

# **Amoxicillin Trihydrate Liquid Formulation**

Version Revision Date: SDS Number: Date of last issue: 06.07.2024 6.1 28.09.2024 1198864-00019 Date of first issue: 05.01.2017

**Section 1: Identification** 

Product name : Amoxicillin Trihydrate Liquid Formulation

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

Section 2: Hazard identification

**GHS Classification** 

Respiratory sensitisation : Category 1

Hazardous to the aquatic environment - acute hazard

Category 1

Hazardous to the aquatic environment - chronic hazard

Category 2

**GHS** label elements

Hazard pictograms



Signal word : Danger

Hazard statements : H334 May cause allergy or asthma symptoms or breathing

difficulties if inhaled.

H400 Very toxic to aquatic life.

H411 Toxic to aquatic life with long lasting effects.

Precautionary statements : Prevention:



# **Amoxicillin Trihydrate Liquid Formulation**

Version Revision Date: SDS Number: Date of last issue: 06.07.2024 6.1 28.09.2024 1198864-00019 Date of first issue: 05.01.2017

P261 Avoid breathing mist or vapours. P273 Avoid release to the environment. P284 Wear respiratory protection.

#### Response:

P304 + P340 IF INHALED: Remove person to fresh air and

keep comfortable for breathing.

P342 + P311 If experiencing respiratory symptoms: Call a

POISON CENTER/ doctor. P391 Collect spillage.

### 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)
Amoxicillin Trihydrate	61336-70-7	>= 10 -< 20
Fatty acids, C14-26, aluminum salts	97404-28-9	>= 1 -< 10

#### Section 4: First-aid measures

General advice : In the case of accident or if you feel unwell, seek medical ad-

vice immediately.

When symptoms persist or in all cases of doubt seek medical

advice.

If inhaled : If inhaled, remove to fresh air.

If not breathing, give artificial respiration. If breathing is difficult, give oxygen.

Get medical attention.

In case of skin contact : Wash with water and soap as a precaution.

Get medical attention if symptoms occur.

In case of eye contact : Flush eyes with water as a precaution.

Get medical attention if irritation develops and persists.

If swallowed : If swallowed, DO NOT induce vomiting.

Get medical attention if symptoms occur. Rinse mouth thoroughly with water.

Most important symptoms : May cause allergy or asthma symptoms or breathing difficul-

and effects, both acute and ties if inhaled. Excessive exp

Excessive exposure may aggravate preexisting asthma and

other respiratory disorders (e.g. emphysema, bronchitis, reac-

tive airways dysfunction syndrome).

Protection of first-aiders : First Aid responders should pay attention to self-protection,

and use the recommended personal protective equipment



# **Amoxicillin Trihydrate Liquid Formulation**

Version Revision Date: SDS Number: Date of last issue: 06.07.2024 6.1 28.09.2024 1198864-00019 Date of first issue: 05.01.2017

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 prod: :

ucts

Carbon oxides

Metal oxides

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances 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.

Hazchem Code : 3Z

Section 6: Accidental release measures

Personal precautions, protec: :

tive equipment and emer-

gency procedures

Use personal protective equipment.

Follow safe handling advice (see section 7) and personal pro-

tective 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 absor-

bent.



# **Amoxicillin Trihydrate Liquid Formulation**

Version Revision Date: SDS Number: Date of last issue: 06.07.2024 6.1 28.09.2024 1198864-00019 Date of first issue: 05.01.2017

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 the control of th

mine 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 breathe mist or vapours.

Do not swallow.

Avoid contact with eyes.

Avoid prolonged or repeated contact with skin.

Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure as-

sessment

Keep container tightly closed.

Already sensitised individuals, and those susceptible to asthma, allergies, chronic or recurrent respiratory diseases.

to asthma, allergies, chronic or recurrent respiratory disease, should consult their physician regarding working with respira-

tory 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. Wash contaminated clothing before re-use.

The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the

use of administrative controls.

Conditions for safe storage : Keep in properly labelled containers.

Keep tightly closed.

Store in accordance with the particular national regulations.

Materials to avoid : Do not store with the following product types:

Strong oxidizing agents

#### Section 8: Exposure controls/personal protection

#### Components with workplace control parameters

Components	CAS-No.	Value type	Control parame-	Basis		
		(Form of	ters / Permissible			
		exposure)	concentration			
Amoxicillin Trihydrate	61336-70-7	TWA	1 mg/m3 (OEB 1)	Internal		
	Further information: RSEN					



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Version Revision Date: SDS Number: Date of last issue: 06.07.2024 6.1 28.09.2024 1198864-00019 Date of first issue: 05.01.2017

Fatty acids, C14-26, aluminum salts	97404-28-9	TWA (Res- pirable par-	1 mg/m3 (Aluminium)	ACGIH
Saits		I	(Alaminam)	
		ticulate mat-		
		ter)		

**Engineering measures** : Use appropriate engineering controls and manufacturing

technologies to control airborne concentrations (e.g., drip-

less quick connections).

All engineering controls should be implemented by facility design and operated in accordance with GMP principles to

protect products, workers, and the environment.

Laboratory operations do not require special containment.

Personal protective equipment

Respiratory protection : If adequate local exhaust ventilation is not available or expo-

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection.

Filter type

Hand protection Material

: Chemical-resistant gloves

Particulates type

Eye protection : Wear safety glasses with side shields or goggles.

If the work environment or activity involves dusty conditions,

mists or aerosols, wear the appropriate goggles.

Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or

aerosols.

Skin and body protection : Work uniform or laboratory coat.

#### Section 9: Physical and chemical properties

Appearance : suspension

Colour : white

Odour : strong

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) : Not applicable



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Version Revision Date: SDS Number: Date of last issue: 06.07.2024 6.1 28.09.2024 1198864-00019 Date of first issue: 05.01.2017

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

Relative density : No data available

Density : 0.99 - 1.10 g/l

Solubility(ies)

Water solubility : No data available

Partition coefficient: n-

octanol/water

: Not applicable

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 : Not applicable

Section 10: Stability and reactivity

Reactivity : Not classified as a reactivity hazard. Chemical stability : Stable under normal conditions.

Possibility of hazardous reac-

tions

Conditions to avoid : None known.
Incompatible materials : Oxidizing agents

Hazardous decomposition

products

No hazardous decomposition products are known.

Can react with strong oxidizing agents.

## **Section 11: Toxicological information**

Exposure routes : Inhalation



# **Amoxicillin Trihydrate Liquid Formulation**

Version Revision Date: SDS Number: Date of last issue: 06.07.2024 6.1 28.09.2024 1198864-00019 Date of first issue: 05.01.2017

Skin contact Ingestion Eye contact

**Acute toxicity** 

Not classified based on available information.

**Components:** 

**Amoxicillin Trihydrate:** 

Acute oral toxicity : LD50 (Rat): > 8,000 mg/kg

LD50 (Mouse): > 10,000 mg/kg

LD50 (Dog): > 3,000 mg/kg

Fatty acids, C14-26, aluminum salts:

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

Remarks: Based on data from similar materials

Skin corrosion/irritation

Not classified based on available information.

**Components:** 

Fatty acids, C14-26, aluminum salts:

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:** 

Fatty acids, C14-26, aluminum salts:

Species : Rabbit

Result : No eye irritation

Method : OECD Test Guideline 405



# **Amoxicillin Trihydrate Liquid Formulation**

Version Revision Date: SDS Number: Date of last issue: 06.07.2024 6.1 28.09.2024 1198864-00019 Date of first issue: 05.01.2017

Remarks : Based on data from similar materials

#### Respiratory or skin sensitisation

#### Skin sensitisation

Not classified based on available information.

#### Respiratory sensitisation

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

### **Components:**

#### **Amoxicillin Trihydrate:**

Result : Sensitiser

Remarks : May cause sensitisation by inhalation.

largely based on human evidence

#### Fatty acids, C14-26, aluminum salts:

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:**

## **Amoxicillin Trihydrate:**

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

Result: negative

Genotoxicity in vivo : Test Type: Micronucleus test

Species: Mouse Result: negative

Test Type: Rodent dominant lethal test (germ cell) (in vivo)

Species: Mouse Result: negative

#### Fatty acids, C14-26, aluminum salts:

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



# **Amoxicillin Trihydrate Liquid Formulation**

Version Revision Date: SDS Number: Date of last issue: 06.07.2024 6.1 28.09.2024 1198864-00019 Date of first issue: 05.01.2017

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:**

## **Amoxicillin Trihydrate:**

Effects on fertility : Test Type: Fertility

Species: Rat

Application Route: Oral

Fertility: NOAEL: 200 mg/kg body weight

Result: Reduced fertility

Remarks: Not classified due to inconclusive data.

Test Type: Fertility Species: Rat

Application Route: Oral

Fertility: LOAEL: 500 mg/kg body weight

Result: Reduced fertility

Remarks: Not classified due to inconclusive data.

Effects on foetal develop-

ment

Test Type: Development

Species: Rat

Application Route: Oral

Developmental Toxicity: NOAEL: >= 1,000 mg/kg body weight

Result: No embryo-foetal toxicity

Test Type: Development

Species: Mouse Application Route: Oral

Developmental Toxicity: LOAEL: 200 mg/kg body weight Result: Some evidence of adverse effects on development,

based on animal experiments.

Remarks: Not classified due to inconclusive data.

Test Type: Development

Species: Rat

Application Route: Oral

Developmental Toxicity: LOAEL: 200 mg/kg body weight Result: Reduced embryonic survival, Reduced offspring

weight gain

Remarks: Not classified due to inconclusive data.

## Fatty acids, C14-26, aluminum salts:

Effects on fertility : Test Type: Combined repeated dose toxicity study with the

reproduction/developmental toxicity screening test



# **Amoxicillin Trihydrate Liquid Formulation**

Version Revision Date: SDS Number: Date of last issue: 06.07.2024 6.1 28.09.2024 1198864-00019 Date of first issue: 05.01.2017

Species: Rat

Application Route: Ingestion Method: OECD Test Guideline 422

Result: negative

Remarks: Based on data from similar materials

Effects on foetal develop-

ment

Test Type: Reproduction/Developmental toxicity screening

test

Species: Rat

Application Route: Ingestion Method: OECD Test Guideline 414

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.

#### **Components:**

## **Amoxicillin Trihydrate:**

Remarks : Not classified due to inconclusive data.

#### Repeated dose toxicity

#### **Components:**

## **Amoxicillin Trihydrate:**

Species : Rat
Application Route : Oral
Exposure time : 6 Months

Remarks : No significant adverse effects were reported

Species : Dog Application Route : Oral Exposure time : 6 Months

Remarks : No significant adverse effects were reported

## Fatty acids, C14-26, aluminum salts:

Species : Rat

>= 1000 mg/kg

Application Route : Ingestion Exposure time : 42 Days

Remarks : Based on data from similar materials

#### **Aspiration toxicity**

Not classified based on available information.



# **Amoxicillin Trihydrate Liquid Formulation**

Version **Revision Date:** SDS Number: Date of last issue: 06.07.2024 1198864-00019 6.1 28.09.2024 Date of first issue: 05.01.2017

#### **Experience with human exposure**

**Components:** 

**Amoxicillin Trihydrate:** 

Symptoms: Nausea, Vomiting, Abdominal pain, Diarrhoea, Ingestion

> flatulence, skin rash, Breathing difficulties Remarks: May produce an allergic reaction.

**Section 12: Ecological information** 

**Ecotoxicity** 

**Components:** 

**Amoxicillin Trihydrate:** 

Toxicity to fish : LC50 (Carassius auratus (goldfish)): 0.035 mg/l

Exposure time: 96 h

Method: OECD Test Guideline 203

Toxicity to algae/aguatic

plants

NOEC (green algae): 530 mg/l

Exposure time: 72 h

EC50 (Synechococcus leopoliensis (blue-green algae)):

0.0022 mg/l

Exposure time: 96 h

NOEC (blue-green algae): 0.0057 mg/l

Exposure time: 72 h

M-Factor (Acute aquatic tox-

icity)

M-Factor (Chronic aquatic

toxicity)

100

Persistence and degradability

Components:

**Amoxicillin Trihydrate:** Result: Readily biodegradable. Biodegradability

Biodegradation: 88 %

Exposure time: 28 d

Method: OECD Test Guideline 301B

Fatty acids, C14-26, aluminum salts:

Biodegradability Result: Readily biodegradable.

> Biodegradation: 81.2 % Exposure time: 28 d

Method: OECD Test Guideline 301B

Remarks: Based on data from similar materials



# **Amoxicillin Trihydrate Liquid Formulation**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.07.2024

 6.1
 28.09.2024
 1198864-00019
 Date of first issue: 05.01.2017

#### Bioaccumulative potential

#### **Components:**

#### **Amoxicillin Trihydrate:**

Bioaccumulation : Remarks: Bioaccumulation is unlikely.

Partition coefficient: n- : log Pow: -0.124

octanol/water Method: OECD Test Guideline 107

## Fatty acids, C14-26, aluminum salts:

Partition coefficient: n- : log Pow: > 7

octanol/water Remarks: Calculation

# Mobility in soil No data available

#### Other adverse effects

#### **Components:**

#### **Amoxicillin Trihydrate:**

Results of PBT and vPvB

assessment

Substance is not persistent, bioaccumulative, and toxic (PBT). Product does not contain substances which are very persis-

tent and very bioaccumulative (vPvB) at levels of 0.1% or

higher.

#### 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 han-

dling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

#### **Section 14: Transport information**

#### **International Regulations**

#### **UNRTDG**

UN number : UN 3082

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.

(Amoxicillin Trihydrate)

Class : 9
Packing group : III
Labels : 9
Environmentally hazardous : yes



# **Amoxicillin Trihydrate Liquid Formulation**

Version Revision Date: SDS Number: Date of last issue: 06.07.2024 6.1 28.09.2024 1198864-00019 Date of first issue: 05.01.2017

**IATA-DGR** 

UN/ID No. : UN 3082

Proper shipping name : Environmentally hazardous substance, liquid, n.o.s.

(Amoxicillin Trihydrate)

Class : 9 Packing group : III

Labels : Miscellaneous

Packing instruction (cargo

aircraft)

Packing instruction (passen: 964

ger aircraft)

Environmentally hazardous : yes

**IMDG-Code** 

UN number : UN 3082

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.

964

(Amoxicillin Trihydrate)

Class : 9
Packing group : III
Labels : 9
EmS Code : F-A. S-F

Marine pollutant : yes

## 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 : UN 3082

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.

(Amoxicillin Trihydrate)

Class : 9
Packing group : III
Labels : 9
Hazchem Code : 3Z
Marine pollutant : no

#### Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

## **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



# **Amoxicillin Trihydrate Liquid Formulation**

Version Revision Date: SDS Number: Date of last issue: 06.07.2024 6.1 28.09.2024 1198864-00019 Date of first issue: 05.01.2017

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

cy, http://echa.europa.eu/

Internal technical data, data from raw material SDSs, OECD

eChem Portal search results and European Chemicals Agen-

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

AICS : not determined

DSL : not determined

IECSC : not determined

#### **Section 16: Other information**

Revision Date : 28.09.2024

**Further information** 

Sources of key data used to

compile the Safety Data Sheet

Date format : dd.mm.yyyy

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

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

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



# **Amoxicillin Trihydrate Liquid Formulation**

Version Revision Date: SDS Number: Date of last issue: 06.07.2024 6.1 28.09.2024 1198864-00019 Date of first issue: 05.01.2017

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

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