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

1.1 Product identifier
Trade name/designation  Epi proColon Positive Control
Article no. (user):  Epi proColon Control Kit (M5-02-003)

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

Relevant identified uses
remark
Epi proColon Control Kit (M5-02-003)

Product categories [PC]
PC21 Laboratory chemicals

Process categories [PROC]
PROC15 Use as laboratory reagent

1.3 Details of the supplier of the safety data sheet

Importer/Only Representative
Epigenomics AG
Geneststrasse 5
D-10829 Berlin
P.O. Box: ---
Telephone: +49 (0)30 24345-0 (9:00 - 16:30)
Telefax: +49 (0)30 24345-555
E-mail: contact@epigenomics.com
www.epigenomics.com

1.4 Emergency telephone number
Giftnotruf Berlin: +49 (0)30 30686-700 (24h)

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

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

2.2 Label elements

2.3 Other hazards
No data available
SECTION 3: Composition / information on ingredients

3.1/3.2 Substances/Mixtures

Hazardous ingredients

edetic acid; (EDTA)  
<0,1 %  
CAS 60-00-4  
EC 200-449-4  
INDEX 607-429-00-8  
Eye Irrit. 2, H319

Albumin, Blutplasma, Cohn Fraktion V  
5 %  
CAS 90604-29-8

2-Amino-2-hydroxymethyl-propan-1,3-diol  
0.1 - <1 %  
CAS 77-86-1  
EC 201-064-4  
Skin Irrit. 2, H315 / Eye Irrit. 2, H319 / STOT SE 3, H335

SECTION 4: First aid measures

4.1 Description of first aid measures

General information
Change contaminated, saturated clothing.

Following inhalation
Provide fresh air. In case of respiratory tract irritation, consult a physician.

Following skin contact
After contact with skin, wash immediately with plenty of water and soap.

After eye contact
In case of contact with eyes flush immediately with plenty of flowing water for 10 to 15 minutes holding eyelids apart. In case of eye irritation consult an ophthalmologist.

After ingestion
Rinse mouth immediately and drink plenty of water. Do not induce vomiting.

4.2 Most important symptoms and effects, both acute and delayed
No data available

4.3 Indication of any immediate medical attention and special treatment needed
Notes for the doctor
Treat symptomatically.

SECTION 5: Firefighting measures

Additional information
The product itself does not burn. Co-ordinate fire-fighting measures to the fire surroundings.

5.1 Extinguishing media
No data available

5.2 Special hazards arising from the substance or mixture
Hazardous combustion products
Can be released in case of fire:  
Nitrogen oxides (NOx)
5.3 Advice for firefighters

Special protective equipment for firefighters:
protective clothing. In case of fire: Wear self-contained breathing apparatus.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Personal precautions
Provide adequate ventilation. Use personal protection equipment.

For emergency responders

Personal protection equipment
Wear breathing apparatus if exposed to vapours/dusts/aerosols.

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

Suitable material for taking up:
Absorbing material, organic

For cleaning up

Suitable material for diluting or neutralizing:
Water

6.4 Reference to other sections
Safe handling: see section 7
Personal protection equipment: see section 8
Disposal: see section 13

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Advices on general occupational hygiene
Minimum standard for preventive measures while handling with working materials are specified in the TRGS 500. When using do not eat, drink, smoke, sniff. Remove contaminated, saturated clothing. Avoid contact with skin, eyes and clothes.

Protective measures

Advices on safe handling
Avoid:
Inhalation of vapours or spray/mists
Skin contact
Eye contact

Measures to prevent fire
The product is not:
Combustible
Explosive
No special fire protection measures are necessary.
Environmental precautions
See section 8.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels
Keep/Store only in original container. Keep container tightly closed.

Hints on joint storage

Storage class
Non-combustible liquids

Further information on storage conditions

storage temperature  -25 - -15 °C

7.3 Specific end use(s)
Recommendation
Observe instructions for use.

SECTION 8: Exposure controls/personal protection

Additional information
Preventive industrial medical examinations are to be offered.

8.1 Control parameters
remark
Does not contain substances above concentration limits fixing an occupational exposure limit.

8.2 Exposure controls

Appropriate engineering controls
Technical measures to prevent exposure
refer to chapter 7. No further action is necessary.

Personal protection equipment

Eye/face protection:
Eye glasses with side protection

Skin protection

Suitable gloves type:
Disposable gloves

Suitable material:
NBR (Nitrile rubber)

Required properties:
liquid-tight

Breakthrough time (maximum wearing time)  \( \geq 480 \) min

Thickness of the glove material  \( \geq 0.11 \) mm

additional hand protection measures
Check leak tightness/impermeability prior to use. Use gloves only once.

remark
Breakthrough times and swelling properties of the material must be taken into consideration.
Body protection:
Suitable protective clothing:
lab coat
Recommended material:
Natural fibres (e.g. cotton)
Respiratory protection
remark
Usually no personal respirative protection necessary.
Environmental exposure controls
Technical measures to prevent exposure
refer to chapter 7. No further action is necessary.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance
Physical state
liquid
Colour
colourless
Odour
odourless
Odour threshold:
odourless

<table>
<thead>
<tr>
<th>parameter</th>
<th>Method - source - remark</th>
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<td>Flash point (°C)</td>
<td>No flash point according to standard method.</td>
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<td>Evaporation rate</td>
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<td>Upper explosion limit</td>
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<td>lower explosion limit</td>
<td>not determined</td>
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<td>Vapour pressure</td>
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<td>Vapour density</td>
<td>not determined</td>
</tr>
<tr>
<td>Density</td>
<td>not determined</td>
</tr>
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<td>Water solubility (g/L)</td>
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<tr>
<td>Soluble (g/L) in</td>
<td>not determined</td>
</tr>
</tbody>
</table>
### 9.2 Other safety information

#### Physical hazards
- **Flammable solids**
  - **Assessment/classification**: Non-flammable.

### SECTION 10: Stability and reactivity

#### 10.1 Reactivity
No information available.

#### 10.2 Chemical stability
The product is stable under storage at normal ambient temperatures.

#### 10.3 Possibility of hazardous reactions
No hazardous reaction when handled and stored according to provisions.

#### 10.4 Conditions to avoid
No information available.

#### 10.5 Incompatible materials
- **Materials to avoid**: Reacts with:
  - Oxidising agent
  - Alkali (lye)

#### 10.6 Hazardous decomposition products
No information available.

### SECTION 11: Toxicological information

#### 11.1 Information on toxicological effects

#### Acute toxicity

##### Acute dermal toxicity
- **ingredient**: 2-Amino-2-hydroxymethyl-propan-1,3-diol
- **Acute dermal toxicity**: >5000 mg/kg

##### Effective dose
- **LD50**:  
  - **Species**: Rat
  - **Method**: OECD 402

#### Acute oral toxicity
- **ingredient**: 2-Amino-2-hydroxymethyl-propan-1,3-diol

<table>
<thead>
<tr>
<th>parameter</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Partition coefficient: n-octanol/water</td>
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<tr>
<td>Temperature 20 °C</td>
<td>OECD 107 Merck AG</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>not determined</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>not determined</td>
</tr>
</tbody>
</table>

---

**Ingredient**: 2-Amino-2-hydroxymethyl-propan-1,3-diol
Acute oral toxicity  >5000 mg/kg

Effective dose
LC50:

Species: Rat
Method OECD 425

Skin corrosion/irritation

Assessment/classification
Not an irritant.

Species: Rabbit
Method OECD 404

CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)

Overall Assessment on CMR properties
Due to missing data no statement can be made whether the substance fullfills the criteria of CMR categories 1 or 2.

STOT-single exposure

STOT SE 3

exposure route
inhalative

Assessment/classification
May cause respiratory irritation.

STOT SE 3

Irritation to respiratory tract

Assessment/classification
May cause respiratory irritation.

SECTION 12: Ecological information

12.1 Toxicity

Aquatic toxicity

Acute (short-term) fish toxicity  460 mg/L

Effective dose
LC50:

Test duration  96 h

species
Leuciscus idus (golden orfe)
Method OECD 203

Acute (short-term) toxicity to crustacea

ingredient  2-Amino-2-hydroxymethyl-propan-1,3-diol
Acute (short-term) toxicity to crustacea  >960 mg/L
Effective dose
EC50
Test duration 48 h
species
Daphnia magna (Big water flea)
Method
OECD 202

Acute (short-term) toxicity to aquatic algae and cyanobacteria
ingredient 2-Amino-2-hydroxymethyl-propan-1,3-diol
Acute (short-term) toxicity to aquatic algae and cyanobacteria 397 mg/L
Effective dose
EC50
Test duration 72 h
species
Pseudokirchneriella subcapitata
Method
OECD 201

Toxicity to microorganisms >1000 mg/L
Effective dose
EC50
Test duration 3 h
Method
OECD 209

12.2 Persistence and degradability
Biodegradation
Degradation rate (%): 89 %
Method
OECD 301D/ EEC 92/69/V, C.4-E
remark
The aquatic toxic ingredients are biodegradable.

12.3 Bioaccumulative potential
Assessment/classification
Based on the n-octanol/water partition coefficient accumulation in organisms is not expected.

Partition coefficient: n-octanol/water
Distribution coefficient (n-octanol / water) (log P O/W): -2.31
Method
OECD 107

12.4 Mobility in soil
No information available.

12.5 Results of PBT and vPvB assessment
This substance does not meet the PBT/vPvB criteria of REACH, annex XIII.

12.6 Other adverse effects
No information available.
SECTION 13: Disposal considerations

13.1 Waste treatment methods

Appropriate disposal / Product
Waste disposal according to official state regulations.

Appropriate disposal / Package
Handle contaminated packaging in the same way as the substance itself.

SECTION 14: Transport information

<table>
<thead>
<tr>
<th>Land transport (ADR/RID)</th>
<th>Sea transport (IMDG)</th>
<th>Air transport (ICAO-TI / IATA-DGR)</th>
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</thead>
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<tr>
<td>14.1 UN-No.</td>
<td>not applicable</td>
<td>not applicable</td>
</tr>
<tr>
<td>14.2 Proper Shipping Name</td>
<td>not applicable</td>
<td>not applicable</td>
</tr>
<tr>
<td>14.3 Class(es)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>14.4 Packing group</td>
<td></td>
<td></td>
</tr>
<tr>
<td>14.5 ENVIRONMENTALLY HAZARDOUS</td>
<td></td>
<td></td>
</tr>
<tr>
<td>14.6 Special precautions for user</td>
<td></td>
<td></td>
</tr>
<tr>
<td>14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Additional information

All transport carriers
Not a hazardous material with respect to transportation regulations.

SECTION 15: Regulatory information

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

National regulations

15.2 Chemical Safety Assessment
For this substance a chemical safety assessment is not required.

SECTION 16: Other information

Abbreviations and acronyms
For abbreviations and acronyms, see: ECHA Guidance on information requirements and chemical safety assessment, chapter R.20 (Table of terms and abbreviations).

Relevant R-, H- and EUH-phrases (Number and full text)
H315 Causes skin irritation.
H319 Causes serious eye irritation.
H335 May cause respiratory irritation.
R36 Irritating to eyes.
R36/37/38 Irritating to eyes, respiratory system and skin.
Key literature references and sources for data

The above information describes exclusively the safety requirements of the product and is based on our present-day knowledge. The information is intended to give you advice about the safe handling of the product named in this safety data sheet, for storage, processing, transport and disposal. The information cannot be transferred to other products. In the case of mixing the product with other products or in the case of processing, the information on this safety data sheet is not necessarily valid for the new made-up material.
SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier
Trade name/designation  Epi proColon Negative Control
Article no. (user):  Epi proColon Control Kit (M5-02-003)

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

Relevant identified uses
remark
Epi proColon Control Kit (M5-02-003)

Product categories [PC]
PC21 Laboratory chemicals

Process categories [PROC]
PROC15 Use as laboratory reagent

1.3 Details of the supplier of the safety data sheet

Importer/Only Representative
Epigenomics AG
Geneststrasse 5
D-10829 Berlin
P.O. Box: ---
Telephone: +49 (0)30 24345-0 (9:00 - 16:30)
Telefax: +49 (0)30 24345-555
E-mail: contact@epigenomics.com
www.epigenomics.com

1.4 Emergency telephone number
Giftnotruf Berlin: +49 (0)30 30686-700 (24h)

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

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

2.2 Label elements

2.3 Other hazards
No data available
SECTION 3: Composition / information on ingredients

3.1/3.2 Substances/Mixtures

Hazardous ingredients

- edetic acid; (EDTA) <0,1 %
  CAS 60-00-4
  EC 200-449-4
  INDEX 607-429-00-8
  Eye Irrit. 2, H319
- Albumin, Blutplasma, Cohn Fraktion V 5 %
  CAS 90604-29-8
- 2-Amino-2-hydroxymethyl-propan-1,3-diol 0,1 - <1 %
  CAS 77-86-1
  EC 201-064-4
  Skin Irrit. 2, H315 / Eye Irrit. 2, H319 / STOT SE 3, H335

SECTION 4: First aid measures

4.1 Description of first aid measures

General information
Change contaminated, saturated clothing.

Following inhalation
Provide fresh air. In case of respiratory tract irritation, consult a physician.

Following skin contact
After contact with skin, wash immediately with plenty of water and soap.

After eye contact
In case of contact with eyes flush immediately with plenty of flowing water for 10 to 15 minutes holding eyelids apart. In case of eye irritation consult an ophthalmologist.

After ingestion
Rinse mouth immediately and drink plenty of water. Do not induce vomiting.

4.2 Most important symptoms and effects, both acute and delayed
No data available

4.3 Indication of any immediate medical attention and special treatment needed
Notes for the doctor
Treat symptomatically.

SECTION 5: Firefighting measures

Additional information
The product itself does not burn. Co-ordinate fire-fighting measures to the fire surroundings.

5.1 Extinguishing media
No data available

5.2 Special hazards arising from the substance or mixture

Hazardous combustion products
Can be released in case of fire:
Nitrogen oxides (NOx)
5.3 Advice for firefighters
Special protective equipment for firefighters:
protective clothing. In case of fire: Wear self-contained breathing apparatus.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures
For non-emergency personnel
Personal precautions
Provide adequate ventilation. Use personal protection equipment.

For emergency responders
Personal protection equipment
Wear breathing apparatus if exposed to vapours/dusts/aerosols.

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
Suitable material for taking up:
Absorbing material, organic

For cleaning up
Suitable material for diluting or neutralizing:
Water

6.4 Reference to other sections
Safe handling: see section 7
Personal protection equipment: see section 8
Disposal: see section 13

SECTION 7: Handling and storage

7.1 Precautions for safe handling
Advices on general occupational hygiene
Minimum standard for preventive measures while handling with working materials are specified in the TRGS 500. When using do not eat, drink, smoke, sniff. Remove contaminated, saturated clothing. Avoid contact with skin, eyes and clothes.

Protective measures
Advices on safe handling
Avoid:
Inhalation of vapours or spray/mists
Skin contact
Eye contact

Measures to prevent fire
The product is not:
Combustible
Explosive
No special fire protection measures are necessary.
Environmental precautions
See section 8.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels
Keep/Store only in original container. Keep container tightly closed.

Hints on joint storage
Storage class
Non-combustible liquids

Further information on storage conditions
storage temperature  -25 - -15 °C

7.3 Specific end use(s)
Recommendation
Observe instructions for use.

SECTION 8: Exposure controls/personal protection

Additional information
Preventive industrial medical examinations are to be offered.

8.1 Control parameters
remark
Does not contain substances above concentration limits fixing an occupational exposure limit.

8.2 Exposure controls
Appropriate engineering controls
Technical measures to prevent exposure
refer to chapter 7. No further action is necessary.

Personal protection equipment
Eye/face protection
Suitable eye protection:
Eye glasses with side protection

Skin protection
Suitable gloves type:
Disposable gloves
Suitable material:
NBR (Nitrile rubber)
Required properties:
liquid-tight
Breakthrough time (maximum wearing time)  >=480 min
Thickness of the glove material  >=0,11 mm

additional hand protection measures
Check leak tightness/impermeability prior to use. Use gloves only once.
remark
Breakthrough times and swelling properties of the material must be taken into consideration.
Body protection:
Suitable protective clothing:
lab coat
Recommended material:
Natural fibres (e.g. cotton)
Respiratory protection
remark
Usually no personal respirative protection necessary.
Environmental exposure controls
Technical measures to prevent exposure
refer to chapter 7. No further action is necessary.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance
Physical state
liquid
Colour
colourless
Odour
odourless
Odour threshold:
odourless

<table>
<thead>
<tr>
<th>parameter</th>
<th>Method - source - remark</th>
</tr>
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<tbody>
<tr>
<td>pH</td>
<td>7,4</td>
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<tr>
<td>Melting point/freezing point</td>
<td></td>
</tr>
<tr>
<td>Initial boiling point and boiling range</td>
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<td>Flash point (°C)</td>
<td>No flash point according to standard method.</td>
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<tr>
<td>Evaporation rate</td>
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<tr>
<td>flammability</td>
<td>not determined</td>
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<td>Upper explosion limit</td>
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<td>lower explosion limit</td>
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<td>Density</td>
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<td>Fat solubility (g/L)</td>
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<td>Water solubility (g/L)</td>
<td>completely miscible</td>
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</table>
_partition coefficient: n-octanol/water | Method - source - remark
--- | ---
-2,31 | OECD 107

**Auto-ignition temperature**
not determined

**Decomposition temperature**
not determined

### 9.2 Other safety information

**Physical hazards**

**Flammable solids**

*Assessment/classification*
Non-flammable.

### SECTION 10: Stability and reactivity

**10.1 Reactivity**
No information available.

**10.2 Chemical stability**
The product is stable under storage at normal ambient temperatures.

**10.3 Possibility of hazardous reactions**
No hazardous reaction when handled and stored according to provisions.

**10.4 Conditions to avoid**
No information available.

**10.5 Incompatible materials**

**Materials to avoid**
Reacts with:
- Oxidising agent
- Alkali (lye)

**10.6 Hazardous decomposition products**
No information available.

### SECTION 11: Toxicological information

**11.1 Information on toxicological effects**

**Acute toxicity**

**Acute dermal toxicity**
- **ingredient**: 2-Amino-2-hydroxymethyl-propan-1,3-diol
- **Acute dermal toxicity**: >5000 mg/kg

**Effective dose**
LD50:

**Species:**
- Rat

**Method**
OECD 402

**Acute oral toxicity**
- **ingredient**: 2-Amino-2-hydroxymethyl-propan-1,3-diol
Acute oral toxicity  >5000 mg/kg
Effective dose
LC50:
Species: Rat
Method OECD 425

Skin corrosion/irritation
Assessment/classification
Not an irritant.
Species: Rabbit
Method OECD 404

CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)
Overall Assessment on CMR properties
Due to missing data no statement can be made whether the substance fulfills the criteria of CMR categories 1 or 2.

STOT-single exposure
STOT SE 3
exposure route
inhalative
Assessment/classification
May cause respiratory irritation.

STOT SE 3
Irritation to respiratory tract
Assessment/classification
May cause respiratory irritation.

SECTION 12: Ecological information

12.1 Toxicity
Aquatic toxicity
Acute (short-term) fish toxicity  460 mg/L
Effective dose
LC50:
Test duration  96 h
species
Leuciscus idus (golden orfe)
Method OECD 203

Acute (short-term) toxicity to crustacea
ingredient  2-Amino-2-hydroxymethyl-propan-1,3-diol
Acute (short-term) toxicity to crustacea  >960 mg/L
Effective dose
EC50
Test duration 48 h
species
Daphnia magna (Big water flea)
Method
OECD 202

Acute (short-term) toxicity to aquatic algae and cyanobacteria
ingredient 2-Amino-2-hydroxymethyl-propan-1,3-diol
Acute (short-term) toxicity to aquatic algae and cyanobacteria 397 mg/L
Effective dose
EC50
Test duration 72 h
species
Pseudokirchneriella subcapitata
Method
OECD 201

Toxicity to microorganisms >1000 mg/L
Effective dose
EC50
Test duration 3 h
Method
OECD 209

12.2 Persistence and degradability
Biodegradation
Degradation rate (%): 89 %
Method
OECD 301D/ EEC 92/69/V, C.4-E
remark
The aquatic toxic ingredients are biodegradable.

12.3 Bioaccumulative potential
Assessment/classification
Based on the n-octanol/water partition coefficient accumulation in organisms is not expected.

Partition coefficient: n-octanol/water
Distribution coefficient (n-octanol / water) (log P O/W): -2.31
Method
OECD 107

12.4 Mobility in soil
No information available.

12.5 Results of PBT and vPvB assessment
This substance does not meet the PBT/vPvB criteria of REACH, annex XIII.

12.6 Other adverse effects
No information available.
SECTION 13: Disposal considerations

13.1 Waste treatment methods

Appropriate disposal / Product
Waste disposal according to official state regulations.

Appropriate disposal / Package
Handle contaminated packaging in the same way as the substance itself.

SECTION 14: Transport information

<table>
<thead>
<tr>
<th></th>
<th>Land transport (ADR/RID)</th>
<th>Sea transport (IMDG)</th>
<th>Air transport (ICAO-TI / IATA-DGR)</th>
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<tr>
<td>14.1 UN-No.</td>
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<td>not applicable</td>
<td>not applicable</td>
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<td>14.2 Proper Shipping Name</td>
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<tr>
<td>14.3 Class(es)</td>
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<td>14.4 Packing group</td>
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<td>14.5 ENVIRONMENTALLY HAZARDOUS</td>
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<tr>
<td>14.6 Special precautions for user</td>
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<tr>
<td>14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code</td>
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</table>

Additional information

All transport carriers
Not a hazardous material with respect to transportation regulations.

SECTION 15: Regulatory information

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

National regulations

15.2 Chemical Safety Assessment
For this substance a chemical safety assessment is not required.

SECTION 16: Other information

Abbreviations and acronyms
For abbreviations and acronyms, see: ECHA Guidance on information requirements and chemical safety assessment, chapter R.20 (Table of terms and abbreviations).

Relevant R-, H- and EUH-phrases (Number and full text)
H315 Causes skin irritation.
H319 Causes serious eye irritation.
H335 May cause respiratory irritation.
R36 Irritating to eyes.
R36/37/38 Irritating to eyes, respiratory system and skin.
Key literature references and sources for data

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