

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



# **Benzylpenicillin / Dihydrostreptomycin Sulphate Formulation**

Version Revision Date: SDS Number: Date of last issue: 12.02.2025  
5.0 14.04.2025 10811386-00010 Date of first issue: 08.07.2022

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

## 1.1 Product identifier

Trade name : Benzylpenicillin / Dihydrostreptomycin Sulphate Formulation

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

Use of the Substance/Mixture : Veterinary product

Recommended restrictions on use : Not applicable

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

Company : MSD  
Walton Manor, Walton  
MK7 7AJ Milton Keynes - United Kingdom

Telephone : +1-908-740-4000

E-mail address of person responsible for the SDS : EHSDATASTEWARD@msd.com

#### 1.4 Emergency telephone number

+1-908-423-6000

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## SECTION 2: Hazards identification

## 2.1 Classification of the substance or mixture

**Classification (REGULATION (EC) No 1272/2008) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)**

Respiratory sensitisation, Category 1 H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled

H317: May cause an allergic skin reaction

Specific target organ toxicity - repeated exposure, Category 1 H372: Causes damage to organs through prolonged or repeated exposure.

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### 2.2 Label elements

**Labelling (REGULATION (EC) No 1272/2008) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)**

Hazard pictograms :



Signal word :

Danger

Hazard statements :

H317      May cause an allergic skin reaction.  
H334      May cause allergy or asthma symptoms or breathing difficulties if inhaled.  
H372      Causes damage to organs through prolonged or repeated exposure.

Precautionary statements :

**Prevention:**  
P264      Wash skin thoroughly after handling.  
P280      Wear protective gloves.

**Response:**

P304 + P340      IF INHALED: Remove person to fresh air and keep comfortable for breathing.  
P333 + P313      If skin irritation or rash occurs: Get medical advice/ attention.  
P342 + P311      If experiencing respiratory symptoms: Call a POISON CENTER/ doctor.  
P362 + P364      Take off contaminated clothing and wash it before reuse.

Hazardous components which must be listed on the label:

Dihydrostreptomycin sulphate  
Benzylpenicillin

### 2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

## SECTION 3: Composition/information on ingredients

### 3.2 Mixtures

#### Components

| Chemical name | CAS-No.<br>EC-No.<br>Index-No.<br>Registration number | Classification | Concentration<br>(% w/w) |
|---------------|---|----------------|--------------------------|
|               |   |                |                          |

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|                                 |                        |  |              |
|---------------------------------|------------------------|--|--------------|
| Dihydrostreptomycin sulphate    | 5490-27-7<br>226-823-7 | STOT RE 1; H372<br>(ear, Kidney, inner<br>ear)   | >= 20 - < 30 |
| Benzylpenicillin                | 61-33-6<br>200-506-3   | Resp. Sens. 1A;<br>H334<br>Skin Sens. 1B;<br>H317<br>Aquatic Acute 1;<br>H400<br>Aquatic Chronic 3;<br>H412<br><br>M-Factor (Acute<br>aquatic toxicity): 1 | >= 20 - < 25 |
| Sodium hydroxymethanesulphinate | 149-44-0<br>205-739-4  | Muta. 2; H341<br>Repr. 2; H361d  | >= 0.1 - < 1 |

For explanation of abbreviations see section 16.

## SECTION 4: First aid measures

### 4.1 Description of first aid measures

General advice : In the case of accident or if you feel unwell, seek medical advice immediately.  
When symptoms persist or in all cases of doubt seek medical advice.

Protection of first-aiders : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

If inhaled : If inhaled, remove to fresh air.  
If not breathing, give artificial respiration.  
If breathing is difficult, give oxygen.  
Get medical attention.

In case of skin contact : In case of contact, immediately flush skin with soap and plenty of water.  
Remove contaminated clothing and shoes.  
Get medical attention.  
Wash clothing before reuse.  
Thoroughly clean shoes before reuse.

In case of eye contact : Flush eyes with water as a precaution.  
Get medical attention if irritation develops and persists.

If swallowed : If swallowed, DO NOT induce vomiting.  
Get medical attention.  
Rinse mouth thoroughly with water.

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

Risks : Excessive exposure may aggravate preexisting asthma and other respiratory disorders (e.g. emphysema, bronchitis, reactive airways dysfunction syndrome).

May cause an allergic skin reaction.  
May cause allergy or asthma symptoms or breathing difficulties if inhaled.  
Causes damage to organs through prolonged or repeated exposure.

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

Treatment : Treat symptomatically and supportively.

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## SECTION 5: Firefighting measures

### 5.1 Extinguishing media

Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
Dry chemical

Unsuitable extinguishing media : None known.

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

Specific hazards during fire-fighting : Exposure to combustion products may be a hazard to health.

Hazardous combustion products : Carbon oxides  
Metal oxides

### 5.3 Advice for firefighters

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.  
Use personal protective equipment.

Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.  
Use water spray to cool unopened containers.  
Remove undamaged containers from fire area if it is safe to do so.  
Evacuate area.

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## SECTION 6: Accidental release measures

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

Personal precautions : Use personal protective equipment.

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Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

### 6.2 Environmental precautions

Environmental precautions : Avoid release to the environment.  
Prevent further leakage or spillage if safe to do so.  
Prevent spreading over a wide area (e.g. by containment or oil barriers).  
Retain and dispose of contaminated wash water.  
If spillage enters rivers or watercourses, inform the Environment Agency (emergency telephone number 0800 807060).

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

Methods for cleaning up : Soak up with inert absorbent material.  
For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container.  
Clean up remaining materials from spill with suitable absorbent.  
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.  
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

### 6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

## SECTION 7: Handling and storage

### 7.1 Precautions for safe handling

Technical measures : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation : Use only with adequate ventilation.

Advice on safe handling : Do not get on skin or clothing.  
Do not breathe mist or vapours.  
Do not swallow.  
Avoid contact with eyes.  
Wash skin thoroughly after handling.  
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment  
Keep container tightly closed.  
Already sensitised individuals, and those susceptible to asthma, allergies, chronic or recurrent respiratory disease, should consult their physician regarding working with respiratory irritants or sensitisers.  
Do not eat, drink or smoke when using this product.

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### Hygiene measures

Take care to prevent spills, waste and minimize release to the environment.

: If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Contaminated work clothing should not be allowed out of the workplace. Wash contaminated clothing before re-use.

The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

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

#### Requirements for storage areas and containers

: Keep in properly labelled containers. Keep tightly closed. Store in accordance with the particular national regulations.

#### Advice on common storage

: Do not store with the following product types:

- Strong oxidizing agents
- Self-reactive substances and mixtures
- Organic peroxides
- Explosives
- Gases

### 7.3 Specific end use(s)

Specific use(s) : No data available

## SECTION 8: Exposure controls/personal protection

### 8.1 Control parameters

#### Occupational Exposure Limits

| Components                   | CAS-No.                         | Value type (Form of exposure) | Control parameters            | Basis    |
|------------------------------|---------------------------------|-------------------------------|-------------------------------|----------|
| Dihydrostreptomycin sulphate | 5490-27-7                       | TWA                           | 4 mg/m <sup>3</sup> (OEB 1)   |          |
|                              | Further information: OTO        |                               |                               |          |
| Benzylpenicillin             | 61-33-6                         | TWA                           | 600 µg/m <sup>3</sup> (OEB 2) | Internal |
|                              | Further information: RSEN, DSEN |                               |                               |          |
|                              |                                 | Wipe limit                    | 100 µg/100 cm <sup>2</sup>    | Internal |

#### Derived No Effect Level (DNEL)

| Substance name                  | End Use | Exposure routes | Potential health effects   | Value                 |
|---------------------------------|---------|-----------------|----------------------------|-----------------------|
| Sodium hydroxymethanesulphonate | Workers | Inhalation      | Long-term systemic effects | 21 mg/m <sup>3</sup>  |
|                                 | Workers | Inhalation      | Acute systemic ef-         | 140 mg/m <sup>3</sup> |

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|  |         |              | fects                      |                          |
|--|---------|--------------|----------------------------|--------------------------|
|  | Workers | Skin contact | Long-term systemic effects | 6 mg/kg bw/day           |
|  | Workers | Skin contact | Acute systemic effects     | 40 mg/kg bw/day          |
|  | Workers | Skin contact | Acute local effects        | 0.225 mg/cm <sup>2</sup> |

### Predicted No Effect Concentration (PNEC)

| Substance name                  | Environmental Compartment | Value                         |
|---------------------------------|---------------------------|-------------------------------|
| Benzylpenicillin                | Water                     | 0.014 mg/l                    |
| Sodium hydroxymethanesulphonate | Fresh water               | 0.056 mg/l                    |
|                                 | Marine water              | 0.006 mg/l                    |
|                                 | Freshwater - intermittent | 0.056 mg/l                    |
|                                 | Sewage treatment plant    | 1 mg/l                        |
|                                 | Fresh water sediment      | 0.046 mg/kg dry weight (d.w.) |
|                                 | Marine sediment           | 0.005 mg/kg dry weight (d.w.) |
|                                 | Soil                      | 0.011 mg/kg dry weight (d.w.) |

## 8.2 Exposure controls

### Engineering measures

Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-less quick connections).

All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

Laboratory operations do not require special containment.

### Personal protective equipment

Eye/face protection : Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Hand protection : Chemical-resistant gloves

Material : Chemical-resistant gloves

Skin and body protection : Work uniform or laboratory coat.

Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. Equipment should conform to BS EN 143

Filter type : Particulates type (P)

## SECTION 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

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|  |   |  |
|--|---|--|
| Appearance                                       | : | suspension   |
| Colour   | : | off-white, white   |
| Odour  | : | No data available  |
| Odour Threshold                                  | : | No data available  |
| pH   | : | 5.0 - 7.2  |
| Melting point/freezing point                     | : | No data available  |
| Initial boiling point and boiling range          | : | No data available  |
| Flash point                                      | : | No data available  |
| Evaporation rate                                 | : | No data available  |
| Flammability (solid, gas)                        | : | Not applicable   |
| Flammability (liquids)                           | : | No data available  |
| Upper explosion limit / Upper flammability limit | : | No data available  |
| Lower explosion limit / Lower flammability limit | : | No data available  |
| Vapour pressure                                  | : | No data available  |
| Relative vapour density                          | : | No data available  |
| Relative density                                 | : | No data available  |
| Density  | : | 1.14 - 1.18 g/cm <sup>3</sup>                            |
| Solubility(ies)                                  |   |  |
| Water solubility                                 | : | No data available  |
| Partition coefficient: n-octanol/water           | : | Not applicable   |
| Auto-ignition temperature                        | : | No data available  |
| Decomposition temperature                        | : | No data available  |
| Viscosity  |   |  |
| Viscosity, kinematic                             | : | No data available  |
| Explosive properties                             | : | Not explosive  |
| Oxidizing properties                             | : | The substance or mixture is not classified as oxidizing. |
| <b>9.2 Other information</b>                     |   |  |
| Molecular weight                                 | : | No data available  |



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LD50 (Mouse): > 5,000 mg/kg

Acute toxicity (other routes of administration) : LD50 (Mouse): 3,500 mg/kg  
Application Route: Intraperitoneal  
  
LD50 (Mouse): 329 mg/kg  
Application Route: Intravenous

### Sodium hydroxymethanesulphinate:

Acute oral toxicity : LD50 (Rat): > 2,000 mg/kg  
Method: OECD Test Guideline 423  
Assessment: The substance or mixture has no acute oral toxicity  
  
Acute dermal toxicity : LD50 (Rat): > 2,000 mg/kg  
Method: OECD Test Guideline 402  
Assessment: The substance or mixture has no acute dermal toxicity

### Skin corrosion/irritation

Not classified based on available information.

### Components:

#### Sodium hydroxymethanesulphinate:

Species : Rat  
Result : No skin irritation

### Serious eye damage/eye irritation

Not classified based on available information.

### Components:

#### Sodium hydroxymethanesulphinate:

Species : Rabbit  
Method : OECD Test Guideline 405  
Result : No eye irritation

### Respiratory or skin sensitisation

#### Skin sensitisation

May cause an allergic skin reaction.

#### Respiratory sensitisation

May cause allergy or asthma symptoms or breathing difficulties if inhaled.

### Components:

#### Benzylpenicillin:

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|                 |   |                                      |
|-----------------|---|--------------------------------------|
| Test Type       | : | Local lymph node assay (LLNA)        |
| Exposure routes | : | Dermal                               |
| Species         | : | Mouse                                |
| Result          | : | Weak sensitizer                      |
| Test Type       | : | Maximisation Test                    |
| Exposure routes | : | Dermal                               |
| Species         | : | Guinea pig                           |
| Result          | : | positive                             |
| Remarks         | : | Based on data from similar materials |
| Result          | : | Strong sensitizer                    |
| Remarks         | : | Based on human experience.           |

### Sodium hydroxymethanesulphinate:

|                 |   |                         |
|-----------------|---|-------------------------|
| Test Type       | : | Maximisation Test       |
| Exposure routes | : | Skin contact            |
| Species         | : | Guinea pig              |
| Method          | : | OECD Test Guideline 406 |
| Result          | : | negative                |

### Germ cell mutagenicity

Not classified based on available information.

### Components:

#### Dihydrostreptomycin sulphate:

|                       |   |  |
|-----------------------|---|--|
| Genotoxicity in vitro | : | Test Type: Chromosome aberration test in vitro<br>Test system: Human lymphocytes<br>Result: negative |
|-----------------------|---|--|

#### Benzylpenicillin:

|                                    |   |  |
|------------------------------------|---|--|
| Germ cell mutagenicity- Assessment | : | Weight of evidence does not support classification as a germ cell mutagen. |
|------------------------------------|---|--|

#### Sodium hydroxymethanesulphinate:

|                       |   |   |
|-----------------------|---|---|
| Genotoxicity in vitro | : | Test Type: Bacterial reverse mutation assay (AMES)<br>Method: OECD Test Guideline 471<br>Result: negative   |
|                       |   | Test Type: In vitro mammalian cell gene mutation test<br>Method: OECD Test Guideline 476<br>Result: positive  |
| Genotoxicity in vivo  | : | Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)<br>Species: Mouse<br>Application Route: Intraperitoneal injection<br>Method: OECD Test Guideline 474 |

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|                                    |   |  |
|------------------------------------|---|--|
|                                    |   | Result: positive   |
| Germ cell mutagenicity- Assessment | : | Positive result(s) from in vivo mammalian somatic cell mutagenicity tests. |

### Carcinogenicity

Not classified based on available information.

### Components:

#### Dihydrostreptomycin sulphate:

|                   |   |                     |
|-------------------|---|---------------------|
| Species           | : | Rat                 |
| Application Route | : | Oral                |
| Exposure time     | : | 2 Years             |
| NOAEL             | : | 5 mg/kg body weight |
| Result            | : | negative            |

#### Reproductive toxicity

Not classified based on available information.

### Components:

#### Dihydrostreptomycin sulphate:

|                               |   |   |
|-------------------------------|---|---|
| Effects on foetal development | : | Test Type: Embryo-foetal development<br>Species: Rabbit<br>Application Route: Oral<br>Developmental Toxicity: NOAEL: 5 mg/kg body weight  |
|                               |   | Test Type: Embryo-foetal development<br>Species: Guinea pig<br>Application Route: Intramuscular<br>General Toxicity Maternal: LOAEL: 100 - 200 mg/kg body weight<br>Developmental Toxicity: NOAEL: 10 mg/kg body weight<br>Result: Maternal toxicity observed., Embryotoxic effects and adverse effects on the offspring were detected. |

#### Benzylpenicillin:

|                      |   |  |
|----------------------|---|--|
| Effects on fertility | : | Test Type: Fertility<br>Species: Mouse<br>Result: No effects on fertility  |
|                      |   | Test Type: Fertility<br>Species: Rat<br>Result: No effects on fertility    |
|                      |   | Test Type: Fertility<br>Species: Rabbit<br>Result: No effects on fertility |

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|                               |  |
|-------------------------------|--|
| Effects on foetal development | : Test Type: Development<br>Species: Mouse<br>Result: No effects on foetal development |
|                               | Test Type: Development<br>Species: Rat<br>Result: No effects on foetal development     |
|                               | Test Type: Development<br>Species: Rabbit<br>Result: No effects on foetal development  |

### Sodium hydroxymethanesulphinate:

|                                    |   |
|------------------------------------|---|
| Effects on fertility               | : Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test<br>Species: Rat<br>Application Route: Ingestion<br>Method: OECD Test Guideline 422<br>Result: negative |
| Effects on foetal development      | : Test Type: Embryo-foetal development<br>Species: Rat<br>Application Route: Ingestion<br>Method: OECD Test Guideline 414<br>Result: positive   |
| Reproductive toxicity - Assessment | : Some evidence of adverse effects on development, based on animal experiments.   |

### STOT - single exposure

Not classified based on available information.

### STOT - repeated exposure

Causes damage to organs through prolonged or repeated exposure.

### Components:

#### Dihydrostreptomycin sulphate:

|            |   |
|------------|---|
| Assessment | : Causes damage to organs through prolonged or repeated exposure. |
|------------|---|

### Repeated dose toxicity

### Components:

#### Dihydrostreptomycin sulphate:

|                   |              |
|-------------------|--------------|
| Species           | : Guinea pig |
| LOAEL             | : 40 mg/kg   |
| Application Route | : Oral       |
| Exposure time     | : 90 d       |
| Target Organs     | : ear        |

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|                   |   |
|-------------------|---|
| Symptoms          | : hearing loss                              |
| Species           | : Cat                                       |
| LOAEL             | : 100 mg/kg                                 |
| Application Route | : Oral                                      |
| Exposure time     | : 60 d                                      |
| Target Organs     | : ear                                       |
| Symptoms          | : ataxia, hearing loss, Reduced body weight |
| Species           | : Cat                                       |
| LOAEL             | : 300 mg/kg                                 |
| Application Route | : Oral                                      |
| Exposure time     | : 21 d                                      |
| Target Organs     | : ear                                       |
| Symptoms          | : ataxia, hearing loss, Reduced body weight |

### Sodium hydroxymethanesulphinate:

|                   |                           |
|-------------------|---------------------------|
| Species           | : Rat                     |
| NOAEL             | : 600 mg/kg               |
| Application Route | : Ingestion               |
| Exposure time     | : 13 Weeks                |
| Method            | : OECD Test Guideline 408 |

### Aspiration toxicity

Not classified based on available information.

### Experience with human exposure

#### Components:

##### Dihydrostreptomycin sulphate:

|                     |   |
|---------------------|---|
| General Information | : Symptoms: Erythema, hearing loss, Nausea, Rash, Vomiting, Headache, hypotension |
|---------------------|---|

##### Benzylpenicillin:

|            |   |
|------------|---|
| Inhalation | : Symptoms: Allergic reactions, Abdominal pain, bronchospasm, skin rash |
|------------|---|

## SECTION 12: Ecological information

### 12.1 Toxicity

#### Components:

##### Benzylpenicillin:

|   |  |
|---|--|
| Toxicity to fish                                    | : LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l<br>Exposure time: 96 hrs<br>Method: OECD Test Guideline 203 |
| Toxicity to daphnia and other aquatic invertebrates | : EC50 (Daphnia magna (Water flea)): 3.6 mg/l<br>Exposure time: 48 hrs   |

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|                                   |   |
|-----------------------------------|---|
|                                   | Method: OECD Test Guideline 202   |
| Toxicity to algae/aquatic plants  | : EC50 (Raphidocelis subcapitata (freshwater green alga)): > 100 mg/l<br>Exposure time: 72 hrs<br>Method: OECD Test Guideline 201 |
|                                   | NOEC (Raphidocelis subcapitata (freshwater green alga)): 50 mg/l<br>Exposure time: 72 hrs<br>Method: OECD Test Guideline 201      |
|                                   | EC50 (blue-green algae): 0.74 mg/l<br>Exposure time: 72 hrs<br>Method: OECD Test Guideline 201                                    |
|                                   | NOEC (blue-green algae): 0.14 mg/l<br>Exposure time: 72 hrs<br>Method: OECD Test Guideline 201                                    |
| M-Factor (Acute aquatic toxicity) | : 1   |
| Toxicity to microorganisms        | : EC50 : > 500 mg/l<br>Exposure time: 3 h<br>Test Type: Respiration inhibition<br>Method: OECD Test Guideline 209                 |
|                                   | NOEC : 5 mg/l<br>Exposure time: 3 h<br>Test Type: Respiration inhibition<br>Method: OECD Test Guideline 209                       |

### Sodium hydroxymethanesulphonate:

|   |   |
|---|---|
| Toxicity to fish                                    | : LC50 (Leuciscus idus (Golden orfe)): > 10,000 mg/l<br>Exposure time: 96 h   |
| Toxicity to daphnia and other aquatic invertebrates | : EC50 (Daphnia magna (Water flea)): > 100 mg/l<br>Exposure time: 48 h<br>Method: OECD Test Guideline 202           |
| Toxicity to algae/aquatic plants                    | : ErC50 (Desmodesmus subspicatus (green algae)): 370 mg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201 |
|   | NOEC (Desmodesmus subspicatus (green algae)): 10 mg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201     |
| Toxicity to microorganisms                          | : NOEC : 10 mg/l<br>Exposure time: 4 h  |

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|  |  |
|--|--|
| Toxicity to fish (Chronic toxicity)                                    | : NOEC: 13.5 mg/l<br>Exposure time: 35 d<br>Species: Danio rerio (zebra fish)<br>Method: OECD Test Guideline 210 |
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : EC10: 8 mg/l<br>Exposure time: 21 d<br>Species: Daphnia magna (Water flea)<br>Method: OECD Test Guideline 211  |

### 12.2 Persistence and degradability

#### Components:

##### **Benzylpenicillin:**

|                  |  |
|------------------|--|
| Biodegradability | : Result: Readily biodegradable.<br>Biodegradation: 70.10 %<br>Exposure time: 28 d<br>Method: OECD Test Guideline 301B |
|------------------|--|

##### **Sodium hydroxymethanesulphinate:**

|                  |   |
|------------------|---|
| Biodegradability | : Result: Readily biodegradable.<br>Biodegradation: 77 %<br>Exposure time: 28 d<br>Method: OECD Test Guideline 301B |
|------------------|---|

### 12.3 Bioaccumulative potential

#### Components:

##### **Sodium hydroxymethanesulphinate:**

|  |                  |
|--|------------------|
| Partition coefficient: n-octanol/water | : log Pow: < 0.3 |
|--|------------------|

### 12.4 Mobility in soil

No data available

### 12.5 Results of PBT and vPvB assessment

#### Product:

|            |  |
|------------|--|
| Assessment | : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher. |
|------------|--|

### 12.6 Other adverse effects

#### Product:

|                                |  |
|--------------------------------|--|
| Endocrine disrupting potential | : This substance/mixture does not contain components consid- |
|--------------------------------|--|

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tial  
ered to have endocrine disrupting properties for environment  
according to UK REACH Article 57(f).

### SECTION 13: Disposal considerations

#### 13.1 Waste treatment methods

|                        |  |
|------------------------|--|
| Product                | : Dispose of in accordance with local regulations.<br>According to the European Waste Catalogue, Waste Codes are not product specific, but application specific.<br>Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.<br>Do not dispose of waste into sewer. |
| Contaminated packaging | : Empty containers should be taken to an approved waste handling site for recycling or disposal.<br>If not otherwise specified: Dispose of as unused product.  |

---

### SECTION 14: Transport information

#### 14.1 UN number

|      |                                     |
|------|-------------------------------------|
| ADN  | : Not regulated as a dangerous good |
| ADR  | : Not regulated as a dangerous good |
| RID  | : Not regulated as a dangerous good |
| IMDG | : Not regulated as a dangerous good |
| IATA | : Not regulated as a dangerous good |

#### 14.2 UN proper shipping name

|      |                                     |
|------|-------------------------------------|
| ADN  | : Not regulated as a dangerous good |
| ADR  | : Not regulated as a dangerous good |
| RID  | : Not regulated as a dangerous good |
| IMDG | : Not regulated as a dangerous good |
| IATA | : Not regulated as a dangerous good |

#### 14.3 Transport hazard class(es)

|      |                                     |
|------|-------------------------------------|
| ADN  | : Not regulated as a dangerous good |
| ADR  | : Not regulated as a dangerous good |
| RID  | : Not regulated as a dangerous good |
| IMDG | : Not regulated as a dangerous good |
| IATA | : Not regulated as a dangerous good |

#### 14.4 Packing group

|     |                                     |
|-----|-------------------------------------|
| ADN | : Not regulated as a dangerous good |
|-----|-------------------------------------|

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|                         |   |                                   |
|-------------------------|---|-----------------------------------|
| <b>ADR</b>              | : | Not regulated as a dangerous good |
| <b>RID</b>              | : | Not regulated as a dangerous good |
| <b>IMDG</b>             | : | Not regulated as a dangerous good |
| <b>IATA (Cargo)</b>     | : | Not regulated as a dangerous good |
| <b>IATA (Passenger)</b> | : | Not regulated as a dangerous good |

## 14.5 Environmental hazards

Not regulated as a dangerous good

## 14.6 Special precautions for user

Not applicable

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

Remarks : Not applicable for product as supplied.

---

## **SECTION 15: Regulatory information**

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

## Relevant EU provisions transposed through retained EU law

|   |   |   |
|---|---|---|
| UK REACH List of restrictions (Annex 17)  | : | Conditions of restriction for the following entries should be considered:<br>Number on list 3   |
| UK REACH Candidate list of substances of very high concern (SVHC) for Authorisation                             | : | Substance(s) or mixture(s) are listed here according to their appearance in the regulation, irrespective of their use/purpose or the conditions of the restriction. Please refer to the conditions in corresponding Regulation to determine whether an entry is applicable to the placing on the market or not. |
| The Persistent Organic Pollutants Regulations (retained Regulation (EU) 2019/1021 as amended for Great Britain) | : | Not applicable  |
| Regulation (EU) No 2024/590 on substances that deplete the ozone layer  | : | Not applicable  |
| UK REACH List of substances subject to authorisation (Annex XIV)  | : | Not applicable  |
| GB Export and import of hazardous chemicals - Prior Informed Consent (PIC) Regulation                           | : | Not applicable  |
| Control of Major Accident Hazards Regulations 2015 (COMAH)  |   | Not applicable  |

### **Other regulations:**

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Take note of The Management of Health and Safety at Work Regulations 1999 (requirements relating to new and expectant mothers at work contained in Regulation 16 to 18) and of the Pregnant Workers Directive 92/85/EEC.

Take note of The Management of Health and Safety at Work Regulations 1999 (requirements relating to protection of young people at work contained in Regulation 19) and of Directive 94/33/EC on the protection of young people at work.

**The components of this product are reported in the following inventories:**

AICS : not determined  
DSL : not determined  
IECSC : not determined

## 15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

## SECTION 16: Other information

Other information : Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

## Full text of H-Statements

H317 : May cause an allergic skin reaction.  
H334 : May cause allergy or asthma symptoms or breathing difficulties if inhaled.  
H341 : Suspected of causing genetic defects.  
H361d : Suspected of damaging the unborn child.  
H372 : Causes damage to organs through prolonged or repeated exposure if swallowed.  
H400 : Very toxic to aquatic life.  
H412 : Harmful to aquatic life with long lasting effects.

## Full text of other abbreviations

|                 |   |  |
|-----------------|---|--|
| Aquatic Acute   | : | Short-term (acute) aquatic hazard                  |
| Aquatic Chronic | : | Long-term (chronic) aquatic hazard                 |
| Muta.           | : | Germ cell mutagenicity                             |
| Repr.           | : | Reproductive toxicity                              |
| Resp. Sens.     | : | Respiratory sensitisation                          |
| Skin Sens.      | : | Skin sensitisation                                 |
| STOT RE         | : | Specific target organ toxicity - repeated exposure |

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergen-

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cy Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECL - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

### Further information

Sources of key data used to compile the Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

### Classification of the mixture:

|               |      |
|---------------|------|
| Resp. Sens. 1 | H334 |
| Skin Sens. 1  | H317 |
| STOT RE 1     | H372 |

### Classification procedure:

|                    |
|--------------------|
| Calculation method |
| Calculation method |
| Calculation method |

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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. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

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