

Betamethasone (0.05%) Lotion Formulation

ORGANON

Version **Revision Date:** SDS Number: Date of last issue: 30.09.2020 09.04.2021 4371262-00006 Date of first issue: 30.05.2019 3.1

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Betamethasone (0.05%) Lotion Formulation

Manufacturer or supplier's details

: Organon & Co. Company

Address Rua Treze de Maio, 1161

Campinas, São Paulo, Brazil B-2220

Telephone 551-430-6000

215-631-6999 Emergency telephone

E-mail address EHSSTEWARD@organon.com

Recommended use of the chemical and restrictions on use

Recommended use Pharmaceutical

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification in accordance with ABNT NBR 14725 Standard

Flammable liquids Category 2

Eye irritation Category 2A

Reproductive toxicity Category 1B

Specific target organ toxicity - :

single exposure

Category 3

repeated exposure

Specific target organ toxicity - : Category 1 (Pituitary gland, Immune system, muscle, thymus

gland, Blood, Adrenal gland)

Long-term (chronic) aquatic

hazard

Category 1

GHS label elements in accordance with ABNT NBR 14725 Standard

Hazard pictograms









Signal Word Danger

Hazard Statements H225 Highly flammable liquid and vapor.

> 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



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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:

P201 Obtain special instructions before use.

P210 Keep away from heat/ sparks/ open flames/ hot surfaces.

No smoking.

P273 Avoid release to the environment.

P280 Wear protective gloves/ protective clothing/ eye protec-

tion/ face protection.

Response:

P308 + P313 IF exposed or concerned: Get medical advice/

attention.

P391 Collect spillage.

Other hazards which do not result in classification

Vapors may form explosive mixture with air.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Classification	Concentration (% w/w)
Propan-2-ol	67-63-0	Flammable liquids, Category 2 Eye irritation, Category 2A Specific target organ toxicity - single expo- sure, Category 3	>= 30 -< 50
Betamethasone	378-44-9	Acute toxicity (Inhalation), Category 2 Reproductive toxicity, Category 1B Specific target organ toxicity - repeated exposure (Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland), Category 1 Long-term (chronic) aquatic hazard, Category 1	>= 0,025 -< 0,1

SECTION 4. FIRST AID MEASURES

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



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advice immediately.

When symptoms persist or in all cases of doubt seek medical

advice.

If inhaled If inhaled, remove to fresh air.

Get medical attention.

In case of skin contact In case of contact, immediately flush skin with 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

delayed

Causes serious eye irritation.

May cause drowsiness or dizziness. 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).

Notes to physician Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media Water spray

> Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing

media

High volume water jet

Specific hazards during fire

fighting

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

Flash back possible over considerable distance.

Vapors may form explosive mixtures with air.

Exposure to combustion products may be a hazard to health.

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 fire-fighters

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

Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES



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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 protective 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/vapors/mists with a water spray

For large spills, provide diking or other appropriate

containment to keep material from spreading. If diked material

can be pumped, store recovered material in appropriate

container.

Clean up remaining materials from spill with suitable

absorbent.

Local or national regulations may apply to releases and disposal of this material, as well as those materials and items

employed in the cleanup of releases. You will need to

determine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

SECTION 7. HANDLING AND STORAGE

Technical measures See Engineering measures under EXPOSURE

CONTROLS/PERSONAL PROTECTION section.

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

ventilation.

Use explosion-proof electrical, ventilating and lighting equip-

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

Do not breathe mist or vapors.

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

assessment

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.

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



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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. 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 labeled 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:

Strong oxidizing agents Organic peroxides Flammable solids Pyrophoric liquids Pyrophoric solids

Self-heating substances and mixtures

Substances and mixtures which in contact with water emit

flammable gases Explosives Gases

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Components	CAS-No.	Value type	Control parame-	Basis	
		(Form of	ters / Permissible		
		exposure)	concentration		
Propan-2-ol	67-63-0	LT	310 ppm	BR OEL	
			765 mg/m ³		
	Further information: Absorption through the skin, Degree of				
	harmfulness: medium				
		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 ²	Internal	

Biological occupational exposure limits

Components	CAS-No.	Control parameters	Biological specimen	Sam- pling time	Permissible concentration	Basis
Propan-2-ol	67-63-0	Acetone	Urine	End of workday at end of	40 mg/l	BR BEI



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		work- week		
Acetone	Urine	End of shift at end of work- week	40 mg/l	ACGIH BEI

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.

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Use explosion-proof electrical, ventilating and lighting

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

Hand protection

Organic vapor Type

Material : Chemical-resistant gloves

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

flammable, 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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : lotion

Color : No data available

Odor : No data available

Odor Threshold : No data available



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pH : No data available

Melting point/freezing point : No data available

Initial boiling point and boiling

range

No data available

Flash point : 21,4 °C

Evaporation rate : No data available

Flammability (solid, gas) : Not applicable

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

Relative density : No data available

Density : No data available

Solubility(ies)

Water solubility : No data available

Partition coefficient: n-

octanol/water

Not applicable

Autoignition 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.

Molecular weight : No data available

Particle size : Not applicable

SECTION 10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.



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Chemical stability : Stable under normal conditions.

Possibility of hazardous reac- : Highly flammable liquid and vapor.

tions

Vapors may form explosive mixture with air. Can react with strong oxidizing agents.

Conditions to avoid : Heat, flames and sparks.

Incompatible materials : Oxidizing agents

Hazardous decomposition : No hazardous dec

products

No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of : Inhalation

exposure 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: vapor

Acute dermal toxicity : LD50 (Rabbit): > 5.000 mg/kg

Betamethasone:

Acute oral toxicity : LD50 (Rat): > 5.000 mg/kg

LD50 (Mouse): > 4.500 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

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Species : Rabbit

Result : Mild skin irritation



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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

Respiratory or skin sensitization

Skin sensitization

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Components:

Propan-2-ol:

Test Type : Buehler Test Routes of exposure : Skin contact Species : Guinea pig

Method : OECD Test Guideline 406

Result : negative

Betamethasone:

Routes of exposure : 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



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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 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 (vapor)

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 fetal development : Test Type: Embryo-fetal development

Species: Rat

Application Route: Ingestion

Result: negative

Betamethasone:

Effects on fetal development : Species: Rabbit

Application Route: Intramuscular

Developmental Toxicity: LOAEL: 0,05 mg/kg body weight Result: Fetotoxicity., Malformations were observed.



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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.

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 (vapor) Exposure time : 104 Weeks

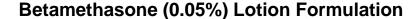
Betamethasone:

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







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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

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

SECTION 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

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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



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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)): 0,052 mg/l

Exposure time: 32 d

Method: OECD Test Guideline 210

NOEC (Oryzias latipes (Japanese medaka)): 0,07 µg/l

Exposure time: 219 d

Method: OECD Test Guideline 229

Toxicity to daphnia and other aquatic invertebrates (Chron-

ic toxicity)

NOEC (Daphnia magna (Water flea)): 8 mg/l

Exposure time: 21 d

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

SECTION 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

handling 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



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sources of ignition. They may explode and cause injury and/or

death.

If not otherwise specified: Dispose of as unused product.

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG

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 : 364

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 Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

Domestic regulation

ANTT

UN number : UN 1219

Proper shipping name : ISOPROPANOL, SOLUTION

Class : 3
Packing group : II
Labels : 3
Hazard Identification Number : 33

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.



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SECTION 15. REGULATORY INFORMATION

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

National List of Carcinogenic Agents for Humans - : Not applicable

(LINACH)

Brazil. List of chemicals controlled by the Federal : Propan-2-ol

Police

International Regulations

The ingredients 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 Material 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/

Full text of other abbreviations

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

BR BEI : Brazil. NR7. Parameters for Biological Control of Occupational

Exposure to Some Chemical Agents

BR OEL : Brazil. NR 15 - Unhealthy activities and operations

ACGIH / TWA : 8-hour, time-weighted average ACGIH / STEL : Short-term exposure limit : Up to 48 hours /week

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 Or-



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ganisation 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.

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