

# SAFETY DATA SHEET



## Betamethasone / Salicylic Acid Ointment Formulation

Version 2.10      Revision Date: 09.04.2021      SDS Number: 1841154-00012      Date of last issue: 10.10.2020  
Date of first issue: 21.08.2017

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### 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Betamethasone / Salicylic Acid Ointment Formulation

#### Manufacturer or supplier's details

Company : Organon & Co.

Address : 30 Hudson Street, 33rd floor  
Jersey City, New Jersey, U.S.A 07302

Telephone : 551-430-6000

Emergency telephone number : 215-631-6999

E-mail address : EHSSTEWARD@organon.com

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

Recommended use : Pharmaceutical

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### 2. HAZARDS IDENTIFICATION

#### GHS Classification

Serious eye damage/eye irritation : Category 1

Reproductive toxicity : Category 1B

Specific target organ toxicity - repeated exposure : Category 1 (Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland)

Long-term (chronic) aquatic hazard : Category 1

#### GHS label elements

Hazard pictograms :



Signal word : Danger

Hazard statements : H318 Causes serious eye damage.  
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:**

# Betamethasone / Salicylic Acid Ointment Formulation

Version 2.10	Revision Date: 09.04.2021	SDS Number: 1841154-00012	Date of last issue: 10.10.2020 Date of first issue: 21.08.2017
-----------------	------------------------------	------------------------------	---

P201 Obtain special instructions before use.  
 P202 Do not handle until all safety precautions have been read and understood.  
 P260 Do not breathe dust/ fume/ gas/ mist/ vapours/ spray.  
 P264 Wash skin thoroughly after handling.  
 P270 Do not eat, drink or smoke when using this product.  
 P273 Avoid release to the environment.  
 P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

**Response:**

P305 + P351 + P338 + P310 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/ doctor.  
 P308 + P313 IF exposed or concerned: Get medical advice/ attention.  
 P391 Collect spillage.

**Storage:**

P405 Store locked up.

**Disposal:**

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

**Other hazards which do not result in classification**

None known.

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

**Components**

Chemical name	CAS-No.	Concentration (% w/w)
Petrolatum	8009-03-8	86.93
Paraffin oil	8012-95-1	10
salicylic acid	69-72-7	3
betamethasone	378-44-9	0.064

### 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.  
 Remove contaminated clothing and shoes.  
 Get medical attention.  
 Wash clothing before reuse.

# SAFETY DATA SHEET



## Betamethasone / Salicylic Acid Ointment For- mulation



Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
2.10	09.04.2021	1841154-00012	Date of first issue: 21.08.2017

---

- In case of eye contact : Thoroughly clean shoes before reuse.  
: 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 immediately.
- If swallowed : If swallowed, DO NOT induce vomiting.  
Get medical attention.  
Rinse mouth thoroughly with water.
- Most important symptoms and effects, both acute and delayed : Causes serious eye damage.  
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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### 5. FIREFIGHTING MEASURES

- Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
Dry chemical
- Unsuitable extinguishing media : None known.
- Specific hazards during fire-fighting : 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 : 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.  
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 : Sweep up or vacuum up spillage and collect in suitable container for disposal.  
Local or national regulations may apply to releases and dis-

# SAFETY DATA SHEET



## Betamethasone / Salicylic Acid Ointment Formulation



Version 2.10      Revision Date: 09.04.2021      SDS Number: 1841154-00012      Date of last issue: 10.10.2020  
Date of first issue: 21.08.2017

posal 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.
- Advice on safe handling : Do not get on skin or clothing.  
Do not breathe dust, fume, gas, mist, vapours or spray.  
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  
Keep container tightly closed.  
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.  
Store in accordance with the particular national regulations.
- Materials to avoid : Do not store with the following product types:  
Strong oxidizing agents

### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Petrolatum	8009-03-8	PEL (long term) (Mist)	5 mg/m <sup>3</sup>	SG OEL
		PEL (short term) (Mist)	10 mg/m <sup>3</sup>	SG OEL
		TWA (Inhalable particulate matter)	5 mg/m <sup>3</sup>	ACGIH
Paraffin oil	8012-95-1	PEL (long term) (Mist)	5 mg/m <sup>3</sup>	SG OEL
		PEL (short term) (Mist)	10 mg/m <sup>3</sup>	SG OEL
		TWA (Inhalable particulate matter)	5 mg/m <sup>3</sup>	ACGIH

# SAFETY DATA SHEET



## Betamethasone / Salicylic Acid Ointment Formulation



Version 2.10      Revision Date: 09.04.2021      SDS Number: 1841154-00012      Date of last issue: 10.10.2020  
Date of first issue: 21.08.2017

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
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

**Engineering measures** : Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., vacuum conveying from a closed system, packout head with inflatable seal from stationary container, ventilated enclosure, etc.).  
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.

### 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.

**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.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

# SAFETY DATA SHEET



## Betamethasone / Salicylic Acid Ointment Formulation



Version 2.10      Revision Date: 09.04.2021      SDS Number: 1841154-00012      Date of last issue: 10.10.2020  
Date of first issue: 21.08.2017

---

Appearance : ointment

Colour : white, translucent

Odour : No data available

Odour 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 : No data available

Evaporation rate : No data available

Flammability (solid, gas) : Not classified as a flammability hazard

Flammability (liquids) : No data available

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.

**Betamethasone / Salicylic Acid Ointment Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
2.10	09.04.2021	1841154-00012	Date of first issue: 21.08.2017

Molecular weight : No data available

Particle size : No data available

**10. STABILITY AND REACTIVITY**

Reactivity : Not classified as a reactivity hazard.  
Chemical stability : Stable under normal conditions.  
Possibility of hazardous reactions : Can react with strong oxidizing agents.  
Conditions to avoid : None known.  
Incompatible materials : Oxidizing agents  
Hazardous decomposition products : No hazardous decomposition products are known.

**11. TOXICOLOGICAL INFORMATION**

Information on likely routes of exposure : 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:****Petrolatum:**

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg  
Method: OECD Test Guideline 401  
Remarks: Based on data from similar materials

Acute dermal toxicity : LD50 (Rat): > 2,000 mg/kg  
Method: OECD Test Guideline 402  
Assessment: The substance or mixture has no acute dermal toxicity  
Remarks: Based on data from similar materials

**Paraffin oil:**

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

# SAFETY DATA SHEET



## Betamethasone / Salicylic Acid Ointment Formulation

Version 2.10      Revision Date: 09.04.2021      SDS Number: 1841154-00012      Date of last issue: 10.10.2020  
Date of first issue: 21.08.2017

---

Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg  
Assessment: The substance or mixture has no acute dermal toxicity

### 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

### betamethasone:

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg  
LD50 (Mouse): > 4,500 mg/kg

Acute inhalation toxicity : LC50 (Rat): 0.4 mg/l  
Exposure time: 4 h

### Skin corrosion/irritation

Not classified based on available information.

### Components:

#### Petrolatum:

Species : Rabbit  
Method : OECD Test Guideline 404  
Result : No skin irritation  
Remarks : Based on data from similar materials

#### Paraffin oil:

Species : Rabbit  
Result : No skin irritation

#### salicylic acid:

Result : Skin irritation

#### betamethasone:

Species : Rabbit  
Result : Mild skin irritation



**Betamethasone / Salicylic Acid Ointment Formulation**

Version 2.10      Revision Date: 09.04.2021      SDS Number: 1841154-00012      Date of last issue: 10.10.2020  
Date of first issue: 21.08.2017

---

**Serious eye damage/eye irritation**

Causes serious eye damage.

**Components:****Petrolatum:**

Species : Rabbit  
Result : No eye irritation  
Method : OECD Test Guideline 405  
Remarks : Based on data from similar materials

**Paraffin oil:**

Species : Rabbit  
Result : No eye irritation

**salicylic acid:**

Species : Rabbit  
Remarks : Severe eye irritation

**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:****Petrolatum:**

Test Type : Buehler Test  
Exposure routes : Skin contact  
Species : Guinea pig  
Result : negative  
Remarks : Based on data from similar materials

**salicylic acid:**

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

**betamethasone:**

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

# Betamethasone / Salicylic Acid Ointment For- mulation

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
2.10	09.04.2021	1841154-00012	Date of first issue: 21.08.2017

---

**Germ cell mutagenicity**

Not classified based on available information.

**Components:****Petrolatum:**

- Genotoxicity in vitro : Test Type: Chromosome aberration test in vitro  
Result: negative  
Remarks: Based on data from similar materials
- Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)  
Species: Mouse  
Application Route: Intraperitoneal injection  
Method: OECD Test Guideline 474  
Result: negative  
Remarks: Based on data from similar materials

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

# Betamethasone / Salicylic Acid Ointment Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
2.10	09.04.2021	1841154-00012	Date of first issue: 21.08.2017

---

**Carcinogenicity**

Not classified based on available information.

**Components:****Petrolatum:**

Species : Rat  
 Application Route : Ingestion  
 Exposure time : 2 Years  
 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:****Petrolatum:**

Effects on fertility : Test Type: Reproduction/Developmental toxicity screening test  
 Species: Rat  
 Application Route: Ingestion  
 Result: negative  
 Remarks: Based on data from similar materials

Effects on foetal development : Test Type: Embryo-foetal development  
 Species: Rat  
 Application Route: Skin contact  
 Result: negative  
 Remarks: Based on data from similar materials

**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  
 Result: No effects on foetal development

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

# Betamethasone / Salicylic Acid Ointment Formulation

Version 2.10	Revision Date: 09.04.2021	SDS Number: 1841154-00012	Date of last issue: 10.10.2020 Date of first issue: 21.08.2017
-----------------	------------------------------	------------------------------	---

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essment

### 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

Not classified based on available information.

### 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:

#### Petrolatum:

Species : Rat  
NOAEL : 5,000 mg/kg  
Application Route : Ingestion  
Exposure time : 2 yr

#### Paraffin oil:

Species : Rat, female  
LOAEL : 161 mg/kg  
Application Route : Ingestion  
Exposure time : 90 Days

# Betamethasone / Salicylic Acid Ointment Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
2.10	09.04.2021	1841154-00012	Date of first issue: 21.08.2017

---

**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.

**Components:****Paraffin oil:**

The substance or mixture is known to cause human aspiration toxicity hazards or has to be regarded as if it causes a human aspiration toxicity hazard.

**Experience with human exposure****Components:****salicylic acid:**

Skin contact : Symptoms: Skin irritation

# Betamethasone / Salicylic Acid Ointment Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
2.10	09.04.2021	1841154-00012	Date of first issue: 21.08.2017

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

**12. ECOLOGICAL INFORMATION****Ecotoxicity****Components:****Petrolatum:**

Toxicity to fish : LL50 (Pimephales promelas (fathead minnow)): > 100 mg/l  
 Exposure time: 96 h  
 Test substance: Water Accommodated Fraction  
 Method: OECD Test Guideline 203  
 Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 10,000 mg/l  
 Exposure time: 48 h  
 Test substance: Water Accommodated Fraction  
 Remarks: Based on data from similar materials

Toxicity to algae/aquatic plants : NOEL (Pseudokirchneriella subcapitata (green algae)): >= 100 mg/l  
 Exposure time: 72 h  
 Test substance: Water Accommodated Fraction  
 Method: OECD Test Guideline 201  
 Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 10 mg/l  
 Exposure time: 21 d  
 Test substance: Water Accommodated Fraction  
 Remarks: Based on data from similar materials

**Paraffin oil:**

Toxicity to fish : LL50 (Scophthalmus maximus (turbot)): > 100 mg/l  
 Exposure time: 96 h  
 Test substance: Water Accommodated Fraction  
 Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates : EL50 (Acartia tonsa): > 100 mg/l  
 Exposure time: 48 h  
 Test substance: Water Accommodated Fraction  
 Remarks: Based on data from similar materials

Toxicity to algae/aquatic plants : EL50 (Skeletonema costatum (marine diatom)): > 100 mg/l  
 Exposure time: 72 h  
 Test substance: Water Accommodated Fraction  
 Remarks: Based on data from similar materials

# Betamethasone / Salicylic Acid Ointment Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 10.10.2020
2.10	09.04.2021	1841154-00012	Date of first issue: 21.08.2017

---

NOELR (Skeletonema costatum (marine diatom)): > 1 mg/l  
 Exposure time: 72 h  
 Test substance: Water Accommodated Fraction  
 Remarks: Based on data from similar materials

**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

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

# SAFETY DATA SHEET



## Betamethasone / Salicylic Acid Ointment Formulation



Version 2.10      Revision Date: 09.04.2021      SDS Number: 1841154-00012      Date of last issue: 10.10.2020  
Date of first issue: 21.08.2017

---

### Persistence and degradability

#### Components:

##### **Petrolatum:**

Biodegradability : Result: Not readily biodegradable.  
Biodegradation: 31 %  
Exposure time: 28 d  
Method: OECD Test Guideline 301F  
Remarks: Based on data from similar materials

### Bioaccumulative potential

#### Components:

##### **Paraffin oil:**

Partition coefficient: n-octanol/water : log Pow: > 4  
Remarks: Calculation

##### **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

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## 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.  
If not otherwise specified: Dispose of as unused product.

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## 14. TRANSPORT INFORMATION

### **International Regulations**

#### **UNRTDG**

UN number : UN 3077  
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (betamethasone)  
Class : 9  
Packing group : III  
Labels : 9

---



# SAFETY DATA SHEET



## Betamethasone / Salicylic Acid Ointment Formulation

Version 2.10      Revision Date: 09.04.2021      SDS Number: 1841154-00012      Date of last issue: 10.10.2020  
Date of first issue: 21.08.2017

---

### IATA-DGR

UN/ID No. : UN 3077  
Proper shipping name : Environmentally hazardous substance, solid, n.o.s. (betamethasone)  
Class : 9  
Packing group : III  
Labels : Miscellaneous  
Packing instruction (cargo aircraft) : 956  
Packing instruction (passenger aircraft) : 956  
Environmentally hazardous : yes

### IMDG-Code

UN number : UN 3077  
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (betamethasone)  
Class : 9  
Packing group : III  
Labels : 9  
EmS Code : F-A, S-F  
Marine pollutant : yes

### Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

### Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

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## 15. REGULATORY INFORMATION

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

#### Workplace Safety and Health Act and Workplace Safety and Health (General Provisions) Regulations: This product is subjected to the SDS, labelling, PEL and other requirements in the Act/Regulations.

Environmental Protection and Management Act and : Not applicable  
Environmental Protection and Management (Hazardous Substances) Regulations

Fire Safety (Petroleum and Flammable Materials) : Not applicable  
Regulations

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

AICS : not determined

# Betamethasone / Salicylic Acid Ointment Formulation

Version 2.10	Revision Date: 09.04.2021	SDS Number: 1841154-00012	Date of last issue: 10.10.2020 Date of first issue: 21.08.2017
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DSL : not determined

IECSC : not determined

## 16. OTHER INFORMATION

### Further information

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 : dd.mm.yyyy

### Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)  
SG OEL : Singapore. Workplace Safety and Health Act - First Schedule Permissible Exposure Limits of Toxic Substances

ACGIH / TWA : 8-hour, time-weighted average  
SG OEL / PEL (long term) : Permissible Exposure Level (PEL) Long Term  
SG OEL / PEL (short term) : Permissible Exposure Level (PEL) Short Term

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; KECl - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

# SAFETY DATA SHEET



## Betamethasone / Salicylic Acid Ointment Formulation



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

SG / EN