

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830 Date of issue: 16/03/2015 Revision date: 15/02/2017

627542

Version: 2.0

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

1.1. Product identifier Product form

| Product form : | Substance |
|------------------|----------------|
| Substance name : | Bacitracin |
| EC No : | 215-786-2 |
| CAS No : | 1405-87-4 |
| Product code : | 627542 |
| Formula : | C66H103N17O16S |
| Product group : | Raw material |

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

1.2.1. Relevant identified uses

| Main use category | : Pharmaceutical industry |
|------------------------------|--|
| Use of the substance/mixture | : Active ingredient for the preparation of pharmaceuticals |

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Supplier

Duchefa Farma BV A. Hofmanweg 71 2031BH Haarlem - Nederland T +31(0)23-5319093 farma@duchefa.nl - www.duchefa-farma.com

1.4. Emergency telephone number

Emergency number

: Supplier contact information:

+31(0)23-5319093 (M-F 09:00-17:00)

+31(0)6-30109355 (outside office hours)

| Country | Organisation/Company | Address | Emergency number | Comment |
|-------------------|---|---------------------------------|---------------------|---------|
| United Kingdom | Guy's & St Thomas' Poisons Unit Medical Toxicology Unit, Centre Hospitalier Universitaire de Constantine | Avonley Road SE14 5ER London | 0870 243 2241 | |

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

| Skin corrosion/irritation, Category 2 | H315 |
|---|------|
| Serious eye damage/eye irritation, Category 2 | H319 |
| Sensitisation — Skin, Category 1 | H317 |
| Specific target organ toxicity — Single exposure, Category 3, | H335 |

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Respiratory tract irritation

Full text of hazard classes and H-statements : see section 16

Adverse physicochemical, human health and environmental effects

No additional information available

2.2. Label elements

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

Hazard pictograms (CLP)

| | GHS07 |
|---------------------------------------|--|
| Signal word (CLP) | : Warning |
| Hazard statements (CLP) | H315 - Causes skin irritation H317 - May cause an allergic skin reaction H319 - Causes serious eye irritation H335 - May cause respiratory irritation |
| Precautionary statements (CLP) | P262 - Do not get in eyes, on skin, or on clothing P280 - Wear eye protection, face protection, protective clothing, protective gloves P305 - IF IN EYES: P351 - Rinse cautiously with water for several minutes P302+P352 - IF ON SKIN: Wash with plenty of soap and water |
| 2.3. Other hazards | |
| Other hazards not contributing to the | : None under normal conditions. |

SECTION 3: Composition/information on ingredients

3.1. Substances

Substance type

classification

: Antibiotics

| Name | Product identifier | % | Classification according to Regulation (EC) No. 1272/2008 [CLP] |
|------------|---|-------------------------------------|--|
| Bacitracin | (CAS No) 1405-87-4 (EC No) 215-786-2 | > 60 IU/mg dried substance | Skin Irrit. 2, H315 Eye Irrit. 2, H319 Skin Sens. 1, H317 STOT SE 3, H335 |

Full text of H-statements: see section 16

3.2. Mixtures

Not applicable

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures after inhalation : Assure fresh air breathing. Get medical advice/attention if you feel unwell.

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| First-aid measures after skin contact | : Wash with plenty of soap and water. |
|---------------------------------------|--|
| First-aid measures after eye contact | : Immediately flush eyes thoroughly with water for at least 15 minutes. |
| First-aid measures after ingestion | : Never give anything by mouth to an unconscious person. Seek medical attention immediately. |

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

| Symptoms/injuries | : Eye irritation. Skin irritation. Slight irritant by inhalation. |
|-------------------|---|
| Chronic symptoms | : Damage to liver. |

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

No additional information available

| SECTION 5: | Fire-fighting | measures |
|------------|----------------------|----------|
|------------|----------------------|----------|

5.1. Extinguishing media

Suitable extinguishing media : dry chemical powder, alcohol-resistant foam, carbon dioxide (CO2). Water spray.

5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in \therefore Nitrogen oxides. Carbon oxides (CO, CO2). case of fire

5.3. Advice for firefighters

No additional information available

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures

: Avoid raising dust.

6.1.1. For non-emergency personnel

No additional information available

6.1.2. For emergency responders

No additional information available

6.2. Environmental precautions

Prevent entry to sewers and public waters.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Sweep up, shovel or vacuum.

6.4. Reference to other sections

Reference to other sections (8, 13).

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Keep away from sources of ignition - No smoking. Protect from moisture.

7.2. Conditions for safe storage, including any incompatibilities

| Storage conditions | : Store in dry, cool, well-ventilated area. |
|---------------------|---|
| Storage temperature | : 2 - 8 °C |

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7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No additional information available

8.2. Exposure controls

Hand protection:

| Туре | Material | Permeation | Thickness (mm) | Standard |
|--------|----------------------|-------------------|----------------|----------|
| Gloves | Nitrile rubber (NBR) | 6 (> 480 minutes) | 0,11 | EN 374 |

Eye protection:

Safety glasses (to European standard EN 166 or equivalent)

Skin and body protection:

Protective clothing (with elasticated cuffs and closed neck). The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace

Respiratory protection:

Dustmask with filtertype P2

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

| Physical state Appearance | : Solid : Powder. |
|--|-----------------------------|
| Molecular mass | : 1422.71 g/mol |
| Colour | : white to slightly yellow. |
| Odour | : No data available |
| Odour threshold | : No data available |
| рН | : 6 - 7 1% solution |
| Relative evaporation rate (butylacetate=1) | : No data available |
| Melting point | : 221 - 225 °C |
| Freezing point | : No data available |
| Boiling point | : No data available |
| Flash point | : No data available |
| Auto-ignition temperature | : No data available |
| Decomposition temperature | : No data available |
| Flammability (solid, gas) | : No data available |
| Vapour pressure | : No data available |
| Relative vapour density at 20 °C | : No data available |
| Relative density | : No data available |
| Solubility | : Soluble in water. |
| Log Pow | : No data available |
| Viscosity, kinematic | : No data available |

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| Viscosity, dynamic | : No data available |
|----------------------|---------------------|
| Explosive properties | : No data available |
| Oxidising properties | : No data available |
| Explosive limits | : No data available |

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

No additional information available

10.2. Chemical stability

Hygroscopic. Under normal conditions of storage and use, hazardous decomposition products should not be produced.

10.3. Possibility of hazardous reactions

No additional information available

10.4. Conditions to avoid

High temperature. Strong oxidizers.

10.5. Incompatible materials

No additional information available

10.6. Hazardous decomposition products

Carbon oxides (CO, CO2). Nitrogen oxides. Sulphur oxides. release of harmful/irritant gases/vapours.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

| Acute toxicity | : Not classified |
|-----------------------------------|---|
| Skin corrosion/irritation | : Causes skin irritation. pH: 6 - 7 1% solution |
| Serious eye damage/irritation | : Causes serious eye irritation. pH: 6 - 7 1% solution |
| Respiratory or skin sensitisation | : May cause an allergic skin reaction. |
| Germ cell mutagenicity | : Not classified |
| Carcinogenicity | : Not classified |
| Reproductive toxicity | : Not classified |
| STOT-single exposure | : May cause respiratory irritation. |
| STOT-repeated exposure | : Not classified |
| Aspiration hazard | : Not classified |

SECTION 12: Ecological information

12.1. Toxicity

No additional information available

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12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

No additional information available

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste disposal recommendations : Dispose in a safe manner in accordance with local/national regulations.

SECTION 14: Transport information

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

| ADR | ΙΑΤΑ | | |
|--|------------------------------------|--|--|
| 14.1. UN number | | | |
| Not applicable | Not applicable | | |
| 14.2. UN proper shipping name | | | |
| Not applicable | Not applicable | | |
| 14.3. Transport hazard class(es) | | | |
| Not applicable | Not applicable | | |
| Not applicable | Not applicable | | |
| 14.4. Packing group | | | |
| Not applicable | Not applicable | | |
| 14.5. Environmental hazards | | | |
| Dangerous for the environment : No | Dangerous for the environment : No | | |
| No supplementary information available | | | |

14.6. Special precautions for user

- Overland transport

No data available

- Air transport

No data available

14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

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

No REACH Annex XVII restrictions Bacitracin is not on the REACH Candidate List

Bacitracin is not on the REACH Annex XIV List

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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:

| 1.1 | EC No | Added | |
|-----|--------------------------|----------|---|
| 1.4 | Emergency telephone | Modified | Added additional information |
| 2 | Classification (DSD/DPD) | Removed | Obsolete |
| 8.2 | Hand protection | Modified | Specified material, thickness, et cetera of gloves |
| 8.2 | Skin and body protection | Modified | Added additional information (type of clothing related to concentration levels) |

Abbreviations and acronyms:

| SDS | Safety Data Sheet |
|-------|---|
| RID | Regulations concerning the International Carriage of Dangerous Goods by Rail |
| REACH | Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006 |
| IMDG | International Maritime Dangerous Goods |
| IATA | International Air Transport Association |
| 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 |
| CLP | Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008 |

Data sources

: REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Full text of H- and EUH-statements:

| Eye Irrit. 2 | Serious eye damage/eye irritation, Category 2 |
|---------------|--|
| Skin Irrit. 2 | Skin corrosion/irritation, Category 2 |
| Skin Sens. 1 | Sensitisation — Skin, Category 1 |
| STOT SE 3 | Specific target organ toxicity — Single exposure, Category 3, Respiratory tract irritation |
| H315 | Causes skin irritation |
| H317 | May cause an allergic skin reaction |
| H319 | Causes serious eye irritation |
| H335 | May cause respiratory irritation |

SDS EU (REACH Annex II) Version 2017

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 not therefore be construed as guaranteeing any specific property of the product