

SAFETY DATA SHEET



Cephalonium Formulation

Version 8.2	Revision Date: 2025/04/14	SDS Number: 26961-00028	Date of last issue: 2024/09/28 Date of first issue: 2014/10/31
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1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Cephalonium Formulation
Other means of identification : Cepravin Dry Cow (A003322)
COOPERS CEPRAVIN DRY COW INTRAMAMMARY
ANTIBIOTIC (47940)

Manufacturer or supplier's details

Company : MSD
Address : 126 E. Lincoln Avenue
Rahway, New Jersey U.S.A. 07065
Telephone : +1-908-740-4000
Emergency telephone number : +1-908-423-6000
E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product
Restrictions on use : Not applicable

2. HAZARDS IDENTIFICATION

GHS Classification

Respiratory sensitisation : Category 1
Skin sensitisation : Category 1
Aspiration hazard : Category 1
Long-term (chronic) aquatic hazard : Category 3

GHS label elements

Hazard pictograms : 
Signal word : Danger
Hazard statements : H304 May be fatal if swallowed and enters airways.
H317 May cause an allergic skin reaction.
H334 May cause allergy or asthma symptoms or breathing

SAFETY DATA SHEET



Cephalonium Formulation

Version
8.2

Revision Date:
2025/04/14

SDS Number:
26961-00028

Date of last issue: 2024/09/28
Date of first issue: 2014/10/31

difficulties if inhaled.
H412 Harmful to aquatic life with long lasting effects.

Precautionary statements

: **Prevention:**

P261 Avoid breathing mist or vapours.
P272 Contaminated work clothing should not be allowed out of the workplace.
P273 Avoid release to the environment.
P280 Wear protective gloves.
P284 Wear respiratory protection.

Response:

P301 + P310 IF SWALLOWED: Immediately call a POISON CENTER/ doctor.
P302 + P352 IF ON SKIN: Wash with plenty of water.
P304 + P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P331 Do NOT induce vomiting.
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.

Storage:

P405 Store locked up.

Disposal:

P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards which do not result in classification

None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Paraffin oil	8012-95-1	>= 60 -<= 100
Cefalonium	5575-21-3	>= 2.5 -< 10
Hydroxyaluminum distearate	300-92-5	< 10

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.

SAFETY DATA SHEET



Cephalonium Formulation

Version
8.2

Revision Date:
2025/04/14

SDS Number:
26961-00028

Date of last issue: 2024/09/28
Date of first issue: 2014/10/31

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. If vomiting occurs have person lean forward. Call a physician or poison control centre immediately. Never give anything by mouth to an unconscious person.
Most important symptoms and effects, both acute and delayed	: Excessive exposure may aggravate preexisting asthma and other respiratory disorders (e.g. emphysema, bronchitis, reactive airways dysfunction syndrome). May be fatal if swallowed and enters airways. May cause an allergic skin reaction. May cause allergy or asthma symptoms or breathing difficulties if inhaled.
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.

5. FIREFIGHTING MEASURES

Suitable extinguishing media	: Water spray Alcohol-resistant foam Carbon dioxide (CO ₂) 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 (NO _x) Sulphur 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.

SAFETY DATA SHEET



Cephalonium Formulation

Version
8.2

Revision Date:
2025/04/14

SDS Number:
26961-00028

Date of last issue: 2024/09/28
Date of first issue: 2014/10/31

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

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 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.

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. Do not breathe mist or vapours. 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 sensitised individuals, and those susceptible to asthma, allergies, chronic or recurrent respiratory disease, should consult their physician regarding working with respiratory irritants or sensitisers. Take care to prevent spills, waste and minimize release to the environment.

Conditions for safe storage : Keep in properly labelled containers.

SAFETY DATA SHEET



Cephalonium Formulation

Version 8.2	Revision Date: 2025/04/14	SDS Number: 26961-00028	Date of last issue: 2024/09/28 Date of first issue: 2014/10/31
----------------	------------------------------	----------------------------	---

Materials to avoid	Store locked up. Keep tightly closed. Store in accordance with the particular national regulations. : No special restrictions on storage with other products.
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8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis
Paraffin oil	8012-95-1	NAB (Mist)	5 mg/m3	ID OEL
		PSD (Mist)	10 mg/m3	ID OEL
		TWA (Inhal- able particu- late matter)	5 mg/m3	ACGIH
Cefalonium	5575-21-3	TWA	2000 µg/m3 (OEB 1)	Internal
Further information: RSEN				
Hydroxyaluminum distearate	300-92-5	NAB	10 mg/m3	ID OEL
		Further information: Not classified as carcinogenic to humans. Not enough data to classify these materials as carcinogenic to humans or animals		
		NAB (Res- pirable par- ticulate mat- ter)	1 mg/m3 (Aluminium)	ID OEL
		Further information: Not classified as carcinogenic to humans. Not enough data to classify these materials as carcinogenic to humans or animals		
		TWA (Inhal- able particu- late matter)	10 mg/m3	ACGIH
		TWA (Res- pirable par- ticulate mat- ter)	3 mg/m3	ACGIH
		TWA (Res- pirable par- ticulate mat- ter)	1 mg/m3 (Aluminium)	ACGIH

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 vapour type

SAFETY DATA SHEET



Cephalonium Formulation

Version 8.2	Revision Date: 2025/04/14	SDS Number: 26961-00028	Date of last issue: 2024/09/28 Date of first issue: 2014/10/31
----------------	------------------------------	----------------------------	---

Hand protection

Material	:	Chemical-resistant gloves
Remarks	:	Choose gloves to protect hands against chemicals depending on the concentration and quantity of the hazardous substance and 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).
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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	suspension
Colour	:	off-white
Odour	:	odourless
Odour 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	:	No data available

SAFETY DATA SHEET



Cephalonium Formulation

Version
8.2

Revision Date:
2025/04/14

SDS Number:
26961-00028

Date of last issue: 2024/09/28
Date of first issue: 2014/10/31

flammability limit

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 : No data available

Solubility(ies)

Water solubility : No data available

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

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.

Molecular weight : No data available

Particle characteristics

Particle size : No data available

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.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure : Inhalation
Skin contact
Ingestion

SAFETY DATA SHEET



Cephalonium Formulation

Version
8.2

Revision Date:
2025/04/14

SDS Number:
26961-00028

Date of last issue: 2024/09/28
Date of first issue: 2014/10/31

Eye contact

Acute toxicity

Not classified based on available information.

Components:

Paraffin oil:

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

Hydroxyaluminum distearate:

Acute oral toxicity : LD50 (Rat, female): > 2,000 mg/kg
Method: OECD Test Guideline 423
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

Skin corrosion/irritation

Not classified based on available information.

Components:

Paraffin oil:

Species : Rabbit
Result : No skin irritation

Hydroxyaluminum distearate:

Species : reconstructed human epidermis (RhE)
Method : OECD Test Guideline 431
Remarks : Based on data from similar materials
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.

Cephalonium Formulation

Version 8.2	Revision Date: 2025/04/14	SDS Number: 26961-00028	Date of last issue: 2024/09/28 Date of first issue: 2014/10/31
----------------	------------------------------	----------------------------	---

Components:**Paraffin oil:**

Species	:	Rabbit
Result	:	No eye irritation

Hydroxyaluminum distearate:

Species	:	Bovine cornea
Method	:	OECD Test Guideline 437
Remarks	:	Based on data from similar materials
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:**Cefalonium:**

Exposure routes	:	Skin contact
Assessment	:	Probability or evidence of skin sensitisation in humans
Exposure routes	:	Inhalation
Assessment	:	May cause sensitisation by inhalation.

Hydroxyaluminum distearate:

Test Type	:	Local lymph node assay (LLNA)
Exposure routes	:	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:**Cefalonium:**

Genotoxicity in vitro	:	Test Type: Bacterial reverse mutation assay (AMES) Result: negative
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Test Type: In vitro mammalian cell gene mutation test
Result: negative

Test Type: Chromosome aberration test in vitro

Cephalonium Formulation

Version 8.2	Revision Date: 2025/04/14	SDS Number: 26961-00028	Date of last issue: 2024/09/28 Date of first issue: 2014/10/31
----------------	------------------------------	----------------------------	---

Result: positive

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

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

Hydroxyaluminum distearate:

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

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

Carcinogenicity

Not classified based on available information.

Reproductive toxicity

Not classified based on available information.

Components:**Cefalonium:**

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

Hydroxyaluminum distearate:

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 foetal development : Test Type: Two-generation reproduction toxicity study
Species: Rat
Application Route: Ingestion
Method: OECD Test Guideline 416

SAFETY DATA SHEET



Cephalonium Formulation

Version
8.2

Revision Date:
2025/04/14

SDS Number:
26961-00028

Date of last issue: 2024/09/28
Date of first issue: 2014/10/31

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:

Paraffin oil:

Species : Rat, female
LOAEL : 161 mg/kg
Application Route : Ingestion
Exposure time : 90 Days

Aspiration toxicity

May be fatal if swallowed and enters airways.

Components:

Paraffin oil:

The substance or mixture is known to cause human aspiration toxicity hazards or has to be regarded as if it causes a human aspiration toxicity hazard.

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Paraffin oil:

Toxicity to fish : LL50 (Scophthalmus maximus (turbot)): > 100 mg/l
Exposure time: 96 h
Test substance: Water Accommodated Fraction
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates : EL50 (Acartia tonsa (Calanoid copepod)): > 100 mg/l
Exposure time: 48 h
Test substance: Water Accommodated Fraction
Remarks: Based on data from similar materials

Toxicity to algae/aquatic plants : EL50 (Skeletonema costatum (marine diatom)): > 100 mg/l
Exposure time: 72 h
Test substance: Water Accommodated Fraction
Remarks: Based on data from similar materials

NOELR (Skeletonema costatum (marine diatom)): > 1 mg/l

Cephalonium Formulation

Version 8.2	Revision Date: 2025/04/14	SDS Number: 26961-00028	Date of last issue: 2024/09/28 Date of first issue: 2014/10/31
----------------	------------------------------	----------------------------	---

Exposure time: 72 h
Test substance: Water Accommodated Fraction
Remarks: Based on data from similar materials

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

Hydroxyaluminum distearate:**Ecotoxicology Assessment**

Chronic aquatic toxicity : No toxicity at the limit of solubility

Persistence and degradability**Components:****Cefalonium:**

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

Hydroxyaluminum distearate:

Biodegradability : Result: Readily biodegradable.

SAFETY DATA SHEET



Cephalonium Formulation

Version 8.2	Revision Date: 2025/04/14	SDS Number: 26961-00028	Date of last issue: 2024/09/28 Date of first issue: 2014/10/31
----------------	------------------------------	----------------------------	---

Remarks: Based on data from similar materials

Bioaccumulative potential

Components:

Paraffin oil:

Partition coefficient: n-octanol/water : log Pow: > 4
Remarks: Calculation

Cefalonium:

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

Hydroxyaluminum distearate:

Partition coefficient: n-octanol/water : log Pow: 15.088
Remarks: Calculation

Mobility in soil

No data available

Other adverse effects

No data available

13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : Do not dispose of waste into sewer.
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.

14. TRANSPORT INFORMATION

International Regulations

UNRTDG

UN number : Not applicable
Proper shipping name : Not applicable
Class : Not applicable
Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable
Environmentally hazardous : no

IATA-DGR

UN/ID No. : Not applicable
Proper shipping name : Not applicable
Class : Not applicable
Subsidiary risk : Not applicable

SAFETY DATA SHEET



Cephalonium Formulation

Version 8.2 Revision Date: 2025/04/14 SDS Number: 26961-00028 Date of last issue: 2024/09/28
Date of first issue: 2014/10/31

Packing group : Not applicable
Labels : Not applicable
Packing instruction (cargo aircraft) : Not applicable
Packing instruction (passenger aircraft) : Not applicable

IMDG-Code

UN number : Not applicable
Proper shipping name : Not applicable
Class : Not applicable
Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable
EmS Code : Not applicable
Marine pollutant : Not applicable

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

Special precautions for user

Not applicable

15. REGULATORY INFORMATION

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

Minister of Industry Regulation No. 23/M-IND/PER/4/2013 concerning the Revision of Minister of Industry Regulation No. 87/M-IND/PER/9/2009 concerning Globally Harmonized System of Classification and Labelling of Chemicals.

Regulation of the Minister of Health No. 472 of 1996 on the Safeguarding of Substances Hazardous to Health

Hazardous substances that must be registered : Not applicable

Government Regulation No. 74 of 2001 on the Management of Hazardous and Toxic Substances

Hazardous substances approved for use : Not applicable
Prohibited substances : Not applicable
Restricted substances : Not applicable

Regulation of the Ministry of Trade No. 7 of 2022 on Distribution and Control of Hazardous Materials

Type of hazardous materials subject to distribution and control, Annex I : Not applicable

Type of hazardous materials subject to distribution and control, Annex II : Not applicable

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

AICS : not determined

SAFETY DATA SHEET



Cephalonium Formulation

Version 8.2 Revision Date: 2025/04/14 SDS Number: 26961-00028 Date of last issue: 2024/09/28 Date of first issue: 2014/10/31

DSL : not determined

IECSC : not determined

16. OTHER INFORMATION

Revision Date : 2025/04/14

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/>

Date format : yyyy/mm/dd

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

ID OEL : Indonesia. Occupational Exposure Limits

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

ID OEL / NAB : Long term exposure limit

ID OEL / PSD : Short term exposure limit

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 Recom-

SAFETY DATA SHEET



Cephalonium Formulation

Version
8.2

Revision Date:
2025/04/14

SDS Number:
26961-00028

Date of last issue: 2024/09/28
Date of first issue: 2014/10/31

mendations 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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