# Public



# **Betamethasone Lotion Formulation**

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 10.10.2020

 5.5
 09.04.2021
 1297390-00012
 Date of first issue: 16.02.2017

#### 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Betamethasone Lotion 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

# 2. HAZARDS IDENTIFICATION

# Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

### Classification

Very highly flammable liquids

### **GHS Classification**

Flammable liquids : Category 2

Serious eye damage/eye irri-

tation

Category 2A

Reproductive toxicity : Category 1B

Specific target organ toxicity -

single exposure

Category 3

Specific target organ toxicity - :

repeated exposure

Category 1 (Pituitary gland, Immune system, muscle, thymus

gland, Blood, Adrenal gland)

Long-term (chronic) aquatic

hazard

Category 1

**GHS** label elements

Hazard pictograms







Signal word : Danger

Hazard statements : H225 Highly flammable liquid and vapour.



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H319 Causes serious eye irritation.
H336 May cause drowsiness or dizziness.

H360D May damage the unborn child.

H372 Causes damage to organs (Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland) through prolonged or repeated exposure.

H410 Very toxic to aquatic life with long lasting effects.

#### Precautionary statements

#### Prevention:

P203 Obtain, read and follow all safety instructions before use. P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

P260 Do not breathe mist or vapours.
P264 Wash skin thoroughly after handling.

P270 Do not eat, drink or smoke when using this product.

P271 Use only outdoors or in a well-ventilated area.

P273 Avoid release to the environment.

P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

#### Response:

P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse affected areas with water. P304 + P340 + P319 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Get medical help if you feel unwell.

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P318 IF exposed or concerned, get medical advice. P337 + P317 If eye irritation persists: Get medical help. 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

Vapours may form explosive mixture with air.

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

### Components

Chemical name	CAS-No.	Concentration (% w/w)
Propan-2-ol	67-63-0	>= 30 - < 50
betamethasone	378-44-9	>= 0.025 - < 0.1

### 4. FIRST AID MEASURES



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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 In case of contact, immediately flush eyes with plenty of water

for at least 15 minutes.

If easy to do, remove contact lens, if worn.

Get medical attention.

If swallowed If swallowed, DO NOT induce vomiting.

Get medical attention.

Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and

Causes serious eye irritation. May cause drowsiness or dizziness.

delayed

May damage the unborn child.

Causes damage to organs through prolonged or repeated

exposure.

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).

Treat symptomatically and supportively. Notes to physician

### 5. FIREFIGHTING MEASURES

Suitable extinguishing media Water spray

> Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing

media

High volume water jet

Specific hazards during fire-

fighting

fire.

Flash back possible over considerable distance. Vapours may form explosive mixtures with air.

Exposure to combustion products may be a hazard to health.

Do not use a solid water stream as it may scatter and spread

Hazardous combustion prod: :

ucts

Carbon oxides

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances and the surrounding environment. Use water spray to cool unopened containers.

Remove undamaged containers from fire area if it is safe to do

SO.

Evacuate area.

Special protective equipment :

for firefighters

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

Use personal protective equipment.



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#### **6. ACCIDENTAL RELEASE MEASURES**

Personal precautions, protec- :

tive equipment and emer-

gency procedures

Remove all sources of ignition.

Ventilate the area.

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.

Prevent spreading over a wide area (e.g. by containment or oil

barriers).

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

Non-sparking tools should be used.

Soak up with inert absorbent material.

Suppress (knock down) gases/vapours/mists with a water

spray jet.

For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absor-

bent.

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 : See Engineering measures under EXPOSURE

CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation : If sufficient ventilation is unavailable, use with local exhaust

ventilation.

Use explosion-proof electrical, ventilating and lighting equip-

ment.

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

Do not breathe mist or vapours.

Do not swallow. Do not get in 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

Non-sparking tools should be used. Keep container tightly closed.

Keep away from heat, hot surfaces, sparks, open flames and

other ignition sources. No smoking.

Take precautionary measures against static discharges. Do not eat, drink or smoke when using this product.



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Take care to prevent spills, waste and minimize release to the

environment.

Conditions for safe storage : Keep in properly labelled containers.

Store locked up. Keep tightly closed.

Keep in a cool, well-ventilated place.

Store in accordance with the particular national regulations.

Keep away from heat and sources of ignition.

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

Self-reactive substances and mixtures

Organic peroxides Oxidizing agents Flammable gases Pyrophoric liquids Pyrophoric solids

Self-heating substances and mixtures

Poisonous gases Explosives

#### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Components with workplace control parameters

Components	CAS-No.	Value type	Control parame-	Basis		
		(Form of	ters / Permissible			
		exposure)	concentration			
Propan-2-ol	67-63-0	TWA	200 ppm	ACGIH		
		STEL	400 ppm	ACGIH		
betamethasone	378-44-9	TWA	1 μg/m3 (OEB 4)	Internal		
	Further information: Skin					
		Wipe limit	10 μg/100 cm <sup>2</sup>	Internal		

### **Biological occupational exposure limits**

Components	CAS-No.	Control	Biological	Sam-	Permissible	Basis
		parameters	specimen	pling	concentra-	
				time	tion	
Propan-2-ol	67-63-0	Acetone	Urine	End of	40 mg/l	ACGIH
				shift at		BEI
				end of		
				work-		
				week		

**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.

Essentially no open handling permitted.

Use closed processing systems or containment technologies. If handled in a laboratory, use a properly designed biosafety cabinet, fume hood, or other containment device if the potential exists for aerosolization. If this potential does not exist,

handle over lined trays or benchtops.

Use explosion-proof electrical, ventilating and lighting equipment.



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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

on

Combined particulates and organic vapour type

Material : Chemical-resistant gloves

Remarks : Consider double gloving. Take note that the product is flam-

mable, which may impact the selection of hand protection.

Eye protection : Wear safety glasses with side shields or goggles.

If the work environment or activity involves dusty conditions,

mists or aerosols, wear the appropriate goggles.

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

aerosols.

Skin and body protection : Work uniform or laboratory coat.

Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable

suits) to avoid exposed skin surfaces.

Use appropriate degowning techniques to remove potentially

contaminated clothing.

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

flushing systems and safety showers close to the working

piace.

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 : lotion

Colour : colourless

Odour : No data available

Odour Threshold : No data available

pH : 4.5

Melting point/freezing point : No data available

Initial boiling point and boiling :

range

No data available

Flash point : 21.4 °C

Method: closed cup



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Evaporation rate No data available

Flammability (solid, gas) Not applicable

Flammability (liquids) Not applicable

Upper explosion limit / Upper

flammability limit

No data available

Lower explosion limit / Lower

flammability limit

No data available

Vapour pressure No data available

Relative vapour density No data available

Relative density No data available

No data available Density

Solubility(ies)

Water solubility No data available

Partition coefficient: n-

octanol/water

Not applicable

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.

Particle size Not applicable

#### 10. STABILITY AND REACTIVITY

Not classified as a reactivity hazard. Reactivity Chemical stability Stable under normal conditions.

Possibility of hazardous reac-

tions

Highly flammable liquid and vapour.

Vapours may form explosive mixture with air.

Can react with strong oxidizing agents.

Heat, flames and sparks. Conditions to avoid

Incompatible materials Oxidizing agents

Hazardous decomposition No hazardous decomposition products are known.

products

### 11. TOXICOLOGICAL INFORMATION



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Information on likely routes of:

exposure

Inhalation
Skin contact
Ingestion
Eye contact

**Acute toxicity** 

Not classified based on available information.

**Components:** 

Propan-2-ol:

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

Acute inhalation toxicity : LC50 (Rat): > 25 mg/l

Exposure time: 6 h
Test atmosphere: vapour

betamethasone:

Acute dermal toxicity

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

LD50 (Mouse): > 4,500 mg/kg

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

Acute inhalation toxicity : LC50 (Rat): 0.4 mg/l

Exposure time: 4 h

Skin corrosion/irritation

Not classified based on available information.

**Components:** 

Propan-2-ol:

Species : Rabbit

Result : No skin irritation

betamethasone:

Species : Rabbit

Result : Mild skin irritation

Serious eye damage/eye irritation

Causes serious eye irritation.

**Components:** 

Propan-2-ol:

Species : Rabbit

Result : Irritation to eyes, reversing within 21 days

betamethasone:

Species : Rabbit

Result : No eye irritation



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### Respiratory or skin sensitisation

#### Skin sensitisation

Not classified based on available information.

# **Respiratory sensitisation**

Not classified based on available information.

#### Components:

Propan-2-ol:

Test Type : Buehler Test Exposure routes : Skin contact Species : Guinea pig

Method : OECD Test Guideline 406

Result : negative

betamethasone:

Exposure routes : Dermal Species : Guinea pig Result : Weak sensitizer

### Germ cell mutagenicity

Not classified based on available information.

#### Components:

Propan-2-ol:

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: Intraperitoneal injection

Result: negative

betamethasone:

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

Result: negative

Test Type: In vitro mammalian cell gene mutation test

Result: negative

Test Type: Chromosome aberration test in vitro

Result: positive

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

cytogenetic assay) Species: Mouse Application Route: Oral



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Result: equivocal

Germ cell mutagenicity -

Assessment

Weight of evidence does not support classification as a germ

cell mutagen.

Carcinogenicity

Not classified based on available information.

**Components:** 

Propan-2-ol:

Species : Rat

Application Route : inhalation (vapour)

Exposure time : 104 weeks

Method : OECD Test Guideline 451

Result : negative

Reproductive toxicity

May damage the unborn child.

**Components:** 

Propan-2-ol:

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

Species: Rat

Application Route: Ingestion

Result: negative

Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Rat

Application Route: Ingestion

Result: negative

betamethasone:

Effects on foetal develop-

ment

Species: Rabbit

Application Route: Intramuscular

Developmental Toxicity: LOAEL: 0.05 mg/kg body weight Result: Fetotoxicity, Malformations were observed.

Species: Rat

Application Route: Subcutaneous

Developmental Toxicity: LOAEL: 0.42 mg/kg body weight

Result: Malformations were observed.

Species: Mouse

Application Route: Intramuscular

Developmental Toxicity: LOAEL: 1 mg/kg body weight

Result: Malformations were observed.

Reproductive toxicity - As-

sessment

Clear evidence of adverse effects on development, based on

animal experiments.



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### STOT - single exposure

May cause drowsiness or dizziness.

### **Components:**

### Propan-2-ol:

Assessment : May cause drowsiness or dizziness.

#### STOT - repeated exposure

Causes damage to organs (Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland) through prolonged or repeated exposure.

### **Components:**

#### betamethasone:

Target Organs : Pituitary gland, Immune system, muscle, thymus gland, Blood,

Adrenal gland

Assessment : Causes damage to organs through prolonged or repeated

exposure.

### Repeated dose toxicity

# **Components:**

# Propan-2-ol:

Species : Rat NOAEL : 12.5 mg/l

Application Route : inhalation (vapour)

Exposure time : 104 Weeks

#### betamethasone:

Species : Rabbit
LOAEL : 0.05 %
Application Route : Skin contact
Exposure time : 10 - 30 d

Target Organs : Pituitary gland, Immune system, muscle

Species : Rat
LOAEL : 0.05 %
Application Route : Skin contact
Exposure time : 8 Weeks
Target Organs : thymus gland

Species : Mouse
LOAEL : 0.1 %
Application Route : Skin contact
Exposure time : 8 Weeks
Target Organs : thymus gland

Species : Dog

LOAEL : 0.05 mg/kg

Application Route : Oral Exposure time : 28 d

Target Organs : Blood, thymus gland, Adrenal gland



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**Aspiration toxicity** 

Not classified based on available information.

Experience with human exposure

**Components:** 

betamethasone:

Inhalation : Target Organs: Adrenal gland

Skin contact : Symptoms: Redness, pruritis, Irritation

12. ECOLOGICAL INFORMATION

**Ecotoxicity** 

Components:

Propan-2-ol:

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 9,640 mg/l

Exposure time: 96 h

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): > 10,000 mg/l

Exposure time: 24 h

Toxicity to microorganisms : EC50 (Pseudomonas putida): > 1,050 mg/l

Exposure time: 16 h

betamethasone:

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Americamysis): > 50 mg/l

Exposure time: 96 h

Toxicity to algae/aquatic

plants

EC50 (Pseudokirchneriella subcapitata (green algae)): > 34

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Remarks: No toxicity at the limit of solubility

NOEC (Pseudokirchneriella subcapitata (green algae)): 34

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: 0.052 mg/l Exposure time: 32 d

Species: Pimephales promelas (fathead minnow)

Method: OECD Test Guideline 210

NOEC: 0.07 µg/l Exposure time: 219 d

Species: Oryzias latipes (Japanese medaka)

Method: OECD Test Guideline 229



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Toxicity to daphnia and other : aquatic invertebrates (Chron-

ic toxicity)

NOEC: 8 mg/l Exposure time: 21 d

Species: Daphnia magna (Water flea) Method: OECD Test Guideline 211

M-Factor (Chronic aquatic

toxicity)

: 1,000

#### Persistence and degradability

### **Components:**

Propan-2-ol:

Biodegradability : Result: rapidly degradable

BOD/COD : BOD: 1.19 (BOD5)COD: 2.23BOD/COD: 53 %

#### Bioaccumulative potential

### **Components:**

Propan-2-ol:

Partition coefficient: n-

octanol/water

log Pow: 0.05

betamethasone:

Partition coefficient: n-

octanol/water

log Pow: 2.11

### Mobility in soil

No data available

#### Other adverse effects

No data available

# 13. DISPOSAL CONSIDERATIONS

### **Disposal methods**

Waste from residues Contaminated packaging

: Dispose of in accordance with local regulations.

: Empty containers should be taken to an approved waste han-

dling site for recycling or disposal.

Empty containers retain residue and can be dangerous. Do not pressurize, cut, weld, braze, solder, drill, grind, or expose such containers to heat, flame, sparks, or other sources of ignition. They may explode and cause injury and/or death. If not otherwise specified: Dispose of as unused product.

# 14. TRANSPORT INFORMATION

#### International Regulations

**UNRTDG** 







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UN number : UN 1219

Proper shipping name : ISOPROPANOL SOLUTION

Class : 3
Packing group : II
Labels : 3

**IATA-DGR** 

UN/ID No. : UN 1219

Proper shipping name : Isopropanol solution

Class : 3 Packing group : II

Labels : Flammable Liquids

Packing instruction (cargo :

aircraft)

Packing instruction (passen: 353

ger aircraft)

**IMDG-Code** 

UN number : UN 1219

Proper shipping name : ISOPROPANOL SOLUTION

(betamethasone)

Class : 3
Packing group : II
Labels : 3
EmS Code : F-E, S-D
Marine pollutant : yes

#### Transport in bulk according to IMO instruments

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

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

AICS : not determined

DSL : not determined

IECSC : not determined

# **16. OTHER INFORMATION**

**Further information** 

Sources of key data used to : compile the Safety Data

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



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Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
ACGIH BEI : ACGIH - Biological Exposure Indices (BEI)

ACGIH / TWA : 8-hour, time-weighted average ACGIH / STEL : Short-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 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; 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.

IN / EN