specific target organ toxicity - single exposure

May cause damage to organs (eye). May cause respiratory irritation.

Hazard category	Target organ	Exposure route
2	eye	if exposed

### 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

Causes serious eye irritation

#### • If inhaled

vertigo, headache, Irritation to respiratory tract, cough, Dyspnoea

#### • If on skin

causes skin irritation, May produce an allergic reaction, pruritis, localised redness

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### • Other information

Other adverse effects: Spasms, Blood pressure drop, Liver and kidney damage, Dizziness, Unconsciousness

### 11.2 Endocrine disrupting properties

None of the ingredients are listed.

### 11.3 Information on other hazards

There is no additional information.

## 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
Formaldehyde ... %	50-00-0	LC50	6,7 mg/l	fish	96 h
Formaldehyde ... %	50-00-0	EC50	5,8 mg/l	aquatic invertebrates	48 h
Formaldehyde ... %	50-00-0	ErC50	4,89 mg/l	algae	72 h
Methanol	67-56-1	LC50	15.400 mg/l	fish	96 h
Methanol	67-56-1	ErC50	22.000 mg/l	algae	96 h

Aquatic toxicity (chronic) of components of the mixture					
Name of substance	CAS No	Endpoint	Value	Species	Exposure time
Formaldehyde ... %	50-00-0	EC50	19 mg/l	microorganisms	3 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
Formaldehyde ... %	50-00-0	DOC removal	99 %	28 d		ECHA
Methanol	67-56-1	biotic/abiotic	99 %	30 d		
Methanol	67-56-1	oxygen depletion	69 %	5 d		ECHA

### 12.3 Bioaccumulative potential

Data are not available.

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Bioaccumulative potential of components of the mixture				
Name of substance	CAS No	BCF	Log KOW	BOD5/COD
Methanol	67-56-1		-0,77	

## 12.4 Mobility in soil

Data are not available.

## 12.5 Results of PBT and vPvB assessment

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. Dispose of contents/container in accordance with local/regional/national/international regulations.

#### 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. Waste catalogue ordinance (Germany).

### 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.                      |

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## 14.8 Information for each of the UN Model Regulations

### Transport of dangerous goods by road, rail and inland waterway (ADR/RID/ADN) - Additional information

Not subject to ADR, RID and ADN.

### International Maritime Dangerous Goods Code (IMDG) - Additional information

Not subject to IMDG.

### International Civil Aviation Organization (ICAO-IATA/DGR) - Additional information

Not subject to ICAO-IATA.

## 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)

#### Restrictions according to REACH, Annex XVII

Dangerous substances with restrictions (REACH, Annex XVII)				
Name of substance	Name acc. to inventory	CAS No	Restriction	No
ROTI®Histofix 10 %	this product meets the criteria for classification in accordance with Regulation No 1272/2008/EC		R3	3
Formaldehyde ... %	formaldehyde	50-00-0	R72	72
Formaldehyde ... %	carcinogenic		R28-30	28
Formaldehyde ... %	substances in tattoo inks and permanent make-up		R75	75
Methanol	methanol	67-56-1	R69	69
Methanol	flammable / pyrophoric		R40	40

#### Legend

R28-30 1. Shall not be placed on the market, or used,

- as substances,
- as constituents of other substances, or,
- in mixtures,

for supply to the general public when the individual concentration in the substance or mixture is equal to or greater than:

- either the relevant specific concentration limit specified in Part 3 of Annex VI to Regulation (EC) No 1272/2008, or,
- the relevant concentration specified in Directive 1999/45/EC where no specific concentration limit is set out in Part 3 of Annex VI to Regulation (EC) No 1272/2008.

Without prejudice to the implementation of other Community provisions relating to the classification, packaging and labelling of substances and mixtures, suppliers shall ensure before the placing on the market that the packaging of such substances and mixtures is marked visibly, legibly and indelibly as follows:

'Restricted to professional users'.

2. By way of derogation, paragraph 1 shall not apply to:

(a) medicinal or veterinary products as defined by Directive 2001/82/EC and Directive 2001/83/EC;

(b) cosmetic products as defined by Directive 76/768/EEC;

(c) the following fuels and oil products:

- motor fuels which are covered by Directive 98/70/EC,
- mineral oil products intended for use as fuel in mobile or fixed combustion plants,
- fuels sold in closed systems (e.g. liquid gas bottles);

(d) artists' paints covered by Directive 1999/45/EC;

(e) the substances listed in Appendix 11, column 1, for the applications or uses listed in Appendix 11, column 2. Where a date is specified in column 2 of Appendix 11, the derogation shall apply until the said date;

(f) devices covered by Regulation (EU) 2017/745.

# Safety data sheet

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



## ROTI®Histofix 10 % formaldehyde, phosphate buffered, pH 7, ready-to-use

article number: **A146**

### Legend

- R3
1. Shall not be used in:
    - ornamental articles intended to produce light or colour effects by means of different phases, for example in ornamental lamps and ashtrays,
    - tricks and jokes,
    - games for one or more participants, or any article intended to be used as such, even with ornamental aspects,
  2. Articles not complying with paragraph 1 shall not be placed on the market.
  3. Shall not be placed on the market if they contain a colouring agent, unless required for fiscal reasons, or perfume, or both, if they:
    - can be used as fuel in decorative oil lamps for supply to the general public, and
    - present an aspiration hazard and are labelled with H304.
  4. Decorative oil lamps for supply to the general public shall not be placed on the market unless they conform to the European Standard on Decorative oil lamps (EN 14059) adopted by the European Committee for Standardisation (CEN).
  5. Without prejudice to the implementation of other Union provisions relating to the classification, labelling and packaging of substances and mixtures, suppliers shall ensure, before the placing on the market, that the following requirements are met:
    - (a) lamp oils, labelled with H304, intended for supply to the general public are visibly, legibly and indelibly marked as follows: "Keep lamps filled with this liquid out of the reach of children"; and, by 1 December 2010, "Just a sip of lamp oil – or even sucking the wick of lamps – may lead to life-threatening lung damage";
    - (b) grill lighter fluids, labelled with H304, intended for supply to the general public are legibly and indelibly marked by 1 December 2010 as follows: "Just a sip of grill lighter fluid may lead to life threatening lung damage";
    - (c) lamps oils and grill lighters, labelled with H304, intended for supply to the general public are packaged in black opaque containers not exceeding 1 litre by 1 December 2010.;
- R40
1. Shall not be used, as substance or as mixtures in aerosol dispensers where these aerosol dispensers are intended for supply to the general public for entertainment and decorative purposes such as the following:
    - metallic glitter intended mainly for decoration,
    - artificial snow and frost,
    - 'whoopee' cushions,
    - silly string aerosols,
    - imitation excrement,
    - horns for parties,
    - decorative flakes and foams,
    - artificial cobwebs,
    - stink bombs.
  2. Without prejudice to the application of other Community provisions on the classification, packaging and labelling of substances, suppliers shall ensure before the placing on the market that the packaging of aerosol dispensers referred to above is marked visibly, legibly and indelibly with:
    - 'For professional users only'.
  3. By way of derogation, paragraphs 1 and 2 shall not apply to the aerosol dispensers referred to Article 8 (1a) of Council Directive 75/324/EEC (2).
  4. The aerosol dispensers referred to in paragraphs 1 and 2 shall not be placed on the market unless they conform to the requirements indicated.
- R69
- Shall not be placed on the market to the general public after 9 May 2019 in windscreen washing or defrosting fluids, in a concentration equal to or greater than 0,6 % by weight.
- R72
1. Shall not be placed on the market after 1 November 2020 in any of the following:
    - (a) clothing or related accessories;
    - (b) textiles other than clothing which, under normal or reasonably foreseeable conditions of use, come into contact with human skin to an extent similar to clothing;
    - (c) footwear;if the clothing, related accessory, textile other than clothing or footwear is for use by consumers and the substance is present in a concentration, measured in homogeneous material, equal to or greater than that specified for that substance in Appendix 12.
  2. By way of derogation, in relation to the placing on the market of formaldehyde [CAS No 50-00-0] in jackets, coats or upholstery, the relevant concentration for the purposes of paragraph 1 shall be 300 mg/kg during the period between 1 November 2020 and 1 November 2023. The concentration specified in Appendix 12 shall apply thereafter.
  3. Paragraph 1 shall not apply to:
    - (a) clothing, related accessories or footwear, or parts of clothing, related accessories or footwear, made exclusively of natural leather, fur or hide;
    - (b) non-textile fasteners and non-textile decorative attachments;
    - (c) second-hand clothing, related accessories, textiles other than clothing or footwear
    - (d) wall-to-wall carpets and textile floor coverings for indoor use, rugs and runners.
  4. Paragraph 1 shall not apply to clothing, related accessories, textiles other than clothing, or footwear within the scope of Regulation (EU) 2016/425 of the European Parliament and of the Council (\*) or Regulation (EU) 2017/745 of the European Parliament and of the Council (\*\*).
  5. Paragraph 1(b) shall not apply to disposable textiles. 'Disposable textiles' means textiles that are designed to be used only once or for a limited time and are not intended for subsequent use for the same or a similar purpose.
  6. Paragraphs 1 and 2 shall apply without prejudice to the application of any stricter restrictions set out in this Annex or in other applicable Union legislation.
  7. The Commission shall review the exemption in paragraph 3(d) and, if appropriate, modify that point accordingly.
- (\*) Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC (OJ L 81, 31.3.2016, p. 51).
- (\*\*) Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1).

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## ROTI®Histofix 10 % formaldehyde, phosphate buffered, pH 7, ready-to-use

article number: **A146**

### Legend

- R75
1. Shall not be placed on the market in mixtures for use for tattooing purposes, and mixtures containing any such substances shall not be used for tattooing purposes, after 4 January 2022 if the substance or substances in question is or are present in the following circumstances:
    - (a) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as carcinogen category 1A, 1B or 2, or germ cell mutagen category 1A, 1B or 2, the substance is present in the mixture in a concentration equal to or greater than 0,00005 % by weight;
    - (b) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as reproductive toxicant category 1A, 1B or 2, the substance is present in the mixture in a concentration equal to or greater than 0,001 % by weight;
    - (c) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as skin sensitiser category 1, 1A or 1B, the substance is present in the mixture in a concentration equal to or greater than 0,001 % by weight;
    - (d) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as skin corrosive category 1, 1A, 1B or 1C or skin irritant category 2, or as serious eye damage category 1 or eye irritant category 2, the substance is present in the mixture in a concentration equal to or greater than:
      - (i) 0,1 % by weight, if the substance is used solely as a pH regulator;
      - (ii) 0,01 % by weight, in all other cases;
    - (e) in the case of a substance listed in Annex II to Regulation (EC) No 1223/2009 (\*1), the substance is present in the mixture in a concentration equal to or greater than 0,00005 % by weight;
    - (f) in the case of a substance for which a condition of one or more of the following kinds is specified in column g (Product type, Body parts) of the table in Annex IV to Regulation (EC) No 1223/2009, the substance is present in the mixture in a concentration equal to or greater than 0,00005 % by weight:
      - (i) "Rinse-off products";
      - (ii) "Not to be used in products applied on mucous membranes";
      - (iii) "Not to be used in eye products";
    - (g) in the case of a substance for which a condition is specified in column h (Maximum concentration in ready for use preparation) or column i (Other) of the table in Annex IV to Regulation (EC) No 1223/2009, the substance is present in the mixture in a concentration, or in some other way, that does not accord with the condition specified in that column;
    - (h) in the case of a substance listed in Appendix 13 to this Annex, the substance is present in the mixture in a concentration equal to or greater than the concentration limit specified for that substance in that Appendix.
  2. For the purposes of this entry use of a mixture "for tattooing purposes" means injection or introduction of the mixture into a person's skin, mucous membrane or eyeball, by any process or procedure (including procedures commonly referred to as permanent make-up, cosmetic tattooing, micro-blading and micro-pigmentation), with the aim of making a mark or design on his or her body.
  3. If a substance not listed in Appendix 13 falls within more than one of points (a) to (g) of paragraph 1, the strictest concentration limit laid down in the points in question shall apply to that substance. If a substance listed in Appendix 13 also falls within one or more of points (a) to (g) of paragraph 1, the concentration limit laid down in point (h) of paragraph 1 shall apply to that substance.
  4. By way of derogation, paragraph 1 shall not apply to the following substances until 4 January 2023:
    - (a) Pigment Blue 15:3 (CI 74160, EC No 205-685-1, CAS No 147-14-8);
    - (b) Pigment Green 7 (CI 74260, EC No 215-524-7, CAS No 1328-53-6).
  5. If Part 3 of Annex VI to Regulation (EC) No 1272/2008 is amended after 4 January 2021 to classify or re-classify a substance such that the substance then becomes caught by point (a), (b), (c) or (d) of paragraph 1 of this entry, or such that it then falls within a different one of those points from the one within which it fell previously, and the date of application of that new or revised classification is after the date referred to in paragraph 1 or, as the case may be, paragraph 4 of this entry, that amendment shall, for the purposes of applying this entry to that substance, be treated as taking effect on the date of application of that new or revised classification.
  6. If Annex II or Annex IV to Regulation (EC) No 1223/2009 is amended after 4 January 2021 to list or change the listing of a substance such that the substance then becomes caught by point (e), (f) or (g) of paragraph 1 of this entry, or such that it then falls within a different one of those points from the one within which it fell previously, and the amendment takes effect after the date referred to in paragraph 1 or, as the case may be, paragraph 4 of this entry, that amendment shall, for the purposes of applying this entry to that substance, be treated as taking effect from the date falling 18 months after entry into force of the act by which that amendment was made.
  7. Suppliers placing a mixture on the market for use for tattooing purposes shall ensure that, after 4 January 2022, the mixture is marked with the following information:
    - (a) the statement "Mixture for use in tattoos or permanent make-up";
    - (b) a reference number to uniquely identify the batch;
    - (c) the list of ingredients in accordance with the nomenclature established in the glossary of common ingredient names pursuant to Article 33 of Regulation (EC) No 1223/2009, or in the absence of a common ingredient name, the IUPAC name. In the absence of a common ingredient name or IUPAC name, the CAS and EC number. Ingredients shall be listed in descending order by weight or volume of the ingredients at the time of formulation. "Ingredient" means any substance added during the process of formulation and present in the mixture for use for tattooing purposes. Impurities shall not be regarded as ingredients. If the name of a substance, used as ingredient within the meaning of this entry, is already required to be stated on the label in accordance with Regulation (EC) No 1272/2008, that ingredient does not need to be marked in accordance with this Regulation;
    - (d) the additional statement "pH regulator" for substances falling under point (d)(i) of paragraph 1;
    - (e) the statement "Contains nickel. Can cause allergic reactions." if the mixture contains nickel below the concentration limit specified in Appendix 13;
    - (f) the statement "Contains chromium (VI). Can cause allergic reactions." if the mixture contains chromium (VI) below the concentration limit specified in Appendix 13;
    - (g) safety instructions for use insofar as they are not already required to be stated on the label by Regulation (EC) No 1272/2008.The information shall be clearly visible, easily legible and marked in a way that is indelible. The information shall be written in the official language(s) of the Member State(s) where the mixture is placed on the market, unless the Member State(s) concerned provide(s) otherwise. Where necessary because of the size of the package, the information listed in the first subparagraph, except for point (a), shall be included instead in the instructions for use. Before using a mixture for tattooing purposes, the person using the mixture shall provide the person undergoing the procedure with the information marked on the package or included in the instructions for use pursuant to this paragraph.
  8. Mixtures that do not contain the statement "Mixture for use in tattoos or permanent make-up" shall not be used for tattooing purposes.



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### Legend

9. This entry does not apply to substances that are gases at temperature of 20 °C and pressure of 101,3 kPa, or generate a vapour pressure of more than 300 kPa at temperature of 50 °C, with the exception of formaldehyde (CAS No 50-00-0, EC No 200-001-8).

10. This entry does not apply to the placing on the market of a mixture for use for tattooing purposes, or to the use of a mixture for tattooing purposes, when placed on the market exclusively as a medical device or an accessory to a medical device, within the meaning of Regulation (EU) 2017/745, or when used exclusively as a medical device or an accessory to a medical device, within the same meaning. Where the placing on the market or use may not be exclusively as a medical device or an accessory to a medical device, the requirements of Regulation (EU) 2017/745 and of this Regulation shall apply cumulatively.

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

None of the ingredients are listed. (Or Concentration of the substance in a mixture: <0.1 % Mass concentration)

### 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	10 – 15 % , 1.394 g/l
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### Industrial Emissions Directive (IED)

VOC content	10 – 15 %
VOC content Water content was discounted	1.394 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
Formaldehyde ... %	Substances and preparations, or the breakdown products of such, which have been proved to possess carcinogenic or mutagenic properties or properties which may affect steroidogenic, thyroid, reproduction or other endocrine-related functions in or via the aquatic environment		A)	

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List of pollutants (WFD)				
Name of substance	Name acc. to inventory	CAS No	Listed in	Remarks
Methanol	Substances and preparations, or the breakdown products of such, which have been proved to possess carcinogenic or mutagenic properties or properties which may affect steroidogenic, thyroid, reproduction or other endocrine-related functions in or via the aquatic environment		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

### Regulation on persistent organic pollutants (POP)

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	AICS	all ingredients are listed
CA	DSL	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	all ingredients are listed
JP	ISHA-ENCS	not all ingredients are listed
KR	KECI	all ingredients are listed
MX	INSQ	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

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Country	Inventory	Status
US	TSCA	all ingredients are listed

### Legend

AICS	Australian Inventory of Chemical Substances
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.

## SECTION 16: Other information

### Indication of changes (revised safety data sheet)

Alignment to regulation: Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU

Restructuring: section 9, section 14

Section	Former entry (text/value)	Actual entry (text/value)	Safety-relevant
2.1		Classification according to Regulation (EC) No 1272/2008 (CLP): change in the listing (table)	yes
2.1		The most important adverse physicochemical, human health and environmental effects: Immediate effects can be expected after short-term exposure.	yes
2.2		Pictograms: change in the listing (table)	yes
2.2		Hazard statements: change in the listing (table)	yes
2.2		Precautionary statements - prevention: change in the listing (table)	yes
2.3	Other hazards: There is no additional information.	Other hazards: This material is combustible, but will not ignite readily.	yes
2.3		Results of PBT and vPvB assessment: This mixture does not contain any substances that are assessed to be a PBT or a vPvB.	yes

### Abbreviations and acronyms

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Abbr.	Descriptions of used abbreviations
2006/15/EC	Commission Directive establishing a second list of indicative occupational exposure limit values in implementation of Council Directive 98/24/EC and amending Directives 91/322/EEC and 2000/39/EC
2019/983/EU	Directive of the European Parliament and of the Council amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work
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
Carc.	Carcinogenicity
CAS	Chemical Abstracts Service (service that maintains the most comprehensive list of chemical substances)
Ceiling-C	Ceiling value
CLP	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures
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)
EH40/2005	EH40/2005 Workplace exposure limits ( <a href="http://www.nationalarchives.gov.uk/doc/open-government-licence/">http://www.nationalarchives.gov.uk/doc/open-government-licence/</a> )
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
Flam. Liq.	Flammable liquid
GHS	"Globally Harmonized System of Classification and Labelling of Chemicals" developed by the United Nations
IARC	International Agency for Research on Cancer
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

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Abbr.	Descriptions of used abbreviations
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
IOELV	Indicative occupational exposure limit value
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
Muta.	Germ cell mutagenicity
NLP	No-Longer Polymer
NTP-RoC	National Toxicology Program: Report on Carcinogens
PBT	Persistent, Bioaccumulative and Toxic
PNEC	Predicted No-Effect Concentration
ppm	Parts per million
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
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
Skin Sens.	Skin sensitisation
STEL	Short-term exposure limit
STOT SE	Specific target organ toxicity - single exposure
SVHC	Substance of Very High Concern
TWA	Time-weighted average
VOC	Volatile Organic Compounds
vPvB	Very Persistent and very Bioaccumulative
WEL	Workplace exposure limit

### Key literature references and sources for data

Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures.  
Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU.

Transport of dangerous goods by road, rail and inland waterway (ADR/RID/ADN). 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).

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

Code	Text
H225	Highly flammable liquid and vapour.
H301	Toxic if swallowed.
H302	Harmful if swallowed.
H311	Toxic in contact with skin.
H312	Harmful in contact with skin.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H331	Toxic if inhaled.
H335	May cause respiratory irritation.
H341	Suspected of causing genetic defects.
H350	May cause cancer.
H370	Causes damage to organs (eye).
H371	May cause damage to organs (eye).

### Disclaimer

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