

# SAFETY DATA SHEET

according to the Hazardous Products Regulations



## Praziquantel Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/14/2025
3.0	06/18/2025	11511874-00003	Date of first issue: 02/19/2025

### SECTION 1. IDENTIFICATION

Product name : Praziquantel Formulation  
Product code : Hadaclean 5%, Hadaclean A  
Other means of identification : No data available

#### Manufacturer or supplier's details

Company name of supplier : Merck & Co., Inc  
Address : 37 McCarville Street  
Charlottetown, PE C1E 2A7  
Telephone : 908-740-4000  
Emergency telephone : 1-908-423-6000  
E-mail address : EHSDATASTEWARD@merck.com

#### Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product  
Restrictions on use : Not applicable

### SECTION 2. HAZARDS IDENTIFICATION

#### GHS classification in accordance with the Hazardous Products Regulations

Skin sensitization : Category 1

#### GHS label elements

Hazard pictograms :



Signal Word : Warning

Hazard Statements : H317 May cause an allergic skin reaction.

Precautionary Statements :

#### Prevention:

P261 Avoid breathing dust, fume, gas, mist, vapors or spray.  
P272 Contaminated work clothing should not be allowed out of the workplace.  
P280 Wear protective gloves.

#### Response:

P302 + P352 IF ON SKIN: Wash with plenty of water.  
P333 + P313 If skin irritation or rash occurs: Get medical attention.  
P362 + P364 Take off contaminated clothing and wash it before reuse.

#### Disposal:

P501 Dispose of contents and container to an approved waste disposal plant.

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### Other hazards

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	Common Name/Synonym	CAS-No.	Concentration (% w/w)
Starch	Sago starch	9005-25-8	$\geq 30 - < 60$ *
Praziquantel	4H-pyrazino-[2,1-a]-isoquinolin-4-one, 2-(cyclohexylcarbonyl)-1,2,3,6,7,11b-hexahydro-	55268-74-1	$\geq 5 - < 10$ *
3,7-Dimethyl 2,6-octadienal	2,6-Octadienal, 3,7-dimethyl-	5392-40-5	$\geq 0.1 - < 1$ *

\* Actual concentration or concentration range is withheld as a trade secret

## 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 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.

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 if symptoms occur.  
Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and delayed : Contact with dust can cause mechanical irritation or drying of the skin.  
Dust contact with the eyes can lead to mechanical irritation.  
May cause an allergic skin reaction.

Protection of first-aiders : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Notes to physician : Treat symptomatically and supportively.

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### SECTION 5. FIRE-FIGHTING MEASURES

- Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
Dry chemical
- Unsuitable extinguishing media : None known.
- Specific hazards during fire fighting : Exposure to combustion products may be a hazard to health.
- Hazardous combustion products : Carbon oxides  
Nitrogen oxides (NO<sub>x</sub>)
- 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 fire-fighters : In the event of fire, wear self-contained breathing apparatus.  
Use personal protective equipment.

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### SECTION 6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, protective equipment and emergency procedures : Use personal protective equipment.  
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).
- Environmental precautions : Avoid release to the environment.  
Prevent further leakage or spillage if safe to do so.  
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 determine 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 : 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.  
Avoid breathing dust, fume, gas, mist, vapors 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 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.
- Conditions for safe storage : Keep in properly labeled containers.  
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

#### Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Starch	9005-25-8	TWA	10 mg/m <sup>3</sup>	CA AB OEL
		TWA (Total dust)	10 mg/m <sup>3</sup>	CA BC OEL
		TWA (respirable dust fraction)	3 mg/m <sup>3</sup>	CA BC OEL
		TWAEV (total dust)	10 mg/m <sup>3</sup>	CA QC OEL
		TWA	10 mg/m <sup>3</sup>	ACGIH
Praziquantel	55268-74-1	TWA	0.5 mg/m <sup>3</sup> (OEB 2)	Internal
3,7-Dimethyl 2,6-octadienal	5392-40-5	TWAEV (inhalable fraction and vapour)	5 ppm	CA QC OEL
		TWA (Inhalable fraction and vapor)	5 ppm	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 exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

Filter type : Particulates type

Hand protection

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.

## SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	: Crystalline solid
Color	: No data available
Odor	: No data available
Odor 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

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Flammability (solid, gas)	:	May form explosive dust-air mixture during processing, handling 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
Vapor pressure	:	Not applicable
Relative vapor 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
Autoignition 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.
Molecular weight	:	No data available
Particle characteristics 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 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.

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

### SECTION 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: > 2,000 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

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

#### Skin corrosion/irritation

Not classified based on available information.

#### Components:

##### Praziquantel:

Species	:	Rabbit
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Method	: Draize Test
Remarks	: slight irritation

### 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
Result	: No eye irritation

#### Praziquantel:

Species	: Rabbit
Result	: Mild eye irritation
Method	: Draize Test

### 3,7-Dimethyl 2,6-octadienal:

Species	: Rabbit
Result	: Irritation to eyes, reversing within 21 days

### Respiratory or skin sensitization

#### Skin sensitization

May cause an allergic skin reaction.

#### Respiratory sensitization

Not classified based on available information.

### Components:

#### Starch:

Test Type	: Maximization Test
Routes of exposure	: Skin contact
Species	: Guinea pig
Result	: negative

#### Praziquantel:

Test Type	: Maximization Test
Routes of exposure	: Dermal
Species	: Guinea pig
Result	: Not a skin sensitizer.

### 3,7-Dimethyl 2,6-octadienal:

Test Type	: Human repeat insult patch test (HRIPT)
Routes of exposure	: Skin contact



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Result : positive

Assessment : Probability or evidence of skin sensitization 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

#### 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 mammalian 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.

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### 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

### **Reproductive toxicity**

Not classified based on available information.

### Components:

#### **Praziquantel:**

Effects on fertility	: Test Type: Fertility
	Species: Rat
	Remarks: No significant adverse effects were reported
	Test Type: Fertility
	Species: Mouse
	Remarks: No significant adverse effects were reported
Effects on fetal development	: Test Type: Development
	Species: Rat
	Remarks: No significant adverse effects were reported
	Test Type: Development
	Species: Mouse
	Remarks: No significant adverse effects were reported

#### **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

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Effects on fetal development : Test Type: One-generation reproduction toxicity study  
Species: Rat  
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:

Species : Rat  
NOAEL :  $\geq 2,000$  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

##### 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

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II

discomfort, decrease body temperature, Allergic reactions

### SECTION 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

##### **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
Toxicity to daphnia and other aquatic invertebrates	: 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:

##### **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.
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II

### Bioaccumulative potential

#### Components:

##### Praziquantel:

Partition coefficient: n-octanol/water : log Pow: 2.012  
pH: 7

##### 3,7-Dimethyl 2,6-octadienal:

Partition coefficient: n-octanol/water : log Pow: 2.76

#### 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 handling site for recycling or disposal.  
If not otherwise specified: Dispose of as unused product.

## SECTION 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 Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

### Domestic regulation

#### TDG

Not regulated as a dangerous good

### Special precautions for user

Not applicable

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### SECTION 15. REGULATORY INFORMATION

**The ingredients of this product are reported in the following inventories:**

AICS	:	not determined
DSL	:	not determined
IECSC	:	not determined

### SECTION 16. OTHER INFORMATION

#### Full text of other abbreviations

ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)
CA AB OEL	:	Canada. Alberta, Occupational Health and Safety Code (table 2: OEL)
CA BC OEL	:	Canada. British Columbia OEL
CA QC OEL	:	Québec. Regulation respecting occupational health and safety, Schedule 1, Part 1: Permissible exposure values for airborne contaminants
ACGIH / TWA	:	8-hour, time-weighted average
CA AB OEL / TWA	:	8-hour Occupational exposure limit
CA BC OEL / TWA	:	8-hour time weighted average
CA QC OEL / TWAEV	:	Time-weighted average exposure value

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 - Transporta-

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tion 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

Sources of key data used to compile the Material Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

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

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.

CA / Z8