

Cefotaxime (100mg/ml)

Apollo Scientific

Chemwatch Hazard Alert Code: 2

Part Number: **BIG1027**

Version No: **2.2**

Safety Data Sheet (Conforms to Annex II of REACH (1907/2006) - Regulation 2020/878)

Issue Date: **10/07/2023**

Print Date: **10/07/2023**

S.REACH.GB-NIR.EN

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

1.1. Product Identifier

| | |
|-------------------------------|-----------------------|
| Product name | Cefotaxime (100mg/ml) |
| Chemical Name | cefotaxime sodium |
| Synonyms | Not Available |
| Chemical formula | C16-H17-N5-O7-S2 .Na |
| Other means of identification | Not Available |
| CAS number | 64485-93-4* |
| EC number | 264-915-9 |

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

| | |
|--------------------------|--|
| Relevant identified uses | Use according to manufacturer's directions. |
| Uses advised against | No specific uses advised against are identified. |

1.3. Details of the manufacturer or supplier of the safety data sheet

| | |
|-------------------------|---|
| Registered company name | Apollo Scientific |
| Address | Whitefield Road, Bredbury SK62QR United Kingdom |
| Telephone | 01614060505 |
| Fax | 0161 406 0506 |
| Website | http://www.apolloscientific.co.uk/ |
| Email | sales@apolloscientific.co.uk |

1.4. Emergency telephone number

| | |
|-----------------------------------|---------------|
| Association / Organisation | Not Available |
| Emergency telephone numbers | Not Available |
| Other emergency telephone numbers | Not Available |

SECTION 2 Hazards identification

2.1. Classification of the substance or mixture

| | |
|---|---|
| Classification according to regulation (EC) No 1272/2008 [CLP] and amendments [1] | H315 - Skin Corrosion/Irritation Category 2, H319 - Serious Eye Damage/Eye Irritation Category 2, H335 - Specific Target Organ Toxicity - Single Exposure (Respiratory Tract Irritation) Category 3 |
| Legend: | 1. Classified by Chemwatch; 2. Classification drawn from Regulation (EU) No 1272/2008 - Annex VI |

2.2. Label elements

| | |
|---------------------|---|
| Hazard pictogram(s) |  |
| Signal word | Warning |

Cefotaxime (100mg/ml)

Hazard statement(s)

| | |
|-------------|-----------------------------------|
| H315 | Causes skin irritation. |
| H319 | Causes serious eye irritation. |
| H335 | May cause respiratory irritation. |

Supplementary statement(s)

Not Applicable

Precautionary statement(s) Prevention

| | |
|-------------|--|
| P271 | Use only outdoors or in a well-ventilated area. |
| P261 | Avoid breathing mist/vapours/spray. |
| P280 | Wear protective gloves, protective clothing, eye protection and face protection. |
| P264 | Wash all exposed external body areas thoroughly after handling. |

Precautionary statement(s) Response

| | |
|-----------------------|--|
| P305+P351+P338 | IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. |
| P312 | Call a POISON CENTER/doctor/physician/first aider/if you feel unwell. |
| P337+P313 | If eye irritation persists: Get medical advice/attention. |
| P302+P352 | IF ON SKIN: Wash with plenty of water. |
| P304+P340 | IF INHALED: Remove person to fresh air and keep comfortable for breathing. |
| P332+P313 | If skin irritation occurs: Get medical advice/attention. |
| P362+P364 | Take off contaminated clothing and wash it before reuse. |

Precautionary statement(s) Storage

| | |
|------------------|--|
| P405 | Store locked up. |
| P403+P233 | Store in a well-ventilated place. Keep container tightly closed. |

Precautionary statement(s) Disposal

| | |
|-------------|--|
| P501 | Dispose of contents/container to authorised hazardous or special waste collection point in accordance with any local regulation. |
|-------------|--|

2.3. Other hazards

REACH - Art.57-59: The mixture does not contain Substances of Very High Concern (SVHC) at the SDS print date.

SECTION 3 Composition / information on ingredients

3.1.Substances

| 1. CAS No 2.EC No 3.Index No 4.REACH No | %[weight] | Name | Classification according to regulation (EC) No 1272/2008 [CLP] and amendments | SCL / M-Factor | Nanoform Particle Characteristics |
|--|-----------|------------------------------|--|----------------|-----------------------------------|
| 1. 64485-93-4 2.264-915-9 3.Not Available 4.Not Available | 100 | <u>Cefotaxime (100mg/ml)</u> | Skin Corrosion/Irritation Category 2, Serious Eye Damage/Eye Irritation Category 2, Specific Target Organ Toxicity - Single Exposure (Respiratory Tract Irritation) Category 3; H315, H319, H335 [1] | 0 | Not Available |

Legend: 1. Classified by Chemwatch; 2. Classification drawn from Regulation (EU) No 1272/2008 - Annex VI; 3. Classification drawn from C&L; * EU IOELVs available; [e] Substance identified as having endocrine disrupting properties

3.2.Mixtures

See 'Information on ingredients' in section 3.1

SECTION 4 First aid measures

4.1. Description of first aid measures

| | |
|---------------------|---|
| Eye Contact | <p>If this product comes in contact with the eyes:</p> <ul style="list-style-type: none"> ▶ Wash out immediately with fresh running water. ▶ Ensure complete irrigation of the eye by keeping eyelids apart and away from eye and moving the eyelids by occasionally lifting the upper and lower lids. ▶ Seek medical attention without delay; if pain persists or recurs seek medical attention. ▶ Removal of contact lenses after an eye injury should only be undertaken by skilled personnel. |
| Skin Contact | <p>If skin contact occurs:</p> <ul style="list-style-type: none"> ▶ Immediately remove all contaminated clothing, including footwear. ▶ Flush skin and hair with running water (and soap if available). ▶ Seek medical attention in event of irritation. |
| Inhalation | <ul style="list-style-type: none"> ▶ If fumes or combustion products are inhaled remove from contaminated area. ▶ Lay patient down. Keep warm and rested. ▶ Prostheses such as false teeth, which may block airway, should be removed, where possible, prior to initiating first aid procedures. ▶ Apply artificial respiration if not breathing, preferably with a demand valve resuscitator, bag-valve mask device, or pocket mask as trained. |

| | |
|------------------|---|
| | <ul style="list-style-type: none"> ▶ Perform CPR if necessary. ▶ Transport to hospital, or doctor, without delay. |
| Ingestion | <ul style="list-style-type: none"> ▶ Immediately give a glass of water. ▶ First aid is not generally required. If in doubt, contact a Poisons Information Centre or a doctor. |

4.2 Most important symptoms and effects, both acute and delayed

See Section 11

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

Treat symptomatically.

SECTION 5 Firefighting measures**5.1. Extinguishing media**

- ▶ There is no restriction on the type of extinguisher which may be used.
- ▶ Use extinguishing media suitable for surrounding area.

5.2. Special hazards arising from the substrate or mixture

| | |
|-----------------------------|-------------|
| Fire Incompatibility | None known. |
|-----------------------------|-------------|

5.3. Advice for firefighters

| | |
|------------------------------|---|
| Fire Fighting | <ul style="list-style-type: none"> ▶ Alert Fire Brigade and tell them location and nature of hazard. ▶ Wear breathing apparatus plus protective gloves in the event of a fire. ▶ Prevent, by any means available, spillage from entering drains or water courses. ▶ Use fire fighting procedures suitable for surrounding area. ▶ DO NOT approach containers suspected to be hot. ▶ Cool fire exposed containers with water spray from a protected location. ▶ If safe to do so, remove containers from path of fire. ▶ Equipment should be thoroughly decontaminated after use. |
| Fire/Explosion Hazard | <ul style="list-style-type: none"> ▶ Non combustible. ▶ Not considered a significant fire risk, however containers may burn. May emit poisonous fumes. May emit corrosive fumes. |

SECTION 6 Accidental release measures**6.1. Personal precautions, protective equipment and emergency procedures**

See section 8

6.2. Environmental precautions

See section 12

6.3. Methods and material for containment and cleaning up

| | |
|---------------------|---|
| Minor Spills | <ul style="list-style-type: none"> ▶ Clean up all spills immediately. ▶ Avoid breathing vapours and contact with skin and eyes. ▶ Control personal contact with the substance, by using protective equipment. ▶ Contain and absorb spill with sand, earth, inert material or vermiculite. ▶ Wipe up. ▶ Place in a suitable, labelled container for waste disposal. |
| Major Spills | Moderate hazard. <ul style="list-style-type: none"> ▶ Clear area of personnel and move upwind. ▶ Alert Fire Brigade and tell them location and nature of hazard. ▶ Wear breathing apparatus plus protective gloves. ▶ Prevent, by any means available, spillage from entering drains or water course. ▶ Stop leak if safe to do so. ▶ Contain spill with sand, earth or vermiculite. ▶ Collect recoverable product into labelled containers for recycling. ▶ Neutralise/decontaminate residue (see Section 13 for specific agent). ▶ Collect solid residues and seal in labelled drums for disposal. ▶ Wash area and prevent runoff into drains. ▶ After clean up operations, decontaminate and launder all protective clothing and equipment before storing and re-using. ▶ If contamination of drains or waterways occurs, advise emergency services. |

6.4. Reference to other sections

Personal Protective Equipment advice is contained in Section 8 of the SDS.

SECTION 7 Handling and storage**7.1. Precautions for safe handling**

| | |
|----------------------|---|
| Safe handling | <ul style="list-style-type: none"> ▶ Avoid all personal contact, including inhalation. ▶ Wear protective clothing when risk of exposure occurs. |
|----------------------|---|

| | |
|--------------------------------------|---|
| | <ul style="list-style-type: none"> ▶ Use in a well-ventilated area. ▶ Avoid contact with moisture. ▶ Avoid contact with incompatible materials. ▶ When handling, DO NOT eat, drink or smoke. ▶ Keep containers securely sealed when not in use. ▶ Avoid physical damage to containers. ▶ Always wash hands with soap and water after handling. ▶ Work clothes should be laundered separately. Launder contaminated clothing before re-use. ▶ Use good occupational work practice. ▶ Observe manufacturer's storage and handling recommendations contained within this SDS. ▶ Atmosphere should be regularly checked against established exposure standards to ensure safe working conditions are maintained. ▶ DO NOT allow clothing wet with material to stay in contact with skin |
| Fire and explosion protection | See section 5 |
| Other information | |

7.2. Conditions for safe storage, including any incompatibilities

| | |
|--|---|
| Suitable container | <ul style="list-style-type: none"> ▶ Polyethylene or polypropylene container. ▶ Packing as recommended by manufacturer. ▶ Check all containers are clearly labelled and free from leaks. |
| Storage incompatibility | Avoid contamination of water, foodstuffs, feed or seed. None known |
| Hazard categories in accordance with Regulation (EC) No 1272/2008 | Not Available |
| Qualifying quantity (tonnes) of dangerous substances as referred to in Article 3(10) for the application of | Not Available |

7.3. Specific end use(s)

See section 1.2

SECTION 8 Exposure controls / personal protection**8.1. Control parameters**

| Ingredient | DNELs Exposure Pattern Worker | PNECs Compartment |
|-------------------|--------------------------------------|--------------------------|
| Not Available | Not Available | Not Available |

* Values for General Population

Occupational Exposure Limits (OEL)**INGREDIENT DATA**

| Source | Ingredient | Material name | TWA | STEL | Peak | Notes |
|---------------|-------------------|----------------------|---------------|---------------|---------------|---------------|
| Not Available | Not Available | Not Available | Not Available | Not Available | Not Available | Not Available |

Not Applicable

Emergency Limits

| Ingredient | TEEL-1 | TEEL-2 | TEEL-3 |
|-----------------------|---------------|---------------|---------------|
| Cefotaxime (100mg/ml) | Not Available | Not Available | Not Available |

| Ingredient | Original IDLH | Revised IDLH |
|-----------------------|----------------------|---------------------|
| Cefotaxime (100mg/ml) | Not Available | Not Available |

Occupational Exposure Banding

| Ingredient | Occupational Exposure Band Rating | Occupational Exposure Band Limit |
|-----------------------|--|---|
| Cefotaxime (100mg/ml) | E | ≤ 0.1 ppm |

Notes:

Occupational exposure banding is a process of assigning chemicals into specific categories or bands based on a chemical's potency and the adverse health outcomes associated with exposure. The output of this process is an occupational exposure band (OEB), which corresponds to a range of exposure concentrations that are expected to protect worker health.

8.2. Exposure controls

| | |
|--|---|
| 8.2.1. Appropriate engineering controls | <p>Engineering controls are used to remove a hazard or place a barrier between the worker and the hazard. Well-designed engineering controls can be highly effective in protecting workers and will typically be independent of worker interactions to provide this high level of protection. The basic types of engineering controls are:</p> <p>Process controls which involve changing the way a job activity or process is done to reduce the risk.</p> <p>Enclosure and/or isolation of emission source which keeps a selected hazard "physically" away from the worker and ventilation that strategically "adds" and "removes" air in the work environment. Ventilation can remove or dilute an air contaminant if designed properly. The design of a ventilation system must match the particular process and chemical or contaminant in use.</p> <p>Employers may need to use multiple types of controls to prevent employee overexposure.</p> <p>General exhaust is adequate under normal operating conditions. Local exhaust ventilation may be required in special circumstances. If risk of</p> |
|--|---|

overexposure exists, wear approved respirator. Supplied-air type respirator may be required in special circumstances. Correct fit is essential to ensure adequate protection. Provide adequate ventilation in warehouses and enclosed storage areas. Air contaminants generated in the workplace possess varying "escape" velocities which, in turn, determine the "capture velocities" of fresh circulating air required to effectively remove the contaminant.

| Type of Contaminant: | Air Speed: |
|---|---------------------------------|
| solvent, vapours, degreasing etc., evaporating from tank (in still air). | 0.25-0.5 m/s (50-100 f/min) |
| aerosols, fumes from pouring operations, intermittent container filling, low speed conveyer transfers, welding, spray drift, plating acid fumes, pickling (released at low velocity into zone of active generation) | 0.5-1 m/s (100-200 f/min.) |
| direct spray, spray painting in shallow booths, drum filling, conveyer loading, crusher dusts, gas discharge (active generation into zone of rapid air motion) | 1-2.5 m/s (200-500 f/min.) |
| grinding, abrasive blasting, tumbling, high speed wheel generated dusts (released at high initial velocity into zone of very high rapid air motion) | 2.5-10 m/s (500-2000 f/min.) |

Within each range the appropriate value depends on:

| Lower end of the range | Upper end of the range |
|--|----------------------------------|
| 1: Room air currents minimal or favourable to capture | 1: Disturbing room air currents |
| 2: Contaminants of low toxicity or of nuisance value only. | 2: Contaminants of high toxicity |
| 3: Intermittent, low production. | 3: High production, heavy use |
| 4: Large hood or large air mass in motion | 4: Small hood-local control only |

Simple theory shows that air velocity falls rapidly with distance away from the opening of a simple extraction pipe. Velocity generally decreases with the square of distance from the extraction point (in simple cases). Therefore the air speed at the extraction point should be adjusted, accordingly, after reference to distance from the contaminating source. The air velocity at the extraction fan, for example, should be a minimum of 1-2 m/s (200-400 f/min) for extraction of solvents generated in a tank 2 meters distant from the extraction point. Other mechanical considerations, producing performance deficits within the extraction apparatus, make it essential that theoretical air velocities are multiplied by factors of 10 or more when extraction systems are installed or used.

8.2.2. Individual protection measures, such as personal protective equipment



Eye and face protection

- ▶ Safety glasses with side shields.
- ▶ Chemical goggles. [AS/NZS 1337.1, EN166 or national equivalent]
- ▶ Contact lenses may pose a special hazard; soft contact lenses may absorb and concentrate irritants. A written policy document, describing the wearing of lenses or restrictions on use, should be created for each workplace or task. This should include a review of lens absorption and adsorption for the class of chemicals in use and an account of injury experience. Medical and first-aid personnel should be trained in their removal and suitable equipment should be readily available. In the event of chemical exposure, begin eye irrigation immediately and remove contact lens as soon as practicable. Lens should be removed at the first signs of eye redness or irritation - lens should be removed in a clean environment only after workers have washed hands thoroughly. [CDC NIOSH Current Intelligence Bulletin 59].

Skin protection

See Hand protection below

Hands/feet protection

- ▶ Wear chemical protective gloves, e.g. PVC.
 - ▶ Wear safety footwear or safety gumboots, e.g. Rubber
- The selection of suitable gloves does not only depend on the material, but also on further marks of quality which vary from manufacturer to manufacturer. Where the chemical is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.
- The exact break through time for substances has to be obtained from the manufacturer of the protective gloves and has to be observed when making a final choice.
- Personal hygiene is a key element of effective hand care. Gloves must only be worn on clean hands. After using gloves, hands should be washed and dried thoroughly. Application of a non-perfumed moisturiser is recommended.
- Suitability and durability of glove type is dependent on usage. Important factors in the selection of gloves include:
- frequency and duration of contact,
 - chemical resistance of glove material,
 - glove thickness and
 - dexterity
- Select gloves tested to a relevant standard (e.g. Europe EN 374, US F739, AS/NZS 2161.1 or national equivalent).
- When prolonged or frequently repeated contact may occur, a glove with a protection class of 5 or higher (breakthrough time greater than 240 minutes according to EN 374, AS/NZS 2161.10.1 or national equivalent) is recommended.
 - When only brief contact is expected, a glove with a protection class of 3 or higher (breakthrough time greater than 60 minutes according to EN 374, AS/NZS 2161.10.1 or national equivalent) is recommended.
 - Some glove polymer types are less affected by movement and this should be taken into account when considering gloves for long-term use.
 - Contaminated gloves should be replaced.
- As defined in ASTM F-739-96 in any application, gloves are rated as:
- Excellent when breakthrough time > 480 min
 - Good when breakthrough time > 20 min
 - Fair when breakthrough time < 20 min
 - Poor when glove material degrades
- For general applications, gloves with a thickness typically greater than 0.35 mm, are recommended.
- It should be emphasised that glove thickness is not necessarily a good predictor of glove resistance to a specific chemical, as the permeation efficiency of the glove will be dependent on the exact composition of the glove material. Therefore, glove selection should also be based on consideration of the task requirements and knowledge of breakthrough times.
- Glove thickness may also vary depending on the glove manufacturer, the glove type and the glove model. Therefore, the manufacturers technical data should always be taken into account to ensure selection of the most appropriate glove for the task.
- Note: Depending on the activity being conducted, gloves of varying thickness may be required for specific tasks. For example:
- Thinner gloves (down to 0.1 mm or less) may be required where a high degree of manual dexterity is needed. However, these gloves are only likely to give short duration protection and would normally be just for single use applications, then disposed of.
 - Thicker gloves (up to 3 mm or more) may be required where there is a mechanical (as well as a chemical) risk i.e. where there is abrasion or puncture potential

| | |
|-------------------------|--|
| | Gloves must only be worn on clean hands. After using gloves, hands should be washed and dried thoroughly. Application of a non-perfumed moisturiser is recommended. |
| Body protection | See Other protection below |
| Other protection | <ul style="list-style-type: none"> ▸ Overalls. ▸ P.V.C apron. ▸ Barrier cream. ▸ Skin cleansing cream. ▸ Eye wash unit. |

8.2.3. Environmental exposure controls

See section 12

SECTION 9 Physical and chemical properties**9.1. Information on basic physical and chemical properties**

| | | | |
|---|---------------|--|---------------|
| Appearance | Not Available | | |
| Physical state | Liquid | Relative density (Water = 1) | Not Available |
| Odour | Not Available | Partition coefficient n-octanol / water | Not Available |
| Odour threshold | Not Available | Auto-ignition temperature (°C) | Not Available |
| pH (as supplied) | Not Available | Decomposition temperature (°C) | Not Available |
| Melting point / freezing point (°C) | Not Available | Viscosity (cSt) | Not Available |
| Initial boiling point and boiling range (°C) | Not Available | Molecular weight (g/mol) | Not Available |
| Flash point (°C) | Not Available | Taste | Not Available |
| Evaporation rate | Not Available | Explosive properties | Not Available |
| Flammability | Not Available | Oxidising properties | Not Available |
| Upper Explosive Limit (%) | Not Available | Surface Tension (dyn/cm or mN/m) | Not Available |
| Lower Explosive Limit (%) | Not Available | Volatile Component (%vol) | Not Available |
| Vapour pressure (kPa) | Not Available | Gas group | Not Available |
| Solubility in water | Not Available | pH as a solution (1%) | Not Available |
| Vapour density (Air = 1) | Not Available | VOC g/L | Not Available |
| Nanoform Solubility | Not Available | Nanoform Particle Characteristics | Not Available |
| Particle Size | Not Available | | |

9.2. Other information

Not Available

SECTION 10 Stability and reactivity

| | |
|---|--|
| 10.1.Reactivity | See section 7.2 |
| 10.2. Chemical stability | <ul style="list-style-type: none"> ▸ Unstable in the presence of incompatible materials. ▸ Product is considered stable. ▸ Hazardous polymerisation will not occur. |
| 10.3. Possibility of hazardous reactions | See section 7.2 |
| 10.4. Conditions to avoid | See section 7.2 |
| 10.5. Incompatible materials | See section 7.2 |
| 10.6. Hazardous decomposition products | See section 5.3 |

SECTION 11 Toxicological information**11.1. Information on toxicological effects**

Continued...

| | |
|---------------------|---|
| Inhaled | The material can cause respiratory irritation in some persons. The body's response to such irritation can cause further lung damage. The material has NOT been classified by EC Directives or other classification systems as "harmful by inhalation". This is because of the lack of corroborating animal or human evidence. |
| Ingestion | The material has NOT been classified by EC Directives or other classification systems as "harmful by ingestion". This is because of the lack of corroborating animal or human evidence. |
| Skin Contact | This material can cause inflammation of the skin on contact in some persons. The material may accentuate any pre-existing dermatitis condition Skin contact is not thought to have harmful health effects (as classified under EC Directives); the material may still produce health damage following entry through wounds, lesions or abrasions. Open cuts, abraded or irritated skin should not be exposed to this material Entry into the blood-stream, through, for example, cuts, abrasions or lesions, may produce systemic injury with harmful effects. Examine the skin prior to the use of the material and ensure that any external damage is suitably protected. |
| Eye | This material can cause eye irritation and damage in some persons. |
| Chronic | Long-term exposure to respiratory irritants may result in airways disease, involving difficulty breathing and related whole-body problems. Substance accumulation, in the human body, may occur and may cause some concern following repeated or long-term occupational exposure. |

Legend: 1. Value obtained from Europe ECHA Registered Substances - Acute toxicity 2. Value obtained from manufacturer's SDS. Unless otherwise specified data extracted from RTECS - Register of Toxic Effect of chemical Substances

| | |
|------------------------------|---|
| Cefotaxime (100mg/ml) | Asthma-like symptoms may continue for months or even years after exposure to the material ends. This may be due to a non-allergic condition known as reactive airways dysfunction syndrome (RADS) which can occur after exposure to high levels of highly irritating compound. Main criteria for diagnosing RADS include the absence of previous airways disease in a non-atopic individual, with sudden onset of persistent asthma-like symptoms within minutes to hours of a documented exposure to the irritant. Other criteria for diagnosis of RADS include a reversible airflow pattern on lung function tests, moderate to severe bronchial hyperreactivity on methacholine challenge testing, and the lack of minimal lymphocytic inflammation, without eosinophilia. RADS (or asthma) following an irritating inhalation is an infrequent disorder with rates related to the concentration of and duration of exposure to the irritating substance. On the other hand, industrial bronchitis is a disorder that occurs as a result of exposure due to high concentrations of irritating substance (often particles) and is completely reversible after exposure ceases. The disorder is characterized by difficulty breathing, cough and mucus production. |
|------------------------------|---|

| | | | |
|--|---|---------------------------------|---|
| Acute Toxicity | ✗ | Carcinogenicity | ✗ |
| Skin Irritation/Corrosion | ✓ | Reproductivity | ✗ |
| Serious Eye Damage/Irritation | ✓ | STOT - Single Exposure | ✓ |
| Respiratory or Skin sensitisation | ✗ | STOT - Repeated Exposure | ✗ |
| Mutagenicity | ✗ | Aspiration Hazard | ✗ |

Legend: ✗ – Data either not available or does not fill the criteria for classification
✓ – Data available to make classification

11.2 Information on other hazards

11.2.1. Endocrine disrupting properties

No evidence of endocrine disrupting properties were found in the current literature.

11.2.2. Other information

See Section 11.1

SECTION 12 Ecological information

12.1. Toxicity

Legend: Extracted from 1. IUCLID Toxicity Data 2. Europe ECHA Registered Substances - Ecotoxicological Information - Aquatic Toxicity 4. US EPA, Ecotox database - Aquatic Toxicity Data 5. ECETOC Aquatic Hazard Assessment Data 6. NITE (Japan) - Bioconcentration Data 7. METI (Japan) - Bioconcentration Data 8. Vendor Data

DO NOT discharge into sewer or waterways.

12.2. Persistence and degradability

| Ingredient | Persistence: Water/Soil | Persistence: Air |
|------------|---------------------------------------|---------------------------------------|
| | No Data available for all ingredients | No Data available for all ingredients |

12.3. Bioaccumulative potential

| Ingredient | Bioaccumulation |
|------------|---------------------------------------|
| | No Data available for all ingredients |

12.4. Mobility in soil

| Ingredient | Mobility |
|------------|---------------------------------------|
| | No Data available for all ingredients |

12.5. Results of PBT and vPvB assessment

Cefotaxime (100mg/ml)

| | P | B | T |
|-------------------------|---------------|---------------|---------------|
| Relevant available data | Not Available | Not Available | Not Available |
| PBT | ✗ | ✗ | ✗ |
| vPvB | ✗ | ✗ | ✗ |
| PBT Criteria fulfilled? | | | No |
| vPvB | | | No |

12.6. Endocrine disrupting properties

No evidence of endocrine disrupting properties were found in the current literature.

12.7. Other adverse effects

No evidence of ozone depleting properties were found in the current literature.

SECTION 13 Disposal considerations

13.1. Waste treatment methods

| | |
|-------------------------------------|--|
| Product / Packaging disposal | <p>Legislation addressing waste disposal requirements may differ by country, state and/ or territory. Each user must refer to laws operating in their area. In some areas, certain wastes must be tracked.</p> <p>A Hierarchy of Controls seems to be common - the user should investigate:</p> <ul style="list-style-type: none"> ▶ Reduction ▶ Reuse ▶ Recycling ▶ Disposal (if all else fails) <p>This material may be recycled if unused, or if it has not been contaminated so as to make it unsuitable for its intended use. If it has been contaminated, it may be possible to reclaim the product by filtration, distillation or some other means. Shelf life considerations should also be applied in making decisions of this type. Note that properties of a material may change in use, and recycling or reuse may not always be appropriate.</p> <ul style="list-style-type: none"> ▶ DO NOT allow wash water from cleaning or process equipment to enter drains. ▶ It may be necessary to collect all wash water for treatment before disposal. ▶ In all cases disposal to sewer may be subject to local laws and regulations and these should be considered first. ▶ Where in doubt contact the responsible authority. ▶ Recycle wherever possible. ▶ Consult manufacturer for recycling options or consult local or regional waste management authority for disposal if no suitable treatment or disposal facility can be identified. ▶ Dispose of by: burial in a land-fill specifically licensed to accept chemical and / or pharmaceutical wastes or incineration in a licensed apparatus (after admixture with suitable combustible material). ▶ Decontaminate empty containers. Observe all label safeguards until containers are cleaned and destroyed. |
| Waste treatment options | Not Available |
| Sewage disposal options | Not Available |

SECTION 14 Transport information

Labels Required

| | |
|-------------------------|----------------|
| Marine Pollutant | NO |
| HAZCHEM | Not Applicable |

Land transport (ADR): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

| | | |
|---|--------------------------------|----------------|
| 14.1. UN number or ID number | Not Applicable | |
| 14.2. UN proper shipping name | Not Applicable | |
| 14.3. Transport hazard class(es) | Class | Not Applicable |
| | Subsidiary risk | Not Applicable |
| 14.4. Packing group | Not Applicable | |
| 14.5. Environmental hazard | Not Applicable | |
| 14.6. Special precautions for user | Hazard identification (Kemler) | Not Applicable |
| | Classification code | Not Applicable |
| | Hazard Label | Not Applicable |
| | Special provisions | Not Applicable |
| | Limited quantity | Not Applicable |
| | Tunnel Restriction Code | Not Applicable |

Air transport (ICAO-IATA / DGR): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

| | |
|--------------------------------------|----------------|
| 14.1. UN number | Not Applicable |
| 14.2. UN proper shipping name | Not Applicable |

| | | |
|---|---|----------------|
| 14.3. Transport hazard class(es) | ICAO/IATA Class | Not Applicable |
| | ICAO / IATA Subrisk | Not Applicable |
| | ERG Code | Not Applicable |
| 14.4. Packing group | Not Applicable | |
| 14.5. Environmental hazard | Not Applicable | |
| 14.6. Special precautions for user | Special provisions | Not Applicable |
| | Cargo Only Packing Instructions | Not Applicable |
| | Cargo Only Maximum Qty / Pack | Not Applicable |
| | Passenger and Cargo Packing Instructions | Not Applicable |
| | Passenger and Cargo Maximum Qty / Pack | Not Applicable |
| | Passenger and Cargo Limited Quantity Packing Instructions | Not Applicable |
| | Passenger and Cargo Limited Maximum Qty / Pack | Not Applicable |

Sea transport (IMDG-Code / GGVSee): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

| | | |
|---|--------------------|----------------|
| 14.1. UN number | Not Applicable | |
| 14.2. UN proper shipping name | Not Applicable | |
| 14.3. Transport hazard class(es) | IMDG Class | Not Applicable |
| | IMDG Subrisk | Not Applicable |
| 14.4. Packing group | Not Applicable | |
| 14.5. Environmental hazard | Not Applicable | |
| 14.6. Special precautions for user | EMS Number | Not Applicable |
| | Special provisions | Not Applicable |
| | Limited Quantities | Not Applicable |

Inland waterways transport (ADN): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

| | | |
|---|---------------------|----------------|
| 14.1. UN number | Not Applicable | |
| 14.2. UN proper shipping name | Not Applicable | |
| 14.3. Transport hazard class(es) | Not Applicable | Not Applicable |
| | | |
| 14.4. Packing group | Not Applicable | |
| 14.5. Environmental hazard | Not Applicable | |
| 14.6. Special precautions for user | Classification code | Not Applicable |
| | Special provisions | Not Applicable |
| | Limited quantity | Not Applicable |
| | Equipment required | Not Applicable |
| | Fire cones number | Not Applicable |

14.7. Maritime transport in bulk according to IMO instruments**14.7.1. Transport in bulk according to Annex II of MARPOL and the IBC code**

Not Applicable

14.7.2. Transport in bulk in accordance with MARPOL Annex V and the IMSBC Code

| Product name | Group |
|-----------------------|---------------|
| Cefotaxime (100mg/ml) | Not Available |

14.7.3. Transport in bulk in accordance with the IGC Code

| Product name | Ship Type |
|-----------------------|---------------|
| Cefotaxime (100mg/ml) | Not Available |

SECTION 15 Regulatory information**15.1. Safety, health and environmental regulations / legislation specific for the substance or mixture**

Cefotaxime (100mg/ml) is found on the following regulatory lists

Europe EC Inventory

European Union - European Inventory of Existing Commercial Chemical Substances (EINECS)

This safety data sheet is in compliance with the following EU legislation and its adaptations - as far as applicable - : Directives 98/24/EC, - 92/85/EEC, - 94/33/EC, - 2008/98/EC, -

Continued...

2010/75/EU; Commission Regulation (EU) 2020/878; Regulation (EC) No 1272/2008 as updated through ATPs.

Information according to 2012/18/EU (Seveso III):

| | |
|------------------------|---------------|
| Seveso Category | Not Available |
|------------------------|---------------|

15.2. Chemical safety assessment

For further information please look at the Chemical Safety Assessment and Exposure Scenarios prepared by your Supply Chain if available.

ECHA SUMMARY

| Ingredient | CAS number | Index No | ECHA Dossier |
|-----------------------|------------|---------------|---------------|
| Cefotaxime (100mg/ml) | 64485-93-4 | Not Available | Not Available |

| Harmonisation (C&L Inventory) | Hazard Class and Category Code(s) | Pictograms Signal Word Code(s) | Hazard Statement Code(s) |
|-------------------------------|---|--------------------------------|--|
| 1 | Skin Sens. 1; Resp. Sens. 1 | GHS08; Dgr | H317; H334 |
| 2 | Skin Sens. 1; Resp. Sens. 1; Skin Irrit. 2; Eye Irrit. 2; lungs; Acute Tox. 4; Acute Tox. 4; Acute Tox. 4 | GHS08; Dgr | H317; H334; H315; H319; H335; H302; H312; H332 |

Harmonisation Code 1 = The most prevalent classification. Harmonisation Code 2 = The most severe classification.

National Inventory Status

| National Inventory | Status |
|--|---|
| Australia - AIC / Australia Non-Industrial Use | No (Cefotaxime (100mg/ml)) |
| Canada - DSL | No (Cefotaxime (100mg/ml)) |
| Canada - NDSL | No (Cefotaxime (100mg/ml)) |
| China - IECSC | Yes |
| Europe - EINEC / ELINCS / NLP | Yes |
| Japan - ENCS | No (Cefotaxime (100mg/ml)) |
| Korea - KECI | No (Cefotaxime (100mg/ml)) |
| New Zealand - NZIoC | Yes |
| Philippines - PICCS | No (Cefotaxime (100mg/ml)) |
| USA - TSCA | No (Cefotaxime (100mg/ml)) |
| Taiwan - TCSI | Yes |
| Mexico - INSQ | Yes |
| Vietnam - NCI | Yes |
| Russia - FBEPH | No (Cefotaxime (100mg/ml)) |
| Legend: | Yes = All CAS declared ingredients are on the inventory No = One or more of the CAS listed ingredients are not on the inventory. These ingredients may be exempt or will require registration. |

SECTION 16 Other information

| | |
|----------------------|------------|
| Revision Date | 10/07/2023 |
| Initial Date | 16/09/2022 |

Full text Risk and Hazard codes

| | |
|-------------|--|
| H302 | Harmful if swallowed. |
| H312 | Harmful in contact with skin. |
| H317 | May cause an allergic skin reaction. |
| H332 | Harmful if inhaled. |
| H334 | May cause allergy or asthma symptoms or breathing difficulties if inhaled. |

SDS Version Summary

| Version | Date of Update | Sections Updated |
|---------|----------------|--|
| 1.2 | 10/07/2023 | Toxicological information - Acute Health (eye), Toxicological information - Acute Health (inhaled), Toxicological information - Acute Health (skin), CAS Number, Toxicological information - Chronic Health, Hazards identification - Classification, Exposure controls / personal protection - Engineering Control, Ecological Information - Environmental, Exposure controls / personal protection - Exposure Standard, Firefighting measures - Fire Fighter (fire/explosion hazard), Firefighting measures - Fire Fighter (fire fighting), First Aid measures - First Aid (eye), First Aid measures - First Aid (inhaled), First Aid measures - First Aid (skin), Handling and storage - Handling Procedure, Composition / information on ingredients - Ingredients, Stability and reactivity - Instability Condition, Exposure controls / personal protection - Personal Protection (other), Exposure controls / personal protection - Personal Protection (eye), Exposure controls / personal protection - Personal Protection (hands/feet), Accidental release measures - Spills (major), Handling and storage - Storage (storage incompatibility), Identification of the substance / mixture and of the company / undertaking - Use |

Other information

Classification of the preparation and its individual components has drawn on official and authoritative sources as well as independent review by the Chemwatch Classification committee using available literature references.

The SDS is a Hazard Communication tool and should be used to assist in the Risk Assessment. Many factors determine whether the reported Hazards are Risks in the workplace or other settings. Risks may be determined by reference to Exposures Scenarios. Scale of use, frequency of use and current or available engineering controls must be considered. For detailed advice on Personal Protective Equipment, refer to the following EU CEN Standards:

EN 166 Personal eye-protection
 EN 340 Protective clothing
 EN 374 Protective gloves against chemicals and micro-organisms
 EN 13832 Footwear protecting against chemicals
 EN 133 Respiratory protective devices

Definitions and abbreviations

PC - TWA: Permissible Concentration-Time Weighted Average
 PC - STEL: Permissible Concentration-Short Term Exposure Limit
 IARC: International Agency for Research on Cancer
 ACGIH: American Conference of Governmental Industrial Hygienists
 STEL: Short Term Exposure Limit
 TEEL: Temporary Emergency Exposure Limit,
 IDLH: Immediately Dangerous to Life or Health Concentrations
 ES: Exposure Standard
 OSF: Odour Safety Factor
 NOAEL :No Observed Adverse Effect Level
 LOAEL: Lowest Observed Adverse Effect Level
 TLV: Threshold Limit Value
 LOD: Limit Of Detection
 OTV: Odour Threshold Value
 BCF: BioConcentration Factors
 BEI: Biological Exposure Index
 AIIIC: Australian Inventory of Industrial Chemicals
 DSL: Domestic Substances List
 NDSL: Non-Domestic Substances List
 IECSC: Inventory of Existing Chemical Substance in China
 EINECS: European INventory of Existing Commercial chemical Substances
 ELINCS: European List of Notified Chemical Substances
 NLP: No-Longer Polymers
 ENCS: Existing and New Chemical Substances Inventory
 KECI: Korea Existing Chemicals Inventory
 NZIoC: New Zealand Inventory of Chemicals
 PICCS: Philippine Inventory of Chemicals and Chemical Substances
 TSCA: Toxic Substances Control Act
 TCSI: Taiwan Chemical Substance Inventory
 INSQ: Inventario Nacional de Sustancias Químicas
 NCI: National Chemical Inventory
 FBEPH: Russian Register of Potentially Hazardous Chemical and Biological Substances

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]

| Classification according to regulation (EC) No 1272/2008 [CLP] and amendments | Classification Procedure |
|---|--------------------------|
| Skin Corrosion/Irritation Category 2, H315 | Expert judgement |
| Serious Eye Damage/Eye Irritation Category 2, H319 | Expert judgement |
| Specific Target Organ Toxicity - Single Exposure (Respiratory Tract Irritation) Category 3 , H335 | Expert judgement |

Powered by AuthorITe, from Chemwatch.