

Vorinostat Formulation

Version 5.1 Revision Date: 30.09.2023 SDS Number: 44842-00021 Date of last issue: 04.04.2023
Date of first issue: 06.01.2015

SECTION 1. IDENTIFICATION

Product name : Vorinostat Formulation

Manufacturer or supplier's details

Company : MSD

Address : Talcahuano 750, 6th floor, Ciudad Autonoma
Buenos Aires, Argentina C1013AAP

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 : Pharmaceutical

Restrictions on use : Not applicable

SECTION 2. HAZARDS IDENTIFICATION**GHS Classification**

Acute toxicity (Oral) : Category 5

Germ cell mutagenicity : Category 2

Reproductive toxicity : Category 1B

Specific target organ toxicity - repeated exposure (Oral) : Category 1 (Blood, thymus gland, Bone marrow, spleen, Gastrointestinal tract)

Short-term (acute) aquatic hazard : Category 1

Long-term (chronic) aquatic hazard : Category 1

GHS label elements

Hazard pictograms :



Signal Word : Danger

Hazard Statements : H303 May be harmful if swallowed.
H341 Suspected of causing genetic defects.

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H360FD May damage fertility. May damage the unborn child.
 H372 Causes damage to organs (Blood, thymus gland, Bone marrow, spleen, Gastrointestinal tract) through prolonged or repeated exposure if swallowed.
 H410 Very toxic to aquatic life with long lasting effects.

Precautionary Statements

: **Prevention:**
 P201 Obtain special instructions before use.
 P202 Do not handle until all safety precautions have been read and understood.
 P260 Do not breathe dust.
 P264 Wash skin thoroughly after handling.
 P270 Do not eat, drink or smoke when using this product.
 P273 Avoid release to the environment.
 P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:
 P312 Call a POISON CENTER/ doctor if you feel unwell.
 P391 Collect spillage.

Storage:
 P405 Store locked up.

Disposal:
 P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards which do not result in classification

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.	Concentration (% w/w)
Vorinostat	149647-78-9	>= 50 -< 70
Cellulose	9004-34-6	>= 20 -< 30

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.

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- 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.
Rinse mouth thoroughly with water.
- Most important symptoms and effects, both acute and delayed : May be harmful if swallowed.
Suspected of causing genetic defects.
May damage fertility. May damage the unborn child.
Causes damage to organs through prolonged or repeated exposure if swallowed.
Contact with dust can cause mechanical irritation or drying of the skin.
- Protection of first-aiders : 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.
-

SECTION 5. FIRE-FIGHTING MEASURES

- Suitable extinguishing media : Water spray
Alcohol-resistant foam
Carbon dioxide (CO₂)
Dry chemical
- Unsuitable extinguishing media : 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 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.

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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.
Wash skin thoroughly after handling.
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.
Do not eat, drink or smoke when using this product.
Take care to prevent spills, waste and minimize release to the environment.

Conditions for safe storage : Keep in properly labeled containers.
Store locked up.
Keep tightly closed.
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
Gases

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SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION**Ingredients with workplace control parameters**

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Vorinostat	149647-78-9	TWA	5 µg/m ³	Internal
		Wipe limit	50 µg/100 cm ²	Internal
Cellulose	9004-34-6	CMP	10 mg/m ³	AR OEL
		TWA	10 mg/m ³	ACGIH

Engineering measures : Minimize workplace exposure concentrations.
 Apply measures to prevent dust explosions.
 Ensure that dust-handling systems (such as exhaust ducts, dust collectors, vessels, and processing equipment) are designed in a manner to prevent the escape of dust into the work area (i.e., there is no leakage from the equipment).
 If sufficient ventilation is unavailable, use with local exhaust ventilation.

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 : Choose gloves to protect hands against chemicals depending on the concentration specific to place of work. Breakthrough time is not determined for the product. Change gloves often!
 For special applications, we recommend clarifying the resistance to chemicals of the aforementioned protective gloves with the glove manufacturer. Wash hands before breaks and at the end of workday.

Eye protection : Wear the following personal protective equipment:
 Safety goggles

Skin and body protection : Select appropriate protective clothing based on chemical resistance data and an assessment of the local exposure potential.
 Skin contact must be avoided by using impervious protective clothing (gloves, aprons, boots, etc).

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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

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Appearance	:	powder
Color	:	No data available
Odor	:	odorless
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	:	No data available
Flammability (solid, gas)	:	May form explosive dust-air mixture during processing, handling or other means.
Flammability (liquids)	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapor pressure	:	No data available
Relative vapor density	:	No data available
Density	:	No data available
Solubility(ies) Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	No data available
Autoignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity Viscosity, dynamic	:	No data available
Viscosity, kinematic	:	No data available
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 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- : May form explosive dust-air mixture during processing,
tions : handling or other means.
Can react with strong oxidizing agents.
Conditions to avoid : Heat, flames and sparks.
Avoid dust formation.
Incompatible materials : Oxidizing agents
Hazardous decomposition : No hazardous decomposition products are known.
products

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of : Inhalation
exposure : Skin contact
 : Ingestion
 : Eye contact

Acute toxicity

May be harmful if swallowed.

Product:

Acute oral toxicity : Acute toxicity estimate: 3.788 mg/kg
Method: Calculation method

Components:**Vorinostat:**

Acute oral toxicity : LD50 (Mouse): > 2.000 mg/kg
LD50 (Rat): > 750 mg/kg

Acute toxicity (other routes of : LDLo (Mouse): 1.250 mg/kg
administration) : Application Route: Intravenous
Exposure time: 4 h

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

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Skin corrosion/irritation

Not classified based on available information.

Components:**Vorinostat:**

Species : Rabbit
Result : No skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

Components:**Vorinostat:**

Species : Bovine cornea
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:**Vorinostat:**

Test Type : Local lymph node assay (LLNA)
Routes of exposure : Skin contact
Species : Mouse
Result : Not a skin sensitizer.

Germ cell mutagenicity

Suspected of causing genetic defects.

Components:**Vorinostat:**

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

Test Type: Chromosome aberration test in vitro
Test system: Chinese hamster ovary cells
Result: positive

Test Type: Chromosome aberration test in vitro
Test system: Human lymphocytes
Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: Oral

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Result: positive

Germ cell mutagenicity - Assessment : Positive result(s) from in vivo mammalian somatic cell mutagenicity tests.

Cellulose:

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

Carcinogenicity

Not classified based on available information.

Components:**Cellulose:**

Species : Rat
 Application Route : Ingestion
 Exposure time : 72 weeks
 Result : negative

Reproductive toxicity

May damage fertility. May damage the unborn child.

Components:**Vorinostat:**

Effects on fertility : Test Type: Fertility/early embryonic development
 Species: Rat, female
 Application Route: Oral
 Fertility: LOAEL: 15 mg/kg body weight
 Result: Preimplantation loss., Increased resorptions.

Test Type: Fertility/early embryonic development
 Species: Rat, male
 Application Route: Oral
 Fertility: NOAEL: 150 mg/kg body weight
 Result: No effects on fertility.

Effects on fetal development : Test Type: Embryo-fetal development
 Species: Rat
 Application Route: Oral
 Developmental Toxicity: LOAEL: 50 mg/kg body weight
 Result: positive

Test Type: Embryo-fetal development

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Species: Rat
 Application Route: Oral
 Developmental Toxicity: NOAEL: 15 mg/kg body weight
 Result: positive

Test Type: Embryo-fetal development
 Species: Rabbit
 Application Route: Oral
 Developmental Toxicity: LOAEL: 150 mg/kg body weight
 Result: Embryotoxic effects.

Test Type: Embryo-fetal development
 Species: Rabbit
 Application Route: Oral
 Developmental Toxicity: NOAEL: 50 mg/kg body weight
 Result: Embryotoxic effects.

Test Type: Embryo-fetal development
 Species: Rabbit
 Application Route: Oral
 Developmental Toxicity: LOAEL: 15 mg/kg body weight
 Result: Malformations were observed.

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

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

STOT-single exposure

Not classified based on available information.

STOT-repeated exposure

Causes damage to organs (Blood, thymus gland, Bone marrow, spleen, Gastrointestinal tract) through prolonged or repeated exposure if swallowed.

Components:**Vorinostat:**

Routes of exposure : Ingestion
 Target Organs : Blood, thymus gland, Bone marrow, spleen, Gastrointestinal tract
 Assessment : Causes damage to organs through prolonged or repeated exposure.

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Repeated dose toxicity**Components:****Vorinostat:**

Species : Rat
LOAEL : 20 mg/kg
Application Route : Oral
Exposure time : 6 Months
Target Organs : Blood, thymus gland, Bone marrow, spleen

Species : Dog
NOAEL : 60 mg/kg
LOAEL : 160 mg/kg
Application Route : Oral
Exposure time : 6 Months
Target Organs : Gastrointestinal tract

Species : Dog
NOAEL : 40 mg/kg
LOAEL : 100 mg/kg
Application Route : Oral
Exposure time : 4 Weeks
Target Organs : Blood

Cellulose:

Species : Rat
NOAEL : ≥ 9.000 mg/kg
Application Route : Ingestion
Exposure time : 90 Days

Aspiration toxicity

Not classified based on available information.

Experience with human exposure**Components:****Vorinostat:**

Ingestion : Symptoms: Diarrhea, Fatigue, Nausea, anorexia

SECTION 12. ECOLOGICAL INFORMATION**Ecotoxicity****Components:****Vorinostat:**

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): > 10 mg/l
Exposure time: 96 h

LC50 (Cyprinodon variegatus (sheepshead minnow)): > 10 mg/l

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- Exposure time: 96 h
- Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 10 mg/l
 Exposure time: 48 h
- EC50 (Americamysis): 7,4 mg/l
 Exposure time: 96 h
- Toxicity to algae/aquatic plants : EC50 (Pseudokirchneriella subcapitata (green algae)): 0,183 mg/l
 Exposure time: 96 h
 Method: OECD Test Guideline 201
- NOEC (Pseudokirchneriella subcapitata (green algae)): 0,011 mg/l
 Exposure time: 96 h
 Method: OECD Test Guideline 201
- M-Factor (Acute aquatic toxicity) : 1
- Toxicity to fish (Chronic toxicity) : NOEC (Pimephales promelas (fathead minnow)): 1,5 mg/l
 Exposure time: 33 d
 Method: OECD Test Guideline 210
- Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 0,15 mg/l
 Exposure time: 21 d
 Method: OECD Test Guideline 211
- M-Factor (Chronic aquatic toxicity) : 1
- Toxicity to microorganisms : EC50: > 1.000 mg/l
 Exposure time: 3 h
 Test Type: Respiration inhibition

Cellulose:

- Toxicity to fish : LC50 (Oryzias latipes (Japanese medaka)): > 100 mg/l
 Exposure time: 48 h
 Remarks: Based on data from similar materials

Persistence and degradability**Components:****Vorinostat:**

- Biodegradability : Result: Not readily biodegradable.
 Biodegradation: 39,5 %
 Exposure time: 28 d
 Method: OECD Test Guideline 314

Cellulose:

- Biodegradability : Result: Readily biodegradable.

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Bioaccumulative potential**Components:****Vorinostat:**

Partition coefficient: n-
octanol/water : log Pow: 1,42

Mobility in soil**Components:****Vorinostat:**

Distribution among environ-
mental compartments : log Koc: 3,37

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.
(Vorinostat)

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.
(Vorinostat)

Class : 9

Packing group : III

Labels : Miscellaneous

Packing instruction (cargo : 956
aircraft)

Packing instruction (passen- : 956
ger aircraft)

Environmentally hazardous : yes

IMDG-Code

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

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**

Argentina. Carcinogenic Substances and Agents Registry. : Not applicable

Control of precursors and essential chemicals for the preparation of drugs. : Not applicable

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

AICS : not determined

DSL : not determined

IECSC : not determined

SECTION 16. OTHER INFORMATIONRevision Date : 30.09.2023
Date format : dd.mm.yyyy**Further information**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/>**Full text of other abbreviations**

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

AR OEL : Argentina. Occupational Exposure Limits

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

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AR OEL / CMP : TLV (Threshold Limit 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; KECl - 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; TECl - 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.

AR / Z8