

## Vaniprevir Formulation

Version 6.0      Revision Date: 04.04.2023      SDS Number: 25767-00021      Date of last issue: 01.10.2022  
Date of first issue: 27.10.2014

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**SECTION 1. IDENTIFICATION**

Product name : Vaniprevir 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

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**SECTION 2. HAZARDS IDENTIFICATION****GHS Classification**

Specific target organ toxicity - repeated exposure (Oral) : Category 2 (gallbladder, Liver)

Short-term (acute) aquatic hazard : Category 3

**GHS label elements**

Hazard pictograms :



Signal Word : Warning

Hazard Statements : H373 May cause damage to organs (gallbladder, Liver) through prolonged or repeated exposure if swallowed.  
H402 Harmful to aquatic life.

Precautionary Statements : **Prevention:**  
P260 Do not breathe dust.  
P273 Avoid release to the environment.  
**Response:**  
P314 Get medical advice/ attention if you feel unwell.

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**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)
Glycerides, C8-10	85409-09-2	>= 50 -< 70
Vaniprevir	923590-37-8	>= 10 -< 20

**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 : Wash with water and soap.  
 Get medical attention if symptoms occur.

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 damage to organs through prolonged or repeated exposure if swallowed.

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 (CO<sub>2</sub>)  
 Dry chemical

Unsuitable extinguishing media : None known.

Specific hazards during fire : Avoid generating dust; fine dust dispersed in air in sufficient

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- fighting 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
- 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 breathe dust. Do not swallow. Avoid contact with eyes. Avoid prolonged or repeated contact with skin. Handle in accordance with good industrial hygiene and safety

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- 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
Vaniprevir	923590-37-8	TWA	300 µg/m <sup>3</sup>	Internal

- Engineering measures** : Ensure adequate ventilation, especially in confined areas.  
 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).

## 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 : Skin should be washed after contact.
- Hygiene measures : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.

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

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**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

Appearance	:	powder
Color	:	tan
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	:	1 g/cm <sup>3</sup>
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

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Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
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 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.
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
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#### Acute toxicity

Not classified based on available information.

#### Components:

##### **Glycerides, C8-10:**

Acute oral toxicity	:	LD50 (Rat): > 5.000 mg/kg Method: OECD Test Guideline 401 Remarks: Based on data from similar materials
Acute inhalation toxicity	:	LD50 (Rat): > 1,86 mg/l Exposure time: 6 h Test atmosphere: dust/mist Remarks: Based on data from similar materials
Acute dermal toxicity	:	LD50 (Rat): > 2.000 mg/kg Method: OECD Test Guideline 402 Assessment: The substance or mixture has no acute dermal toxicity Remarks: Based on data from similar materials

##### **Vaniprevir:**

Acute oral toxicity	:	LD50 (Rat): > 750 mg/kg Remarks: No adverse effect has been observed in acute tox-
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icity tests.

LD0 (Dog): > 300 mg/kg

Remarks: No adverse effect has been observed in acute toxicity tests.

LD50 (Mouse): > 2.000 mg/kg

Remarks: No mortality observed at this dose.

**Skin corrosion/irritation**

Not classified based on available information.

**Components:****Glycerides, C8-10:**

Species : Rabbit  
Method : OECD Test Guideline 404  
Result : No skin irritation  
Remarks : Based on data from similar materials

**Vaniprevir:**

Species : Rabbit  
Result : No skin irritation

**Serious eye damage/eye irritation**

Not classified based on available information.

**Components:****Glycerides, C8-10:**

Species : Rabbit  
Result : No eye irritation  
Method : OECD Test Guideline 405  
Remarks : Based on data from similar materials

**Vaniprevir:**

Species : Bovine cornea  
Result : Mild eye irritation  
Method : Bovine cornea (BCOP)

**Respiratory or skin sensitization****Skin sensitization**

Not classified based on available information.

**Respiratory sensitization**

Not classified based on available information.

**Components:****Glycerides, C8-10:**

Test Type : Buehler Test  
Routes of exposure : Skin contact

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Species : Guinea pig  
Method : OECD Test Guideline 406  
Result : negative  
Remarks : Based on data from similar materials

**Vaniprevir:**

Test Type : Local lymph node assay (LLNA)  
Species : Mouse  
Result : negative

**Germ cell mutagenicity**

Not classified based on available information.

**Components:****Glycerides, C8-10:**

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Method: OECD Test Guideline 471  
Result: negative  
Remarks: Based on data from similar materials

Test Type: Chromosome aberration test in vitro  
Method: OECD Test Guideline 473  
Result: negative  
Remarks: Based on data from similar materials

Test Type: In vitro mammalian cell gene mutation test  
Method: OECD Test Guideline 476  
Result: negative  
Remarks: Based on data from similar materials

**Vaniprevir:**

Genotoxicity in vitro : Test Type: Chromosomal aberration  
Test system: Chinese hamster ovary cells  
Result: negative

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

Test Type: Alkaline elution assay  
Test system: rat hepatocytes  
Result: negative

Genotoxicity in vivo : Test Type: Micronucleus test  
Species: Mouse  
Application Route: Oral  
Result: negative

**Carcinogenicity**

Not classified based on available information.



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**Components:****Vaniprevir:**

Species : Rat, male and female  
 Application Route : Oral  
 Activity duration : 104 Weeks  
 :  $\geq$  120 mg/kg body weight  
 Result : negative

Species : Mouse  
 Application Route : Oral  
 Activity duration : 6 Months  
 :  $\geq$  300 mg/kg body weight  
 : 75 mg/kg body weight  
 Result : negative  
 Target Organs : gallbladder

**Reproductive toxicity**

Not classified based on available information.

**Components:****Glycerides, C8-10:**

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  
 Remarks: Based on data from similar materials

Effects on fetal development : 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  
 Remarks: Based on data from similar materials

**Vaniprevir:**

Effects on fertility : Test Type: Fertility/early embryonic development  
 Species: Rat, male and female  
 Application Route: Oral  
 General Toxicity Parent: NOAEL:  $\geq$  250 mg/kg body weight  
 Result: No effects on fertility.

Effects on fetal development : Test Type: Development  
 Species: Rat, female  
 Application Route: Oral  
 General Toxicity Maternal: NOAEL: 120 mg/kg body weight  
 Developmental Toxicity: LOAEC F1: 180 mg/kg body weight  
 Symptoms: No specific developmental abnormalities.  
 Result: negative

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Test Type: Development  
 Species: Rabbit, female  
 Application Route: Oral  
 General Toxicity Maternal: NOAEL: 120 mg/kg body weight  
 Developmental Toxicity: NOAEL F1:  $\geq$  240 mg/kg body weight  
 Symptoms: No specific developmental abnormalities.  
 Result: negative

**STOT-single exposure**

Not classified based on available information.

**STOT-repeated exposure**

May cause damage to organs (gallbladder, Liver) through prolonged or repeated exposure if swallowed.

**Components:****Vaniprevir:**

Routes of exposure : Ingestion  
 Target Organs : gallbladder, Liver  
 Assessment : May cause damage to organs through prolonged or repeated exposure.

**Repeated dose toxicity****Components:****Glycerides, C8-10:**

Species : Rat  
 NOAEL :  $\geq$  1.000 mg/kg  
 Application Route : Ingestion  
 Exposure time : 28 Days  
 Method : OECD Test Guideline 407  
 Remarks : Based on data from similar materials

**Vaniprevir:**

Species : Rat  
 NOAEL : 120 mg/kg  
 LOAEL : 360 mg/kg  
 Application Route : Oral  
 Exposure time : 6 Months  
 Target Organs : Liver

Species : Dog  
 NOAEL : 15 mg/kg  
 LOAEL : 30 mg/kg  
 Application Route : Oral  
 Exposure time : 9 Months  
 Target Organs : Liver, gallbladder  
 Symptoms : Gastrointestinal disturbance

Species : Mouse  
 NOAEL : 150 mg/kg

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LOAEL : 300 mg/kg  
 Application Route : Oral  
 Exposure time : 90 d  
 Target Organs : Liver, Kidney, Gastrointestinal tract, Heart, gallbladder, Stomach

**Aspiration toxicity**

Not classified based on available information.

**Experience with human exposure****Components:****Vaniprevir:**

Ingestion : Symptoms: stomach discomfort, Diarrhea, Nausea, Headache

**SECTION 12. ECOLOGICAL INFORMATION****Ecotoxicity****Components:****Glycerides, C8-10:**

Toxicity to fish : LL50 (Danio rerio (zebra fish)): > 10 - 100 mg/l  
 Exposure time: 96 h  
 Test substance: Water Accommodated Fraction  
 Method: OECD Test Guideline 203  
 Remarks: Based on data from similar materials

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  
 Remarks: Based on data from similar materials

Toxicity to algae/aquatic plants : NOEC (Desmodesmus subspicatus (green algae)): > 1 mg/l  
 Exposure time: 72 h  
 Test substance: Water Accommodated Fraction  
 Method: OECD Test Guideline 201  
 Remarks: Based on data from similar materials

EL50 (Desmodesmus subspicatus (green algae)): > 10 - 100 mg/l  
 Exposure time: 72 h  
 Test substance: Water Accommodated Fraction  
 Method: OECD Test Guideline 201  
 Remarks: Based on data from similar materials

**Vaniprevir:**

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 4 mg/l  
 Exposure time: 48 h  
 Method: OECD Test Guideline 202  
 Remarks: No toxicity at the limit of solubility.

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		LC50 (Americamysis): > 4 mg/l Exposure time: 96 h Method: US-EPA OPPTS 850.1035 Remarks: No toxicity at the limit of solubility.
Toxicity to algae/aquatic plants	:	EC50 (Pseudokirchneriella subcapitata (green algae)): > 4 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 Remarks: No toxicity at the limit of solubility.
		NOEC (Pseudokirchneriella subcapitata (green algae)): 4 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 Remarks: No toxicity at the limit of solubility.
Toxicity to microorganisms	:	EC50: > 1.000 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209
		NOEC: 1.000 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209

**Persistence and degradability****Components:****Glycerides, C8-10:**

Biodegradability	:	Result: Readily biodegradable. Remarks: Based on data from similar materials
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**Vaniprevir:**

Biodegradability	:	Result: not rapidly degradable Method: OECD Test Guideline 314
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**Bioaccumulative potential****Components:****Glycerides, C8-10:**

Partition coefficient: n-octanol/water	:	log Pow: < 4
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**Vaniprevir:**

Partition coefficient: n-octanol/water	:	log Pow: 4,12
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**Mobility in soil**

No data available

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**Other adverse effects**

No data available

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**SECTION 13. DISPOSAL CONSIDERATIONS****Disposal methods**

- Waste from residues : Dispose of in accordance with local regulations.  
Do not dispose of waste into sewer.
- 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.
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**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.

**Special precautions for user**

Not applicable

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**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

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**SECTION 16. OTHER INFORMATION**

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Date format : dd.mm.yyyy

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**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/>

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**

AIIIC - 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; 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.

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