

# **Orbifloxacin Solid Formulation**

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 3.1 30.09.2023 801088-00018 Date of first issue: 15.07.2016

#### **Section 1: Identification**

Product name : Orbifloxacin Solid 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** 

Reproductive toxicity : Category 2

**GHS** label elements

Hazard pictograms :

Signal word : Warning

Hazard statements : H361d Suspected of damaging the unborn child.

Precautionary statements : Prevention:

P201 Obtain special instructions before use.

P202 Do not handle until all safety precautions have been read

and understood.

P280 Wear protective gloves/ protective clothing/ eye protec-

tion/ face protection.

Response:

P308 + P313 IF exposed or concerned: Get medical advice/

attention.



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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

Dust contact with the eyes can lead to mechanical irritation.

Contact with dust can cause mechanical irritation or drying of the skin.

May form explosive dust-air mixture during processing, handling or other means.

### Section 3: Composition/information on ingredients

Substance / Mixture Mixture

#### Components

Chemical name	CAS-No.	Concentration (% w/w)	
Orbifloxacin	113617-63-3	>= 1 -< 10	
Magnesium stearate	557-04-0	>= 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.

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 If in eyes, rinse well with water.

Get medical attention if irritation develops and persists.

If swallowed If swallowed, DO NOT induce vomiting.

Get medical attention.

Rinse mouth thoroughly with water.

Most important symptoms

Suspected of damaging the unborn child.

and effects, both acute and

Contact with dust can cause mechanical irritation or drying of

delayed

the skin.

Dust contact with the eyes can lead to mechanical irritation. 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).

Treat symptomatically and supportively. Notes to physician

#### Section 5: Fire-fighting measures



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Suitable extinguishing media : Water spray

Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing

media

None known.

Specific hazards during fire-

fighting

Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a

potential dust explosion hazard.

Exposure to combustion products may be a hazard to health.

Hazardous combustion prod: :

ucts

Carbon oxides

Nitrogen oxides (NOx)

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.

#### Section 6: Accidental release measures

Personal precautions, protective 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. 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

Sweep up or vacuum up spillage and collect in suitable con-

tainer for disposal.

Avoid dispersal of dust in the air (i.e., clearing dust surfaces

with compressed air).

Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. 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 deter-

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



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Technical measures : Static electricity may accumulate and ignite suspended dust

causing an explosion.

Provide adequate precautions, such as electrical grounding

and bonding, or inert atmospheres.

Local/Total ventilation

: Use only with adequate ventilation.

Advice on safe handling : Do not breathe dust.

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

Minimize dust generation and accumulation. Keep container closed when not in use. Keep away from heat and sources of ignition.

Take precautionary measures against static discharges.

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.

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
Orbifloxacin	113617-63-3	TWA	0.2 mg/m3 (OEB 2)	Internal
Magnesium stearate	557-04-0	WES-TWA	10 mg/m3	NZ OEL
		TWA (Inhal- able particu- late matter)	10 mg/m3	ACGIH
		TWA (Respirable particulate matter)	3 mg/m3	ACGIH



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**Engineering measures** : Use feasible engineering controls to minimize exposure to

compound.

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

protect products, workers, and the environment.

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

Particulates type

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 : powder

Colour : No data available

Odour : No data available

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 : Not applicable

Evaporation rate : No data available

Flammability (solid, gas) : May form explosive dust-air mixture during processing, han-

dling or other means.

Flammability (liquids) : No data available

Upper explosion limit / Upper

flammability limit

No data available



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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 : 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 size : No data available

### Section 10: Stability and reactivity

Reactivity : Not classified as a reactivity hazard.

Chemical stability : Stable under normal conditions.

Possibility of hazardous reac-

tions

May form explosive dust-air mixture during processing, han-

dling or other means.

Can react with strong oxidizing agents.

Conditions to avoid : Heat, flames and sparks.

Avoid dust formation.

Incompatible materials

Hazardous decomposition

Oxidizing agents

products

No hazardous decomposition products are known.

### **Section 11: Toxicological information**

Exposure routes : Inhalation

Skin contact Ingestion



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Eye contact

**Acute toxicity** 

Not classified based on available information.

**Components:** 

Orbifloxacin:

Acute oral toxicity : LD50 (Rat): > 3,000 mg/kg

Remarks: No mortality observed at this dose.

LD50 (Mouse): > 2,000 mg/kg

Remarks: No mortality observed at this dose.

LD50 (Dog): > 600 mg/kg Symptoms: Vomiting

Remarks: No mortality observed at this dose.

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : Remarks: No data available

Acute toxicity (other routes of:

administration)

LD50 (Rat): > 200 mg/kg

Application Route: Intramuscular

LD50 (Mouse): 500 mg/kg Application Route: Intramuscular

LD50 (Rat): 233 mg/kg

Application Route: Intravenous

LD50 (Mouse): 250 mg/kg Application Route: Intravenous

Magnesium stearate:

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

Method: OECD Test Guideline 423

Assessment: The substance or mixture has no acute oral tox-

icity

Remarks: Based on data from similar materials

Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg

Remarks: Based on data from similar materials

Skin corrosion/irritation

Not classified based on available information.

**Components:** 

Orbifloxacin:

Species : Rabbit Method : Draize Test



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Result : No skin irritation

Magnesium stearate:

Species : Rabbit

Result : No skin irritation

Remarks : Based on data from similar materials

Serious eye damage/eye irritation

Not classified based on available information.

**Components:** 

Orbifloxacin:

Species : Rabbit

Result : Mild eye irritation
Method : Draize Test

Magnesium stearate:

Species : Rabbit

Result : No eye irritation

Remarks : Based on data from similar materials

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

**Components:** 

Orbifloxacin:

Test Type : Maximisation Test

Exposure routes : Dermal Species : Guinea pig

Result : Not a skin sensitizer.

Magnesium stearate:

Test Type : Maximisation Test
Exposure routes : Skin contact
Species : Guinea pig

Method : OECD Test Guideline 406

Result : negative

Remarks : Based on data from similar materials



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### **Chronic toxicity**

### Germ cell mutagenicity

Not classified based on available information.

### **Components:**

Orbifloxacin:

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

Result: equivocal

Test Type: Mouse Lymphoma

Result: positive

Test Type: Chromosomal aberration Test system: Human lymphocytes

Result: positive

Genotoxicity in vivo : Test Type: Micronucleus test

Species: Mouse

Cell type: Bone marrow

Application Route: Intraperitoneal injection

Result: negative

Test Type: unscheduled DNA synthesis assay

Species: Rat Cell type: Liver cells Application Route: Oral Result: negative

Germ cell mutagenicity -

Assessment

Weight of evidence does not support classification as a germ

cell mutagen.

Magnesium stearate:

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

Result: negative

Remarks: Based on data from similar materials

Test Type: Chromosome aberration test in vitro

Method: OECD Test Guideline 473

Result: negative

Remarks: Based on data from similar materials

Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

Remarks: Based on data from similar materials

### Carcinogenicity

Not classified based on available information.



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#### **Components:**

Orbifloxacin:

Species : Rat
Application Route : Oral
Exposure time : 2 Years

NOAEL : 200 mg/kg body weight

Result : negative

Species : Mouse
Application Route : Oral
Exposure time : 2 Years

NOAEL : 200 mg/kg body weight

Result : negative

Reproductive toxicity

Suspected of damaging the unborn child.

**Components:** 

Orbifloxacin:

Effects on fertility : Test Type: Two-generation reproduction toxicity study

Species: Rat

Application Route: Oral

General Toxicity - Parent: NOAEL: 50 mg/kg body weight Early Embryonic Development: NOAEL: 50 mg/kg body

weight

Result: No adverse effects

Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Rat

**Application Route: Oral** 

Embryo-foetal toxicity: LOAEL: 333 mg/kg body weight Result: No teratogenic effects, Embryotoxic effects and adverse effects on the offspring were detected only at high ma-

ternally toxic doses

Test Type: Embryo-foetal development

Species: Rabbit Application Route: Oral

General Toxicity Maternal: NOAEL: 20 mg/kg body weight Embryo-foetal toxicity: NOAEL: 60 mg/kg body weight Result: No effects on early embryonic development, Embryotoxic effects and adverse effects on the offspring were detected only at high maternally toxic doses, Reduced maternal

body weight gain

Test Type: Development

Species: Dog

Application Route: Oral

Developmental Toxicity: LOAEL: 2.5 mg/kg body weight Result: Effects on postnatal development, Skeletal malfor-



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mations

Reproductive toxicity - As-

sessment

Some evidence of adverse effects on development, based on

animal experiments.

Magnesium stearate:

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

reproduction/developmental toxicity screening test

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: Embryo-foetal development

Species: Rat

Application Route: Ingestion

Result: negative

Remarks: Based on data from similar materials

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

Not classified based on available information.

Repeated dose toxicity

# Components:

### Orbifloxacin:

Species : Rat
NOAEL : 20 mg/kg
LOAEL : 80 mg/kg
Application Route : Oral
Exposure time : 3 Months

Target Organs : Testis, Liver, Kidney, spleen

Species : Mouse
NOAEL : 80 mg/kg
LOAEL : 250 mg/kg
Application Route : Oral
Exposure time : 3 Months

Species : Juvenile dog
NOAEL : 50 mg/kg
LOAEL : 250 mg/kg
Application Route : Oral
Exposure time : 14 Days
Target Organs : Heart, Bone

Symptoms : Gastrointestinal disturbance

Remarks : mortality observed



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Species : Juvenile dog
NOAEL : 2 mg/kg
LOAEL : 3 mg/kg
Application Route : Oral
Exposure time : 90 Days
Target Organs : Bone

Remarks : No significant adverse effects were reported

Species : Dog

NOAEL : 37.5 mg/kg Application Route : Oral Exposure time : 30 Days

Species : Cat
NOAEL : 7.5 mg/kg
LOAEL : 22.5 mg/kg
Application Route : Oral
Exposure time : 1 Months

Symptoms : Gastrointestinal disturbance

Magnesium stearate:

Species : Rat

NOAEL : > 100 mg/kg
Application Route : Ingestion
Exposure time : 90 Days

Remarks : Based on data from similar materials

**Aspiration toxicity** 

Not classified based on available information.

Experience with human exposure

**Components:** 

Orbifloxacin:

Ingestion : Symptoms: central nervous system effects, Gastrointestinal

disturbance, liver function change, anaphylaxis, Rash

Remarks: May cause photosensitisation.

**Section 12: Ecological information** 

**Ecotoxicity** 

**Components:** 

Magnesium stearate:

Toxicity to fish : LC50 (Leuciscus idus (Golden orfe)): > 100 mg/l

Exposure time: 48 h Method: DIN 38412

Remarks: Based on data from similar materials



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Toxicity to daphnia and other :

aquatic invertebrates

EL50 (Daphnia magna (Water flea)): > 1 mg/l

Exposure time: 47 h

Test substance: Water Accommodated Fraction Method: Directive 67/548/EEC, Annex V, C.2. Remarks: Based on data from similar materials

No toxicity at the limit of solubility

Toxicity to algae/aquatic

plants

EL50 (Pseudokirchneriella subcapitata (green algae)): > 1

mg/l

Exposure time: 72 h

Test substance: Water Accommodated Fraction

Method: OECD Test Guideline 201

Remarks: Based on data from similar materials

No toxicity at the limit of solubility

NOELR (Pseudokirchneriella subcapitata (green algae)): > 1

mg/l

Exposure time: 72 h

Test substance: Water Accommodated Fraction

Method: OECD Test Guideline 201

Remarks: Based on data from similar materials

Toxicity to microorganisms : EC10 (Pseudomonas putida): > 100 mg/l

Exposure time: 16 h

Test substance: Water Accommodated Fraction Remarks: Based on data from similar materials

Persistence and degradability

**Components:** 

Magnesium stearate:

Biodegradability : Result: Not biodegradable

Remarks: Based on data from similar materials

Bioaccumulative potential

**Components:** 

Magnesium stearate:

Partition coefficient: n-

: log Pow: > 4

octanol/water

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 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 Not applicable Not applicable Proper shipping name Not applicable Class Subsidiary risk Not applicable Not applicable Packing group Labels Not applicable

# IATA-DGR

UN/ID No. Not applicable Proper shipping name Not applicable Class Not applicable Not applicable Subsidiary risk Packing group Not applicable Labels Not applicable Packing instruction (cargo Not applicable

aircraft)

Packing instruction (passen-

ger aircraft)

Not applicable

### **IMDG-Code**

UN number Not applicable Proper shipping name Not applicable Class Not applicable Not applicable Subsidiary risk Not applicable Packing group Labels Not applicable **EmS Code** Not applicable Not applicable Marine pollutant

### 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 Not applicable Class Not applicable Subsidiary risk



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Packing group Not applicable Labels Not applicable Hazchem Code Not applicable

Special precautions for user

Not applicable

# **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 Agen-

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

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 Atmospher-

ic Contaminants

ACGIH / TWA 8-hour, time-weighted average

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



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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; 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