according to the Globally Harmonized System



Praziquantel Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 19.02.2025

 2.0
 14.04.2025
 11511879-00002
 Date of first issue: 19.02.2025

1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Praziquantel Formulation

Product code : Hadaclean 5%, Hadaclean A

Manufacturer or supplier's details

Company : MSD

Address : Briahnager - Off Pune Nagar Road

Wagholi - Pune - India 412 207

Telephone : +1-908-740-4000

Emergency telephone number : +1-908-423-6000

E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product Restrictions on use : Not applicable

2. HAZARDS IDENTIFICATION

Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

Classification

Not classified as hazardous according to criteria laid down in Part I of Schedule-1.

GHS Classification

Not a hazardous substance or mixture.

GHS label elements

No hazard pictogram, no signal word, no hazard statement(s), no precautionary statement(s) required.

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.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (%	
		w/w)	

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Starch	9005-25-8	>= 50 - < 70
praziquantel	55268-74-1	>= 5 - < 10
Dimethyl octadienol	78-70-6	>= 0.1 - < 0.25
3,7-Dimethyl 2,6-octadienal	5392-40-5	>= 0.1 - < 0.25

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 if symptoms occur.

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.

If in eyes, rinse well with water. In case of eye contact

Get medical attention if irritation develops and persists.

If swallowed, DO NOT induce vomiting. If swallowed

Get medical attention if symptoms occur. Rinse mouth thoroughly with water.

Most important symptoms

and effects, both acute and

delaved Protection of first-aiders Contact with dust can cause mechanical irritation or drying of

the skin.

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

5. FIREFIGHTING 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 prod: :

ucts

Carbon oxides Nitrogen oxides (NOx)

Specific extinguishing methods

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.

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for firefighters

Special protective equipment : In the event of fire, wear self-contained breathing apparatus.

Use personal protective equipment.

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).

Avoid release to the environment. Environmental precautions

> 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 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.

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 Advice on safe handling Use only with adequate ventilation. Do not get on skin or clothing.

Avoid breathing dust, fume, gas, mist, vapours or spray.

Do not swallow.

Avoid contact with eyes.

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.

Keep in properly labelled containers. Conditions for safe storage

Store in accordance with the particular national regulations.

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Materials to avoid : Do not store with the following product types:

Strong oxidizing agents

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Starch	9005-25-8	TWA	10 mg/m3	ACGIH
praziquantel	55268-74-1	TWA	0.5 mg/m3 (OEB 2)	Internal
3,7-Dimethyl 2,6-octadienal	5392-40-5	TWA (Inhalable fraction and vapor)	5 ppm	ACGIH

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.

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.

Contaminated work clothing should not be allowed out of the

workplace.

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.

9. PHYSICAL AND CHEMICAL PROPERTIES

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Appearance : Crystalline solid

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 : Not applicable

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

dling or other means.

Flammability (liquids) : Not applicable

Upper explosion limit / Upper

flammability limit

No data available

Lower explosion limit / Lower

flammability limit

No data available

Vapour pressure : Not applicable

Relative vapour density : Not applicable

Relative density : No data available

Density : No data available

Solubility(ies)

Water solubility : No data available

Partition coefficient: n-

octanol/water

: Not applicable

Auto-ignition temperature : No data available

Decomposition temperature : No data available

Viscosity

Viscosity, kinematic : Not applicable

Explosive properties : Not explosive

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

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Molecular weight : No data available

Particle characteristics

Particle size : No data available

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. Oxidizing agents

Incompatible materials

Hazardous decomposition

products

No hazardous decomposition products are known.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of:

exposure

Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity

Not classified based on available information.

Product:

Acute oral toxicity : Acute toxicity estimate: > 5,000 mg/kg

Method: Calculation method

Components:

Starch:

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

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

praziquantel:

Acute oral toxicity : LD50 (Rat): 2,480 mg/kg

LD50 (Mouse): 2,454 mg/kg

LD50 (Dog): > 200 mg/kg

LD50 (Rabbit): 1,050 mg/kg

Dimethyl octadienol:

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Acute oral toxicity : LD50 (Rat): 2,790 mg/kg

Method: OECD Test Guideline 401

Remarks: The test was conducted equivalent or similar to

guideline

Acute inhalation toxicity : LC50 (Mouse): > 3.2 mg/l

Exposure time: 90 min Test atmosphere: vapour

Remarks: No test guideline followed

Acute dermal toxicity : LD50 (Rabbit): 5,610 mg/kg

Method: OECD Test Guideline 402

Remarks: The test was conducted equivalent or similar to

guideline

3,7-Dimethyl 2,6-octadienal:

Acute oral toxicity : LD50 (Rat, female): 4,895 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 0.68 mg/l

Exposure time: 7 h

Test atmosphere: vapour

Acute dermal toxicity : LD50 (Rabbit): 2,250 mg/kg

Skin corrosion/irritation

Not classified based on available information.

Components:

praziquantel:

Species : Rabbit
Method : Draize Test
Remarks : slight irritation

Dimethyl octadienol:

Species : Rabbit

Method : OECD Test Guideline 404

Result : Skin irritation

Remarks : The test was conducted according to guideline

3,7-Dimethyl 2,6-octadienal:

Species : Rabbit Result : Skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

Components:

Starch:

Species : Rabbit

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Result No eye irritation

praziquantel:

Species Rabbit Method : Draize Test Result : Mild eye irritation

Dimethyl octadienol:

Species : Rabbit

Method : OECD Test Guideline 405

Result : Irritation to eyes, reversing within 21 days

Remarks : The test was conducted equivalent or similar to guideline

3,7-Dimethyl 2,6-octadienal:

Species Rabbit

Result Irritation to eyes, reversing within 21 days

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Components:

Starch:

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

praziquantel:

: Maximisation Test Test Type

Exposure routes Dermal Species : Guinea pig

Not a skin sensitizer. Result

Dimethyl octadienol:

Test Type : Local lymph node assay (LLNA)

: Skin contact Exposure routes

: Mouse Species

Method : OECD Test Guideline 429

Result positive

Remarks The test was conducted according to guideline

Probability or evidence of low to moderate skin sensitisation Assessment

rate in humans

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3,7-Dimethyl 2,6-octadienal:

Test Type : Human repeat insult patch test (HRIPT)

Exposure routes : Skin contact Result : positive

Assessment : Probability or evidence of skin sensitisation in humans

Germ cell mutagenicity

Not classified based on available information.

Components:

Starch:

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

Result: negative

praziquantel:

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

Result: negative

Test Type: Chromosomal aberration Test system: Chinese hamster cells

Result: negative

Genotoxicity in vivo : Test Type: Micronucleus test

Species: Rat Result: negative

Dimethyl octadienol:

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

Method: OECD Test Guideline 471

Result: negative

Remarks: The test was conducted equivalent or similar to

guideline

Test Type: In vitro mammalian cell gene mutation test

Method: OECD Test Guideline 476

Result: negative

Remarks: The test was conducted equivalent or similar to

guideline

Test Type: Chromosome aberration test in vitro

Method: OECD Test Guideline 473

Result: negative

Remarks: The test was conducted equivalent or similar to

guideline

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

cytogenetic assay) Species: Mouse

Application Route: Ingestion

Method: OECD Test Guideline 474

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Result: negative

Remarks: The test was conducted according to guideline

3,7-Dimethyl 2,6-octadienal:

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

Result: negative

Test Type: In vitro mammalian cell gene mutation test

Method: OECD Test Guideline 476

Result: negative

Test Type: Chromosome aberration test in vitro

Result: negative

Test Type: In vitro sister chromatid exchange assay in mam-

malian cells Result: positive

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

cytogenetic assay) Species: Mouse

Application Route: Ingestion

Result: negative

Carcinogenicity

Not classified based on available information.

Components:

praziquantel:

Species : Hamster
Application Route : Oral
Exposure time : 80 weeks

NOAEL : 100 mg/kg body weight

Result : negative

Remarks : No significant adverse effects were reported

Species : Rat
Application Route : Oral
Exposure time : 104 weeks

NOAEL : 250 mg/kg body weight

Result : negative

Remarks : No significant adverse effects were reported

3,7-Dimethyl 2,6-octadienal:

Species : Mouse
Application Route : Ingestion
Exposure time : 104 - 105 weeks

Result : negative

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Reproductive toxicity

Not classified based on available information.

Components:

praziquantel:

Test Type: Fertility Effects on fertility

Species: Rat

Remarks: No significant adverse effects were reported

Test Type: Fertility Species: Mouse

Remarks: No significant adverse effects were reported

Effects on foetal develop-

ment

Test Type: Development

Species: Rat

Remarks: No significant adverse effects were reported

Test Type: Development

Species: Mouse

Remarks: No significant adverse effects were reported

Dimethyl octadienol:

Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Rat

Application Route: Ingestion

Result: negative

Remarks: No test guideline followed

3,7-Dimethyl 2,6-octadienal:

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

Species: Rat

Application Route: Ingestion

Method: OECD Test Guideline 443

Result: negative

Effects on foetal develop-

Species: Rat

ment

Test Type: One-generation reproduction toxicity study

Application Route: Ingestion Method: OECD Test Guideline 443

Result: negative

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

Not classified based on available information.

Repeated dose toxicity

Components:

Starch:

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Species : Rat

NOAEL : >= 2,000 mg/kg
Application Route : Skin contact
Exposure time : 28 Days

Method : OECD Test Guideline 410

praziquantel:

Species : Rat

NOAEL : 1,000 mg/kg

Application Route : Oral

Remarks : No significant adverse effects were reported

 Species
 : Dog

 NOAEL
 : 60 mg/kg

 LOAEL
 : 180 mg/kg

Application Route : Oral

Target Organs : Gastrointestinal tract

Remarks : No significant adverse effects were reported

Dimethyl octadienol:

Species : Rat, male

NOAEL : >= 497.9 mg/kg

Application Route : Ingestion

Exposure time : 96 Days

Method : OECD Test Guideline 408

Remarks : The test was conducted according to guideline

Species : Rat

NOAEL : 250 mg/kg

Application Route : Skin contact

Exposure time : 91 Days

Method : OECD Test Guideline 411

Remarks : The test was conducted equivalent or similar to guideline

3,7-Dimethyl 2,6-octadienal:

Species : Rat, female
LOAEL : 335 mg/kg
Application Route : Ingestion
Exposure time : 14 Weeks

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Components:

praziquantel:

Inhalation : Symptoms: Headache, Tiredness, Dizziness, Gastrointestinal

discomfort, decrease body temperature, Allergic reactions

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12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

praziquantel:

Toxicity to fish : LC50 (Carassius auratus (goldfish)): 29.2 mg/l

Exposure time: 96 hrs

Method: OECD Test Guideline 203

LC50 (Danio rerio (zebra fish)): 31.6 mg/l

Exposure time: 96 hrs

Method: OECD Test Guideline 203

Toxicity to daphnia and other:

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 35 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

Toxicity to microorganisms : EC50 (activated sludge): > 1,000 mg/l

Exposure time: 3 h

Test Type: Respiration inhibition of activated sludge

Method: OECD Test Guideline 209

Dimethyl octadienol:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 27.8 mg/l

Exposure time: 96 h

Method: OECD Test Guideline 203

Remarks: The test was conducted according to guideline

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 59 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

Remarks: The test was conducted according to guideline

Toxicity to algae/aquatic

plants

ErC50 (Desmodesmus subspicatus (green algae)): 156.7

mg/l

Exposure time: 96 h

EC10 (Desmodesmus subspicatus (green algae)): 54.3 mg/l

Exposure time: 96 h

Toxicity to microorganisms : EC10 (activated sludge): > 100 mg/l

Exposure time: 3 h

Method: OECD Test Guideline 209

Remarks: The test was conducted according to guideline

3,7-Dimethyl 2,6-octadienal:

Toxicity to fish : LC50 (Leuciscus idus (Golden orfe)): 6.78 mg/l

Exposure time: 96 h Method: DIN 38412

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aquatic invertebrates

Toxicity to daphnia and other : EC50 (Daphnia magna (Water flea)): 6.8 mg/l

Exposure time: 48 h

Toxicity to algae/aquatic

plants

ErC50 (Desmodesmus subspicatus (green algae)): 103.8

mg/l

Exposure time: 72 h

EC10 (Desmodesmus subspicatus (green algae)): 3 mg/l

Exposure time: 72 h

Toxicity to microorganisms EC50 (activated sludge): 160 mg/l

Exposure time: 30 min

Method: OECD Test Guideline 209

Persistence and degradability

Components:

Dimethyl octadienol:

Biodegradability Result: Readily biodegradable.

> Biodegradation: 64.2 % Exposure time: 28 d

Method: OECD Test Guideline 301D

Remarks: The test was conducted according to guideline

3,7-Dimethyl 2,6-octadienal:

Biodegradability Result: Readily biodegradable.

Biodegradation: > 90 % Exposure time: 28 d

Method: Directive 67/548/EEC Annex V, C.4.D.

Bioaccumulative potential

Components:

praziquantel:

Partition coefficient: n-

log Pow: 2.012

octanol/water

pH: 7

Dimethyl octadienol:

Partition coefficient: n-

log Pow: 2.84

octanol/water

Method: OECD Test Guideline 107

Remarks: The test was conducted equivalent or similar to

guideline

3,7-Dimethyl 2,6-octadienal:

Partition coefficient: n-

octanol/water

log Pow: 2.76

Mobility in soil

No data available

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Other adverse effects

No data available

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.

14. TRANSPORT INFORMATION

International Regulations

UNRTDG

Not regulated as a dangerous good

IATA-DGR

Not regulated as a dangerous good

IMDG-Code

Not regulated as a dangerous good

Transport in bulk according to IMO instruments

Not applicable for product as supplied.

Special precautions for user

Not applicable

15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mix-

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

AICS : not determined

DSL : not determined

IECSC : not determined

16. OTHER INFORMATION

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Further information

Sources of key data used to

compile the Safety Data

eChem Portal search results and European Chemicals Agency, http://echa.europa.eu/

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

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

Internal technical data, data from raw material SDSs, OECD

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Date format : dd.mm.yyyy

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

ACGIH / TWA : 8-hour, 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 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.

IN / EN