

Ivermectin (3.5%) Formulation

SDS Number: Date of last issue: 30.09.2023 Version **Revision Date:** 5.3 06.04.2024 4698075-00018 Date of first issue: 29.07.2019

SECTION 1: IDENTIFICATION

Product name Ivermectin (3.5%) Formulation

Manufacturer or supplier's details

Intervet Australia Pty Limited (trading as MSD Animal Health) Company

Address 91-105 Harpin Street

Bendigo 3550, Victoria Austrailia

1 800 033 461 Telephone

Emergency telephone number : Poisons Information Centre: Phone 13 11 26

E-mail address EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

: Veterinary product Recommended use Restrictions on use Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification

Acute toxicity (Oral) : Category 4

single exposure (Oral)

Specific target organ toxicity - : Category 2 (Central nervous system)

repeated exposure (Oral)

Specific target organ toxicity - : Category 2 (Central nervous system)

GHS label elements

Hazard pictograms

Signal word Warning

Hazard statements H302 Harmful if swallowed.

H371 May cause damage to organs (Central nervous system) if

swallowed.

H373 May cause damage to organs (Central nervous system)

through prolonged or repeated exposure if swallowed.

Precautionary statements Prevention:

P260 Do not breathe vapours.



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P264 Wash skin thoroughly after handling.

P270 Do not eat, drink or smoke when using this product.

Response:

P301 + P312 + P330 IF SWALLOWED: Call a POISON CENTER/ doctor if you feel unwell. Rinse mouth.

P308 + P311 IF exposed or concerned: Call a POISON

CENTER/ doctor.

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)
Ivermectin	70288-86-7	>= 1 -< 10
Aluminum tristearate	637-12-7	< 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, remove to fresh air. If inhaled

Get medical attention if symptoms occur. Wash with water and soap as a precaution.

In case of skin contact

Get medical attention if symptoms occur. Flush eyes with water as a precaution.

In case of eye contact Get medical attention if irritation develops and persists.

If swallowed If swallowed, DO NOT induce vomiting unless directed to do

so by medical personnel. Get medical attention.

Rinse mouth thoroughly with water.

Never give anything by mouth to an unconscious person.

Most important symptoms

and effects, both acute and

delayed

May cause damage to organs if swallowed.

May cause damage to organs through prolonged or repeated

exposure if swallowed.

Harmful if swallowed.

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

and use the recommended personal protective equipment when the potential for exposure exists (see section 8).



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Notes to physician Treat symptomatically and supportively.

SECTION 5. FIREFIGHTING MEASURES

Suitable extinguishing media Water spray

> Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing

None known.

Specific hazards during fire-

fiahtina

Exposure to combustion products may be a hazard to health.

Hazardous combustion prod: :

ucts

Carbon oxides Metal oxides

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances and the surrounding environment. Use water spray to cool unopened containers.

Remove undamaged containers from fire area if it is safe to do

SO.

Evacuate area.

Special protective equipment

for firefighters

In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

Hazchem Code •3Z

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protec- :

tive equipment and emer-

gency procedures

Use personal protective equipment.

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

tective equipment recommendations (see section 8).

Environmental precautions Avoid release to the environment.

Prevent further leakage or spillage if safe to do so.

Prevent spreading over a wide area (e.g. by containment or oil

barriers).

Retain and dispose of contaminated wash water.

Local authorities should be advised if significant spillages

cannot be contained.

Methods and materials for containment and cleaning up Soak up with inert absorbent material.

For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absor-

bent.

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.



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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 vapours.

Do not swallow.

Avoid contact with 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 as-

sessment

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.

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	
Ivermectin	70288-86-7	TWA	30 μg/m3 (OEB 3)	Internal	
	Further information: Skin				
		Wipe limit	300 µg/100 cm2	Internal	
Aluminum tristearate	637-12-7	TWA	10 mg/m3	AU OEL	
		TWA (Inhal- able particu- late matter)	10 mg/m3	ACGIH	
		TWA (Respirable particulate matter)	3 mg/m3	ACGIH	
		TWA (Res-	1 mg/m3	ACGIH	



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	pirable par- ticulate mat- ter)	(Aluminium)	
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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.

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 con-

tainment devices). Minimize open handling.

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. Combined particulates and organic vapour type

Filter type Hand protection

la protoction

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, dis-

posable suits) to avoid exposed skin surfaces.

Use appropriate degowning techniques to remove potentially

contaminated clothing.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : gel

Colour : off-white

Odour : characteristic

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

170 °C

Flash point : 237.2 °C

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 : 0.93 - 0.95

Density : No data available

Solubility(ies)

Water solubility : practically insoluble

Partition coefficient: n-

octanol/water

Not applicable

Auto-ignition temperature : No data available

Decomposition temperature : No data available

Viscosity

Viscosity, dynamic : 382 - 384 mPa.s (25 °C)

Viscosity, kinematic : No data available

Explosive properties : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

Molecular weight : No data available

Particle characteristics

Particle size : Not applicable



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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 reac- : Can react with strong oxidizing agents.

tions

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

Incompatible materials : Oxidizing agents
Hazardous decomposition : No hazardous decomposition products are known.

products

SECTION 11. TOXICOLOGICAL INFORMATION

Exposure routes : Inhalation

Skin contact Ingestion Eye contact

Acute toxicity

Harmful if swallowed.

Product:

Acute oral toxicity : Acute toxicity estimate: 1,511 mg/kg

Method: Calculation method

Acute dermal toxicity : Acute toxicity estimate: > 2,000 mg/kg

Method: Calculation method

Components:

Ivermectin:

Acute oral toxicity : LD50 (Rat): 50 mg/kg

LD50 (Mouse): 25 mg/kg

LD50 (Monkey): > 24 mg/kg

Target Organs: Central nervous system Symptoms: Vomiting, Dilatation of the pupil Remarks: No mortality observed at this dose.

Acute inhalation toxicity : LC50 (Rat): 5.11 mg/l

Exposure time: 1 h

Test atmosphere: dust/mist

Acute dermal toxicity : LD50 (Rabbit): 406 mg/kg

LD50 (Rat): > 660 mg/kg

Aluminum tristearate:

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

Remarks: Based on data from similar materials



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Acute inhalation toxicity : LC50 (Rat): > 5.15 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist

Method: OECD Test Guideline 403

Remarks: Based on data from similar materials

Skin corrosion/irritation

Not classified based on available information.

Components:

Ivermectin:

Species : Rabbit

Result : No skin irritation

Aluminum tristearate:

Species : reconstructed human epidermis (RhE)

Method : OECD Test Guideline 439

Remarks : Based on data from similar materials

Result : No skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

Components:

Ivermectin:

Species : Rabbit

Result : Mild eye irritation

Aluminum tristearate:

Species : Rabbit

Result : No eye irritation

Method : OECD Test Guideline 405

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:

Ivermectin:

Exposure routes : Dermal



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Species : Humans

Result : Does not cause skin sensitisation.

Aluminum tristearate:

Test Type : Local lymph node assay (LLNA)

Exposure routes : Skin contact Species : Mouse

Method : OECD Test Guideline 429

Result : negative

Remarks : Based on data from similar materials

Chronic toxicity

Germ cell mutagenicity

Not classified based on available information.

Components:

Ivermectin:

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

Result: negative

Test Type: DNA damage and repair, unscheduled DNA syn-

thesis in mammalian cells (in vitro)
Test system: human diploid fibroblasts

Result: negative

Test Type: Mouse Lymphoma

Result: negative

Aluminum tristearate:

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

Method: OECD Test Guideline 476

Result: negative

Remarks: Based on data from similar materials

Test Type: Bacterial reverse mutation assay (AMES)

Method: OECD Test Guideline 471

Result: negative

Remarks: Based on data from similar materials

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo

cytogenetic assay) Species: Rat

Application Route: Ingestion Method: OECD Test Guideline 474

Result: negative

Remarks: Based on data from similar materials



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Carcinogenicity

Not classified based on available information.

Components:

Ivermectin:

Species : Rat Application Route : Oral

NOAEL : 1.5 mg/kg body weight

Result : negative

Remarks : Based on data from similar materials

Species : Mouse Application Route : Oral

NOAEL : 2.0 mg/kg body weight

Result : negative

Remarks : Based on data from similar materials

Reproductive toxicity

Not classified based on available information.

Components:

Ivermectin:

Effects on fertility : Test Type: Fertility

Species: Rat

Application Route: Oral

Fertility: NOAEL: 0.6 mg/kg body weight

Result: Animal testing did not show any effects on fertility.

Effects on foetal develop-

ment

Test Type: Development

Species: Mouse

Application Route: Oral

Developmental Toxicity: NOAEL: 0.2 mg/kg body weight Result: Teratogenic effects, Embryotoxic effects and adverse effects on the offspring were detected only at high maternally

toxic doses

Test Type: Development

Species: Rat

Application Route: Oral

Developmental Toxicity: LOAEL: 0.4 mg/kg body weight Result: Embryotoxic effects and adverse effects on the off-

spring were detected.

Remarks: The mechanism or mode of action may not be rele-

vant in humans.

Test Type: Development

Species: Rabbit Application Route: Oral

Result: Teratogenic effects, Embryotoxic effects and adverse effects on the offspring were detected only at high maternally



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toxic doses

Aluminum tristearate:

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

Species: Rat

Application Route: Ingestion Method: OECD Test Guideline 416

Result: negative

Remarks: Based on data from similar materials

Effects on foetal develop-

ment

Test Type: Fertility/early embryonic development

Species: Rat

Application Route: Ingestion

Result: negative

Remarks: Based on data from similar materials

STOT - single exposure

May cause damage to organs (Central nervous system) if swallowed.

Components:

Ivermectin:

Target Organs : Central nervous system
Assessment : Causes damage to organs.

STOT - repeated exposure

May cause damage to organs (Central nervous system) through prolonged or repeated exposure if swallowed.

Components:

Ivermectin:

Target Organs : Central nervous system

Assessment : Causes damage to organs through prolonged or repeated

exposure.

Repeated dose toxicity

Components:

Ivermectin:

Species : Dog
NOAEL : 0.5 mg/kg
LOAEL : 1 mg/kg
Application Route : Oral
Exposure time : 14 Weeks

Target Organs : Central nervous system

Symptoms : Dilatation of the pupil, Tremors, Lack of coordination, anorexia

Species : Monkey NOAEL : 1.2 mg/kg



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Application Route : Oral Exposure time : 2 Weeks

Remarks : No significant adverse effects were reported

Species : Rat
NOAEL : 0.4 mg/kg
LOAEL : 0.8 mg/kg
Application Route : Oral
Exposure time : 3 Months

Target Organs : spleen, Bone marrow, Kidney

Aluminum tristearate:

Species : Rat

NOAEL : >= 5,000 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:

Ivermectin:

Skin contact : Remarks: Can be absorbed through skin.

Eye contact : Remarks: May irritate eyes.

Ingestion : Symptoms: Drowsiness, Dilatation of the pupil, Tremors, Vom-

iting, anorexia, Lack of coordination

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Ivermectin:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 0.003 mg/l

Exposure time: 96 h

LC50 (Lepomis macrochirus (Bluegill sunfish)): 0.0048 mg/l

Exposure time: 96 h

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 0.000025 mg/l

Exposure time: 48 h

Toxicity to algae/aquatic

plants

EC50 (Pseudokirchneriella subcapitata (green algae)): > 9.1

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201



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NOEC (Pseudokirchneriella subcapitata (green algae)): 9.1

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Aluminum tristearate:

Ecotoxicology Assessment

Acute aquatic toxicity : Toxic effects cannot be excluded

Chronic aquatic toxicity : Toxic effects cannot be excluded

Persistence and degradability

Components:

Ivermectin:

Biodegradability : Result: Not readily biodegradable.

Biodegradation: 50 % Exposure time: 240 d

Bioaccumulative potential

Components:

Ivermectin:

Bioaccumulation : Bioconcentration factor (BCF): 74

Partition coefficient: n-

octanol/water

log Pow: 3.22

Mobility in soil

No data available

Other adverse effects

No data available

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



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UNRTDG

UN number : UN 3082

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.

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.

(Ivermectin)

Class : 9 Packing group : III

Labels : Miscellaneous

Packing instruction (cargo : 964

aircraft)

Packing instruction (passen-

ger aircraft)

Environmentally hazardous : yes

IMDG-Code

UN number : UN 3082

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.

964

(Ivermectin)

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

ADG

UN number : UN 3082

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.

(Ivermectin)

Class : 9
Packing group : III
Labels : 9
Hazchem Code : •3Z
Environmentally hazardous : yes

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

Therapeutic Goods (Poisons:

Standard) Instrument

Schedule 7 (Please use the original publication to check for specific uses, specific conditions or threshold limits that might

apply for this chemical)

Prohibition/Licensing Requirements There is no applicable prohibition,

> authorisation and restricted use requirements, including for carcinogens referred to in Schedule 10 of the model WHS Act and Regula-

tions.

Internal technical data, data from raw material SDSs, OECD

eChem Portal search results and European Chemicals Agen-

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

AICS not determined

DSL not determined

IECSC not determined

SECTION 16: ANY OTHER RELEVANT INFORMATION

Further information

Revision Date 06.04.2024

Sources of key data used to compile the Safety Data

Sheet

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

Date format dd.mm.yyyy

Full text of other abbreviations

ACGIH USA. ACGIH Threshold Limit Values (TLV)

AU OEL Australia. Workplace Exposure Standards for Airborne Con-

taminants.

ACGIH / TWA 8-hour, time-weighted average

AU OEL / TWA 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 con-



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centration; 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.

AU / EN