SAFETY DATA SHEET

Cephalonium Formulation

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Cephalonium Formulation

Manufacturer or supplier’s details
Company name of supplier: MSD
Address: Avenida 16 de Septiembre No. 301
Xaltocan - Xochimilco Mexico 16090
Telephone: 52 55 57284444
Telefax: 908-735-1496
Emergency telephone: 1-908-423-6000
E-mail address: EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use
Recommended use: Veterinary product

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification
Respiratory sensitization: Category 1
Skin sensitization: Category 1

GHS label elements
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.

Precautionary Statements: Prevention:
P261 Avoid breathing mist or vapors.
P272 Contaminated work clothing should not be allowed out of the workplace.
P280 Wear protective gloves.
P284 Wear respiratory protection.

Response:
P302 + P352 IF ON SKIN: Wash with plenty of water.
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 or doctor/physician.
P362 + P364 Take off contaminated clothing and wash it before reuse.
SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

<table>
<thead>
<tr>
<th>Components</th>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>White mineral oil (petroleum)</td>
<td>8042-47-5</td>
<td>&gt;= 90 -&lt;= 100</td>
</tr>
<tr>
<td></td>
<td>Cefalonium</td>
<td>5575-21-3</td>
<td>&gt;= 5 -&lt; 10</td>
</tr>
<tr>
<td></td>
<td>Aluminum tristearate</td>
<td>637-12-7</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.
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 if symptoms occur.

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
SAFETY DATA SHEET

Cephalonium Formulation

Version 3.3  Revision Date: 09/13/2019  SDS Number: 26969-00013  Date of last issue: 24.04.2019

| Unsuitable extinguishing media | : Alcohol-resistant foam
Carbon dioxide (CO2)
Dry chemical

| Specific hazards during firefighting | : 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 and personal protective equipment recommendations.

| Environmental precautions | : Discharge into the environment must be avoided.
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 inhalation of vapor or mist. 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. 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/PERSOAL 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>VLE-PPT (Mist)</td>
<td>5 mg/m³</td>
<td>NOM-010-STPS-2014</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Inhalable fraction)</td>
<td>5 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Aluminum tristearate</td>
<td>637-12-7</td>
<td>VLE-PPT</td>
<td>10 mg/m³</td>
<td>NOM-010-STPS-2014</td>
</tr>
<tr>
<td></td>
<td></td>
<td>VLE-PPT (Respirable fraction)</td>
<td>1 mg/m³ (Aluminum)</td>
<td>NOM-010-STPS-2014</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable fraction)</td>
<td>1 mg/m³ (Aluminum)</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Inhalable fraction)</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable fraction)</td>
<td>3 mg/m³</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

Reactivity : Not classified as a reactivity hazard.
Chemical stability : Stable under normal conditions.
Possibility of hazardous reactions : None known.
Conditions to avoid : None known.
Incompatible materials : None.
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
Cephalonium Formulation

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:
Method: OECD Test Guideline 439
Result: No skin irritation
Remarks: Based on data from similar materials

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

Routes of exposure: Inhalation
Assessment: 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
Genotoxicity in vivo: Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)  
Species: Rat  
Application Route: Ingestion  
Result: negative

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):
Cephalonium Formulation

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
SAFETY DATA SHEET

Cephalonium Formulation

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date</th>
<th>SDS Number</th>
<th>Date of last issue</th>
<th>Date of first issue</th>
</tr>
</thead>
</table>

**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 |

**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

**Toxicity to microorganisms:**
- **EC50:** > 1,000 mg/l
- **Exposure time:** 3 h
- **NOEC:** 0.48 mg/l
- **Exposure time:** 3 h

**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

NOM-002-SCT
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
Federal Law for the control of chemical precursors, essential chemical products and machinery for producing capsules, tablets and pills. : 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

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

NOM-010-STPS-2014 : Mexico. Norm NOM-010-STPS-2014 on Chemicals Polluting the Work Environment - Identification, Assessment and Control - Appendix 1 Occupational Exposure Limits

ACGIH / TWA : 8-hour, time-weighted average

NOM-010-STPS-2014 / VLE-PPT : Time weighted average limit value

AICS - Australian Inventory of Chemical Substances; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR -
SAFETY DATA SHEET

Cephalonium Formulation

Version 3.3  Revision Date: 09/13/2019  SDS Number: 26969-00013  Date of last issue: 24.04.2019  Date of first issue: 31.10.2014

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; 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; 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; 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


Revision Date: 09/13/2019

The information is considered as correct, but not exhaustive, and will be used only as a guide, which is based in the current knowledge of the substance or mixture, and is applicable to proper safety precautions for the product.

MX / Z8