

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Cephalonium Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/28/2024
8.0	04/14/2025	26950-00029	Date of first issue: 10/31/2014

### SECTION 1. IDENTIFICATION

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

#### Manufacturer or supplier's details

Company name of supplier : Merck & Co., Inc  
Address : 37 McCarville Street  
Charlottetown, PE C1E 2A7  
Telephone : 908-740-4000  
Emergency telephone : 1-908-423-6000  
E-mail address : EHSDATASTEWARD@merck.com

#### Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product  
Restrictions on use : Not applicable

### SECTION 2. HAZARDS IDENTIFICATION

#### GHS classification in accordance with the Hazardous Products Regulations

Respiratory sensitization : Category 1  
Skin sensitization : Category 1  
Aspiration hazard : Category 1

#### 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 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:

P301 + P310 IF SWALLOWED: Immediately call a POISON CENTER.

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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 attention.  
P342 + P311 If experiencing respiratory symptoms: Call a doctor.  
P362 + P364 Take off contaminated clothing and wash it before reuse.

### Storage:

P405 Store locked up.

### Disposal:

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

### Other hazards

None known.

## SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

### Components

Chemical name	Common Name/Synonym	CAS-No.	Concentration (% w/w)
Paraffin oil	No data available	8012-95-1	$\geq 80 - < 100$ *
Cefalonium	Pyridinium, 4-carbamoyl-1-((2-carboxy-8-oxo-7-(2-(2-thienyl)acetamido)-5-thia-1-azabicyclo(4.2.0)oct-2-en-3-yl)methyl)-hydroxide,	5575-21-3	$\geq 5 - < 10$ *
Hydroxyaluminum distearate	Aluminum, hydroxybis(octadecanoato- $\kappa$ O)-	300-92-5	$\geq 1 - < 5$ *

\* Actual concentration or concentration range is withheld as a trade secret

## 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.

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		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 center 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.

### 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.

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### 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.  
Do not breathe 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, and those susceptible to asthma, allergies, chronic or recurrent respiratory disease, should consult their physician regarding working with respiratory irritants or sensitizers.  
Take care to prevent spills, waste and minimize release to the environment.
- Conditions for safe storage : Keep in properly labeled containers.  
Store locked up.  
Keep tightly closed.

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Materials to avoid : Store in accordance with the particular national regulations.  
: No special restrictions on storage with other products.

### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Paraffin oil	8012-95-1	TWA (Mist)	5 mg/m <sup>3</sup>	CA AB OEL
		STEL (Mist)	10 mg/m <sup>3</sup>	CA AB OEL
		TWAEV (Mist - Inhalable dust)	5 mg/m <sup>3</sup>	CA QC OEL
		TWA (Mist)	1 mg/m <sup>3</sup>	CA BC OEL
		TWA (Inhalable particulate matter)	5 mg/m <sup>3</sup>	ACGIH
Cefalonium	5575-21-3	TWA	2000 µg/m <sup>3</sup> (OEB 1)	Internal
Further information: RSEN				
Hydroxyaluminum distearate	300-92-5	TWA	10 mg/m <sup>3</sup>	CA AB OEL
		TWA (Respirable)	1 mg/m <sup>3</sup> (Aluminum)	CA BC OEL
		TWA (Inhalable)	10 mg/m <sup>3</sup>	CA BC OEL
		TWA (Respirable)	3 mg/m <sup>3</sup>	CA BC OEL
		TWAEV (respirable aerosol fraction)	5 mg/m <sup>3</sup>	CA QC OEL
		TWAEV (inhalable dust)	10 mg/m <sup>3</sup>	CA QC OEL
		TWAEV (respirable aerosol fraction)	3 mg/m <sup>3</sup>	CA QC OEL
		TWA (Inhalable particulate matter)	10 mg/m <sup>3</sup>	ACGIH
		TWA (Respirable particulate matter)	3 mg/m <sup>3</sup>	ACGIH
		TWA (Respirable particulate matter)	1 mg/m <sup>3</sup> (Aluminum)	ACGIH

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**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

Material : 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).

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.

## 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

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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 characteristics		
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.

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### 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:

##### 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
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##### 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



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||Result : No skin irritation

### Serious eye damage/eye irritation

Not classified based on available information.

### 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 sensitization

#### Skin sensitization

May cause an allergic skin reaction.

#### Respiratory sensitization

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

### Components:

#### 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.

#### Hydroxyaluminum distearate:

||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:

#### Cefalonium:

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

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Genotoxicity in vivo	:	Test Type: In vitro mammalian cell gene mutation test Result: negative
	:	Test Type: Chromosome aberration test in vitro Result: positive
	:	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 fetal development	:	Test Type: Embryo-fetal development Species: Rat Application Route: Ingestion Result: negative
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#### 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
	:	Test Type: Two-generation reproduction toxicity study

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Species: Rat  
Application Route: Ingestion  
Method: OECD Test Guideline 416  
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.

## SECTION 12. ECOLOGICAL INFORMATION

### Ecotoxicity

#### Components:

##### Paraffin oil:

Toxicity to fish	: LL50 ( <i>Scophthalmus maximus</i> (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 ( <i>Acartia tonsa</i> (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 ( <i>Skeletonema costatum</i> (marine diatom)): > 100 mg/l Exposure time: 72 h Test substance: Water Accommodated Fraction Remarks: Based on data from similar materials

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

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

### Hydroxylaluminum 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

### Hydroxylaluminum distearate:

Biodegradability : Result: Readily biodegradable.  
Remarks: Based on data from similar materials

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### 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
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##### 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

## SECTION 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.

## 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

#### TDG

Not regulated as a dangerous good

### Special precautions for user

Not applicable

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### SECTION 15. REGULATORY INFORMATION

**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)
CA AB OEL	: Canada. Alberta, Occupational Health and Safety Code (table 2: OEL)
CA BC OEL	: Canada. British Columbia OEL
CA QC OEL	: Québec. Regulation respecting occupational health and safety, Schedule 1, Part 1: Permissible exposure values for air-borne contaminants
ACGIH / TWA	: 8-hour, time-weighted average
CA AB OEL / TWA	: 8-hour Occupational exposure limit
CA AB OEL / STEL	: 15-minute occupational exposure limit
CA BC OEL / TWA	: 8-hour time weighted average
CA QC OEL / TWAEV	: Time-weighted average exposure value

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 Tempera-

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ture; 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

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

Revision Date : 04/14/2025  
Date format : mm/dd/yyyy

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

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.

CA / Z8