

# **Rizatriptan Orally Disintegrating Formulation**

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Version **Revision Date:** SDS Number: Date of last issue: 23.03.2020 10.10.2020 809073-00010 Date of first issue: 22.07.2016 1.9

**Section 1: Identification** 

Product name Rizatriptan Orally Disintegrating Formulation

Manufacturer or supplier's details

Company : Organon & Co.

Address 30 Hudson Street, 33nd floor

Jersey City, New Jersey, U.S.A 07302

Telephone 551-430-6000

Emergency telephone number : 215-631-6999

E-mail address EHSSTEWARD@organon.com

Recommended use of the chemical and restrictions on use

Recommended use Pharmaceutical

## **Section 2: Hazard identification**

**GHS Classification** 

Skin sensitisation Category 1

Specific target organ toxicity - : Category 2 (Cardio-vascular system)

repeated exposure (Oral)

**GHS** label elements

Hazard pictograms



Signal word

Hazard statements H317 May cause an allergic skin reaction.

H373 May cause damage to organs (Cardio-vascular system)

through prolonged or repeated exposure if swallowed.

Precautionary statements Prevention:

P260 Do not breathe dust.

P272 Contaminated work clothing should not be allowed out of

the workplace.

P280 Wear protective gloves.

Response:

P302 + P352 IF ON SKIN: Wash with plenty of soap and water.

P314 Get medical advice/ attention if you feel unwell.

P333 + P313 If skin irritation or rash occurs: Get medical ad-

vice/ attention.

P363 Wash contaminated clothing before reuse.



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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.

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)	
Cellulose	9004-34-6	>= 10 -< 30	
Peppermint oil	8006-90-4	>= 1 -< 10	
Starch	9005-25-8	< 10	
Rizatriptan	145202-66-0	>= 1 -< 3	

#### Section 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 : In case of contact, immediately flush skin with plenty of water.

Remove contaminated clothing and shoes.

Get medical attention.
Wash clothing before reuse.

Thoroughly clean shoes before reuse.

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

Get medical attention if irritation develops and persists.

If swallowed, DO NOT induce vomiting.

Get medical attention.

Rinse mouth thoroughly with water.

May cause an allergic skin reaction.

Most important symptoms and effects, both acute and

delayed

May cause an allergic skin reaction.

May cause damage to organs through prolonged or repeated

exposure if swallowed.

Dust contact with the eyes can lead to mechanical irritation.

Protection of first-aiders : First Aid responders should pay attention to self-protection,

and use the recommended personal protective equipment

when the potential for exposure exists (see section 8).

Notes to physician : Treat symptomatically and supportively.

#### Section 5: Fire-fighting measures

Suitable extinguishing media : Water spray

Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical



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Unsuitable extinguishing

media

Specific hazards during fire-

fighting

: None known.

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

Nitrogen oxides (NOx)

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.

### 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 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.

### 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
Advice on safe handling

Use only with adequate ventilation.

Do not get on skin or clothing.

Do not breathe dust.



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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 as-

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. Do not eat, drink or smoke when using this product.

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.

Contaminated work clothing should not be allowed out of the

workplace.

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 labelled 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

## Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Cellulose	9004-34-6	WES-TWA	10 mg/m3	NZ OEL
		TWA	10 mg/m3	ACGIH
Starch	9005-25-8	WES-TWA	10 mg/m3	NZ OEL
		TWA	10 mg/m3	ACGIH
Rizatriptan	145202-66-0	TWA	10 μg/m3 (OEB 3)	Internal
		Wipe limit	100 μg/100 cm <sup>2</sup>	Internal

**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 con-

tainment devices). Minimize open handling.



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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

Hand protection

Particulates type

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, dis-

posable suits) to avoid exposed skin surfaces.

Use appropriate degowning techniques to remove potentially

contaminated clothing.

### Section 9: Physical and chemical properties

Appearance : powder

Colour : No data available

Odour : No data available

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 : No data available

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



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Vapour pressure : No data available

Relative vapour density : No data available

Relative density : No data available

Density : No data available

Solubility(ies)

Water solubility : No data available

Partition coefficient: n-

octanol/water

Auto-ignition temperature : No data available

Decomposition temperature : No data available

Viscosity

Viscosity, kinematic : No data available

Explosive properties : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

No data available

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-

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 : Oxidizing agents

Hazardous decomposition

products

No hazardous decomposition products are known.

**Section 11: Toxicological information** 

Exposure routes : Inhalation

Skin contact Ingestion Eye contact

**Acute toxicity** 

Not classified based on available information.

**Product:** 

Acute oral toxicity : Acute toxicity estimate: > 2,000 mg/kg



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Method: Calculation method

**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

Peppermint oil:

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

Acute dermal toxicity : LD50 (Rabbit): > 5,000 mg/kg

Starch:

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

Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg

Rizatriptan:

Acute oral toxicity : LD50 (Rat): 2,227 mg/kg

LD50 (Mouse): 700 - 1,631 mg/kg

Skin corrosion/irritation

Not classified based on available information.

**Components:** 

Peppermint oil:

Species : Rabbit Result : Skin irritation

Remarks : Based on data from similar materials

Rizatriptan:

Species : Rabbit

Result : No skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

**Components:** 

Peppermint oil:

Species : Rabbit

Result : Irritation to eyes, reversing within 21 days Remarks : Based on data from similar materials



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Starch:

Species : Rabbit

Result : No eye irritation

Rizatriptan:

Species : Bovine cornea

Remarks : Moderate eye irritation

Respiratory or skin sensitisation

Skin sensitisation

May cause an allergic skin reaction.

**Respiratory sensitisation** 

Not classified based on available information.

**Components:** 

Peppermint oil:

Test Type : Local lymph node assay (LLNA)

Exposure routes : Skin contact

Species : Mouse

Method : OECD Test Guideline 429

Result : positive

Remarks : Based on data from similar materials

Assessment : Probability or evidence of skin sensitisation in humans

Starch:

Test Type : Maximisation Test
Exposure routes : Skin contact
Species : Guinea pig
Result : negative

Rizatriptan:

Test Type : Maximisation Test

Exposure routes : Dermal Species : Guinea pig

Assessment : Does not cause skin sensitisation.

Result : negative

**Chronic toxicity** 

Germ cell mutagenicity

Not classified based on available information.

**Components:** 

Cellulose:

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

Result: negative



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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

Starch:

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

Result: negative

Rizatriptan:

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

Result: negative

Test Type: Alkaline elution assay

Result: negative

Test Type: In vitro mammalian cell gene mutation test

Result: negative

Test Type: Chromosome aberration test in vitro

Result: negative

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

cytogenetic assay) Species: Mouse Application Route: Oral

Result: negative

## Carcinogenicity

Not classified based on available information.

#### Components:

#### Cellulose:

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

Rizatriptan:

Species : Mouse
Application Route : Oral
Exposure time : 100 weeks

NOAEL : 125 mg/kg body weight

Result : negative

Species : Rat



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Application Route : Oral Exposure time : 106 weeks

NOAEL : 106 mg/kg body weight

Result : negative

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

Rizatriptan:

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

Species: Rat, female Application Route: Oral

Fertility: LOAEL: 100 mg/kg body weight

Symptoms: altered estrus cycles

Result: No effects on fertility and early embryonic develop-

ment were detected.

Test Type: Fertility/early embryonic development

Species: Rat, male Application Route: Oral

Fertility: NOAEL: 250 mg/kg body weight

Result: No effects on fertility and early embryonic develop-

ment were detected.

Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Rat

Application Route: Oral

Developmental Toxicity: LOAEL: 10 mg/kg body weight Result: No teratogenic effects, Embryo-foetal toxicity

Test Type: Embryo-foetal development

Species: Rabbit Application Route: Oral

Developmental Toxicity: LOAEL: 100 mg/kg body weight Result: No teratogenic effects, Embryo-foetal toxicity

Remarks: The effects were seen only at maternally toxic dos-

es.

Reproductive toxicity - As-

sessment

Some evidence of adverse effects on development, based on

animal experiments.



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### STOT - single exposure

Not classified based on available information.

### **Components:**

## Rizatriptan:

Assessment : May cause drowsiness or dizziness.

#### STOT - repeated exposure

May cause damage to organs (Cardio-vascular system) through prolonged or repeated exposure if swallowed.

### **Components:**

## Rizatriptan:

Target Organs : Cardio-vascular system

Assessment : Causes damage to organs through prolonged or repeated

exposure.

## Repeated dose toxicity

### **Components:**

## Cellulose:

Species : Rat

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

#### Starch:

Species : Rat

NOAEL : >= 2,000 mg/kg
Application Route : Skin contact
Exposure time : 28 Days

Method : OECD Test Guideline 410

#### Rizatriptan:

Species : Rat
LOAEL : 1 mg/kg
Application Route : Oral
Exposure time : 14 Weeks

Symptoms : Dilatation of the pupil, Increased pulse rate, Redness

Species : Dog
LOAEL : 0.05 mg/kg
Application Route : Intravenous
Exposure time : 2 Weeks

Symptoms : Dilatation of the pupil, Increased pulse rate, Redness

Species: DogLOAEL: 0.2 mg/kgApplication Route: OralExposure time: 1 yr



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Symptoms : Dilatation of the pupil

**Aspiration toxicity** 

Not classified based on available information.

Experience with human exposure

Components:

Rizatriptan:

Ingestion : Target Organs: Cardio-vascular system

Symptoms: asthenia, Fatigue, Pain, Dizziness, Weakness,

**Drowsiness** 

**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

Peppermint oil:

Toxicity to fish : LL50 (Danio rerio (zebra fish)): > 10 - 100 mg/l

Exposure time: 96 h

Remarks: Based on data from similar materials

Toxicity to daphnia and other :

aquatic invertebrates

EL50 (Daphnia magna (Water flea)): > 10 - 100 mg/l

Exposure time: 48 h

Remarks: Based on data from similar materials

Toxicity to algae/aquatic

plants

EL50 (Desmodesmus subspicatus (green algae)): > 10 - 100

mg/l

Exposure time: 72 h

Remarks: Based on data from similar materials

Toxicity to microorganisms : EC10: 51 mg/l

Exposure time: 3 h

Remarks: Based on data from similar materials

Rizatriptan:

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): > 1,000 mg/l

Exposure time: 96 h

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 1,000 mg/l

Exposure time: 48 h

Toxicity to algae/aquatic

plants

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

mg/l

Exposure time: 72 h



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Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 48

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Toxicity to fish (Chronic tox-

icity)

NOEC (Pimephales promelas (fathead minnow)): 9.6 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)): 110 mg/l

Exposure time: 21 d

Method: OECD Test Guideline 211

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:**

Cellulose:

Biodegradability : Result: Readily biodegradable.

Peppermint oil:

Biodegradability : Result: Readily biodegradable.

Remarks: Based on data from similar materials

Rizatriptan:

Biodegradability : Result: Not readily biodegradable.

Biodegradation: 50 % Exposure time: 13 d

Method: OECD Test Guideline 314

#### Bioaccumulative potential

## **Components:**

Peppermint oil:

Partition coefficient: n- : log Pow: > 4

octanol/water Remarks: Based on data from similar materials

Rizatriptan:

Partition coefficient: n- : log Pow: -0.649



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octanol/water

Mobility in soil

**Components:** 

Rizatriptan:

Distribution among environ-

mental compartments

log Koc: 3.83

Method: OECD Test Guideline 106

Other adverse effects

No data available

Section 13: Disposal considerations

**Disposal methods** 

Waste from residues

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.

**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.

**National Regulations** 

NZS 5433

Not regulated as a dangerous good

**Section 15: Regulatory information** 

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

**HSNO Approval Number** 

HSR100425 Pharmaceutical Active Ingredients Group Standard 2017

**HSW Controls** 

Certified handler certificate not required.

Tracking hazardous substance not required.

Refer to the Health and Safety at Work (Hazardous Substances) Regulations 2017, for further information.



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

AICS : not determined

DSL : not determined

IECSC : not determined

#### Section 16: Other information

#### **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/

Date format : dd.mm.yyyy

#### Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

NZ OEL : New Zealand. Workplace Exposure Standards for Atmospher-

ic Contaminants

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

NZ OEL / WES-TWA : Workplace Exposure Standard - Time Weighted average

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; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods;



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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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