



Version Revision Date: SDS Number: Date of last issue: 2024/04/06 3.0 2024/07/06 529961-00024 Date of first issue: 2016/02/23

## 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Elbasvir Formulation

Manufacturer or supplier's details

Company : MSD

Address : 126 E. Lincoln Avenue

Rahway, New Jersey U.S.A. 07065

Telephone : 908-740-4000

Emergency telephone number : 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

#### 2. HAZARDS IDENTIFICATION

**GHS Classification** 

Long-term (chronic) aquatic

hazard

Category 1

**GHS** label elements

Hazard pictograms :

¥2>

Signal word : Warning

Hazard statements : H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements : Prevention:

P273 Avoid release to the environment.

Response:

P391 Collect spillage.

Disposal:

P501 Dispose of contents/ container to an approved waste

disposal plant.





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#### 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.

#### 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture Mixture

#### Components

Chemical name	CAS-No.	Concentration (% w/w)	
Cellulose	9004-34-6	>= 10 -< 30	
Elbasvir	1370468-36-2	>= 2.5 -< 10	
Titanium dioxide	13463-67-7	< 1	

## 4. FIRST AID MEASURES

General advice In the case of accident or if you feel unwell, seek medical ad-

vice 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 Wash with water and soap.

Get medical attention if symptoms occur.

If in eyes, rinse well with water. In case of eye contact

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

Protection of first-aiders

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).

Notes to physician Treat symptomatically and supportively.

#### 5. FIREFIGHTING 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 prod- : Carbon oxides





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ucts Metal oxides

Chlorine compounds

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 firefighters

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

Use personal protective equipment.

## 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emer-

gency procedures

Use personal protective equipment.

Follow safe handling advice (see section 7) and personal pro-

tective 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 con-

tainer 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 deter-

mine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

#### 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 Advice on safe handling Use only with adequate ventilation.

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 practice, based on the results of the workplace exposure as-





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sessment

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 labelled containers.

Store in accordance with the particular national regulations.

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

Strong oxidizing agents

#### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis	
Cellulose	9004-34-6	NAB	10 mg/m3	ID OEL	
		TWA	10 mg/m3	ACGIH	
Elbasvir	1370468-36- 2	TWA	150 μg/m3 (OEB 2)	Internal	
Titanium dioxide	13463-67-7	NAB	10 mg/m3	ID OEL	
	enough data to	Further information: Not classified as carcinogenic to humans. Not enough data to classify these materials as carcinogenic to humans or animals			

**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 expo-

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection.

Filter type Particulates type

Hand protection

Material Chemical-resistant gloves

Eye protection Wear safety glasses with side shields or goggles.

If the work environment or activity involves dusty conditions,

mists or aerosols, wear the appropriate goggles.

Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or

aerosols.

Skin and body protection

Work uniform or laboratory coat.

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

eye flushing systems and safety showers close to the work-





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ing 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.

#### 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : powder

Colour : brown

Odour : odourless

Odour 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) : May form explosive dust-air mixture during processing, han-

dling 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

Vapour pressure : Not applicable

Relative vapour density : Not applicable

Relative density : No data available

Density : No data available

Solubility(ies)

Water solubility : No data available

Partition coefficient: n- : Not applicable





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octanol/water

Auto-ignition 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.

Particle characteristics

Particle size : No data available

## 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, han-

dling or other means.

Can react with strong oxidizing agents.

Conditions to avoid : Heat, flames and sparks.

Avoid dust formation.

Incompatible materials

Hazardous decomposition

products

Oxidizing agents

No hazardous decomposition products are known.

# 11. TOXICOLOGICAL INFORMATION

Information on likely routes of : Inhalation

exposure 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



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Elbasvir:

Acute oral toxicity : LD50 (Rat): > 2,000 mg/kg

LD50 (Mouse): > 1,000 mg/kg

Titanium dioxide:

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

Acute inhalation toxicity : LC50 (Rat): > 6.82 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist

Assessment: The substance or mixture has no acute inhala-

tion toxicity

Skin corrosion/irritation

Not classified based on available information.

**Components:** 

Elbasvir:

Species : reconstructed human epidermis (RhE)

Result : No skin irritation

Titanium dioxide:

Species : Rabbit

Result : No skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

**Components:** 

Elbasvir:

Species : Bovine cornea Result : No eye irritation

Titanium dioxide:

Species : Rabbit

Result : No eye irritation

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.



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## Components:

Elbasvir:

Test Type : Local lymph node assay (LLNA)

Exposure routes : Dermal Species : Mouse Result : negative

Titanium dioxide:

Test Type : Local lymph node assay (LLNA)

Exposure routes : Skin contact
Species : Mouse
Result : negative

Germ cell mutagenicity

Not classified based on available information.

**Components:** 

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

Elbasvir:

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

Result: negative

Test Type: Chromosome aberration test in vitro

Result: negative

Genotoxicity in vivo : Test Type: In vivo micronucleus test

Species: Rat

Application Route: Oral

Result: negative

Germ cell mutagenicity -

Weight of evidence does not support classification as a germ

cell mutagen.

Titanium dioxide:

Assessment

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

Result: negative



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Genotoxicity in vivo : Test Type: In vivo micronucleus test

Species: Mouse Result: negative

## Carcinogenicity

Not classified based on available information.

## **Components:**

#### Cellulose:

Species : Rat

Application Route : Ingestion

Exposure time : 72 weeks

Result : negative

#### Titanium dioxide:

Species : Rat

Application Route : inhalation (dust/mist/fume)

Exposure time : 2 Years

Method : OECD Test Guideline 453

Result : positive

Remarks : The mechanism or mode of action may not be relevant in hu-

mans

Carcinogenicity - Assess-

ment

Limited evidence of carcinogenicity in inhalation studies with

animals.

## Reproductive toxicity

Not classified based on available information.

#### **Components:**

#### Cellulose:

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

Species: Rat

Application Route: Ingestion

Result: negative

Effects on foetal develop-

ment

: Test Type: Fertility/early embryonic development

Species: Rat

Application Route: Ingestion

Result: negative

#### Elbasvir:

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

Species: Rat, male and female

Application Route: Oral

Fertility: NOAEL: 1,000 mg/kg body weight

Result: No effects on fertility





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Effects on foetal develop: Test Type: Embryo-foetal development

ment Species: Rat

Application Route: Oral

Developmental Toxicity: NOAEL: 1,000 mg/kg body weight

Result: No effects on early embryonic development

Test Type: Embryo-foetal development

Species: Rabbit Application Route: Oral

Developmental Toxicity: NOAEL: 1,000 mg/kg body weight

Result: No effects on early embryonic development

## STOT - single exposure

Not classified based on available information.

## STOT - repeated exposure

Not classified based on available information.

#### Repeated dose toxicity

# **Components:**

## Cellulose:

Species : Rat

NOAEL : >= 9,000 mg/kg
Application Route : Ingestion
Exposure time : 90 Days

## Elbasvir:

Species : Rat

NOAEL : 1,000 mg/kg

Application Route : Oral Exposure time : 180 d

Remarks : No significant adverse effects were reported

Species : Dog

NOAEL : 1,000 mg/kg

Application Route : Oral Exposure time : 270 d

Remarks : No significant adverse effects were reported

#### Titanium dioxide:

Species : Rat

NOAEL : 24,000 mg/kg
Application Route : Ingestion
Exposure time : 28 Days

Species : Rat NOAEL : 10 mg/m3

Application Route : inhalation (dust/mist/fume)



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Exposure time : 2 yr

**Aspiration toxicity** 

Not classified based on available information.

**Experience with human exposure** 

**Components:** 

Elbasvir:

Ingestion : Symptoms: Headache, Abdominal pain, constipation, Nausea,

Fatigue, muscle pain, joint pain, Dizziness, Cough, Skin irrita-

tion, rhinitis, Drowsiness, nasal congestion

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

Elbasvir:

Toxicity to fish : LC50 (Lepomis macrochirus (Bluegill sunfish)): > 10 mg/l

Exposure time: 96 h

Method: OECD Test Guideline 203

Remarks: No toxicity at the limit of solubility

LC50 (Menidia beryllina (Silverside)): > 10 mg/l

Exposure time: 96 h

Remarks: No toxicity at the limit of solubility

Toxicity to daphnia and other:

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): > 10 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

Remarks: No toxicity at the limit of solubility

LC50 (Americamysis): 7.7 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 (algae)): > 0.081 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Remarks: No toxicity at the limit of solubility

NOEC (Pseudokirchneriella subcapitata (green algae)): 0.081





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mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Remarks: No toxicity at the limit of solubility

Toxicity to fish (Chronic tox-

icity)

NOEC (Pimephales promelas (fathead minnow)): 0.0023 mg/l

Exposure time: 32 d

Method: OECD Test Guideline 210

Toxicity to daphnia and other :

aquatic invertebrates (Chron-

ic toxicity)

NOEC (Daphnia magna (Water flea)): 0.84 mg/l

Exposure time: 21 d

Method: OECD Test Guideline 211

Remarks: No toxicity at the limit of solubility

M-Factor (Chronic aquatic

toxicity)

10

Toxicity to microorganisms : EC50: > 1,000 mg/l

Exposure time: 3 h

Test Type: Respiration inhibition Method: OECD Test Guideline 209

NOEC: 271.9 mg/l Exposure time: 3 h

Test Type: Respiration inhibition Method: OECD Test Guideline 209

Titanium dioxide:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l

Exposure time: 96 h

Method: OECD Test Guideline 203

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): > 100 mg/l

Exposure time: 48 h

Toxicity to algae/aquatic

plants

EC50 (Skeletonema costatum (marine diatom)): > 10,000 mg/l

Exposure time: 72 h

Toxicity to microorganisms : EC50: > 1,000 mg/l

Exposure time: 3 h

Method: OECD Test Guideline 209

Persistence and degradability

Components:

Cellulose:

Biodegradability : Result: Readily biodegradable.

Elbasvir:

Biodegradability : Result: Not readily biodegradable.

Biodegradation: 37 %





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Exposure time: 28 d

**Bioaccumulative potential** 

**Components:** 

Elbasvir:

Bioaccumulation : Species: Lepomis macrochirus (Bluegill sunfish)

Bioconcentration factor (BCF): 82 Method: OECD Test Guideline 305

Partition coefficient: n-

octanol/water

log Pow: 6.54

Mobility in soil

**Components:** 

Elbasvir:

Distribution among environ-

mental compartments

: log Koc: 5.24

Other adverse effects

No data available

#### 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 han-

dling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

# 14. TRANSPORT INFORMATION

## International Regulations

**UNRTDG** 

UN number : UN 3077

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S.

(Elbasvir)

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.

(Elbasvir)

Class : 9



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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.

(Elbasvir)

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.

#### 15. REGULATORY INFORMATION

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

Minister of Industry Regulation No. 23/M-IND/PER/4/2013 concerning the Revision of Minister of Industry Regulation No. 87/M-IND/PER/9/2009 concerning Globally Harmonized System of Classification and Labelling of Chemicals.

# Regulation of the Minister of Health No. 472 of 1996 on the Safeguarding of Substances Hazardous to Health

Hazardous substances that must be registered : Not applicable

# Government Regulation No. 74 of 2001 on the Management of Hazardous and Toxic Substances

Hazardous substances approved for use : Not applicable

Prohibited substances : Not applicable

Restricted substances : Not applicable

# Regulation of the Ministry of Trade No. 7 of 2022 on Distribution and Control of Hazardous Materials

Type of hazardous materials subject to distribution and : Not applicable





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control, Annex I

Type of hazardous materials subject to distribution and : Not applicable

control. Annex II

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

AICS : not determined

DSL : not determined

IECSC : not determined

#### 16. OTHER INFORMATION

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**Further information** 

Sources of key data used to compile the Safety Data Sheet

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

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.

Date format : yyyy/mm/dd

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
ID OEL : Indonesia. Occupational Exposure Limits

ACGIH / TWA : 8-hour, time-weighted average ID OEL / NAB : Long term exposure limit

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

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.

ID / EN