

Carbimazole Formulation

Version Revision Date: SDS Number: Date of last issue: 06.07.2024 28.09.2024 4098647-00016 Date of first issue: 22.03.2019 6.0

SECTION 1. IDENTIFICATION

Product identifier : Carbimazole Formulation

Other means of identification Vidalta 10 (A010622)

Vidalta 15 (A011752)

VIDALTA 15 MG TABLETS FOR CATS (66165) VIDALTA 10 MG TABLETS FOR CATS (66158)

Manufacturer or supplier's details

Company MSD

Address : Rua Coronel Bento Soares, 530

Cruzeiro - Sao Paulo - Brazil CEP 12730-340

Telephone 908-740-4000

Emergency telephone 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

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification in accordance with ABNT NBR 14725 Standard

Reproductive toxicity : Category 1A

repeated exposure (Dermal)

Specific target organ toxicity - : Category 2 (Thyroid, Adrenal gland, Testis)

Short-term (acute) aquatic

hazard

Category 2

Long-term (chronic) aquatic

hazard

: Category 2

GHS label elements in accordance with ABNT NBR 14725 Standard

Hazard pictograms

Signal Word Danger

Hazard Statements H360 May damage fertility or the unborn child.



Carbimazole Formulation

Version Revision Date: SDS Number: Date of last issue: 06.07.2024 6.0 28.09.2024 4098647-00016 Date of first issue: 22.03.2019

H373 May cause damage to organs (Thyroid, Adrenal gland, Testis) through prolonged or repeated exposure in contact with

skin.

H411 Toxic to aquatic life with long lasting effects.

Precautionary Statements : Prevention:

P201 Obtain special instructions before use.

P260 Do not breathe dust.

P273 Avoid release to the environment.

P280 Wear protective gloves/ protective clothing/ eye protec-

tion/ face protection.

Response:

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

attention.

P391 Collect spillage.

Storage:

P405 Store locked up.

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.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Classification	Concentration (% w/w)
Cellulose	9004-34-6		>= 30 -< 50
Carbimazole	22232-54-8	Repr., 1A STOT RE, (Der- mal)(Thyroid, Adrenal gland, Testis), 2 Aquatic Acute, 1 Aquatic Chronic, 1	>= 10 -< 20
Talc	14807-96-6		>= 1 -< 5

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.



Carbimazole Formulation

Version **Revision Date:** SDS Number: Date of last issue: 06.07.2024 28.09.2024 4098647-00016 Date of first issue: 22.03.2019 6.0

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, DO NOT induce vomiting. If swallowed

Get medical attention.

Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and

Protection of first-aiders

May damage fertility or the unborn child.

May cause damage to organs through prolonged or repeated

exposure in contact with skin.

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).

Treat symptomatically and supportively. Notes to physician

SECTION 5. FIRE-FIGHTING MEASURES

Water spray Suitable extinguishing media :

> Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing

media

delayed

None known.

Specific hazards during fire

fighting

Avoid generating dust; fine dust dispersed in air in sufficient

concentrations, and in the presence of an ignition source is a

potential dust explosion hazard.

Exposure to combustion products may be a hazard to health.

Hazardous combustion prod- :

ucts

Carbon 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 fire-fighters

In the event of fire, wear self-contained breathing apparatus.

Use personal protective equipment.

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 protective equipment recommendations (see section 8).

Environmental precautions Avoid release to the environment.

Prevent further leakage or spillage if safe to do so.



Carbimazole Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.07.2024

 6.0
 28.09.2024
 4098647-00016
 Date of first issue: 22.03.2019

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.

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 : If sufficient ventilation is unavailable, use with local exhaust

ventilation.

Advice on safe handling : Do not get on skin or clothing.

Do not breathe dust. 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

Keep container tightly closed.

Minimize dust generation and accumulation. Keep container closed when not in use. Keep away from heat and sources of ignition.

Take precautionary measures against static discharges. Take care to prevent spills, waste and minimize release to the

environment.

Hygiene measures : If exposure to chemical is likely during typical use, provide eye

flushing systems and safety showers close to the working

place.

When using do not eat, drink or smoke. Wash contaminated clothing before re-use.

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 labeled containers.

Store locked up. Keep tightly closed.



Carbimazole Formulation

Version Revision Date: SDS Number: Date of last issue: 06.07.2024 6.0 28.09.2024 4098647-00016 Date of first issue: 22.03.2019

Store in accordance with the particular national regulations.

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

Strong oxidizing agents

Self-reactive substances and mixtures

Organic peroxides

Explosives

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Cellulose	9004-34-6	TWA	10 mg/m ³	ACGIH
Carbimazole	22232-54-8	TWA	20 μg/m3 (OEB 3)	Internal
		Wipe limit	200 μg/100 cm ²	Internal
Talc	14807-96-6	TWA (Respirable particulate matter)	2 mg/m³	ACGIH

Engineering measures : 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

containment devices).

Minimize open handling.

Personal protective equipment

Respiratory protection : If adequate local exhaust ventilation is not available or

exposure assessment demonstrates exposures outside the

recommended guidelines, use respiratory protection.

Filter type

Particulates type

Hand protection

Material : Chemical-resistant gloves

Remarks : 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,

disposable suits) to avoid exposed skin surfaces.

Use appropriate degowning techniques to remove potentially

contaminated clothing.



Carbimazole Formulation

Version Revision Date: SDS Number: Date of last issue: 06.07.2024 6.0 28.09.2024 4098647-00016 Date of first issue: 22.03.2019

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state : tablet, powder

Color : pink

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 : No data available

Evaporation rate : Not applicable

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



Carbimazole Formulation

Version Revision Date: SDS Number: Date of last issue: 06.07.2024 6.0 28.09.2024 4098647-00016 Date of first issue: 22.03.2019

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 reac-

tions

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.

Oxidizing agents

Incompatible materials

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.

Components:

Cellulose:

Acute oral toxicity : LD50 (Rat): > 5.000 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 5,8 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist

Acute dermal toxicity : LD50 (Rabbit): > 2.000 mg/kg

Carbimazole:

Acute oral toxicity : LD50 (Rat): 2.250 mg/kg

Assessment: The substance or mixture has no acute oral tox-

icity

LD50 (Mouse): 860 mg/kg

Remarks: Based on data from similar materials

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : Remarks: No data available



Carbimazole Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.07.2024

 6.0
 28.09.2024
 4098647-00016
 Date of first issue: 22.03.2019

Talc:

Acute oral toxicity : LD50 (Rat): > 5.000 mg/kg

Remarks: Based on data from similar materials

Skin corrosion/irritation

Not classified based on available information.

Components:

Carbimazole:

Remarks : No data available

Talc:

Species : Rabbit

Result : No skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

Components:

Carbimazole:

Remarks : No data available

Talc:

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:

Carbimazole:

Remarks : No data available

Talc:

Routes of exposure : Skin contact
Species : Humans
Result : negative

Germ cell mutagenicity

Not classified based on available information.

Components:

Cellulose:



Carbimazole Formulation

Version Revision Date: SDS Number: Date of last issue: 06.07.2024 6.0 28.09.2024 4098647-00016 Date of first issue: 22.03.2019

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

Result: negative

Test Type: In vitro mammalian cell gene mutation test

Result: negative

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

cytogenetic assay) Species: Mouse

Application Route: Ingestion

Result: negative

Carbimazole:

Genotoxicity in vitro : Test Type: Chromosome aberration test in vitro

Result: positive

Remarks: Based on data from similar materials

Genotoxicity in vivo : Test Type: Mutagenicity (in vivo mammalian bone-marrow

cytogenetic test, chromosomal analysis)

Species: Mouse

Application Route: Subcutaneous

Result: equivocal

Remarks: Based on data from similar materials

Test Type: Mammalian erythrocyte micronucleus test (in vivo

cytogenetic assay) Species: Mouse

Application Route: Subcutaneous

Result: negative

Remarks: Based on data from similar materials

Talc:

Genotoxicity in vitro : Test Type: DNA damage and repair, unscheduled DNA syn-

thesis in mammalian cells (in vitro)

Result: negative

Genotoxicity in vivo : Test Type: Chromosome aberration test in vitro

Species: Rat

Application Route: Ingestion

Result: negative

Carcinogenicity

Not classified based on available information.

Components:

Cellulose:

Species : Rat

Application Route : Ingestion

Exposure time : 72 weeks

Result : negative



Carbimazole Formulation

Version Revision Date: SDS Number: Date of last issue: 06.07.2024 6.0 28.09.2024 4098647-00016 Date of first issue: 22.03.2019

Carbimazole:

Species : Mouse
Application Route : Oral
Result : positive

Remarks : Based on data from similar materials

Species : Rat
Application Route : Oral
Result : positive

Remarks : Based on data from similar materials

Talc:

Species : Mouse

Application Route : inhalation (dust/mist/fume)

Exposure time : 2 Years
Result : negative

Reproductive toxicity

May damage fertility or the unborn child.

Components:

Cellulose:

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

Species: Rat

Application Route: Ingestion

Result: negative

Effects on fetal development : Test Type: Fertility/early embryonic development

Species: Rat

Application Route: Ingestion

Result: negative

Carbimazole:

Reproductive toxicity - As-

sessment

May damage fertility or the unborn child.

Talc:

Effects on fetal development : Test Type: Embryo-fetal development

Species: Rat

Application Route: Ingestion

Result: negative

STOT-single exposure

Not classified based on available information.

STOT-repeated exposure

May cause damage to organs (Thyroid, Adrenal gland, Testis) through prolonged or repeated exposure in contact with skin.



Carbimazole Formulation

Version **Revision Date:** SDS Number: Date of last issue: 06.07.2024 28.09.2024 4098647-00016 Date of first issue: 22.03.2019 6.0

Components:

Carbimazole:

Routes of exposure Skin contact

Target Organs : Thyroid, Adrenal gland, Testis

Assessment : May cause damage to organs through prolonged or repeated

exposure.

Repeated dose toxicity

Components:

Cellulose:

Species : Rat

NOAEL >= 9.000 mg/kg

: Ingestion Application Route : 90 Days Exposure time

Carbimazole:

Species : Rat LOAEL : 0,5 mg/kg Application Route
Exposure time : Intraperitoneal : 15 Days : Thyroid Target Organs

Species : Rat

Species : Rat
LOAEL : 1,35 mg/k
Application Route : Oral
Exposure time : 8 Weeks : 1,35 mg/kg Target Organs : Thyroid, Testis

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Components:

Carbimazole:

Ingestion Symptoms: Rash, hearing loss, Headache, Nausea, hair loss

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Cellulose:

Toxicity to fish : LC50 (Oryzias latipes (Japanese medaka)): > 100 mg/l

Exposure time: 48 h

Remarks: Based on data from similar materials

Carbimazole:



Carbimazole Formulation

Version Revision Date: SDS Number: Date of last issue: 06.07.2024 28.09.2024 4098647-00016 Date of first issue: 22.03.2019 6.0

LC50 (Pimephales promelas (fathead minnow)): > 120 mg/l Toxicity to fish

Exposure time: 96 h

Method: OECD Test Guideline 203

Remarks: Based on data from similar materials

Toxicity to daphnia and other:

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 0,43 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

Remarks: Based on data from similar materials

LC50 (Americamysis): 2,1 mg/l

Exposure time: 96 h

Remarks: Based on data from similar materials

Toxicity to algae/aquatic

plants

EC50 (Pseudokirchneriella subcapitata (green algae)): > 100

mg/l

Exposure time: 72 h

Remarks: Based on data from similar materials

NOEC (Pseudokirchneriella subcapitata (green algae)): 25

mg/l

: 1

Exposure time: 72 h

Remarks: Based on data from similar materials

M-Factor (Acute aquatic tox-

M-Factor (Chronic aquatic

toxicity)

Toxicity to microorganisms

: EC50: > 1.000 mg/l Exposure time: 3 h

Test Type: Respiration inhibition

Remarks: Based on data from similar materials

NOEC: > 1.000 mg/l Exposure time: 3 h

Test Type: Respiration inhibition

Remarks: Based on data from similar materials

Talc:

Toxicity to fish : LC50 (Brachydanio rerio (zebrafish)): > 100.000 mg/l

Exposure time: 24 h

Persistence and degradability

Components:

Cellulose:

Biodegradability : Result: Readily biodegradable.

Bioaccumulative potential

No data available



Carbimazole Formulation

Version Revision Date: SDS Number: Date of last issue: 06.07.2024 6.0 28.09.2024 4098647-00016 Date of first issue: 22.03.2019

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

UN number : UN 3077

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S.

(Carbimazole)

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.

(Carbimazole)

Class : 9 Packing group : III

Labels : Miscellaneous

Packing instruction (cargo : 956

aircraft)

Packing instruction (passen: 956

ger aircraft)

Environmentally hazardous : yes

IMDG-Code

UN number : UN 3077

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S.

(Carbimazole)

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.



Carbimazole Formulation

Version Revision Date: SDS Number: Date of last issue: 06.07.2024 6.0 28.09.2024 4098647-00016 Date of first issue: 22.03.2019

Domestic regulation

ANTT

UN number : UN 3077

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S.

(Carbimazole)

Class : 9
Packing group : III
Labels : 9
Hazard Identification Number : 90

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

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

National List of Carcinogenic Agents for Humans - : Not applicable

(LINACH)

Brazil. List of chemicals controlled by the Federal : Not applicable

Police

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

AICS : not determined

DSL : not determined

IECSC : not determined

SECTION 16. OTHER INFORMATION

Revision Date : 28.09.2024 Date format : dd.mm.yyyy

Further information

Sources of key data used to compile the Material Safety

Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen-

Data 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.

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

ACGIH / TWA : 8-hour, time-weighted average



Carbimazole Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.07.2024

 6.0
 28.09.2024
 4098647-00016
 Date of first issue: 22.03.2019

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.

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