

## Cephalonium Formulation

Version 11.0      Revision Date: 16.05.2024      SDS Number: 26974-00026      Date of last issue: 06.04.2024  
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 : 33 Whakatiki Street - Private Bag 908  
Upper Hutt - New Zealand  
Telephone : 0800 800 543  
Emergency telephone number : 0800 764 766 (0800 POISON)    0800 243 622 (0800  
CHEMCALL)  
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: Hazard identification

#### GHS Classification

Respiratory sensitisation : Category 1  
Skin sensitisation : Category 1  
Aspiration hazard : Category 1  
Hazardous to the aquatic  
environment - chronic 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.

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Precautionary statements	<p>H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.          H412 Harmful to aquatic life with long lasting effects.</p> <p><b>Prevention:</b>          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.</p> <p><b>Response:</b>          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.</p> <p><b>Storage:</b>          P405 Store locked up.</p> <p><b>Disposal:</b>          P501 Dispose of contents/ container to an approved waste disposal plant.</p>
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**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	>= 2.5 -< 10
Hydroxyaluminum distearate	300-92-5	>= 1 -< 10

**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 : 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.

**Section 5: Fire-fighting measures**

- Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
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<sub>x</sub>)  
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.
- Special protective equipment for firefighters : 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 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.

### Section 7: Handling and storage

- Technical measures : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
- Local/Total ventilation : Use only with adequate ventilation.
- Advice on safe handling : Do not get on skin or clothing. Avoid breathing mist or 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.
- 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.

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Contaminated work clothing should not be allowed out of the workplace.  
 Wash contaminated clothing before re-use.

Conditions for safe storage : Keep in properly labelled containers.  
 Store locked up.  
 Keep tightly closed.  
 Store in accordance with the particular national regulations.

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

## Section 8: Exposure controls/personal protection

## Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Paraffin oil	8012-95-1	WES-TWA (Mist)	5 mg/m <sup>3</sup>	NZ OEL
		WES-STEL (Mist)	10 mg/m <sup>3</sup>	NZ 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	WES-TWA	10 mg/m <sup>3</sup>	NZ OEL
		WES-TWA (Respirable dust)	1 mg/m <sup>3</sup> (Aluminium)	NZ 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> (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  
 Hand protection

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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).

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**Section 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 flammability limit : No data available

Lower explosion limit / Lower flammability limit : No data available

Vapour pressure : No data available

Relative vapour density : No data available

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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

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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

Exposure routes : Inhalation  
Skin contact  
Ingestion  
Eye contact

#### Acute toxicity

|| Not classified based on available information.

#### Components:

**Paraffin oil:**

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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.

**Components:****Paraffin oil:**

Species : Rabbit  
Result : No eye irritation



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**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

**Chronic toxicity****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)

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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  
 Result: negative  
 Remarks: Based on data from similar materials

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**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 (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

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**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

**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**

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
Packing group	:	Not applicable
Labels	:	Not applicable

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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.

**National Regulations****NZS 5433**

UN number : Not applicable  
Proper shipping name : Not applicable  
Class : Not applicable  
Subsidiary risk : Not applicable  
Packing group : Not applicable  
Labels : Not applicable  
Hazchem Code : Not applicable

**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****HSNO Approval Number**

HSR100759 Veterinary Medicines Non dispersive Open System Application Group Standard

Tolerable Exposure Limits (TEL)

Not applicable

Environmental Exposure Limits (EEL)

Not applicable

**HSW Controls**

Certified handler certificate not required.

Tracking hazardous substance not required.

Refer to the Health and Safety at Work (Hazardous Substances) Regulations 2017, for further information.

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

AICS : not determined

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DSL : not determined

IECSC : not determined

**Section 16: Other information**

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**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/>

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

Date format : dd.mm.yyyy

**Full text of other abbreviations**ACGIH : USA. ACGIH Threshold Limit Values (TLV)  
NZ OEL : New Zealand. Workplace Exposure Standards for Atmospheric ContaminantsACGIH / TWA : 8-hour, time-weighted average  
NZ OEL / WES-TWA : Workplace Exposure Standard - Time Weighted average  
NZ OEL / WES-STEL : Workplace Exposure Standard - 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; 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,

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tion, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

NZ / EN