

# SAFETY DATA SHEET



## Betamethasone / Salicylic Acid Lotion Formulation



Version 5.2      Revision Date: 2024/04/06      SDS Number: 1832965-00019      Date of last issue: 2023/09/30  
Date of first issue: 2017/07/13

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### 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Betamethasone / Salicylic Acid Lotion Formulation

#### Manufacturer or supplier's details

Company : Organon & Co.

Address : JL Raya Pandaan KM. 48  
Pandaan, Jawa Timur - Indonesia

Telephone : +1-551-430-6000

Emergency telephone number : +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

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### 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)

Long-term (chronic) aquatic hazard : Category 1

#### GHS label elements

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- Hazard pictograms :    
- Signal word : Danger
- Hazard statements : H225 Highly flammable liquid and vapour.  
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.  
H410 Very toxic to aquatic life with long lasting effects.
- 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/ sparks/ open flames/ hot surfaces. No smoking.  
P233 Keep container tightly closed.  
P241 Use explosion-proof electrical/ ventilating/ lighting equipment.  
P242 Use only non-sparking tools.  
P243 Take precautionary measures against static discharge.  
P260 Do not breathe mist or vapours.  
P264 Wash skin thoroughly after handling.  
P270 Do not eat, drink or smoke when using this product.  
P271 Use only outdoors or in a well-ventilated area.  
P273 Avoid release to the environment.  
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.
- Response:**  
P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/ shower.  
P304 + P340 + P312 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER/ 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 advice/ attention.  
P332 + P313 If skin irritation occurs: Get medical advice/ attention.  
P337 + P313 If eye irritation persists: Get medical advice/ attention.

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P362 + P364 Take off contaminated clothing and wash it before reuse.

P391 Collect spillage.

### Storage:

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

P405 Store locked up.

### Disposal:

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

### Other hazards which do not result in classification

Vapours may form explosive mixture with air.

## 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

### Components

Chemical name	CAS-No.	Concentration (% w/w)
Propan-2-ol	67-63-0	>= 30 -< 60
salicylic acid	69-72-7	>= 1 -< 3
Sodium hydroxide	1310-73-2	>= 0.5 -< 1
betamethasone	378-44-9	>= 0.025 -< 0.25

## 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.

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Protection of first-aiders : May damage the unborn child.  
Causes damage to organs through prolonged or repeated exposure.  
: 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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### 5. FIREFIGHTING 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.  
Vapours 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 so.  
Evacuate area.

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

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### 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, 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.

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Methods and materials for containment and cleaning up : Non-sparking tools should be used.  
Soak up with inert absorbent material.  
Suppress (knock down) gases/vapours/mists with a water spray jet.  
For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container.  
Clean up remaining materials from spill with suitable 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.

## 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 vapours.  
Do not swallow.  
Do not get in eyes.  
Wash skin thoroughly after handling.  
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure 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 labelled containers.  
Store locked up.  
Keep tightly closed.  
Keep in a cool, well-ventilated place.  
Store in accordance with the particular national regulations.  
Keep away from heat and sources of ignition.

Materials to avoid : Do not store with the following product types:  
Self-reactive substances and mixtures  
Organic peroxides  
Oxidizing agents

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Flammable gases  
 Pyrophoric liquids  
 Pyrophoric solids  
 Self-heating substances and mixtures  
 Poisonous gases  
 Explosives

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis	
Propan-2-ol	67-63-0	NAB	400 ppm 983 mg/m <sup>3</sup>	ID OEL	
		PSD	500 ppm 1,230 mg/m <sup>3</sup>	ID OEL	
		TWA	200 ppm	ACGIH	
		STEL	400 ppm	ACGIH	
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	KTD	2 mg/m <sup>3</sup>	ID OEL	
		C	2 mg/m <sup>3</sup>	ACGIH	
betamethasone	378-44-9	TWA	1 µg/m <sup>3</sup> (OEB 4)	Internal	
		Further information: Skin			
		Wipe limit	10 µg/100 cm <sup>2</sup>	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	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 : Combined particulates and organic vapour 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, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.
- Skin and body protection : Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.
- Hygiene measures : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working 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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## 9. PHYSICAL AND CHEMICAL PROPERTIES

- Appearance : lotion
- Colour : colourless, translucent
- Odour : No data available
- Odour Threshold : No data available
- pH : 4.6 - 5.3
- Melting point/freezing point : No data available

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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

Vapour pressure : No data available

Relative vapour density : No data available

Relative density : No data available

Density : No data available

Solubility(ies)  
Water solubility : No data available

Partition coefficient: n-octanol/water : No data available

Auto-ignition temperature : No data available

Decomposition temperature : No data available

Viscosity  
Viscosity, kinematic : No data available

Explosive properties : Not explosive

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

Molecular weight : No data available

Particle characteristics  
Particle size : No data available

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### 10. STABILITY AND REACTIVITY



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Reactivity : Not classified as a reactivity hazard.  
Chemical stability : Stable under normal conditions.  
Possibility of hazardous reactions : Highly flammable liquid and vapour.  
Vapours 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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### 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: > 2,000 mg/kg  
Method: Calculation method

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

Acute dermal toxicity : Acute toxicity estimate: > 2,000 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: vapour

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

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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:**

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

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**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 sensitisation****Skin sensitisation**

Not classified based on available information.

**Respiratory sensitisation**

Not classified based on available information.

**Components:****Propan-2-ol:**

Test Type : Buehler Test  
Exposure routes : Skin contact  
Species : Guinea pig  
Method : OECD Test Guideline 406  
Result : negative

**salicylic acid:**

Test Type : Local lymph node assay (LLNA)  
Species : Mouse  
Result : negative

**Sodium hydroxide:**

Test Type : Human repeat insult patch test (HRIPT)  
Exposure routes : Skin contact  
Result : negative

**betamethasone:**

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

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**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

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

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Germ cell mutagenicity - Assessment : Weight of evidence does not support classification as a germ cell mutagen.

### Carcinogenicity

Not classified based on available information.

#### Components:

##### Propan-2-ol:

Species : Rat  
 Application Route : inhalation (vapour)  
 Exposure time : 104 weeks  
 Method : OECD Test Guideline 451  
 Result : negative

##### salicylic acid:

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

### Reproductive toxicity

May damage the unborn child.

#### Components:

##### Propan-2-ol:

Effects on fertility : Test Type: Two-generation reproduction toxicity study  
 Species: Rat  
 Application Route: Ingestion  
 Result: negative

Effects on foetal development : Test Type: Embryo-foetal development  
 Species: Rat  
 Application Route: Ingestion  
 Result: negative

##### salicylic acid:

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

Test Type: Embryo-foetal development  
 Species: Rat  
 Application Route: Oral  
 Developmental Toxicity: NOAEL: 80 mg/kg body weight

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Result: No effects on foetal development

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

**betamethasone:**

Effects on foetal 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.

**Repeated dose toxicity**

**Components:**

**Propan-2-ol:**

Species : Rat

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NOAEL : 12.5 mg/l  
 Application Route : inhalation (vapour)  
 Exposure time : 104 Weeks

**salicylic acid:**

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

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.

**Experience with human exposure**

**Components:**

**salicylic acid:**

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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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### 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  
Method: OECD Test Guideline 201  
Remarks: No toxicity at the limit of solubility



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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

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: 2,23  
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

# SAFETY DATA SHEET



## Betamethasone / Salicylic Acid Lotion Formulation



Version 5.2      Revision Date: 2024/04/06      SDS Number: 1832965-00019      Date of last issue: 2023/09/30  
Date of first issue: 2017/07/13

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### Other adverse effects

No data available

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## 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.

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## 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.

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**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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**15. REGULATORY INFORMATION****Safety, health and environmental regulations/legislation specific for the substance or mixture**

**Minister of Industry Regulation No. 23/M-IND/PER/4/2013 concerning the Revision of Minister of Industry Regulation No. 87/M-IND/PER/9/2009 concerning Globally Harmonized System of Classification and Labelling of Chemicals.**

**Regulation of the Minister of Health No. 472 of 1996 on the Safeguarding of Substances Hazardous to Health**

Hazardous substances that must be registered : Not applicable

**Government Regulation No. 74 of 2001 on the Management of Hazardous and Toxic Substances**

Hazardous substances approved for use : Propan-2-ol  
Sodium hydroxide

Prohibited substances : Not applicable

Restricted substances : Not applicable

**Regulation of the Ministry of Trade No. 7 of 2022 on Distribution and Control of Hazardous Materials**

Type of hazardous materials subject to distribution and control, Annex I : salicylic acid

Type of hazardous materials subject to distribution and control, Annex II : Not applicable

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

AICS : not determined

DSL : not determined

IECSC : not determined

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**16. OTHER INFORMATION**

Revision Date : 2024/04/06

**Further information**

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

Date format : yyyy/mm/dd

### Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)  
 ACGIH BEI : ACGIH - Biological Exposure Indices (BEI)  
 ID OEL : Indonesia. Occupational Exposure Limits

ACGIH / TWA : 8-hour, time-weighted average  
 ACGIH / STEL : Short-term exposure limit  
 ACGIH / C : Ceiling limit  
 ID OEL / NAB : Long term exposure limit  
 ID OEL / PSD : Short term exposure limit  
 ID OEL / KTD : Ceiling

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

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

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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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