

# SAFETY DATA SHEET



## Betamethasone / Salicylic Acid Lotion Formulation



Version 4.5      Revision Date: 04/09/2021      SDS Number: 1832977-00012      Date of last issue: 10/10/2020  
Date of first issue: 07/13/2017

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### SECTION 1. IDENTIFICATION

Product name : Betamethasone / Salicylic Acid Lotion Formulation

#### Manufacturer or supplier's details

Company name of supplier : Organon & Co.  
Address : 30 Hudson Street, 33rd floor  
Jersey City, New Jersey, U.S.A 07302  
Telephone : 551-430-6000  
Emergency telephone : 215-631-6999  
E-mail address : EHSSTEWARD@organon.com

#### Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical

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### SECTION 2. HAZARDS IDENTIFICATION

#### GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

Flammable liquids : Category 2  
Skin irritation : Category 2  
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.

Precautionary Statements : **Prevention:**

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P201 Obtain special instructions before use.  
P202 Do not handle until all safety precautions have been read and understood.  
P210 Keep away from heat, sparks, open flame and hot surfaces. - No smoking.  
P233 Keep container tightly closed.  
P241 Use explosion-proof electrical, ventilating and lighting equipment.  
P242 Use only non-sparking tools.  
P243 Take precautionary measures against static discharge.  
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 and 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 person to fresh air and keep comfortable for breathing. Call a doctor 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 attention.  
P332 + P313 If skin irritation occurs: Get medical attention.  
P337 + P313 If eye irritation persists: Get medical attention.  
P362 + P364 Take off contaminated clothing and wash it before reuse.

**Storage:**

P403 + P235 Store in a well-ventilated place. Keep cool.  
P405 Store locked up.

**Disposal:**

P501 Dispose of contents and 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 - < 5
Sodium hydroxide	1310-73-2	>= 0.5 - < 1
Betamethasone	378-44-9	>= 0.01 - < 0.1

Actual concentration is withheld as a trade secret

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### 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.
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### SECTION 5. FIRE-FIGHTING MEASURES

- Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
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.
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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

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.

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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 environment.

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 (Form of exposure)	Control parameters / Permissible concentration	Basis
Propan-2-ol	67-63-0	TWA	200 ppm	ACGIH
		STEL	400 ppm	ACGIH
		TWA	400 ppm 980 mg/m <sup>3</sup>	NIOSH REL
		ST	500 ppm 1,225 mg/m <sup>3</sup>	NIOSH REL
		TWA	400 ppm 980 mg/m <sup>3</sup>	OSHA Z-1
Salicylic acid	69-72-7	TWA	100 µg/m <sup>3</sup> (OEB 2)	Internal
Further information: DSEN				
		Wipe limit	100 µg/100 cm <sup>2</sup>	Internal
Sodium hydroxide	1310-73-2	C	2 mg/m <sup>3</sup>	ACGIH
		C	2 mg/m <sup>3</sup>	NIOSH REL
		TWA	2 mg/m <sup>3</sup>	OSHA Z-1
Betamethasone	378-44-9	TWA	1 µg/m <sup>3</sup> (OEB 4)	Internal

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Further information: Skin			
	Wipe limit	10 µg/100 cm <sup>2</sup>	Internal

### Biological occupational exposure limits

Components	CAS-No.	Control parameters	Biological specimen	Sam-pling time	Permissible concentra-tion	Basis
Propan-2-ol	67-63-0	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** : General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

### 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, 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

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Hygiene measures : task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.  
Use appropriate degowning techniques to remove potentially contaminated clothing.  
: 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.

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### 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 : 70.5 - 72.0 °F / 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

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Solubility(ies)  
Water solubility : No data available

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 size : No data available

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### 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.

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### 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: 11.25 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist

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Method: Calculation method

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

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### Salicylic acid:

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

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**Salicylic acid:**

Test Type : Local lymph node assay (LLNA)  
 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:**

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- 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

#### Salicylic acid:

- Species : Mouse  
Application Route : Skin contact  
Exposure time : 1 Years  
NOAEL : 2 mg/cm<sup>2</sup>  
Result : negative

**IARC** No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

**OSHA** No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

**NTP** No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

### Reproductive toxicity

May damage the unborn child.

### Components:

#### Propan-2-ol:

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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:

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.

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## 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

#### **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

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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:

##### **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

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## 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	:	NOEC (Daphnia magna (Water flea)): 10 mg/l

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aquatic invertebrates (Chronic toxicity)

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  
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: 2.23BOD/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



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## Betamethasone / Salicylic Acid Lotion Formulation



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octanol/water

### Mobility in soil

No data available

### Other adverse effects

No data available

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## 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 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.

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## 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 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.

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### Domestic regulation

#### 49 CFR

UN/ID/NA number : UN 1219  
Proper shipping name : Isopropanol SOLUTION  
Class : 3  
Packing group : II  
Labels : FLAMMABLE LIQUID  
ERG Code : 129  
Marine pollutant : yes(Betamethasone)

#### 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

### CERCLA Reportable Quantity

Components	CAS-No.	Component RQ (lbs)	Calculated product RQ (lbs)
Sodium hydroxide	1310-73-2	1000	200000

### SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

### SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

**SARA 311/312 Hazards** : Flammable (gases, aerosols, liquids, or solids)  
Reproductive toxicity  
Specific target organ toxicity (single or repeated exposure)  
Skin corrosion or irritation  
Serious eye damage or eye irritation

**SARA 313** : The following components are subject to reporting levels established by SARA Title III, Section 313:

Propan-2-ol      67-63-0      >= 30 - < 50 %

### US State Regulations

#### Pennsylvania Right To Know

Water      7732-18-5  
Propan-2-ol      67-63-0  
Sodium hydroxide      1310-73-2

#### California List of Hazardous Substances

Propan-2-ol      67-63-0  
Salicylic acid      69-72-7

#### California Permissible Exposure Limits for Chemical Contaminants

Propan-2-ol      67-63-0

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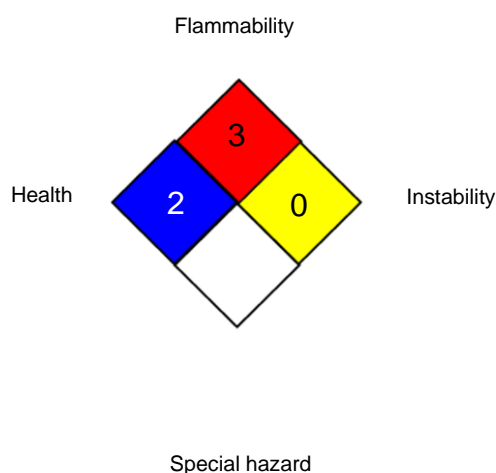
The ingredients of this product are reported in the following inventories:

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

### SECTION 16. OTHER INFORMATION

#### Further information

##### NFPA 704:



##### HMIS® IV:

HEALTH	*	3
FLAMMABILITY		3
PHYSICAL HAZARD		0

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "\*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

#### Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)  
ACGIH BEI : ACGIH - Biological Exposure Indices (BEI)  
NIOSH REL : USA. NIOSH Recommended Exposure Limits  
OSHA Z-1 : USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants  
ACGIH / TWA : 8-hour, time-weighted average  
ACGIH / STEL : Short-term exposure limit  
ACGIH / C : Ceiling limit  
NIOSH REL / TWA : Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek  
NIOSH REL / ST : STEL - 15-minute TWA exposure that should not be exceeded at any time during a workday  
NIOSH REL / C : Ceiling value not be exceeded at any time.  
OSHA Z-1 / TWA : 8-hour time weighted average

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Sub-

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stances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; 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; HMIS - Hazardous Materials Identification System; 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; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance 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

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/>

Revision Date : 04/09/2021

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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