

Chlorhexidine / Glycerine Formulation

Version 4.1 Revision Date: 04.12.2023 SDS Number: 10829208-00006 Date of last issue: 30.09.2023
Date of first issue: 10.08.2022

Section 1: Identification

Product name : Chlorhexidine / Glycerine Formulation
Other means of identification : Hibitane Plus (A3521)

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**

Serious eye damage/eye irritation : Category 2
Specific target organ toxicity - repeated exposure : Category 2 (Liver)
Hazardous to the aquatic environment - chronic hazard : Category 2

GHS label elements

Hazard pictograms :   

Signal word : Warning

Hazard statements : H319 Causes serious eye irritation.
H373 May cause damage to organs (Liver) through prolonged or repeated exposure.
H411 Toxic to aquatic life with long lasting effects.

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Precautionary statements

:

Prevention:

P260 Do not breathe mist or vapours.
 P264 Wash skin thoroughly after handling.
 P273 Avoid release to the environment.
 P280 Wear eye protection/ face protection.

Response:

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
 P314 Get medical advice/ attention if you feel unwell.
 P337 + P313 If eye irritation persists: Get medical advice/ attention.
 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)
Glycerine	56-81-5	>= 50 -< 70
Chlorhexidine	55-56-1	>= 10 -< 20
Nonylphenol, ethoxylated	9016-45-9	>= 0.25 -< 1

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.
 Get medical attention if symptoms occur.

In case of skin contact : In case of contact, immediately flush skin with soap and plenty of water.
 Get medical attention if symptoms occur.

In case of eye contact : In case of contact, immediately flush eyes with plenty of water for at least 15 minutes.
 If easy to do, remove contact lens, if worn.
 Get medical attention.

If swallowed : If swallowed, DO NOT induce vomiting.
 Get medical attention if symptoms occur.

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Most important symptoms and effects, both acute and delayed	:	Rinse mouth thoroughly with water. Causes serious eye irritation. May cause damage to organs through prolonged or repeated exposure.
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 ₂) Dry chemical
Unsuitable extinguishing media	:	None known.
Specific hazards during fire-fighting	:	Exposure to combustion products may be a hazard to health.
Hazardous combustion products	:	Carbon oxides
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.
Hazchem Code	:	3Z

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 dis-

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posal 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 breathe mist or vapours.
Do not swallow.
Do not get in eyes.
Avoid prolonged or repeated contact with skin.
Wash skin thoroughly after handling.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
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.
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 (Form of exposure)	Control parameters / Permissible concentration	Basis
Glycerine	56-81-5	WES-TWA (Mist)	10 mg/m ³	NZ OEL
Chlorhexidine	55-56-1	TWA	40 µg/m ³ (OEB 3)	Internal
Further information: RSEN				
		Wipe limit	400 µg/100 cm ²	Internal

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

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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.

Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices).

Minimize open handling.

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	:	
Material	:	Chemical-resistant gloves
Remarks	:	Consider double gloving.
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. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.

Section 9: Physical and chemical properties

Appearance	:	Aqueous solution
Colour	:	dark blue
Odour	:	No data available
Odour Threshold	:	No data available
pH	:	< 8.5 (20 °C)
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)	:	Not applicable
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	:	1.145 - 1.155 (20 °C)
Density	:	No data available
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 size	:	Not applicable

Section 10: Stability and reactivity

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	Can react with strong oxidizing agents.
Conditions to avoid	:	None known.
Incompatible materials	:	Oxidizing agents
Hazardous decomposition	:	No hazardous decomposition products are known.

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products

Section 11: Toxicological information

Exposure routes : Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity

Not classified based on available information.

Product:

Acute oral toxicity : Acute toxicity estimate: > 2,000 mg/kg
Method: Calculation method

Components:**Glycerine:**

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

Chlorhexidine:

Acute oral toxicity : LD50 Oral (Mouse): 1,260 mg/kg
LD50 Oral (Rabbit): 1,100 mg/kg
LD50 Oral (Rat): 2,000 mg/kg

Acute toxicity (other routes of administration) : LD50 (Rat): 21 mg/kg
Application Route: Intravenous

Nonylphenol, ethoxylated:

Acute oral toxicity : LD50 (Rat): 500 - 2,000 mg/kg

Skin corrosion/irritation

Not classified based on available information.

Components:**Glycerine:**

Species : Rabbit
Result : No skin irritation

Nonylphenol, ethoxylated:

Species : Rabbit
Method : OECD Test Guideline 404
Result : No skin irritation

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Serious eye damage/eye irritation

Causes serious eye irritation.

Components:**Glycerine:**

Species : Rabbit
Result : No eye irritation

Chlorhexidine:

Species : Rabbit
Result : Mild eye irritation

Nonylphenol, ethoxylated:

Species : Rabbit
Result : Irreversible effects on the eye
Method : OECD Test Guideline 405

Respiratory or skin sensitisation**Skin sensitisation**

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Components:**Nonylphenol, ethoxylated:**

Test Type : Maximisation Test
Exposure routes : Skin contact
Species : Guinea pig
Result : negative
Remarks : Based on data from similar materials

Chronic toxicity**Germ cell mutagenicity**

Not classified based on available information.

Components:**Glycerine:**

Genotoxicity in vitro : Test Type: In vitro mammalian cell gene mutation test
Result: negative

Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Test Type: Chromosome aberration test in vitro
Result: negative

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Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)
Result: negative

Chlorhexidine:

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

Test Type: Chromosomal aberration
Test system: Chinese hamster ovary cells
Result: negative

Genotoxicity in vivo : Test Type: dominant lethal test
Species: Mouse
Result: negative

Test Type: Cytogenetic assay
Species: Hamster
Result: negative

Nonylphenol, ethoxylated:

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

Carcinogenicity

Not classified based on available information.

Components:**Glycerine:**

Species : Rat
Application Route : Ingestion
Exposure time : 2 Years
Result : negative

Chlorhexidine:

Species : Rat
Application Route : oral (drinking water)
Exposure time : 2 Years
Frequency of Treatment : daily
NOAEL : 38 mg/kg body weight
Result : negative

Species : Rat
Application Route : oral (drinking water)
Exposure time : 2 Years
Frequency of Treatment : daily
NOAEL : 158 mg/kg body weight

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Result : negative

Reproductive toxicity

Not classified based on available information.

Components:**Glycerine:**

Effects on fertility : Test Type: Two-generation reproduction toxicity study
Species: Rat
Application Route: Ingestion
Result: negative

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

Chlorhexidine:

Effects on fertility : Species: Rat
Fertility: NOAEL: 100 mg/kg body weight

Effects on foetal development : Species: Rat
Developmental Toxicity: NOAEL: 300 mg/kg body weight

Species: Rabbit
Developmental Toxicity: NOAEL: 40 mg/kg body weight

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

May cause damage to organs (Liver) through prolonged or repeated exposure.

Components:**Chlorhexidine:**

Target Organs : Liver
Assessment : May cause damage to organs through prolonged or repeated exposure.

Repeated dose toxicity**Components:****Glycerine:**

Species : Rat
NOAEL : 0.167 mg/l
LOAEL : 0.622 mg/l
Application Route : inhalation (dust/mist/fume)
Exposure time : 13 Weeks

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Species	:	Rat
NOAEL	:	8,000 - 10,000 mg/kg
Application Route	:	Ingestion
Exposure time	:	2 yr

Species	:	Rabbit
NOAEL	:	5,040 mg/kg
Application Route	:	Skin contact
Exposure time	:	45 Weeks

Chlorhexidine:

Species	:	Rat
NOAEL	:	158 mg/kg
Application Route	:	Oral
Exposure time	:	2 yr

Species	:	Rabbit
LOAEL	:	250 mg/kg
Application Route	:	Dermal
Exposure time	:	13 Weeks
Target Organs	:	Skin, Liver

Aspiration toxicity

Not classified based on available information.

Experience with human exposure**Components:****Chlorhexidine:**

General Information	:	Symptoms: Headache
Inhalation	:	Target Organs: Lungs Symptoms: Asthmatic appearance, bronchospasm, discomfort in the chest, upper respiratory tract infection
Ingestion	:	Target Organs: Gastrointestinal tract Symptoms: Gastrointestinal disturbance, Gastrointestinal tract damage

Section 12: Ecological information**Ecotoxicity****Components:****Glycerine:**

Toxicity to fish	:	LC50 (Oncorhynchus mykiss (rainbow trout)): 54,000 mg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): 1,955 mg/l Exposure time: 48 h

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Toxicity to microorganisms : NOEC (*Pseudomonas putida*): > 10,000 mg/l
 Exposure time: 16 h
 Method: DIN 38 412 Part 8

Chlorhexidine:

Toxicity to fish : (Fish): 2.088 mg/l
 Exposure time: 96 h
 Method: ECOSAR (Ecological Structure Activity Relationships)

Toxicity to daphnia and other aquatic invertebrates : EC50 (*Daphnia magna* (Water flea)): 0.222 mg/l
 Exposure time: 48 h
 Method: ECOSAR (Ecological Structure Activity Relationships)

Toxicity to algae/aquatic plants : ErC50 (*Pseudokirchneriella subcapitata* (green algae)): 1.124 mg/l
 End point: Growth rate
 Exposure time: 96 hrs
 Method: ECOSAR (Ecological Structure Activity Relationships)

M-Factor (Acute aquatic toxicity) : 1

M-Factor (Chronic aquatic toxicity) : 1

Nonylphenol, ethoxylated:

Toxicity to fish : LC50 (*Pimephales promelas* (fathead minnow)): > 0.1 - 1 mg/l
 Exposure time: 96 h
 Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates : EC50 (*Ceriodaphnia dubia* (water flea)): > 0.1 - 1 mg/l
 Exposure time: 48 h
 Remarks: Based on data from similar materials

Toxicity to algae/aquatic plants : ErC50 (*Selenastrum capricornutum* (green algae)): > 1 - 10 mg/l
 Exposure time: 72 h
 Method: OECD Test Guideline 201
 Remarks: Based on data from similar materials

EC10 (*Selenastrum capricornutum* (green algae)): > 1 mg/l
 Exposure time: 72 h
 Method: OECD Test Guideline 201
 Remarks: Based on data from similar materials

M-Factor (Acute aquatic toxicity) : 1

Toxicity to fish (Chronic toxicity) : NOEC (*Oryzias latipes* (Japanese medaka)): > 0.1 - 1 mg/l
 Exposure time: 100 d

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Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Mysidopsis bahia (opossum shrimp)): > 0.001 - 0.01 mg/l
Exposure time: 28 d
Remarks: Based on data from similar materials

M-Factor (Chronic aquatic toxicity) : 10

Persistence and degradability**Components:****Glycerine:**

Biodegradability : Result: Readily biodegradable.
Biodegradation: 92 %
Exposure time: 30 d
Method: OECD Test Guideline 301D

Chlorhexidine:

Biodegradability : Remarks: Not inherently biodegradable.

Nonylphenol, ethoxylated:

Biodegradability : Result: Not readily biodegradable.
Remarks: Based on data from similar materials

Bioaccumulative potential**Components:****Glycerine:**

Partition coefficient: n-octanol/water : log Pow: -1.75

Chlorhexidine:

Partition coefficient: n-octanol/water : log Pow: 4.85

Nonylphenol, ethoxylated:

Partition coefficient: n-octanol/water : log Pow: 4.48

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.

Section 14: Transport information

International Regulations

UNRTDG

UN number : UN 3082

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
(Chlorhexidine)

Class : 9

Packing group : III

Labels : 9

Environmentally hazardous : yes

IATA-DGR

UN/ID No. : UN 3082

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

Class : 9

Packing group : III

Labels : Miscellaneous

Packing instruction (cargo aircraft) : 964

Packing instruction (passenger aircraft) : 964

Environmentally hazardous : yes

IMDG-Code

UN number : UN 3082

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
(Chlorhexidine)

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

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UN number	:	UN 3082
Proper shipping name	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Chlorhexidine)
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

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

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/>

Date format : dd.mm.yyyy

Full text of other abbreviations

NZ OEL : New Zealand. Workplace Exposure Standards for Atmospheric Contaminants

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NZ OEL / WES-TWA : Workplace Exposure Standard - 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 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; TECl - 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