

SAFETY DATA SHEET



Betamethasone / Salicylic Acid Lotion Formulation

Version 5.2 Revision Date: 06.04.2024 SDS Number: 1832950-00018 Date of last issue: 30.09.2023
Date of first issue: 13.07.2017

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Betamethasone / Salicylic Acid Lotion Formulation

Manufacturer or supplier's details

Company name of supplier : Organon & Co.
Address : Avenida 16 de Septiembre No. 301
Xaltocan - Xochimilco Mexico 16090
Telephone : +52 55 57284444
Emergency telephone : 1-215-631-6999
E-mail address : EHSSTEWARD@organon.com

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical
Restrictions on use : Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification

Flammable liquids : Category 2
Skin corrosion/irritation : Category 2
Serious eye damage/eye irritation : 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)

GHS label elements

Hazard pictograms : 

Signal Word : Danger

Hazard Statements : H225 Highly flammable liquid and vapor.
H315 Causes skin irritation.
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.

SAFETY DATA SHEET



Betamethasone / Salicylic Acid Lotion Formulation

Version 5.2 Revision Date: 06.04.2024 SDS Number: 1832950-00018 Date of last issue: 30.09.2023
Date of first issue: 13.07.2017

Precautionary Statements

Prevention:

P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P260 Do not breathe mist or vapors.
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.
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 skin with water.
P304 + P340 + P312 IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. Call a POISON CENTER or doctor/ physician 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.
P308 + P313 IF exposed or concerned: Get medical advice/ attention.
P332 + P313 If skin irritation occurs: Get medical advice/ attention.
P337 + P313 If eye irritation persists: Get medical advice/ attention.
P362 + P364 Take off contaminated clothing and wash it before reuse.

Storage:

P405 Store locked up.

Disposal:

P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards

Vapors may form explosive mixture with air.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Propan-2-ol	67-63-0	>= 30 -< 50
Salicylic acid	69-72-7	>= 1 -< 3
Sodium hydroxide	1310-73-2	>= 0.5 -< 1
Betamethasone	378-44-9	>= 0.01 -< 0.1

SAFETY DATA SHEET



Betamethasone / Salicylic Acid Lotion Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
5.2	06.04.2024	1832950-00018	Date of first issue: 13.07.2017

SECTION 4. FIRST AID MEASURES

- General advice : In the case of accident or if you feel unwell, seek medical advice immediately.
When symptoms persist or in all cases of doubt seek medical advice.
- If inhaled : If inhaled, remove to fresh air.
Get medical attention.
- In case of skin contact : In case of contact, immediately flush skin with plenty of water for at least 15 minutes while removing 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 skin irritation.
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 fire.
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 products : Carbon oxides
- Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Use water spray to cool unopened containers.
Remove undamaged containers from fire area if it is safe to do

SAFETY DATA SHEET



Betamethasone / Salicylic Acid Lotion Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
5.2	06.04.2024	1832950-00018	Date of first issue: 13.07.2017

Special protective equipment for fire-fighters : so.
Evacuate area.
In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency 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 jet.
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.

Local/Total ventilation : If sufficient ventilation is unavailable, use with local exhaust ventilation.
Use explosion-proof electrical, ventilating and lighting equipment.

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

SAFETY DATA SHEET



Betamethasone / Salicylic Acid Lotion Formulation

Version 5.2 Revision Date: 06.04.2024 SDS Number: 1832950-00018 Date of last issue: 30.09.2023
Date of first issue: 13.07.2017

- 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 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
Self-reactive substances and mixtures
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
Very acutely toxic substances and mixtures

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Propan-2-ol	67-63-0	VLE-PPT	200 ppm	NOM-010-STPS-2014
		VLE-CT	400 ppm	NOM-010-STPS-2014
		TWA	200 ppm	ACGIH
		STEL	400 ppm	ACGIH

SAFETY DATA SHEET



Betamethasone / Salicylic Acid Lotion Formulation

Version 5.2 Revision Date: 06.04.2024 SDS Number: 1832950-00018 Date of last issue: 30.09.2023
 Date of first issue: 13.07.2017

Salicylic acid	69-72-7	TWA	100 µg/m ³ (OEB 2)	Internal
Further information: DSEN				
		Wipe limit	100 µg/100 cm ²	Internal
Sodium hydroxide	1310-73-2	VLE-P	2 mg/m ³	NOM-010-STPS-2014
		C	2 mg/m ³	ACGIH
Betamethasone	378-44-9	TWA	1 µg/m ³ (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	Sampling time	Permissible concentration	Basis
Propan-2-ol	67-63-0	Acetone	Urine	End of shift at end of work-week	40 mg/l	MX BEI
		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. 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 : Combined particulates and organic vapor type

Hand protection

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,

SAFETY DATA SHEET



Betamethasone / Salicylic Acid Lotion Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
5.2	06.04.2024	1832950-00018	Date of first issue: 13.07.2017

Skin and body protection : 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.
: 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	: colorless, translucent
Odor	: No data available
Odor Threshold	: No data available
pH	: 4.6 - 5.3
Melting point/freezing point	: No data available
Initial boiling point and boiling range	: No data available
Flash point	: 21.4 - 22.2 °C
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
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

SAFETY DATA SHEET



Betamethasone / Salicylic Acid Lotion Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
5.2	06.04.2024	1832950-00018	Date of first issue: 13.07.2017

Partition coefficient: n-octanol/water	:	No data available
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 characteristics	:	
Particle size	:	No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	Highly flammable liquid and vapor. 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 products	:	No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity

Not classified based on available information.

Product:

Acute oral toxicity	:	Acute toxicity estimate: > 5,000 mg/kg Method: Calculation method
Acute inhalation toxicity	:	Acute toxicity estimate: > 10 mg/l Exposure time: 4 h Test atmosphere: dust/mist Method: Calculation method

SAFETY DATA SHEET



Betamethasone / Salicylic Acid Lotion Formulation

Version 5.2 Revision Date: 06.04.2024 SDS Number: 1832950-00018 Date of last issue: 30.09.2023
Date of first issue: 13.07.2017

Acute dermal toxicity : Acute toxicity estimate: > 5,000 mg/kg
Method: Calculation method

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

Salicylic acid:

Acute oral toxicity : LD50 (Mouse): 480 mg/kg
LD50 (Rat): 891 mg/kg
LD50 (Rabbit): 1,300 mg/kg

Acute inhalation toxicity : LC50 (Rat): 0.9 mg/l
Exposure time: 1 h

Acute dermal toxicity : LD50 (Rat): 2,000 mg/kg
LD50 (Rabbit): 10,000 mg/kg

Sodium hydroxide:

Acute inhalation toxicity : Assessment: Corrosive to the respiratory tract.

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

Causes skin irritation.

Components:

Propan-2-ol:

Species : Rabbit
Result : No skin irritation

Salicylic acid:

Betamethasone / Salicylic Acid Lotion Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
5.2	06.04.2024	1832950-00018	Date of first issue: 13.07.2017

Result : Skin irritation

Sodium hydroxide:

Result : Corrosive after 3 minutes or less of exposure

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

Salicylic acid:

Species : Rabbit
Remarks : Severe eye irritation

Sodium hydroxide:

Result : Irreversible effects on the eye
Remarks : Based on skin corrosivity.

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

Salicylic acid:

Test Type : Local lymph node assay (LLNA)

SAFETY DATA SHEET



Betamethasone / Salicylic Acid Lotion Formulation

Version 5.2 Revision Date: 06.04.2024 SDS Number: 1832950-00018 Date of last issue: 30.09.2023
Date of first issue: 13.07.2017

Species : Mouse
Result : negative

Sodium hydroxide:

Test Type : Human repeat insult patch test (HRIPT)
Routes of exposure : Skin contact
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

Salicylic acid:

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

Genotoxicity in vivo : Test Type: Mammalian bone marrow sister chromatid exchange
Species: Mouse
Application Route: Intraperitoneal injection
Result: negative

Test Type: Sister chromatid exchange analysis in spermatogonia
Species: Mouse
Application Route: Intraperitoneal injection
Result: negative

Betamethasone:

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

Betamethasone / Salicylic Acid Lotion Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
5.2	06.04.2024	1832950-00018	Date of first issue: 13.07.2017

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

Salicylic acid:

Species : Mouse
Application Route : Skin contact
Exposure time : 1 Years
NOAEL : 2 mg/cm²
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

Salicylic acid:

SAFETY DATA SHEET



Betamethasone / Salicylic Acid Lotion Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
5.2	06.04.2024	1832950-00018	Date of first issue: 13.07.2017

Effects on fetal development : Test Type: Embryo-fetal development
Species: Rat
Application Route: Subcutaneous
Developmental Toxicity: LOAEL: 380 mg/kg body weight
Result: Maternal toxicity observed., Embryo-fetal toxicity.

Test Type: Embryo-fetal development
Species: Rat
Application Route: Oral
Developmental Toxicity: NOAEL: 80 mg/kg body weight
Result: No effects on fetal development.

Reproductive toxicity - Assessment : Suspected of damaging the unborn child.

Betamethasone:

Effects on fetal development : 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 - Assessment : 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.

Betamethasone / Salicylic Acid Lotion Formulation

Version 5.2 Revision Date: 06.04.2024 SDS Number: 1832950-00018 Date of last issue: 30.09.2023
Date of first issue: 13.07.2017

Repeated dose toxicity**Components:****Propan-2-ol:**

Species : Rat
NOAEL : 12.5 mg/l
Application Route : inhalation (vapor)
Exposure time : 104 Weeks

Salicylic acid:

Species : Rat
NOAEL : 50 mg/kg
Application Route : Ingestion
Exposure time : 2 y

Species : Rat
LOAEL : 500 mg/kg
Application Route : Oral
Exposure time : 3 d
Target Organs : Liver

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

Aspiration toxicity

Not classified based on available information.

Betamethasone / Salicylic Acid Lotion Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
5.2	06.04.2024	1832950-00018	Date of first issue: 13.07.2017

Experience with human exposure

Components:

Salicylic acid:

Skin contact	:	Symptoms: Skin irritation
Eye contact	:	Symptoms: Severe irritation
Ingestion	:	Symptoms: Gastrointestinal discomfort, hearing loss, Dizziness, electrolyte imbalance

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

Salicylic acid:

Toxicity to fish	:	LC50 (Pimephales promelas (fathead minnow)): 1,380 mg/l Exposure time: 96 h Remarks: Based on data from similar materials
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): 870 mg/l Exposure time: 48 h
Toxicity to algae/aquatic plants	:	EC50 (Desmodesmus subspicatus (green algae)): > 100 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC (Daphnia magna (Water flea)): 10 mg/l Exposure time: 21 d

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

SAFETY DATA SHEET



Betamethasone / Salicylic Acid Lotion Formulation

Version 5.2 Revision Date: 06.04.2024 SDS Number: 1832950-00018 Date of last issue: 30.09.2023
Date of first issue: 13.07.2017

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 toxicity) : 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 (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 8 mg/l
Exposure time: 21 d
Method: OECD Test Guideline 211

Persistence and degradability

Components:

Propan-2-ol:

Biodegradability : Result: rapidly degradable

BOD/COD : BOD: 1,19 (BOD5)
COD: 2,23
BOD/COD: 53 %

Bioaccumulative potential

Components:

Propan-2-ol:

Partition coefficient: n-octanol/water : log Pow: 0.05

Salicylic acid:

Partition coefficient: n-octanol/water : log Pow: 2.25

Betamethasone:

Partition coefficient: n-octanol/water : log Pow: 2.11

Mobility in soil

No data available

Other adverse effects

No data available

Betamethasone / Salicylic Acid Lotion Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
5.2	06.04.2024	1832950-00018	Date of first issue: 13.07.2017

SECTION 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 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 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
Environmentally hazardous : no

IATA-DGR

- UN/ID No. : UN 1219
Proper shipping name : Isopropanol solution
Class : 3
Packing group : II
Labels : Flammable Liquids
Packing instruction (cargo aircraft) : 364
Packing instruction (passenger aircraft) : 353

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

NOM-002-SCT

- UN number : UN 1219

SAFETY DATA SHEET



Betamethasone / Salicylic Acid Lotion Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
5.2	06.04.2024	1832950-00018	Date of first issue: 13.07.2017

Proper shipping name : ISOPROPANOL, SOLUTION
Class : 3
Packing group : II
Labels : 3

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.

SECTION 15. REGULATORY INFORMATION

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

Federal Law for the control of chemical precursors, essential chemical products and machinery for producing capsules, tablets and pills. : Not applicable

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

AICS : not determined
DSL : not determined
IECSC : not determined

SECTION 16. OTHER INFORMATION

Revision Date : 06.04.2024
Date format : dd.mm.yyyy

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
ACGIH BEI : ACGIH - Biological Exposure Indices (BEI)
MX BEI : Official Mexican Norm NOM-047-SSA1-2011, Environmental Health - Biological exposure indices for workers occupationally exposed to chemical agents
NOM-010-STPS-2014 : Mexico. Norm NOM-010-STPS-2014 on Chemicals Polluting the Work Environment - Identification, Assessment and Control - Appendix 1 Occupational Exposure Limits
ACGIH / TWA : 8-hour, time-weighted average
ACGIH / STEL : Short-term exposure limit
ACGIH / C : Ceiling limit
NOM-010-STPS-2014 / VLE- : Time weighted average limit value
PPT
NOM-010-STPS-2014 / VLE- : Short term exposure limit value
CT
NOM-010-STPS-2014 / VLE- : Ceiling value
P

SAFETY DATA SHEET



Betamethasone / Salicylic Acid Lotion Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
5.2	06.04.2024	1832950-00018	Date of first issue: 13.07.2017

AllC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECl - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

Sources of key data used to compile the Material Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

The information is considered as correct, but not exhaustive, and will be used only as a guide, which is based in the current knowledge of the substance or mixture, and is applicable to proper safety precautions for the product.

MX / Z8