

# SAFETY DATA SHEET



## Gentamicin (10%) Injection Formulation

Version 6.2      Revision Date: 30.09.2023      SDS Number: 804050-00018      Date of last issue: 04.04.2023  
Date of first issue: 15.07.2016

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### Section 1: Identification

Product name : Gentamicin (10%) Injection 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

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### Section 2: Hazard identification

#### GHS Classification

Reproductive toxicity : Category 1

Specific target organ toxicity - repeated exposure (Oral) : Category 1 (Kidney, inner ear)

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 : H360D May damage the unborn child.  
H372 Causes damage to organs (Kidney, inner ear) through prolonged or repeated exposure if swallowed.  
H400 Very toxic to aquatic life.

# SAFETY DATA SHEET



## Gentamicin (10%) Injection Formulation

Version 6.2	Revision Date: 30.09.2023	SDS Number: 804050-00018	Date of last issue: 04.04.2023 Date of first issue: 15.07.2016
----------------	------------------------------	-----------------------------	---

H411 Toxic to aquatic life with long lasting effects.

### Precautionary statements

#### **Prevention:**

P201 Obtain special instructions before use.  
P260 Do not breathe mist or vapours.  
P264 Wash skin thoroughly after handling.  
P270 Do not eat, drink or smoke when using this product.  
P273 Avoid release to the environment.  
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

#### **Response:**

P308 + P313 IF exposed or concerned: Get medical advice/ attention.  
P391 Collect spillage.

#### **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)
Gentamicin	1403-66-3	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 advice.

If inhaled : If inhaled, remove to fresh air.  
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.

# SAFETY DATA SHEET



## Gentamicin (10%) Injection Formulation

Version 6.2      Revision Date: 30.09.2023      SDS Number: 804050-00018      Date of last issue: 04.04.2023  
Date of first issue: 15.07.2016

---

If swallowed : If swallowed, DO NOT induce vomiting.  
Get medical attention.  
Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and delayed : May damage the unborn child.  
Causes damage to organs through prolonged or repeated exposure if swallowed.

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.

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### Section 5: Fire-fighting measures

Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO2)  
Dry chemical

Unsuitable extinguishing media : None known.

Specific hazards during fire-fighting : Exposure to combustion products may be a hazard to health.

Hazardous combustion products : Carbon oxides

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

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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 absor-

# SAFETY DATA SHEET



## Gentamicin (10%) Injection Formulation

Version 6.2	Revision Date: 30.09.2023	SDS Number: 804050-00018	Date of last issue: 04.04.2023 Date of first issue: 15.07.2016
----------------	------------------------------	-----------------------------	---

bent.

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	: If sufficient ventilation is unavailable, use with local exhaust ventilation.
Advice on safe handling	: Do not get on skin or clothing. Do not breathe mist or vapours. Do not swallow. Avoid contact with eyes. Wash skin thoroughly after handling. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment Keep container tightly closed. Do not eat, drink or smoke when using this product. 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 locked up. 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 (Form of exposure)	Control parame- ters / Permissible concentration	Basis
Gentamicin	1403-66-3	TWA	0.1 mg/m3 (OEB)	Internal

# SAFETY DATA SHEET



## Gentamicin (10%) Injection Formulation

Version 6.2      Revision Date: 30.09.2023      SDS Number: 804050-00018      Date of last issue: 04.04.2023  
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Further information: OTO				

**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 exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

Filter type : Particulates type

Hand protection : Chemical-resistant gloves

Material : Chemical-resistant gloves

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 : liquid

Colour : clear

Odour : odourless

Odour Threshold : No data available

pH : 3.0 - 5.5

Melting point/freezing point : No data available

Initial boiling point and boiling range : > 100 °C

Flash point : No data available

Evaporation rate : 1

Flammability (solid, gas) : Not applicable

Flammability (liquids) : No data available

# SAFETY DATA SHEET



## Gentamicin (10%) Injection Formulation

Version 6.2      Revision Date: 30.09.2023      SDS Number: 804050-00018      Date of last issue: 04.04.2023  
Date of first issue: 15.07.2016

---

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 : No data available

Solubility(ies)  
Water solubility : soluble

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 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 : Can react with strong oxidizing agents.

Conditions to avoid : None known.

Incompatible materials : Oxidizing agents

Hazardous decomposition products : No hazardous decomposition products are known.

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### Section 11: Toxicological information

Exposure routes : Inhalation  
Skin contact  
Ingestion

# SAFETY DATA SHEET



## Gentamicin (10%) Injection Formulation

Version 6.2      Revision Date: 30.09.2023      SDS Number: 804050-00018      Date of last issue: 04.04.2023  
Date of first issue: 15.07.2016

---

### Eye contact

#### **Acute toxicity**

Not classified based on available information.

#### **Components:**

##### **Gentamicin:**

Acute oral toxicity	:	LD50 (Rat): 8,000 - 10,000 mg/kg
		LD50 (Mouse): 10,000 mg/kg
Acute inhalation toxicity	:	LC50 (Rat): > 0.2 mg/l Exposure time: 4 h Test atmosphere: dust/mist Remarks: No mortality observed at this dose.
Acute toxicity (other routes of administration)	:	LD50 (Rat): 67 - 96 mg/kg Application Route: Intravenous
		LD50 (Rat): 371 - 384 mg/kg Application Route: Intramuscular
		LDLo (Monkey): 30 mg/kg Application Route: Intravenous

### **Skin corrosion/irritation**

Not classified based on available information.

#### **Components:**

##### **Gentamicin:**

Species	:	Rabbit
Result	:	Mild skin irritation

### **Serious eye damage/eye irritation**

Not classified based on available information.

#### **Components:**

##### **Gentamicin:**

Species	:	Rabbit
Result	:	Mild eye irritation

### **Respiratory or skin sensitisation**

#### **Skin sensitisation**

Not classified based on available information.

#### **Respiratory sensitisation**

Not classified based on available information.

# SAFETY DATA SHEET



## Gentamicin (10%) Injection Formulation

Version 6.2      Revision Date: 30.09.2023      SDS Number: 804050-00018      Date of last issue: 04.04.2023  
Date of first issue: 15.07.2016

---

### Components:

#### **Gentamicin:**

Remarks : No data available

### **Chronic toxicity**

#### **Germ cell mutagenicity**

Not classified based on available information.

### Components:

#### **Gentamicin:**

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

Test Type: Chromosome aberration test in vitro  
Result: equivocal

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)  
Species: Mouse  
Application Route: Intravenous injection  
Result: negative

### **Carcinogenicity**

Not classified based on available information.

### Components:

#### **Gentamicin:**

Carcinogenicity - Assessment : No data available

### **Reproductive toxicity**

May damage the unborn child.

### Components:

#### **Gentamicin:**

Effects on fertility : Test Type: Two-generation reproduction toxicity study  
Species: Rat  
Fertility: NOAEL: 20 mg/kg body weight  
Result: No significant adverse effects were reported

Effects on foetal development : Test Type: Embryo-foetal development  
Species: Rabbit  
Developmental Toxicity: NOAEL: 3.6 mg/kg body weight  
Result: No embryo-foetal toxicity

Test Type: Embryo-foetal development  
Species: Rat  
Application Route: Intraperitoneal

**Gentamicin (10%) Injection Formulation**Version  
6.2Revision Date:  
30.09.2023SDS Number:  
804050-00018Date of last issue: 04.04.2023  
Date of first issue: 15.07.2016

Developmental Toxicity: LOAEL: 75 mg/kg body weight  
Result: Embryo-foetal toxicity

Test Type: Embryo-foetal development  
Species: Mouse  
Application Route: Intraperitoneal  
Developmental Toxicity: LOAEL: 10 mg/kg body weight  
Result: foetal mortality, No malformations were observed.

Test Type: Embryo-foetal development  
Species: Rat  
Application Route: Intraperitoneal  
Developmental Toxicity: LOAEL: 50 mg/kg body weight  
Result: foetal mortality, No malformations were observed.

Reproductive toxicity - Assessment : Positive evidence of adverse effects on development from human epidemiological studies.

**STOT - single exposure**

Not classified based on available information.

**STOT - repeated exposure**

Causes damage to organs (Kidney, inner ear) through prolonged or repeated exposure if swallowed.

**Components:****Gentamicin:**

Target Organs : Kidney, inner ear  
Assessment : Causes damage to organs through prolonged or repeated exposure.

**Repeated dose toxicity****Components:****Gentamicin:**

Species : Dog  
LOAEL : 3 mg/kg  
Application Route : Intramuscular  
Exposure time : 12 Months  
Target Organs : Kidney  
Symptoms : Vomiting, Salivation

Species : Monkey  
LOAEL : 50 mg/kg  
Application Route : Subcutaneous  
Exposure time : 3 Weeks  
Target Organs : Kidney, inner ear

Species : Monkey  
LOAEL : 6 mg/kg

# SAFETY DATA SHEET



## Gentamicin (10%) Injection Formulation

Version 6.2      Revision Date: 30.09.2023      SDS Number: 804050-00018      Date of last issue: 04.04.2023  
Date of first issue: 15.07.2016

---

Application Route	:	Intramuscular
Exposure time	:	3 Weeks
Target Organs	:	Blood, Kidney, inner ear, Liver
Species	:	Rat
NOAEL	:	5 mg/kg
LOAEL	:	10 mg/kg
Application Route	:	Intramuscular
Exposure time	:	52 Weeks
Target Organs	:	Kidney, Blood
Species	:	Rat
NOAEL	:	12.5 mg/kg
LOAEL	:	50 mg/kg
Application Route	:	Intramuscular
Exposure time	:	13 Weeks
Target Organs	:	Kidney

### Aspiration toxicity

Not classified based on available information.

### Experience with human exposure

#### Components:

#### **Gentamicin:**

Ingestion : Target Organs: Kidney  
Target Organs: inner ear  
Symptoms: Dizziness, Vertigo, hearing loss, tinnitus, fetal deafness

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## Section 12: Ecological information

### Ecotoxicity

#### Components:

#### **Gentamicin:**

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 86 mg/l  
Exposure time: 48 h  
Method: OECD Test Guideline 202

LC50 (Americamysis): 30 mg/l  
Exposure time: 96 h  
Method: US-EPA OPPTS 850.1035

Toxicity to algae/aquatic plants : EC50 (Pseudokirchneriella subcapitata (green algae)): 10 µg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 1.5 µg/l

# SAFETY DATA SHEET



## Gentamicin (10%) Injection Formulation

Version 6.2      Revision Date: 30.09.2023      SDS Number: 804050-00018      Date of last issue: 04.04.2023  
Date of first issue: 15.07.2016

---

Exposure time: 72 h  
Method: OECD Test Guideline 201

EC50 (Anabaena flos-aquae (cyanobacterium)): 4.7 µg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

NOEC (Anabaena flos-aquae (cyanobacterium)): 1.6 µg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

M-Factor (Acute aquatic toxicity) : 100  
M-Factor (Chronic aquatic toxicity) : 1  
Toxicity to microorganisms : EC50: 288.7 mg/l  
Exposure time: 3 h  
Test Type: Respiration inhibition  
Method: OECD Test Guideline 209

### Persistence and degradability

#### Components:

##### **Gentamicin:**

Biodegradability : Result: rapidly degradable  
Biodegradation: 100 %  
Exposure time: 28 d  
Method: OECD Test Guideline 314

### Bioaccumulative potential

#### Components:

##### **Gentamicin:**

Partition coefficient: n-octanol/water : log Pow: < -2

### **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.

# SAFETY DATA SHEET



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Version 6.2      Revision Date: 30.09.2023      SDS Number: 804050-00018      Date of last issue: 04.04.2023  
Date of first issue: 15.07.2016

---

### Section 14: Transport information

#### International Regulations

##### UNRTDG

UN number : UN 3082  
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.  
(Gentamicin)  
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.  
(Gentamicin)  
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.  
(Gentamicin)  
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.  
(Gentamicin)  
Class : 9  
Packing group : III  
Labels : 9  
Hazchem Code : 3Z  
Marine pollutant : no

# SAFETY DATA SHEET



## Gentamicin (10%) Injection Formulation

Version 6.2      Revision Date: 30.09.2023      SDS Number: 804050-00018      Date of last issue: 04.04.2023  
Date of first issue: 15.07.2016

---

### 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.

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### Section 15: Regulatory information

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

##### HSNO Approval Number

not allocated

#### The components 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 : 30.09.2023

#### 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

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;

# SAFETY DATA SHEET



## Gentamicin (10%) Injection Formulation

---

Version 6.2	Revision Date: 30.09.2023	SDS Number: 804050-00018	Date of last issue: 04.04.2023 Date of first issue: 15.07.2016
----------------	------------------------------	-----------------------------	---

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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

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