

Helimatic Neutralizer C

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878
Issue date: 3/14/2012 Revision date: 4/18/2023 Supersedes: 5/18/2020 Version: 2.1
SDS No: 00056-0197

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

1.1. Product identifier

Product form : Mixture
Product name : Helimatic Neutralizer C
UFI : XD8V-D7MD-C00R-3JUG

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

1.2.1. Relevant identified uses

Use of the substance/mixture : Neutralising agent

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Manufacturer

B. Braun Medical AG
Seesatz 17
CH-6204 Sempach
Switzerland
T +41 (0) 58 / 258 50 00
info.bbmch@bbraun.com

Supplier

B. Braun Melsungen AG
Carl-Braun-Straße 1
D-34212 Melsungen
Germany
T +49(0) 5661 / 71-4422
logistics.service@bbraun.com

E-mail address of competent person responsible for the SDS: sds@gbk-ingelheim.de

1.4. Emergency telephone number

Emergency number : INTERNATIONAL: +49 - (0) 6132 - 84463, GBK GmbH (24h - 7d/w - 365d/a)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

Serious eye damage/eye irritation, Category 2 H319
Specific target organ toxicity – Single exposure, Category 3, Respiratory tract irritation H335

Full text of H- and EUH-statements: see section 16

Adverse physicochemical, human health and environmental effects

Causes serious eye irritation. May cause respiratory irritation.

2.2. Label elements

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

Hazard pictograms (CLP) :



Signal word (CLP) :

Warning

Contains :

Citric acid monohydrate

Hazard statements (CLP) :

H319 - Causes serious eye irritation.
H335 - May cause respiratory irritation.

Precautionary statements (CLP) :

P280 - Wear protective gloves, protective clothing, eye protection, face protection.
P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P337+P313 - If eye irritation persists: Get medical advice/attention.
P501 - Dispose of contents and container to an approved waste disposal plant.

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Labelling according to: exemption for packages of a capacity of 125ml or less
Hazard pictograms (CLP) :



GHS07

Signal word (CLP) : Warning
Hazardous ingredients : Citric acid monohydrate

2.3. Other hazards

This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII
This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII
Contains no PBT/vPvB substances $\geq 0.1\%$ assessed in accordance with REACH Annex XIII

The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Comments : Mixture of the substances listed below with nonhazardous additives

| Name | Product identifier | % | Classification according to Regulation (EC) No. 1272/2008 [CLP] |
|-------------------------|---|------|---|
| Citric acid monohydrate | CAS-No.: 5949-29-1 EC-No.: 201-069-1 REACH-no: 01-2119457026-42 | < 30 | Eye Irrit. 2, H319 STOT SE 3, H335 |

Full text of H- and EUH-statements: see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general : Data of item 4 do partly not refer to the use and the regular employing of the product (in this sense consult package leaflet and expert information), but to liberation of major amounts in case of accidents and irregularities. Take off immediately all contaminated clothing. If you feel unwell, seek medical advice.

First-aid measures after inhalation : Remove person to fresh air and keep comfortable for breathing. If you feel unwell, seek medical advice.

First-aid measures after skin contact : Wash off immediately with soap and plenty of water. Get medical advice if skin irritation persists.

First-aid measures after eye contact : Wash immediately with plenty water (during 20 minutes), also under eyelids. Call a physician immediately.

First-aid measures after ingestion : Call a physician immediately. Do not induce vomiting. Drink plenty of water. Do not give an unconscious person anything to drink. Do not induce vomiting without medical advice.

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

Symptoms/effects after inhalation : May cause respiratory irritation.
Symptoms/effects after eye contact : Causes serious eye irritation.

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

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : Product itself does not burn. Use extinguishing media appropriate for surrounding fire.
Unsuitable extinguishing media : high volume water jet.

5.2. Special hazards arising from the substance or mixture

Fire hazard : Not flammable.
Explosion hazard : Product is not explosive.
Hazardous decomposition products in case of fire : Carbon oxides (CO, CO₂).

5.3. Advice for firefighters

Precautionary measures fire : Cool endangered containers with water spray jet.
Firefighting instructions : Move containers from fire area if it can be done without personal risk. Fight fire from safe distance and protected location.
Protection during firefighting : Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.
Other information : Fire residues and contaminated firefighting water must be disposed of in accordance with the local regulations.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures : Ventilate spillage area. Evacuate unnecessary personnel.

6.1.1. For non-emergency personnel

Emergency procedures : Avoid contact with skin and eyes. Do not breathe mist.

6.1.2. For emergency responders

Protective equipment : Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

6.2. Environmental precautions

Do not allow to enter into surface water or drains. Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

For containment : Dike and contain spill.
Methods for cleaning up : Absorb with liquid-binding material (e.g. sand, diatomaceous earth, acid- or universal binding agents). Notify authorities if product enters sewers or public waters.
Other information : Dispose of materials or solid residues at an authorized site.

6.4. Reference to other sections

Refer to protective measures listed in sections 7 and 8. For further information refer to section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Additional hazards when processed : Avoid contact with skin, eyes and clothing.
Precautions for safe handling : Ensure good ventilation of the work station. Wear personal protective equipment.
Hygiene measures : Wash contaminated clothing before reuse. Do not eat, drink or smoke when using this product. Always wash hands after handling the product.

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7.2. Conditions for safe storage, including any incompatibilities

| | |
|------------------------------|---|
| Technical measures | : Provide for a tub to collect spills. |
| Storage conditions | : Keep container tightly closed in a dry, cool and well-ventilated place. |
| Incompatible products | : Strong bases. Strong oxidizing agent. |
| Information on mixed storage | : Keep away from food, drink and animal feeding stuffs. |

7.3. Specific end use(s)

See Section 1.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1 National occupational exposure and biological limit values

No additional information available

8.1.2. Recommended monitoring procedures

| Monitoring methods | |
|-------------------------------|---|
| Monitoring methods | A specific exposure sampling method is not available. |
| Biological monitoring methods | A specific exposure sampling method is not available |

8.1.3. Air contaminants formed

No additional information available

8.1.4. DNEL and PNEC

| Citric acid monohydrate (5949-29-1) | |
|-------------------------------------|-----------------|
| PNEC (Water) | |
| PNEC aqua (freshwater) | 0.44 mg/l |
| PNEC aqua (marine water) | 0.044 mg/l |
| PNEC (Sediment) | |
| PNEC sediment (freshwater) | 7.52 mg/kg dwt |
| PNEC sediment (marine water) | 0.752 mg/kg dwt |
| PNEC (Soil) | |
| PNEC soil | 29.2 mg/kg dwt |

8.1.5. Control banding

No additional information available

8.2. Exposure controls

8.2.1. Appropriate engineering controls

Appropriate engineering controls:

Ensure good ventilation of the work station.

8.2.2. Personal protection equipment

Personal protective equipment:

Data of item 8 do partly not refer to the use and the regular employing of the product (in this sense consult package leaflet and expert information), but to liberation of major amounts in case of accidents and irregularities.

8.2.2.1. Eye and face protection

Eye protection:

Eyewash bottle with clean water (EN 15154)

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| Eye protection | | | |
|-----------------------------|---------------------------|-----------------|----------|
| Type | Field of application | Characteristics | Standard |
| Protective goggles (EN 166) | Liquid splashes may occur | | EN 166 |

8.2.2.2. Skin protection

| Skin and body protection | |
|----------------------------------|-------------|
| Type | Standard |
| Long sleeved protective clothing | EN ISO 6530 |

Hand protection:

This recommendation refers exclusively to the chemical compatibility and the lab test conforming to EN 374 carried out under lab conditions. Requirements can vary as a function of the use. Therefore it is necessary to adhere additionally to the recommendations given by the manufacturer of protective gloves

| Hand protection | | | | | |
|--|----------------|-------------------|----------------|-------------|------------|
| Type | Material | Permeation | Thickness (mm) | Penetration | Standard |
| Chemically resistant protective gloves | Natural rubber | 6 (> 480 minutes) | 0,6 | | EN ISO 374 |

8.2.2.3. Respiratory protection

Respiratory protection:

No personal breathing protective equipment is normally required

8.2.2.4. Thermal hazards

No additional information available

8.2.3. Environmental exposure controls

Environmental exposure controls:

Avoid release to the environment.

Other information:

Do not breathe vapours. Wash hands immediately after handling the product. Wash hands before breaks and at the end of workday. Do not eat, drink or smoke in areas where product is used. Avoid contact with eyes.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

| | |
|-----------------------------|-----------------------------|
| Physical state | : Liquid |
| Colour | : Colourless. |
| Appearance | : Liquid. |
| Odour | : Neutral. |
| Odour threshold | : Not available |
| Melting point | : Not available |
| Freezing point | : Not available |
| Boiling point | : ≈ 100 °C |
| Flammability (solid, gas) | : Not applicable |
| Explosive properties | : Product is not explosive. |
| Oxidising properties | : Not oxidising. |
| Explosive limits | : Not available |
| Lower explosive limit (LEL) | : Not available |
| Upper explosive limit (UEL) | : Not available |
| Flash point | : Not available |
| Auto-ignition temperature | : Not available |
| Decomposition temperature | : Not available |
| pH | : 2.5 (20°C) |

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| | |
|---|--|
| pH solution concentration | : 10 g/l |
| Viscosity, kinematic | : Not available |
| Solubility | : Water: Miscible |
| Partition coefficient n-octanol/water (Log Kow) | : Not available |
| Vapour pressure | : Not available |
| Vapour pressure at 50°C | : Not available |
| Density | : 1.11 – 1.13 g/cm ³ (20°C) |
| Relative density | : Not available |
| Relative vapour density at 20°C | : Not available |
| Particle characteristics | : Not applicable |

9.2. Other information

9.2.1. Information with regard to physical hazard classes

No additional information available

9.2.2. Other safety characteristics

| | |
|-----------------|-------|
| VOC content | : 0 % |
| Solvent content | : 0 % |

SECTION 10: Stability and reactivity

10.1. Reactivity

No decomposition if stored normally.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

Exothermic reaction on contact with : Strong bases. Reactions with oxidizing agents.

10.4. Conditions to avoid

To avoid thermal decomposition, do not overheat.

10.5. Incompatible materials

Strong bases. Strong oxidizing agent.

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced. Fire may produce: Carbon oxides (CO, CO₂).

SECTION 11: Toxicological information

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

| | |
|-----------------------------|---|
| Acute toxicity (oral) | : Not classified (Based on available data, the classification criteria are not met) |
| Acute toxicity (dermal) | : Not classified (Based on available data, the classification criteria are not met) |
| Acute toxicity (inhalation) | : Not classified (Based on available data, the classification criteria are not met) |

| Citric acid monohydrate (5949-29-1) | |
|-------------------------------------|------------------|
| LD50 oral | 5400 mg/kg mouse |
| LD50 dermal rabbit | > 2000 |

| | |
|-----------------------------------|---|
| Skin corrosion/irritation | : Not classified (Based on available data, the classification criteria are not met) pH: 2.5 (20°C) |
| Serious eye damage/irritation | : Causes serious eye irritation. pH: 2.5 (20°C) |
| Respiratory or skin sensitisation | : Not classified (Based on available data, the classification criteria are not met) |

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| | |
|------------------------|---|
| Germ cell mutagenicity | : Not classified (Based on available data, the classification criteria are not met) |
| Carcinogenicity | : Not classified (Based on available data, the classification criteria are not met) |
| Reproductive toxicity | : Not classified (Based on available data, the classification criteria are not met) |
| STOT-single exposure | : May cause respiratory irritation. |

Citric acid monohydrate (5949-29-1)

| | |
|------------------------|---|
| STOT-single exposure | May cause respiratory irritation. |
| STOT-repeated exposure | : Not classified (Based on available data, the classification criteria are not met) |
| Aspiration hazard | : Not classified (Based on available data, the classification criteria are not met) |

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Adverse health effects caused by endocrine disrupting properties : The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %

11.2.2. Other information

No additional information available

SECTION 12: Ecological information

12.1. Toxicity

| | |
|---|---|
| Ecology - general | : No ecotoxicological data about this product are known. |
| Hazardous to the aquatic environment, short-term (acute) | : Not classified (Based on available data, the classification criteria are not met) |
| Hazardous to the aquatic environment, long-term (chronic) | : Not classified |

Citric acid monohydrate (5949-29-1)

| | |
|----------------|--|
| LC50 fish 1 | 440 – 706 mg/l |
| EC50 Daphnia 1 | 1535 mg/l 48 h, Daphnia magna (Water flea) |

12.2. Persistence and degradability

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| | |
|-------------------------------|--|
| Persistence and degradability | The surfactant(s) contained in this preparation complies(comply) with the biodegradability criteria as laid down in Regulation (EC) No. 648/2004 on detergents. Data to support this assertion are held at the disposal of the competent authorities of the Member States and will be made available to them, at their direct request or at the request of a detergent manufacturer. |
|-------------------------------|--|

12.3. Bioaccumulative potential

Citric acid monohydrate (5949-29-1)

| | |
|---------|---------|
| Log Pow | ≈ -1.72 |
|---------|---------|

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

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This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII

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This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

12.6. Endocrine disrupting properties

Adverse effects on the environment caused by endocrine disrupting properties : The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %.

12.7. Other adverse effects

Additional information : Prevent entry to sewers and public waters

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste treatment methods : Can be incinerated according to local regulations. Recycling is preferred to disposal or incineration. Dispose of contents/container in accordance with licensed collector's sorting instructions.

Product/Packaging disposal recommendations : Empty containers should be taken for local recycling, recovery or waste disposal. Contaminated packaging should be emptied as far as possible and after appropriate cleansing may be taken for reuse. Packaging that cannot be cleaned should be disposed of like the product.

European List of Waste (LoW) code : 07 06 04* - other organic solvents, washing liquids and mother liquors

SECTION 14: Transport information

In accordance with ADR / IMDG / IATA / ADN / RID

| ADR | IMDG | IATA | ADN | RID |
|---|---------------|---------------|---------------|---------------|
| 14.1. UN number or ID number | | | | |
| Not regulated | Not regulated | Not regulated | Not regulated | Not regulated |
| 14.2. UN proper shipping name | | | | |
| Not regulated | Not regulated | Not regulated | Not regulated | Not regulated |
| 14.3. Transport hazard class(es) | | | | |
| Not regulated | Not regulated | Not regulated | Not regulated | Not regulated |
| 14.4. Packing group | | | | |
| Not regulated | Not regulated | Not regulated | Not regulated | Not regulated |
| 14.5. Environmental hazards | | | | |
| Not regulated | Not regulated | Not regulated | Not regulated | Not regulated |
| No supplementary information available | | | | |

14.6. Special precautions for user

Overland transport

Not regulated

Transport by sea

Not regulated

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Air transport

Not regulated

Inland waterway transport

Not regulated

Rail transport

Not regulated

14.7. Maritime transport in bulk according to IMO instruments

Not applicable

SECTION 15: Regulatory information

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

15.1.1. EU-Regulations

REACH Annex XVII (Restriction List)

Contains no substance(s) listed on REACH Annex XVII (Restriction Conditions)

REACH Annex XIV (Authorisation List)

Contains no substance(s) listed on REACH Annex XIV (Authorisation List)

REACH Candidate List (SVHC)

Contains no substance(s) listed on the REACH Candidate List

PIC Regulation (Prior Informed Consent)

Contains no substance(s) listed on the PIC list (Regulation EU 649/2012 concerning the export and import of hazardous chemicals)

POP Regulation (Persistent Organic Pollutants)

Contains no substance(s) listed on the POP list (Regulation EU 2019/1021 on persistent organic pollutants)

Ozone Regulation (1005/2009)

Contains no substance(s) listed on the Ozone Depletion list (Regulation EU 1005/2009 on substances that deplete the ozone layer)

VOC Directive (2004/42)

VOC content : 0 %

Explosives Precursors Regulation (2019/1148)

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

Drug Precursors Regulation (273/2004)

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Indication of changes:

All chapters have been modified since the previous version.

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| Abbreviations and acronyms: | |
|-----------------------------|---|
| ADR | European Agreement concerning the International Carriage of Dangerous Goods by Road |
| ADN | European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways |
| IATA | International Air Transport Association |
| IMDG | International Maritime Dangerous Goods |
| RID | Regulations concerning the International Carriage of Dangerous Goods by Rail |
| DOT | Department of Transport |
| TDG | Transportation of Dangerous Goods |
| REACH | Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006 |
| GHS | Globally Harmonized System of Classification, Labelling and Packaging of Chemicals |
| IARC | International Agency for Research on Cancer |
| vPvB | Very Persistent and Very Bioaccumulative |
| PBT | Persistent Bioaccumulative Toxic |
| PNEC | Predicted No-Effect Concentration |
| CAS | CAS (Chemical Abstracts Service) number |
| IBC-Code | International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk |
| ATE | Acute Toxicity Estimate |
| CLP | Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008 |
| BCF | Bioconcentration factor |
| MARPOL 73/78 | MARPOL 73/78: International Convention for the Prevention of Pollution From Ships |
| ADG | Transport of Australian Dangerous Goods |

Other information : Data of sections 4 to 8, as well as 10 to 12, do partly not refer to the use and the regular employing of the product (in this sense consult information on use and on product), but to liberation of major amounts in case of accidents and irregularities. The information describes exclusively the safety requirements for the product(s) and is based on the present level of our knowledge. The delivery specifications are contained in the corresponding product sheet. This data does not constitute a guarantee for the characteristics of the product(s) as defined by the legal warranty regulations.

| Full text of H- and EUH-statements: | |
|-------------------------------------|--|
| Eye Irrit. 2 | Serious eye damage/eye irritation, Category 2 |
| H319 | Causes serious eye irritation. |
| H335 | May cause respiratory irritation. |
| STOT SE 3 | Specific target organ toxicity – Single exposure, Category 3, Respiratory tract irritation |

| Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]: | | |
|---|------|--------------------|
| Eye Irrit. 2 | H319 | Calculation method |
| STOT SE 3 | H335 | Calculation method |

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should therefore not be construed as guaranteeing any specific property of the product.