

# SAFETY DATA SHEET



## Cephalonium Formulation

Version  
8.2

Revision Date:  
14.04.2025

SDS Number:  
26940-00027

Date of last issue: 28.09.2024  
Date of first issue: 31.10.2014

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### SECTION 1. 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 : Talcahuano 750, 6th floor, Ciudad Autonoma  
Buenos Aires, Argentina C1013AAP  
Telephone : 908-740-4000  
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  
Restrictions on use : Not applicable

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### SECTION 2. HAZARDS IDENTIFICATION

#### GHS Classification

Respiratory sensitization : Category 1  
Skin sensitization : Category 1  
Aspiration hazard : Category 1  
Short-term (acute) aquatic hazard : Category 2  
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.

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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:

P261 Avoid breathing mist or vapors.  
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.

## SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

### Components

Chemical name	CAS-No.	Concentration (% w/w)
Paraffin oil	8012-95-1	>= 90 -< 100
Cefalonium	5575-21-3	>= 5 -< 10
Hydroxyaluminum distearate	300-92-5	>= 1 -< 5

## 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

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	advice.
If inhaled	<ul style="list-style-type: none"><li>: If inhaled, remove to fresh air.</li><li>  If not breathing, give artificial respiration.</li><li>  If breathing is difficult, give oxygen.</li><li>  Get medical attention.</li></ul>
In case of skin contact	<ul style="list-style-type: none"><li>: In case of contact, immediately flush skin with soap and plenty of water.</li><li>  Remove contaminated clothing and shoes.</li><li>  Get medical attention.</li><li>  Wash clothing before reuse.</li></ul>
In case of eye contact	<ul style="list-style-type: none"><li>: Flush eyes with water as a precaution.</li><li>  Get medical attention if irritation develops and persists.</li></ul>
If swallowed	<ul style="list-style-type: none"><li>: If swallowed, DO NOT induce vomiting.</li><li>  If vomiting occurs have person lean forward.</li><li>  Call a physician or poison control center immediately.</li><li>  Never give anything by mouth to an unconscious person.</li></ul>
Most important symptoms and effects, both acute and delayed	<ul style="list-style-type: none"><li>: Excessive exposure may aggravate preexisting asthma and other respiratory disorders (e.g. emphysema, bronchitis, reactive airways dysfunction syndrome).</li><li>  May be fatal if swallowed and enters airways.</li><li>  May cause an allergic skin reaction.</li><li>  May cause allergy or asthma symptoms or breathing difficulties if inhaled.</li></ul>
Protection of first-aiders	<ul style="list-style-type: none"><li>: 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).</li></ul>
Notes to physician	<ul style="list-style-type: none"><li>: Treat symptomatically and supportively.</li></ul>

**SECTION 5. FIRE-FIGHTING MEASURES**

Suitable extinguishing media	<ul style="list-style-type: none"><li>: Water spray</li><li>  Alcohol-resistant foam</li><li>  Carbon dioxide (CO<sub>2</sub>)</li><li>  Dry chemical</li></ul>
Unsuitable extinguishing media	<ul style="list-style-type: none"><li>: None known.</li></ul>
Specific hazards during fire fighting	<ul style="list-style-type: none"><li>: Exposure to combustion products may be a hazard to health.</li></ul>
Hazardous combustion products	<ul style="list-style-type: none"><li>: Carbon oxides</li><li>  Nitrogen oxides (NO<sub>x</sub>)</li><li>  Sulfur oxides</li><li>  Metal oxides</li></ul>
Specific extinguishing methods	<ul style="list-style-type: none"><li>: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.</li><li>  Use water spray to cool unopened containers.</li><li>  Remove undamaged containers from fire area if it is safe to do so.</li><li>  Evacuate area.</li></ul>
Special protective equipment	<ul style="list-style-type: none"><li>: In the event of fire, wear self-contained breathing apparatus.</li></ul>

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for fire-fighters

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. 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 parame- ters / Permissible concentration	Basis
Paraffin oil	8012-95-1	CMP (Mist)	5 mg/m <sup>3</sup>	AR OEL
		CMP - CPT (Mist)	10 mg/m <sup>3</sup>	AR 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	CMP	10 mg/m <sup>3</sup>	AR OEL
Further information: A4 - Not classifiable as a human carcinogen				
		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

**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

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Eye protection	breaks and at the end of workday. : 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
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

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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

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## 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
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### 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:

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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.

**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.

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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
		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 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
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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

**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 fetal development : 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

**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.

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**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.

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**SECTION 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  
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 tox- : 1

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icity)

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

**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

**Hydroxylaluminum distearate:**

Partition coefficient: n-octanol/water : log Pow: 15,088  
Remarks: Calculation

**Mobility in soil**

No data available

**Other adverse effects**

No data available

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### 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.

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### 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.

#### Special precautions for user

Not applicable

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### SECTION 15. REGULATORY INFORMATION

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

Argentina. Carcinogenic Substances and Agents Registry. : Not applicable

Control of precursors and essential chemicals for the preparation of drugs. : Not applicable

#### The ingredients of this product are reported in the following inventories:

AICS : not determined

DSL : not determined

IECSC : not determined

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### SECTION 16. OTHER INFORMATION

Revision Date : 14.04.2025  
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#### Further information

Sources of key data used to : Internal technical data, data from raw material SDSs, OECD

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compile the Material Safety  
Data Sheet

eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

### Full text of other abbreviations

ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)
AR OEL	:	Argentina. Occupational Exposure Limits
ACGIH / TWA	:	8-hour, time-weighted average
AR OEL / CMP	:	TLV (Threshold Limit Value)
AR OEL / CMP - CPT	:	STEL (Short Term Limit 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; 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; 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

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AR / Z8