

# SAFETY DATA SHEET



## Indinavir Formulation

Version 5.1      Revision Date: 30.09.2023      SDS Number: 42774-00022      Date of last issue: 04.04.2023  
Date of first issue: 07.01.2015

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### Section 1: Identification

Product name : Indinavir 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 : Pharmaceutical

Restrictions on use : Not applicable

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### Section 2: Hazard identification

#### GHS Classification

Serious eye damage/eye irritation : Category 2

Reproductive toxicity : Category 2

#### GHS label elements

Hazard pictograms :



Signal word : Warning

Hazard statements : H319 Causes serious eye irritation.  
H361d Suspected of damaging the unborn child.

Precautionary statements :

P201 Obtain special instructions before use.

P202 Do not handle until all safety precautions have been read and understood.

P264 Wash skin thoroughly after handling.

P280 Wear protective gloves/ protective clothing/ eye protec-

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tion/ 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.

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

P337 + P313 If eye irritation persists: Get medical advice/ attention.

**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

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

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## Section 3: Composition/information on ingredients

Substance / Mixture : Mixture

**Components**

Chemical name	CAS-No.	Concentration (% w/w)
Indinavir	157810-81-6	>= 70 -< 90
Magnesium stearate	557-04-0	>= 1 -< 10

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## 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 plenty of water.  
Remove contaminated clothing and shoes.  
Get medical attention.  
Wash clothing before reuse.

In case of eye contact : Thoroughly clean shoes before reuse.  
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.  
Rinse mouth thoroughly with water.

Most important symptoms : Causes serious eye irritation.

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and effects, both acute and delayed	Suspected of damaging the unborn child.
Protection of first-aiders	: First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).
Notes to physician	: Treat symptomatically and supportively.

### Section 5: Fire-fighting measures

Suitable extinguishing media	: Water spray Alcohol-resistant foam Carbon dioxide (CO <sub>2</sub> ) Dry chemical
Unsuitable extinguishing media	: None known.
Specific hazards during fire-fighting	: 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 products	: Carbon oxides Metal oxides
Specific extinguishing methods	: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.
Special protective equipment for firefighters	: In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

### 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. 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 container 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

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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	: 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 get on skin or clothing. Do not breathe dust. Do not swallow. Do not get in 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 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.
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 parame- ters / Permissible concentration	Basis
Indinavir	157810-81-6	TWA	1,000 µg/m3	Internal
Magnesium stearate	557-04-0	WES-TWA	10 mg/m3	NZ OEL
		TWA (Inhal- able particu- late matter)	10 mg/m3	ACGIH
		TWA (Res- pirable par- ticle)	3 mg/m3	ACGIH

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**Engineering measures** : Ensure adequate ventilation, especially in confined areas. Minimize workplace exposure concentrations. Apply measures to prevent dust explosions. Ensure that dust-handling systems (such as exhaust ducts, dust collectors, vessels, and processing equipment) are designed in a manner to prevent the escape of dust into the work area (i.e., there is no leakage from the equipment).

### 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

Material : Chemical-resistant gloves

Remarks : Choose gloves to protect hands against chemicals depending on the concentration and quantity of the hazardous substance and specific to place of work. Breakthrough time is not determined for the product. Change gloves often! For special applications, we recommend clarifying the resistance to chemicals of the aforementioned protective gloves with the glove manufacturer. Wash hands before breaks and at the end of workday.

Eye protection : Wear the following personal protective equipment:  
Safety goggles

Skin and body protection : Select appropriate protective clothing based on chemical resistance data and an assessment of the local exposure potential.  
Skin contact must be avoided by using impervious protective clothing (gloves, aprons, boots, etc).

## Section 9: Physical and chemical properties

Appearance : powder

Colour : white

Odour : odourless

Odour Threshold : No data available

pH : No data available

Melting point/freezing point : No data available

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Initial boiling point and boiling range : No data available

Flash point : No data available

Evaporation rate : No data available

Flammability (solid, gas) : May form explosive dust-air mixture during processing, handling or other means.

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

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, dynamic : No data available

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.

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Possibility of hazardous reactions	: May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents.
Conditions to avoid	: Heat, flames and sparks. Avoid dust formation.
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 Eye contact
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#### Acute toxicity

Not classified based on available information.

#### Components:

##### **Indinavir:**

Acute oral toxicity	: LD50 (Rat): > 5,000 mg/kg LD50 (Mouse): > 5,000 mg/kg
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##### **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 toxicity 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:

##### **Indinavir:**

Species	: Rabbit
Result	: Mild skin irritation
Remarks	: slight irritation

##### **Magnesium stearate:**

Species	: Rabbit
Result	: No skin irritation
Remarks	: Based on data from similar materials

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

Causes serious eye irritation.

#### **Components:**

##### **Indinavir:**

Species : Bovine cornea  
Remarks : Severe eye irritation

##### **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:**

##### **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

### **Chronic toxicity**

#### **Germ cell mutagenicity**

Not classified based on available information.

#### **Components:**

##### **Indinavir:**

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

Test Type: Chromosome aberration test in vitro  
Result: negative

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

Test Type: Alkaline elution assay

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Result: negative

Genotoxicity in vivo : Test Type: Mammalian bone marrow sister chromatid exchange  
Application Route: Intraperitoneal injection  
Result: negative

### **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.

### **Components:**

#### **Indinavir:**

Species : Rat  
Application Route : Oral  
NOAEL : 640 mg/kg body weight  
Result : negative

Species : Mouse  
Application Route : Oral  
Result : negative

### **Reproductive toxicity**

Suspected of damaging the unborn child.

### **Components:**

#### **Indinavir:**

Effects on fertility : Test Type: Fertility  
Species: Rat  
Result: No effects on mating performance

Effects on foetal development : Test Type: Embryo-foetal development  
Species: Monkey  
Developmental Toxicity: LOAEL: 160 mg/kg body weight  
Result: Effects on foetal development

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Test Type: Embryo-foetal development  
Species: Rat  
Developmental Toxicity: NOAEL: 40 mg/kg body weight  
Result: Effects on foetal development

Test Type: Embryo-foetal development  
Species: Rabbit  
Application Route: Oral  
Embryo-foetal toxicity: NOAEL: 240 mg/kg body weight  
Result: No effects on foetal development

Reproductive toxicity - Assessment : 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 development : 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:**

#### **Indinavir:**

Species : Rat  
NOAEL : 10 mg/kg  
Application Route : Oral  
Exposure time : 53 Weeks  
Remarks : No significant adverse effects were reported

Species : Dog  
NOAEL : 10 mg/kg  
Application Route : Oral  
Exposure time : 53 Weeks  
Remarks : No significant adverse effects were reported

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Species : Monkey  
NOAEL : 80 mg/kg  
Application Route : Oral  
Exposure time : 5 Weeks  
Remarks : No significant adverse effects were reported

### **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:

##### **Indinavir:**

Ingestion : Symptoms: Nausea, Abdominal pain, Headache, Kidney disorders, liver function change

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## Section 12: Ecological information

### **Ecotoxicity**

#### Components:

##### **Indinavir:**

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): > 20 mg/l  
Exposure time: 96 h  
Method: OECD Test Guideline 203  
Remarks: No toxicity at the limit of solubility

LC50 (Oncorhynchus mykiss (rainbow trout)): 438 mg/l  
Exposure time: 96 h  
Method: OECD Test Guideline 203  
Remarks: No toxicity at the limit of solubility

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 20 mg/l  
Exposure time: 48 h  
Method: OECD Test Guideline 202  
Remarks: No toxicity at the limit of solubility

Toxicity to algae/aquatic plants : NOEC (Pseudokirchneriella subcapitata (green algae)): 6.47 mg/l  
Exposure time: 10 d  
Method: OECD Test Guideline 201

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Toxicity to microorganisms : EC50: > 20 mg/l  
Exposure time: 3 h  
Test Type: Respiration inhibition  
Method: OECD Test Guideline 209  
Remarks: No toxicity at the limit of solubility

NOEC: 10 mg/l  
Exposure time: 3 h  
Test Type: Respiration inhibition  
Method: OECD Test Guideline 209  
Remarks: No toxicity at the limit of solubility

### **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

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:**

##### **Indinavir:**

Stability in water : Hydrolysis: 50 %(651 d)

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### **Magnesium stearate:**

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

### **Bioaccumulative potential**

### **Components:**

#### **Indinavir:**

Partition coefficient: n-octanol/water : log Pow: 2.66

#### **Magnesium stearate:**

Partition coefficient: n-octanol/water : log Pow: > 4

#### **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.

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## **Section 14: Transport information**

### **International Regulations**

#### **UNRTDG**

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

#### **IATA-DGR**

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

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aircraft)

Packing instruction (passenger aircraft) : Not applicable

### IMDG-Code

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

### Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

### National Regulations

#### NZS 5433

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

### Special precautions for user

Not applicable

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## Section 15: Regulatory information

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

#### HSNO Approval Number

HSR100425 Pharmaceutical Active Ingredients 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

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### 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

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

NZ OEL : New Zealand. Workplace Exposure Standards for Atmospheric 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 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

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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