

SAFETY DATA SHEET

according to the Hazardous Products Regulations



Fenbendazole (0.5%) Crumbles Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/30/2023
1.11	09/28/2024	6116954-00012	Date of first issue: 07/17/2020

SECTION 1. IDENTIFICATION

Product name : Fenbendazole (0.5%) Crumbles Formulation
Other means of identification : No data available

Manufacturer or supplier's details

Company name of supplier : Merck & Co., Inc
Address : 126 E. Lincoln Avenue
Rahway, New Jersey U.S.A. 07065
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

Reproductive toxicity : Category 2

GHS label elements

Hazard pictograms :



Signal Word : Warning

Hazard Statements : H361fd Suspected of damaging fertility. Suspected of damaging the unborn child.

Precautionary Statements : **Prevention:**
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P280 Wear protective gloves, protective clothing, eye protection and face protection.
Response:
P308 + P313 IF exposed or concerned: Get medical attention.
Storage:
P405 Store locked up.
Disposal:
P501 Dispose of contents and container to an approved waste disposal plant.

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Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	Common Name/Synonym	CAS-No.	Concentration (% w/w)
Calcium carbonate	Carbonic acid calcium salt	471-34-1	$\geq 1 - < 5$ *
Paraffin oil	No data available	8012-95-1	$\geq 1 - < 5$ *
fenbendazole	No data available	43210-67-9	$\geq 0.1 - < 1$ *

* 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.

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 : Flush eyes with water as a precaution.
Get medical attention if irritation develops and persists.

If swallowed : If swallowed, DO NOT induce vomiting.
Get medical attention.
Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and delayed : Suspected of damaging fertility. 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 (CO₂)
Dry chemical

Unsuitable extinguishing : None known.

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media

Specific hazards during fire fighting : 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 fire-fighters : 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.
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.

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 swallow.
Avoid contact with eyes.
Avoid prolonged or repeated contact with skin.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
Take care to prevent spills, waste and minimize release to the

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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
Calcium carbonate	471-34-1	TWAEV (total dust)	10 mg/m ³	CA QC OEL
		TWA	10 mg/m ³ (Calcium carbonate)	CA AB OEL
		TWA (Total dust)	10 mg/m ³	CA BC OEL
		TWA (respirable dust fraction)	3 mg/m ³	CA BC OEL
		STEL	20 mg/m ³	CA BC OEL
Paraffin oil	8012-95-1	TWA (Mist)	5 mg/m ³	CA AB OEL
		STEL (Mist)	10 mg/m ³	CA AB OEL
		TWAEV (Mist - Inhalable dust)	5 mg/m ³	CA QC OEL
		TWA (Mist)	1 mg/m ³	CA BC OEL
		TWA (Inhalable particulate matter)	5 mg/m ³	ACGIH
fenbendazole	43210-67-9	TWA	100 µg/m ³ (OEB 2)	Internal

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 : Combined particulates and organic vapor type

Hand protection : Chemical-resistant gloves

Material

Eye protection : Wear safety glasses with side shields or goggles.

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Skin and body protection	:	If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.
Hygiene measures	:	Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.
	:	Work uniform or laboratory coat.
	:	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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	pellets
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
Flammability (solid, gas)	:	No data available
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

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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	:	Can react with strong oxidizing agents.
Conditions to avoid	:	None known.
Incompatible materials	:	Oxidizing agents
Hazardous decomposition products	:	No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Skin contact
Ingestion
Eye contact

Acute toxicity

Not classified based on available information.

Components:

Calcium carbonate:

Acute oral toxicity	:	LD50 (Rat): > 2,000 mg/kg Method: OECD Test Guideline 420 Assessment: The substance or mixture has no acute oral toxicity
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Acute inhalation toxicity : LC50 (Rat): > 3 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: OECD Test Guideline 403
Assessment: The substance or mixture has no acute inhalation toxicity

Acute dermal toxicity : LD50 (Rat): > 2,000 mg/kg
Method: OECD Test Guideline 402
Assessment: The substance or mixture has no acute dermal toxicity

Paraffin oil:

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

Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg
Assessment: The substance or mixture has no acute dermal toxicity

fenbendazole:

Acute oral toxicity : LD50 (Rat): > 10,000 mg/kg
LD50 (Mouse): > 10,000 mg/kg

Skin corrosion/irritation

Not classified based on available information.

Components:

Calcium carbonate:

Species : Rabbit
Method : OECD Test Guideline 404
Result : No skin irritation

Paraffin oil:

Species : Rabbit
Result : No skin irritation

fenbendazole:

Species : Rabbit
Result : No skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

Components:

Calcium carbonate:

Species : Rabbit
Result : No eye irritation

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Method : OECD Test Guideline 405

Paraffin oil:

Species : Rabbit
Result : No eye irritation

fenbendazole:

Species : Rabbit
Result : No eye irritation

Respiratory or skin sensitization

Skin sensitization

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Components:

Calcium carbonate:

Test Type : Local lymph node assay (LLNA)
Routes of exposure : Skin contact
Species : Mouse
Method : OECD Test Guideline 429
Result : negative

Germ cell mutagenicity

Not classified based on available information.

Components:

Calcium carbonate:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Method: OECD Test Guideline 471
Result: negative

Test Type: Chromosome aberration test in vitro
Method: OECD Test Guideline 473
Result: negative

Test Type: In vitro mammalian cell gene mutation test
Method: OECD Test Guideline 476
Result: negative

fenbendazole:

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

Test Type: DNA Repair
Result: negative

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Test Type: Chromosomal aberration
Result: negative

Test Type: in vitro test
Test system: mouse lymphoma cells
Metabolic activation: Metabolic activation
Result: equivocal

Carcinogenicity

Not classified based on available information.

Components:

fenbendazole:

Species : Mouse
Application Route : oral (feed)
Exposure time : 2 Years
NOAEL : 405 mg/kg body weight
Result : negative

Species : Rat
Application Route : Oral
Exposure time : 2 Years
NOAEL : 5 mg/kg body weight
Result : negative
Target Organs : Lymph nodes, Liver

Reproductive toxicity

Suspected of damaging fertility. Suspected of damaging the unborn child.

Components:

Calcium carbonate:

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

Effects on fetal development : Test Type: Embryo-fetal development
Species: Rat
Application Route: Ingestion
Method: OECD Test Guideline 414
Result: negative

fenbendazole:

Effects on fertility : Test Type: Three-generation reproduction toxicity study
Species: Rat
Application Route: oral (feed)
General Toxicity Parent: NOAEL: 15 mg/kg body weight
Fertility: LOAEL: 45 mg/kg body weight

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Result: Effects on fertility.

Effects on fetal development : Test Type: Development
Species: Dog, female
Application Route: Oral
Developmental Toxicity: LOAEL: 100 mg/kg body weight
Result: Embryotoxic effects and adverse effects on the offspring were detected., No teratogenic effects.

Test Type: Embryo-fetal development
Species: Rabbit
Application Route: Oral
Developmental Toxicity: NOAEL: 25 mg/kg body weight
Result: Fetotoxicity.

Test Type: Embryo-fetal development
Species: Rabbit
Application Route: Oral
Developmental Toxicity: LOAEL: 63 mg/kg body weight

Test Type: Embryo-fetal development
Species: Rat
Application Route: Oral
Developmental Toxicity: NOAEL: 120 mg/kg body weight
Result: No effects on fetal development.

Reproductive toxicity - Assessment : Some evidence of adverse effects on sexual function and fertility, based on animal experiments., Some evidence of adverse effects on development, based on animal experiments.

STOT-single exposure

Not classified based on available information.

STOT-repeated exposure

Not classified based on available information.

Components:

fenbendazole:

Routes of exposure : Ingestion
Target Organs : Liver, Stomach, Nervous system, Lymph nodes
Assessment : May cause damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Components:

Calcium carbonate:

Species : Rat
NOAEL : > 1,000 mg/kg
Application Route : Ingestion
Exposure time : 28 Days

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Method : OECD Test Guideline 422

Paraffin oil:

Species : Rat, female
LOAEL : 161 mg/kg
Application Route : Ingestion
Exposure time : 90 Days

fenbendazole:

Species : Rat
LOAEL : 500 mg/kg
Application Route : Oral
Exposure time : 2 Weeks
Target Organs : Kidney, Liver

Species : Rat
NOAEL : > 2,500 mg/kg
Application Route : Oral
Exposure time : 30 Days
Remarks : No significant adverse effects were reported

Species : Rat
LOAEL : 1,600 mg/kg
Application Route : Oral
Exposure time : 90 Days
Target Organs : Central nervous system
Symptoms : Tremors

Species : Dog
NOAEL : 4 mg/kg
LOAEL : 8 mg/kg
Exposure time : 6 Months
Target Organs : Stomach, Nervous system, Lymph nodes

Aspiration toxicity

Not classified based on available information.

Components:

Paraffin oil:

The substance or mixture is known to cause human aspiration toxicity hazards or has to be regarded as if it causes a human aspiration toxicity hazard.

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No aspiration toxicity classification

Experience with human exposure

Components:

fenbendazole:

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Ingestion : Symptoms: Rapid respiration, Salivation, anorexia, Diarrhea

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Calcium carbonate:

Toxicity to fish	: LL50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l Exposure time: 96 h Test substance: Water Accommodated Fraction Method: OECD Test Guideline 203
Toxicity to daphnia and other aquatic invertebrates	: EL50 (Daphnia magna (Water flea)): > 100 mg/l Exposure time: 48 h Test substance: Water Accommodated Fraction Method: OECD Test Guideline 202
Toxicity to algae/aquatic plants	: NOELR (Pseudokirchneriella subcapitata (green algae)): 50 mg/l Exposure time: 72 h Test substance: Water Accommodated Fraction Method: OECD Test Guideline 201 EL50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l Exposure time: 72 h Test substance: Water Accommodated Fraction Method: OECD Test Guideline 201
Toxicity to microorganisms	: NOEC: 1,000 mg/l Exposure time: 3 h Method: OECD Test Guideline 209 EC50: > 1,000 mg/l Exposure time: 3 h Method: OECD Test Guideline 209

Paraffin oil:

Toxicity to fish	: LL50 (Scophthalmus maximus (turbot)): > 100 mg/l Exposure time: 96 h Test substance: Water Accommodated Fraction Remarks: Based on data from similar materials
Toxicity to daphnia and other aquatic invertebrates	: EL50 (Acartia tonsa (Calanoid copepod)): > 100 mg/l Exposure time: 48 h Test substance: Water Accommodated Fraction Remarks: Based on data from similar materials
Toxicity to algae/aquatic plants	: EL50 (Skeletonema costatum (marine diatom)): > 100 mg/l Exposure time: 72 h Test substance: Water Accommodated Fraction

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Remarks: Based on data from similar materials

NOELR (Skeletonema costatum (marine diatom)): > 1 mg/l
Exposure time: 72 h
Test substance: Water Accommodated Fraction
Remarks: Based on data from similar materials

fenbendazole:

Toxicity to fish : LC50 (Lepomis macrochirus (Bluegill sunfish)): 0.009 mg/l
Exposure time: 21 d

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 0.0088 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 0.00113 mg/l
Exposure time: 21 Days
Method: OECD Test Guideline 211

Persistence and degradability

No data available

Bioaccumulative potential

Components:

Paraffin oil:

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

fenbendazole:

Partition coefficient: n-octanol/water : log Pow: 3.32

Mobility in soil

Components:

fenbendazole:

Distribution among environmental compartments : log Koc: 3.8 - 4.7
Method: FDA 3.08

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.

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If not otherwise specified: Dispose of as unused product.

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG

UN number	:	UN 3077
Proper shipping name	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (fenbendazole)
Class	:	9
Packing group	:	III
Labels	:	9
Environmentally hazardous	:	yes

IATA-DGR

UN/ID No.	:	UN 3077
Proper shipping name	:	Environmentally hazardous substance, solid, n.o.s. (fenbendazole)
Class	:	9
Packing group	:	III
Labels	:	Miscellaneous
Packing instruction (cargo aircraft)	:	956
Packing instruction (passenger aircraft)	:	956
Environmentally hazardous	:	yes

IMDG-Code

UN number	:	UN 3077
Proper shipping name	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (fenbendazole)
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.

Domestic regulation

TDG

UN number	:	UN 3077
Proper shipping name	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (fenbendazole)
Class	:	9
Packing group	:	III
Labels	:	9
ERG Code	:	171
Marine pollutant	:	yes(fenbendazole)

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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.

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 AB OEL / STEL	: 15-minute occupational exposure limit
CA BC OEL / TWA	: 8-hour time weighted average
CA BC OEL / STEL	: short-term exposure limit
CA QC OEL / TWAEL	: 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

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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

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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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