

# SAFETY DATA SHEET

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

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## NovaCleaner

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

#### 1.1. Product identifier

**Trade name/designation:**

NovaCleaner

**Article No.:**

1002 0220055\_V01.3

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

**Use of the substance/mixture:**

Ready to use Rapid Spray Disinfectant for Medical Devices

A non-alcohol based fast affecting ready-to-use disinfectant for the surfaces of medical devices

**Relevant identified uses:**

**Sector of uses [SU]**

**SU 20:** Health services

**Product Categories [PC]**

**PC 8:** Biocidal product

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

**Manufacturer:**

**ACTO GmbH**

Quality Management

Büchnerstr. 11

38118 Braunschweig

Germany

**Telephone:** (+49) (0) 531-239 508-0

**Telefax:** (+49) (0) 531-239 508-11

**E-mail:** info@actogmbh.com

**Website:** http://www.actogmbh.com

**Distributor:**

**NOVAFON - Elektromedizinische Geräte GmbH**

Daimlerstr. 13,

71384 Weinstadt

Germany

**E-mail (competent person):** info@actogmbh.com

Poison Control Center-Nord (GIZ-Nord)

University Medical Center Göttingen

Robert-Koch-Str. 40, 37075 Göttingen

Emergency number for Citizens: +49 (0) 551-19 24 0

Consulting physician: +49 (0) 551-38 31 80

E-mail: giznord@giz-nord.de

Web-Page: http://www.giz-nord.de

#### 1.4. Emergency telephone number

Name: Erdi Günher

Profession: Chemist

Certificate No.: GBF-A-0-3313

Validity: 14.07.2024

Telephone: +90 535 865 4635

E-mail (competent person): erdi.gunher@actopharma.com, 24h: GIZ-Nord: +49-551-19 24 0, Safety

Officer: +49-531-2395080; +49-172-8560648 (Only available during office hours.)

### SECTION 2: Hazards identification

#### 2.1. Classification of the substance or mixture

**Classification according to Regulation (EC) No 1272/2008 [CLP]**

The mixture is classified as not hazardous according to regulation (EC) No 1272/2008 [CLP].

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### 2.2. Label elements

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

According to EC directives or the corresponding national regulations the product does not have to be labelled.

#### Hazard components for labelling:

According to EC directives or the corresponding national regulations the product does not have to be labelled.

##### Hazard statements for environmental hazards

H412	Harmful to aquatic life with long lasting effects.
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##### Supplemental hazard information

EUH208	Contains Polyaminopropyl biguanide. May produce an allergic reaction.
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##### Precautionary statements Prevention

P234	Keep only in original packaging.
P270	Do not eat, drink or smoke when using this product.
P273	Avoid release to the environment.

##### Precautionary statements Response

P301 + P312	IF SWALLOWED: Call a POISON CENTER/doctor/Physician/ if you feel unwell.
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.

##### Precautionary statements Disposal

P501	Dispose of contents/container to in accordance with national regulations..
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#### Special rules for supplemental label elements for certain mixtures:

According to EC directives or the corresponding national regulations the product does not have to be labelled.

### 2.3. Other hazards

#### Adverse environmental effects:

Avoid release of large amounts to the environment.




## SECTION 3: Composition/information on ingredients

### 3.2. Mixtures

#### Description:

Aqueous solution

#### Hazardous ingredients / Hazardous impurities / Stabilisers:

Product identifiers	Substance name Classification according to Regulation (EC) No 1272/2008 [CLP]	Concentration
CAS No.: 160875-66-1	<b>Poly(oxy-1,2-ethanediyl), alpha-(2-propylheptyl)-omega-hydroxy-</b> The substance is classified as not hazardous according to regulation (EC) No 1272/2008 [CLP].	0.45 – 0.55 weight-%
CAS No.: 7173-51-5 EC No.: 230-525-2	<b>didecyldimethylammonium chloride</b> The substance is classified as not hazardous according to regulation (EC) No 1272/2008 [CLP].	0.25 – 0.31 weight-%
CAS No.: 32289-58-0 Index No.: 616-207-00-X	<b>Polyaminopropyl Biguanide</b> Acute Tox. 2 (H330), Acute Tox. 4 (H302), Aquatic Acute 1 (H400), Aquatic Chronic 1 (H410), Carc. 2 (H351), Eye Dam. 1 (H318), STOT RE 1 (H372), Skin Sens. 1B (H317)    <b>Danger</b> M-factor (acute): 10 M-factor (chronic): 10	0.2 – 0.25 weight-%

Full text of H- and EUH-phrases: see section 16.

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### 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). Remove victim out of the danger area. Remove contaminated, saturated clothing. If unconscious but breathing normally, place in recovery position and seek medical advice. Do not leave affected person unattended.

##### Following inhalation:

Remove casualty to fresh air and keep warm and at rest. If unconscious but breathing normally, place in recovery position and seek medical advice. In case of irregular breathing or respiratory arrest provide artificial respiration. Provide fresh air. In case of respiratory tract irritation, consult a physician.

##### In case of skin contact:

Following skin contact Subsequently wash off with: Water and soap In case of skin irritation, consult a physician.

IF ON CLOTHING: Take off immediately all contaminated clothing. Wash contaminated clothing prior to re-use.

##### After eye contact:

Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

##### Following ingestion:

Rinse mouth. Let water be drunken in little sips (dilution effect). Get medical advice/attention if you feel unwell.

##### Self-protection of the first aider:

Warning First aider: Pay attention to self-protection! Use personal protection equipment.

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

Contains: Polyaminopropyl biguanide. May produce an allergic reaction.

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

Treat symptomatically.

You can refer to data sources in section 16 to find detailed toxicity information of each component.

### SECTION 5: Firefighting measures

#### 5.1. Extinguishing media

##### Suitable extinguishing media:

Co-ordinate fire-fighting measures to the fire surroundings. Foam Extinguishing powder Carbon dioxide (CO<sub>2</sub>) Water spray

##### Unsuitable extinguishing media:

Full water jet

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

In case of fire: Gases/vapours, toxic. Do not breathe gas/fumes/vapour/spray.

##### Hazardous combustion products:

Nitrogen oxides (NO<sub>x</sub>), Carbon monoxide, Carbon dioxide (CO<sub>2</sub>).

#### 5.3. Advice for firefighters

Wear a self-contained breathing apparatus and chemical protective clothing.

### SECTION 6: Accidental release measures

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

##### 6.1.1. For non-emergency personnel

##### Personal precautions:

Avoid contact with eyes and skin. Wear personal protection equipment. Do not breathe gas/vapour/aerosol. Provide adequate ventilation. Keep out of reach of children. Wash contaminated clothing prior to re-use. See protective measures under point 7 and 8.

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### Protective equipment:

Wear suitable protective clothing and eye/face protection.

### Emergency procedures:

Provide eye shower and label its location conspicuously

### 6.1.2. For emergency responders

#### Personal protection equipment:

Personal protection equipment: see section 8

### 6.2. Environmental precautions

Do not allow to enter into surface water or drains.

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

#### For containment:

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

#### For cleaning up:

Water

### 6.4. Reference to other sections

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

### 6.5. Additional information

Eliminate leaks immediately. See protective measures under point 7 and 8.

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

#### Protective measures

#### Advices on safe handling:

Handle in accordance with good industrial hygiene and safety practice. Wear personal protection equipment (refer to section 8).

#### Fire prevent measures:

No special measures are necessary.

#### Environmental precautions:

Avoid release of large amounts to the environment.

#### Advices on general occupational hygiene

Wash hands before breaks and after work. When using do not eat, drink or smoke. Avoid contact with eyes and skin.

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

#### Technical measures and storage conditions:

Keep container tightly closed in a cool, well-ventilated place. storage temperature: 5-40 °C

#### Requirements for storage rooms and vessels:

Floors should be impervious, resistant to liquids and easy to clean. Ensure adequate ventilation of the storage area. Keep/Store only in original container.

#### Hints on storage assembly:

Do not store together with: Food and feedingstuffs

**Storage class (TRGS 510, Germany):** 12 - non-combustible liquids that cannot be assigned to any of the above storage classes

#### Further information on storage conditions:

Storage at room temperature

### 7.3. Specific end use(s)

#### Recommendation:

Disinfectant

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### SECTION 8: Exposure controls/personal protection

#### 8.1. Control parameters

##### 8.1.1. Occupational exposure limit values

No data available

##### 8.1.2. Biological limit values

No data available

##### 8.1.3. DNEL-/PNEC-values

Substance name	DNEL value	① DNEL type ② Exposure route
propan-2-ol CAS No.: 67-63-0 EC No.: 200-661-7	500 mg/m <sup>3</sup>	① DNEL worker ② Long-term - inhalation, systemic effects
propan-2-ol CAS No.: 67-63-0 EC No.: 200-661-7	89 mg/m <sup>3</sup>	① DNEL Consumer ② Long-term - inhalation, systemic effects
propan-2-ol CAS No.: 67-63-0 EC No.: 200-661-7	888 mg/m <sup>3</sup>	① DNEL worker ② Long-term - dermal, systemic effects
propan-2-ol CAS No.: 67-63-0 EC No.: 200-661-7	319 mg/kg bw/ day	① DNEL Consumer ② Long-term - dermal, systemic effects
propan-2-ol CAS No.: 67-63-0 EC No.: 200-661-7	26 mg/kg bw/ day	① DNEL Consumer ② Long-term - oral, systemic effects

Substance name	PNEC Value	① PNEC type
propan-2-ol CAS No.: 67-63-0 EC No.: 200-661-7	140.9 mg/L	① PNEC aquatic, freshwater
propan-2-ol CAS No.: 67-63-0 EC No.: 200-661-7	140.9 mg/L	① PNEC aquatic, marine water
propan-2-ol CAS No.: 67-63-0 EC No.: 200-661-7	2.251 g/m <sup>3</sup>	① PNEC sewage treatment plant
propan-2-ol CAS No.: 67-63-0 EC No.: 200-661-7	552 mg/kg bw/ day	① PNEC sediment, freshwater
propan-2-ol CAS No.: 67-63-0 EC No.: 200-661-7	552 mg/kg bw/ day	① PNEC sediment, marine water
propan-2-ol CAS No.: 67-63-0 EC No.: 200-661-7	140.9 mg/L	① PNEC aquatic, intermittent release

#### 8.2. Exposure controls

##### 8.2.1. Appropriate engineering controls

Handle in accordance with good industrial hygiene and safety practice.

##### 8.2.2. Personal protection equipment



##### Eye/face protection:

Eye glasses with side protection EN 166 (Berufsgenossenschaftliche Regeln (DGUV-Regeln) 192)

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### Skin protection:

Tested protective gloves must be worn EN ISO 374. Wash hands before breaks and after work. Apply skin care products after work. 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.

### Respiratory protection:

Use only in well-ventilated areas. With correct and proper use, and under normal conditions, breathing protection is not required.

### Other protection measures:

General health and safety measures: When using do not eat, drink, smoke, sniff. Avoid contact with skin, eyes and clothes. Wash hands before breaks and after work. Wash contaminated clothing prior to re-use.

### 8.2.3. Environmental exposure controls

See chapter 7. No additional measures necessary.

## SECTION 9: Physical and chemical properties

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

#### Appearance

**Physical state:** Liquid

**Colour:** greenish

**Odour:** characteristic

#### Safety relevant basis data

Parameter	Value	at °C	① Method ② Remark
pH	$\geq 5.5 - \leq 7.5$	20 °C	
Melting point	<i>not determined</i>		
Freezing point	<i>not determined</i>		
Initial boiling point and boiling range	<i>not determined</i>		
Decomposition temperature	<i>not determined</i>		
Flash point	<i>not determined</i>		
Evaporation rate	<i>not determined</i>		
Auto-ignition temperature	<i>not determined</i>		
Upper/lower flammability or explosive limits	<i>not determined</i>		
Vapour pressure	<i>not determined</i>		
Vapour density	<i>not determined</i>		
Density	$\geq 0.9 - \leq 1.07 \text{ g/mL}$	20 °C	
Relative density	<i>not determined</i>		
Bulk density	<i>not determined</i>		
Water solubility	completely miscible		
Partition coefficient: n-octanol/water	<i>not determined</i>		
Dynamic viscosity	<i>not determined</i>		
Kinematic viscosity	<i>not determined</i>		

### 9.2. Other information

no data available

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

no data available

### 10.2. Chemical stability

Stable under recommended storage conditions.

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### 10.3. Possibility of hazardous reactions

No hazardous reactions with other chemicals was observed when use as prescribed and with proper storage

### 10.4. Conditions to avoid

no data available

### 10.5. Incompatible materials

no data available

### 10.6. Hazardous decomposition products

no data available

## SECTION 11: Toxicological information

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

<b>Polyaminopropyl Biguanide</b>	<b>CAS No.:</b> 32289-58-0
<b>LD<sub>50</sub> oral:</b> =501 mg/kg (Ratte)	
<b>LD<sub>50</sub> dermal:</b> >5,000 mg/kg (Ratte)	
<b>LC<sub>50</sub> Acute inhalation toxicity (gas):</b> ≈0.37 mg/L (Ratte)	
<b>Poly(oxy-1,2-ethanediyl), alpha-(2-propylheptyl)-omega-hydroxy-</b>	<b>CAS No.:</b> 160875-66-1
<b>LD<sub>50</sub> oral:</b> 500 mg/kg (Ratte)	
<b>didecyldimethylammonium chloride</b>	<b>CAS No.:</b> 7173-51-5 <b>EC No.:</b> 230-525-2
<b>LD<sub>50</sub> oral:</b> 238 mg/kg (Ratte) OECD 401	
<b>LD<sub>50</sub> dermal:</b> 3,342 mg/kg (Kaninchen)	

#### Acute oral toxicity:

The classification criteria for this hazard class are not met by definition.

#### Acute dermal toxicity:

The classification criteria for this hazard class are not met by definition.

#### Acute inhalation toxicity:

The classification criteria for this hazard class are not met by definition.

#### Skin corrosion/irritation:

The classification criteria for this hazard class are not met by definition.

#### Serious eye damage/irritation:

The classification criteria for this hazard class are not met by definition.

#### Respiratory or skin sensitisation:

not sensitising. Practical experience/human evidence

#### Germ cell mutagenicity:

The classification criteria for this hazard class are not met by definition.

#### Carcinogenicity:

The classification criteria for this hazard class are not met by definition.

#### Reproductive toxicity:

The classification criteria for this hazard class are not met by definition.

#### STOT-single exposure:

The classification criteria for this hazard class are not met by definition.

#### STOT-repeated exposure:

The classification criteria for this hazard class are not met by definition.

#### Aspiration hazard:

The classification criteria for this hazard class are not met by definition.

### 11.2. Information on other hazards

No data available

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### SECTION 12: Ecological information

#### 12.1. Toxicity

<b>Polyaminopropyl Biguanide</b> CAS No.: 32289-58-0
LC <sub>50</sub> : 0.026 mg/L 4 d (fish, Fische)
EC <sub>50</sub> : 0.09 mg/L 2 d (crustaceans, Daphnien) OECD 202 (Daphnien, Immobilisierung)
ErC <sub>50</sub> : 0.0191 mg/L 3 d (Algae/water plant, Pseudokirchneriella subcapitata)
NOEC: 0.0084 mg/L 21 d (crustaceans, Daphnia magna (Big water flea))
<b>Poly(oxy-1,2-ethanediyl), alpha-(2-propylheptyl)-omega-hydroxy-</b> CAS No.: 160875-66-1
LC <sub>50</sub> : 55 mg/L 4 d (Fische)
EC <sub>50</sub> : 55 mg/L 3 d (Algen)
EC <sub>50</sub> : 55 mg/L 2 d (Daphnien) OECD 202 (Daphnien, Immobilisierung)
<b>didecyldimethylammonium chloride</b> CAS No.: 7173-51-5 EC No.: 230-525-2
LC <sub>50</sub> : 0.19 mg/L 4 d (fish, fathead minnow) US-EPA
NOEC: 0.03 mg/L -∞ h (fish, Danio rerio (zebra fish)) OECD 210
EC <sub>50</sub> : 0.06 mg/L 2 d (crustaceans, Daphnia magna (Water flea)) EPA-FIFRA
NOEC: 0.01 mg/L -∞ h (crustaceans, Daphnia magna (Water flea)) OECD 211
ErC <sub>50</sub> : 0.02 mg/L 4 d (Algae/water plant, Pseudokirchneriella subcapitata (green algae)) OECD Test Guideline 201

#### 12.2. Persistence and degradability

<b>Poly(oxy-1,2-ethanediyl), alpha-(2-propylheptyl)-omega-hydroxy-</b> CAS No.: 160875-66-1
Biodegradation: Yes, rapidly
Remark: Readily biodegradable (according to OECD criteria).

#### 12.3. Bioaccumulative potential

##### Accumulation / Evaluation:

No indication of bioaccumulation potential.

#### 12.4. Mobility in soil

If product enters soil, it will be mobile and may contaminate groundwater.

#### 12.5. Results of PBT and vPvB assessment

<b>Polyaminopropyl Biguanide</b> CAS No.: 32289-58-0
Results of PBT and vPvB assessment: —
<b>Poly(oxy-1,2-ethanediyl), alpha-(2-propylheptyl)-omega-hydroxy-</b> CAS No.: 160875-66-1
Results of PBT and vPvB assessment: —
<b>didecyldimethylammonium chloride</b> CAS No.: 7173-51-5 EC No.: 230-525-2
Results of PBT and vPvB assessment: —

#### 12.6. Endocrine disrupting properties

No data available

#### 12.7. Other adverse effects

No data available

### SECTION 13: Disposal considerations

#### 13.1. Waste treatment methods

Consult the appropriate local waste disposal expert about waste disposal.

##### 13.1.1. Product/Packaging disposal

##### Waste codes/waste designations according to EWC/AVV

##### Waste code product

07 06 99	Wastes not otherwise specified
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### Waste code packaging

15 01 10 *	packaging containing residues of or contaminated by dangerous substances
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\*: Evidence for disposal must be provided.

### Waste treatment options

#### Appropriate disposal / Product:

Dispose of waste according to applicable legislation. Consult the appropriate local waste disposal expert about waste disposal.

#### Appropriate disposal / Package:

Dispose according to legislation. Consult the appropriate local waste disposal expert about waste disposal.

### 13.2. Additional information

Dispose waste in accordance with national regulations!

## SECTION 14: Transport information

Land transport (ADR/RID)	Inland waterway craft (ADN)	Sea transport (IMDG)	Air transport (ICAO-TI / IATA-DGR)
<b>14.1. UN number or ID number</b>			
No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.
<b>14.2. UN proper shipping name</b>			
No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.
<b>14.3. Transport hazard class(es)</b>			
not relevant	not relevant	not relevant	not relevant
<b>14.4. Packing group</b>			
not relevant	not relevant	not relevant	not relevant
<b>14.5. Environmental hazards</b>			
not relevant	not relevant	not relevant	not relevant
<b>14.6. Special precautions for user</b>			
not relevant	not relevant	not relevant	not relevant

### 14.7. Maritime transport in bulk according to IMO instruments

No data available

## SECTION 15: Regulatory information

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

#### 15.1.1. EU legislation

##### Authorisations:

Class II-A Medical product according to Medical Devices Directive 93/42/EEC with amendment 2007/47/EC.

##### Other regulations (EU):

Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work Classification according to Regulation (EC) No 1272/2008 [CLP], according to Regulation (EC) No. 1907/2006 (amended by Regulation (EU) No 453/2010). Classification according to Directive 67/548/EEC or 1999/45/EC Observe restrictions to employment for juveniles according to the 'juvenile work protection guideline' (94/33/EC).

#### 15.1.2. National regulations

##### [DE] National regulations

##### Restrictions of occupation

4 MuSchRiV. 5 MuSchRiV. 22 JArbSchG.

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### Annex Chemikalien-Verbotsverordnung (ChemVerbotsV)

Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work

### Technische Anleitung zur Reinhaltung der Luft (TA-Luft)

#### Remark:

Total dust emission value may not be exceeded (see number 5.2.1).

### Water hazard class

#### WGK:

1 - Mildly water-hazardous

#### Source:

Self-classification

### Other regulations, restrictions and prohibition regulations

TRGS 401 "Risks resulting from skin contact - identification, assessment, measures"

TRGS 510 "Storage of hazardous substances in non-stationary containers"

BGI 595 "Instructions M 004: Irritating substances / corrosive substances"

### 15.2. Chemical Safety Assessment

No data available

## SECTION 16: Other information

### 16.1. Indication of changes

No data available

### 16.2. Abbreviations and acronyms

No data available

### 16.3. Key literature references and sources for data

You can refer to data sources below to find detailed toxicity information of each component.

<http://www.baua.de/>

<http://gestis.itrust.de/>

<http://www.gefahrstoff-info.de/>

<http://esis.jrc.ec.europa.eu/>

<http://www.echemportal.org/>

<http://www.gischem.de>

### 16.4. Classification for mixtures and used evaluation method according to regulation (EC) No 1272/2008 [CLP]

The mixture is classified as not hazardous according to regulation (EC) No 1272/2008 [CLP].

### 16.5. Relevant R-, H- and EUH-phrases (Number and full text)

Hazard statements	
H302	Harmful if swallowed.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H330	Fatal if inhaled.
H351	Suspected of causing cancer.
H372	Causes damage to organs through prolonged or repeated exposure.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.

### 16.6. Training advice

Do not handle until all safety precautions have been read and understood.

### 16.7. Additional information

DISCLAIMER: The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. ACTO GmbH assumes no liability for damage arising from the use of the information or for any errors or omissions. The information given is designed only as guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific product

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designated and may not be valid for such product used in combination with any other materials or in any process, unless specified in the text.