SAFETY DATA SHEET

Cephalonium Formulation

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Cephalonium Formulation

Manufacturer or supplier's details

Company: MSD
Address: Rua Coronel Bento Soares, 530
Cruzeiro - Sao Paulo - Brazil  CEP 12730-340
Telephone: 908-740-4000
Emergency telephone: 1-908-423-6000
E-mail address: EHSDATASTEW@msd.com

Recommended use of the chemical and restrictions on use

Recommended use: Veterinary product

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification in accordance with ABNT NBR 14725 Standard

Respiratory sensitization: Category 1
Skin sensitization: Category 1
Short-term (acute) aquatic hazard: Category 2
Long-term (chronic) aquatic hazard: Category 3

GHS label elements in accordance with ABNT NBR 14725 Standard

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.
H401 Toxic to aquatic life.
H412 Harmful to aquatic life with long lasting effects.

Precautionary Statements:

Prevention:
P273 Avoid release to the environment.
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.

Additional Labeling
The following percentage of the mixture consists of ingredient(s) with unknown hazards to the aquatic environment: 2.97 %

Other hazards which do not result in classification
None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mixture</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>White mineral oil (petroleum)</td>
<td>8042-47-5</td>
<td>Respiratory sensitization, Category 1, Skin sensitization, Category 1</td>
<td>&gt;= 90 &lt;= 100</td>
</tr>
<tr>
<td>Cefalonium</td>
<td>5575-21-3</td>
<td>Short-term (acute) aquatic hazard, Category 1</td>
<td>&gt;= 5 &lt; 10</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Long-term (chronic) aquatic hazard, Category 2</td>
<td></td>
</tr>
<tr>
<td>Aluminum tristearate</td>
<td>637-12-7</td>
<td></td>
<td>&gt;= 1 &lt; 5</td>
</tr>
</tbody>
</table>

SECTION 4. 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.

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.
SAFETY DATA SHEET

Cephalonium Formulation

Version 3.4 Revision Date: 27.08.2021 SDS Number: 26949-00015 Date of last issue: 16.10.2020 Date of first issue: 31.10.2014

In case of eye contact: Thoroughly clean shoes before reuse.
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 if symptoms occur.
Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and delayed: May cause an allergic skin reaction.
May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Excessive exposure may aggravate preexisting asthma and other respiratory disorders (e.g. emphysema, bronchitis, reactive airways dysfunction syndrome).

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).

Notes to physician: Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media: Water spray
Alcohol-resistant foam
Carbon dioxide (CO2)
Dry chemical

Unsuitable extinguishing media: None known.

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

Hazardous combustion products: Carbon oxides
Nitrogen oxides (NOx)
Sulfur oxides
Metal oxides

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.

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

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures: Use personal protective equipment.
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

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.
Local authorities should be advised if significant spillages cannot be contained.
Methods and materials for containment and cleaning up:
- Soak up with inert absorbent material.
- For large spills, provide diking or other appropriate containment to keep material from spreading. If diked 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.

SECTION 7. HANDLING AND STORAGE

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.
- Avoid breathing mist or vapors.
- Do not swallow.
- Avoid contact with eyes.
- Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment.
- Keep container tightly closed.
- Already sensitized individuals should consult their physician regarding working with respiratory irritants or sensitizers.
- Take care to prevent spills, waste and minimize release to the environment.

Hygiene measures:
- 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.

Conditions for safe storage:
- Keep in properly labeled containers.
- Keep tightly closed.
- Store in accordance with the particular national regulations.

Materials to avoid:
- No special restrictions on storage with other products.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>White mineral oil (petroleum)</td>
<td>8042-47-5</td>
<td>TWA (Inhalable particulate)</td>
<td>5 mg/m³</td>
<td>ACGIH</td>
</tr>
</tbody>
</table>
Aluminum tristearate 637-12-7

<table>
<thead>
<tr>
<th>Substance</th>
<th>TWA (Inhalable particulate matter)</th>
<th>TWA (Respirable particulate matter)</th>
<th>TWA (Respirable particulate matter) (Aluminum)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>10 mg/m³</td>
<td>3 mg/m³</td>
<td>1 mg/m³</td>
</tr>
<tr>
<td></td>
<td>ACGIH</td>
<td>ACGIH</td>
<td>ACGIH</td>
</tr>
</tbody>
</table>

**Engineering measures**: Ensure adequate ventilation, especially in confined areas. Minimize workplace exposure concentrations.

**Personal protective equipment**

- **Respiratory protection**: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
  - **Filter type**: Combined particulates and organic vapor type
  - **Hand protection**: Chemical-resistant gloves

**Remarks**: Choose gloves to protect hands against chemicals depending on the concentration specific to place of work. Breakthrough time is not determined for the product. Change gloves often!

For special applications, we recommend clarifying the resistance to chemicals of the aforementioned protective gloves with the glove manufacturer. Wash hands before breaks and at the end of workday.

- **Eye protection**: Wear the following personal protective equipment:
  - Safety glasses

- **Skin and body protection**: Select appropriate protective clothing based on chemical resistance data and an assessment of the local exposure potential. Skin contact must be avoided by using impervious protective clothing (gloves, aprons, boots, etc).

**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

- **Appearance**: suspension
- **Color**: off-white
- **Odor**: odorless
- **Odor Threshold**: No data available
- **pH**: No data available
- **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)
- No data available

### Flammability (liquids)
- No data available

### Upper explosion limit / Upper flammability limit
- No data available

### Lower explosion limit / Lower flammability limit
- No data available

### Vapor pressure
- No data available

### Relative vapor density
- No data available

### Relative density
- No data available

### Density
- No data available

### Solubility(ies)
- Water solubility: No data available

### Partition coefficient: n-octanol/water
- No data available

### Autoignition 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.

### Molecular weight
- No data available

### Particle size
- No data available

### SECTION 10. STABILITY AND REACTIVITY

<table>
<thead>
<tr>
<th>Property</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reactivity</td>
<td>Not classified as a reactivity hazard.</td>
</tr>
<tr>
<td>Chemical stability</td>
<td>Stable under normal conditions.</td>
</tr>
<tr>
<td>Possibility of hazardous reactions</td>
<td>None known.</td>
</tr>
<tr>
<td>Conditions to avoid</td>
<td>None known.</td>
</tr>
<tr>
<td>Incompatible materials</td>
<td>None.</td>
</tr>
</tbody>
</table>
Hazardous decomposition products: No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure:
- Inhalation
- Skin contact
- Ingestion
- Eye contact

Acute toxicity:
Not classified based on available information.

Components:

White mineral oil (petroleum):
- Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg
- Acute inhalation toxicity: LC50 (Rat): > 5 mg/l
  Exposure time: 4 h
  Test atmosphere: dust/mist
  Assessment: The substance or mixture has no acute inhalation toxicity
- Acute dermal toxicity: LD50 (Rabbit): > 2,000 mg/kg
  Assessment: The substance or mixture has no acute dermal toxicity

Cefalonium:
- Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg

Aluminum tristearate:
- Acute oral toxicity: LD50 (Rat, female): > 2,000 mg/kg
  Remarks: Based on data from similar materials
- Acute inhalation toxicity: LC50 (Rat): > 5,15 mg/l
  Exposure time: 4 h
  Test atmosphere: dust/mist
  Method: OECD Test Guideline 403
  Remarks: Based on data from similar materials

Skin corrosion/irritation:
Not classified based on available information.

Components:

White mineral oil (petroleum):
- Species: Rabbit
- Result: No skin irritation

Aluminum tristearate:
- Species: reconstructed human epidermis (RhE)
- Method: OECD Test Guideline 439
Remarks : Based on data from similar materials
Result : No skin irritation

**Serious eye damage/eye irritation**
Not classified based on available information.

**Components:**

**White mineral oil (petroleum):**
Species : Rabbit
Result : No eye irritation

**Aluminum tristearate:**
Species : Rabbit
Result : No eye irritation
Method : OECD Test Guideline 405
Remarks : Based on data from similar materials

**Respiratory or skin sensitization**

**Skin sensitization**
May cause an allergic skin reaction.

**Respiratory sensitization**
May cause allergy or asthma symptoms or breathing difficulties if inhaled.

**Components:**

**White mineral oil (petroleum):**
Test Type : Buehler Test
Routes of exposure : Skin contact
Species : Guinea pig
Result : negative

**Cefalonium:**
Routes of exposure : Skin contact
Assessment : Probability or evidence of skin sensitization in humans
Inhalation : May cause sensitization by inhalation.

**Aluminum tristearate:**
Test Type : Local lymph node assay (LLNA)
Routes of exposure : Skin contact
Species : Mouse
Method : OECD Test Guideline 429
Result : negative
Remarks : Based on data from similar materials

**Germ cell mutagenicity**
Not classified based on available information.
## Components:

### White mineral oil (petroleum):

**Genotoxicity in vitro**
- Test Type: In vitro mammalian cell gene mutation test
- Result: negative

**Genotoxicity in vivo**
- Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
  - Species: Mouse
  - Application Route: Intraperitoneal injection
  - Method: OECD Test Guideline 474
  - Result: negative
  - Remarks: Based on data from similar materials

### Cefalonium:

**Genotoxicity in vitro**
- Test Type: Bacterial reverse mutation assay (AMES)
  - Result: negative

- Test Type: In vitro mammalian cell gene mutation test
  - Result: negative

- Test Type: Chromosome aberration test in vitro
  - Result: positive

**Genotoxicity in vivo**
- Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
  - Species: Rat
  - Application Route: Ingestion
  - Method: OECD Test Guideline 474
  - Result: negative
  - Remarks: Based on data from similar materials

- Test Type: Unscheduled DNA synthesis (UDS) test with mammalian liver cells in vivo
  - Species: Rat
  - Application Route: Ingestion
  - Result: negative

### Aluminum tristearate:

**Genotoxicity in vitro**
- Test Type: In vitro mammalian cell gene mutation test
  - Method: OECD Test Guideline 476
  - Result: negative
  - Remarks: Based on data from similar materials

- Test Type: Bacterial reverse mutation assay (AMES)
  - Method: OECD Test Guideline 471
  - Result: negative
  - Remarks: Based on data from similar materials

**Genotoxicity in vivo**
- Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
  - Species: Rat
  - Application Route: Ingestion
  - Method: OECD Test Guideline 474
  - Result: negative
  - Remarks: Based on data from similar materials
Carcinogenicity
Not classified based on available information.

Components:

White mineral oil (petroleum):
Species: Rat
Application Route: Ingestion
Exposure time: 24 Months
Result: negative

Reproductive toxicity
Not classified based on available information.

Components:

White mineral oil (petroleum):
Effects on fertility: Test Type: One-generation reproduction toxicity study
Species: Rat
Application Route: Skin contact
Result: negative

Effects on fetal development: Test Type: Embryo-fetal development
Species: Rat
Application Route: Ingestion
Result: negative

Cefalonium:
Effects on fetal development: Test Type: Embryo-fetal development
Species: Rat
Application Route: Ingestion
Result: negative

Aluminum tristearate:
Effects on fertility: Test Type: Two-generation reproduction toxicity study
Species: Rat
Application Route: Ingestion
Method: OECD Test Guideline 416
Result: negative
Remarks: Based on data from similar materials

Effects on fetal development: Test Type: Fertility/early embryonic development
Species: Rat
Application Route: Ingestion
Result: negative
Remarks: Based on data from similar materials

STOT-single exposure
Not classified based on available information.
STOT-repeated exposure
Not classified based on available information.

Repeated dose toxicity

Components:

White mineral oil (petroleum):
Species: Rat
LOAEL: 160 mg/kg
Application Route: Ingestion
Exposure time: 90 Days

Species: Rat
LOAEL: >= 1 mg/l
Application Route: inhalation (dust/mist/fume)
Exposure time: 4 Weeks
Method: OECD Test Guideline 412

Aluminum tristearate:
Species: Rat
NOAEL: >= 5,000 mg/kg
Application Route: Ingestion
Exposure time: 90 Days
Remarks: Based on data from similar materials

Aspiration toxicity
Not classified based on available information.

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

White mineral oil (petroleum):
Toxicity to fish: LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l
    Exposure time: 96 h
    Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): > 100 mg/l
    Exposure time: 48 h
    Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants: NOEC (Pseudokirchneriella subcapitata (green algae)): 100 mg/l
    Exposure time: 72 h
    Method: OECD Test Guideline 201

Toxicity to fish (Chronic toxicity): NOEC (Oncorhynchus mykiss (rainbow trout)): 1.000 mg/l
    Exposure time: 28 d

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity): NOEC (Daphnia magna (Water flea)): 1,000 mg/l
    Exposure time: 21 d
ic toxicity)

**Cefalonium:**

Toxicity to fish:
- LC50 (Pimephales promelas (fathead minnow)): > 1 mg/l
  - Exposure time: 96 h
  - Method: OECD Test Guideline 203
  - Remarks: No toxicity at the limit of solubility.

Toxicity to daphnia and other aquatic invertebrates:
- EC50 (Daphnia magna (Water flea)): > 1 mg/l
  - Exposure time: 48 h
  - Method: OECD Test Guideline 202
  - Remarks: No toxicity at the limit of solubility.

Toxicity to algae/aquatic plants:
- NOEC (Anabaena flos-aquae (cyanobacterium)): 0.213 mg/l
  - Exposure time: 72 h
  - Method: OECD Test Guideline 201

- ErC50 (Anabaena flos-aquae (cyanobacterium)): 0.315 mg/l
  - Exposure time: 72 h
  - Method: OECD Test Guideline 201

M-Factor (Acute aquatic toxicity):
- 1

Toxicity to microorganisms:
- EC50: > 1.000 mg/l
  - Exposure time: 3 h
  - Method: OECD Test Guideline 209

- NOEC: 0.48 mg/l
  - Exposure time: 3 h
  - Method: OECD Test Guideline 209

**Aluminum tristearate:**

Ecotoxicology Assessment

Acute aquatic toxicity: Toxic effects cannot be excluded

Chronic aquatic toxicity: Toxic effects cannot be excluded

Persistence and degradability

**Components:**

**White mineral oil (petroleum):**

Biodegradability:
- Result: Not readily biodegradable.
- Biodegradation: 31%
- Exposure time: 28 d

**Cefalonium:**

Biodegradability:
- Result: Not readily biodegradable.
- Biodegradation: 32%
- Exposure time: 28 d
- Method: OECD Test Guideline 301B
Bioaccumulative potential

Components:

Cefalonium:
Partition coefficient: n-octanol/water : log Pow: 0.188

Mobility in soil
No data available

Other adverse effects
No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods
Waste from residues : Dispose of in accordance with local regulations.
Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.
If not otherwise specified: Dispose of as unused product.

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG
Not regulated as a dangerous good

IATA-DGR
Not regulated as a dangerous good

IMDG-Code
Not regulated as a dangerous good

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.

Domestic regulation

ANTT
Not regulated as a dangerous good

Special precautions for user
Not applicable

SECTION 15. REGULATORY INFORMATION

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

National List of Carcinogenic Agents for Humans - (LINACH) : Not applicable

Brazil, List of chemicals controlled by the Federal Police : Not applicable
The ingredients of this product are reported in the following inventories:

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

SECTION 16. OTHER INFORMATION

Further information

Full text of other abbreviations
- ACGIH: USA. ACGIH Threshold Limit Values (TLV)
- ACGIH / TWA: 8-hour, time-weighted average
- AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; 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; KECI - 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; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; 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; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; 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; WHMIS - Workplace Hazardous Materials Information System
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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