

SAFETY DATA SHEET



Mometasone Ointment Formulation



Version 3.1 Revision Date: 30.09.2023 SDS Number: 1758815-00014 Date of last issue: 04.04.2023
Date of first issue: 14.06.2017

SECTION 1. IDENTIFICATION

Product name : Mometasone 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 : 1-551-430-6000

Emergency telephone : 1-215-631-6999

E-mail address : EHSSTEWARD@organon.com

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical

Restrictions on use : Not applicable



SECTION 2. HAZARDS IDENTIFICATION

GHS Classification

Reproductive toxicity : Category 2

Long-term (chronic) aquatic hazard : Category 2

GHS label elements

Hazard pictograms :  

Signal Word : Warning

Hazard Statements : H361d Suspected of damaging the unborn child.
H411 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.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:

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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.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

| Chemical name | CAS-No. | Concentration (% w/w) |
|-------------------------------|------------|-----------------------|
| Petrolatum | 8009-03-8 | >= 70 -< 90 |
| 2-Methyl-2,4-pentanediol | 107-41-5 | >= 10 -< 20 |
| Propylene glycol monostearate | 1323-39-3 | >= 1 -< 5 |
| Mometasone | 83919-23-7 | >= 0,1 -< 0,25 |

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 soap and plenty of water.
Remove contaminated clothing and shoes.
Get medical attention.
Wash clothing before reuse.
Thoroughly clean shoes before reuse.
- In case of eye contact : Flush eyes with water as a precaution.
Get medical attention if irritation develops and persists.
- 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 : Suspected of damaging the unborn child.
- Protection of first-aiders : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).
- Notes to physician : Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING MEASURES

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- Suitable extinguishing media : Water spray
Alcohol-resistant foam
Carbon dioxide (CO₂)
Dry chemical
- Unsuitable extinguishing media : None known.
- Specific hazards during fire fighting : Vapors may form explosive mixtures with air.
Exposure to combustion products may be a hazard to health.
- Hazardous combustion products : Carbon oxides
- Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Use water spray to cool unopened containers.
Remove undamaged containers from fire area if it is safe to do 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 : 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 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.
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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.
- Advice on safe handling : Do not get on skin or clothing.
Do not swallow.
Avoid contact with eyes.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment

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- Keep container tightly closed.
 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.
 Store in accordance with the particular national regulations.
- Materials to avoid : Do not store with the following product types:
 Strong oxidizing agents
 Self-reactive substances and mixtures
 Organic peroxides
 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 | |
|-------------------------------|------------|--|--|----------|--|
| Petrolatum | 8009-03-8 | CMP (Mist) | 5 mg/m ³ | AR OEL | |
| | | CMP - CPT (Mist) | 10 mg/m ³ | AR OEL | |
| | | TWA (Inhalable particulate matter) | 5 mg/m ³ | ACGIH | |
| 2-Methyl-2,4-pentanediol | 107-41-5 | CMP-C | 25 ppm | AR OEL | |
| | | TWA (Vapor) | 25 ppm | ACGIH | |
| | | STEL (Vapor) | 50 ppm | ACGIH | |
| | | STEL (Inhalable fraction, Aerosol only) | 10 mg/m ³ | ACGIH | |
| Propylene glycol monostearate | 1323-39-3 | CMP | 10 mg/m ³ | AR OEL | |
| | | Further information: A4 - Not classifiable as a human carcinogen | | | |
| | | TWA (Inhalable particulate matter) | 10 mg/m ³ | ACGIH | |
| | | TWA (Respirable particulate matter) | 3 mg/m ³ | ACGIH | |
| Mometasone | 83919-23-7 | TWA | 1 µg/m ³ (OEB 4) | Internal | |
| | | Further information: Skin | | | |
| | | Wipe limit | 10 µg/100 cm ² | 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)

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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 vapor 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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

- Appearance : ointment
- Color : white to off-white
- Odor : No data available
- Odor Threshold : No data available
- pH : No data available
- Melting point/freezing point : No data available

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Initial boiling point and boiling range : No data available

Flash point : > 93,3 °C

Evaporation rate : No data available

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

Flammability (liquids) : Not applicable

Upper explosion limit / Upper flammability limit : No data available

Lower explosion limit / Lower flammability limit : No data available

Vapor pressure : No data available

Relative vapor density : No data available

Relative density : No data available

Density : No data available

Solubility(ies)
Water solubility : No data available

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

SECTION 10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.

Chemical stability : Stable under normal conditions.

Possibility of hazardous reactions : Vapors may form explosive mixture with air.
Can react with strong oxidizing agents.

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| | | |
|----------------------------------|---|--|
| Conditions to avoid | : | None known. |
| Incompatible materials | : | Oxidizing agents |
| Hazardous decomposition products | : | No hazardous decomposition products are known. |

SECTION 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: > 5.000 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

2-Methyl-2,4-pentanediol:

Acute oral toxicity : LD50 (Rat): > 2.000 mg/kg
Method: OECD Test Guideline 420

Acute dermal toxicity : LD50 (Rat): > 2.000 mg/kg
Method: OECD Test Guideline 402
Assessment: The substance or mixture has no acute dermal toxicity

Propylene glycol monostearate:

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

Mometasone:

Acute oral toxicity : LD50 (Rat): > 2.000 mg/kg
LD50 (Mouse): > 2.000 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 3,3 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Remarks: No mortality observed at this dose.

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LC50 (Mouse): > 3,2 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist

Acute toxicity (other routes of administration) : LD50 (Rat): 300 mg/kg
Application Route: Subcutaneous
Symptoms: Breathing difficulties

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

2-Methyl-2,4-pentanediol:

Species : Rabbit
Method : OECD Test Guideline 404
Result : No skin irritation

Propylene glycol monostearate:

Result : No skin irritation

Mometasone:

Species : Rabbit
Result : No skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

Components:**Petrolatum:**

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

2-Methyl-2,4-pentanediol:

Species : Rabbit
Result : No eye irritation
Method : OECD Test Guideline 405

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Species : Rabbit
Result : No eye irritation

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Respiratory or skin sensitization**Skin sensitization**

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Components:**Petrolatum:**

Test Type : Buehler Test
Routes of exposure : Skin contact
Species : Guinea pig
Result : negative
Remarks : Based on data from similar materials

2-Methyl-2,4-pentanediol:

Test Type : Maximization Test
Routes of exposure : Skin contact
Species : Guinea pig
Method : OECD Test Guideline 406
Result : negative

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Test Type : Maximization Test
Routes of exposure : Dermal
Species : Guinea pig
Assessment : Does not cause skin sensitization.
Result : negative
Remarks : The results of a test on guinea pigs showed this substance to be a weak skin sensitizer.

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

2-Methyl-2,4-pentanediol:

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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
Method: OECD Test Guideline 476
Result: negative

Test Type: Chromosome aberration test in vitro
Result: negative

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

Test Type: Chromosomal aberration
Test system: Chinese hamster lung cells
Result: negative

Test Type: Chromosomal aberration
Test system: Chinese hamster ovary cells
Result: positive

Test Type: Mouse Lymphoma
Result: negative

Genotoxicity in vivo : Test Type: Micronucleus test
Species: Mouse
Application Route: Oral
Result: negative

Test Type: Chromosomal aberration
Species: Rat
Cell type: Bone marrow
Result: negative

Test Type: unscheduled DNA synthesis assay
Species: Rat
Cell type: Liver cells
Result: negative

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

Carcinogenicity

Not classified based on available information.

Components:**Petrolatum:**

Species : Rat
Application Route : Ingestion
Exposure time : 2 Years
Result : negative

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Species : Rat
 Application Route : Inhalation
 Exposure time : 2 Years
 Dose : 0.067 mg/kg body weight
 Result : negative

Species : Mouse
 Application Route : Inhalation
 Exposure time : 19 Months
 Dose : 0.160 mg/kg body weight
 Result : negative

Reproductive toxicity

Suspected of damaging 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 fetal development : Test Type: Embryo-fetal development
 Species: Rat
 Application Route: Skin contact
 Result: negative
 Remarks: Based on data from similar materials

2-Methyl-2,4-pentanediol:

Effects on fertility : Test Type: One-generation reproduction toxicity study
 Species: Rat
 Application Route: Ingestion
 Method: OECD Test Guideline 443
 Result: negative

Effects on fetal development : Test Type: One-generation reproduction toxicity study
 Species: Rat
 Application Route: Ingestion
 Method: OECD Test Guideline 443
 Result: positive

Reproductive toxicity - Assessment : Some evidence of adverse effects on development, based on animal experiments.

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Effects on fertility : Test Type: Fertility
 Species: Rat
 Application Route: Subcutaneous
 Fertility: NOAEL: 0,015 mg/kg body weight

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Symptoms: Reduced embryonic survival, Reduced fetal weight.

Result: No effects on fertility., Effect on reproduction capacity.

Effects on fetal development : Test Type: Embryo-fetal development
Species: Mouse
Application Route: Subcutaneous
Embryo-fetal toxicity.: LOAEL: 0,06 mg/kg body weight
Result: Embryotoxic effects., Teratogenicity and developmental toxicity

Test Type: Embryo-fetal development
Species: Rat
Application Route: Dermal
Embryo-fetal toxicity.: LOAEL: 0,3 mg/kg body weight
Result: Embryo-fetal toxicity.

Test Type: Embryo-fetal development
Species: Rabbit
Application Route: Dermal
Embryo-fetal toxicity.: LOAEL: 0,15 mg/kg body weight
Result: Embryo-fetal toxicity., Malformations were observed.

Test Type: Embryo-fetal development
Species: Rat
Application Route: Subcutaneous
Embryo-fetal toxicity.: LOAEL: 0,15 mg/kg body weight
Result: Effects on newborn.

Test Type: Embryo-fetal development
Species: Rabbit
Application Route: Oral
Embryo-fetal toxicity.: LOAEL: 0,7 mg/kg body weight
Result: Embryo-fetal toxicity., Malformations were observed.

Reproductive toxicity - Assessment : Clear evidence of adverse effects on development, based on animal experiments., Some evidence of adverse effects on sexual function and fertility, based on animal experiments.

STOT-single exposure

Not classified based on available information.

Components:**Mometasone:**

Remarks : Based on available data, the classification criteria are not met.

STOT-repeated exposure

Not classified based on available information.

Components:**Mometasone:**

Routes of exposure : inhalation (dust/mist/fume)

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Target Organs : Immune system, Liver, Kidney, Skin
 Assessment : May cause 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 y

2-Methyl-2,4-pentanediol:

Species : Rat
 NOAEL : >= 450 mg/kg
 Application Route : Ingestion
 Exposure time : 13 Weeks
 Method : OECD Test Guideline 408

Mometasone:

Species : Rat
 NOAEL : 0,005 mg/kg
 LOAEL : 0,3 mg/kg
 Application Route : Oral
 Exposure time : 30 d
 Target Organs : Lymph nodes, Liver, Adrenal gland, Skin, thymus gland

Species : Dog
 LOAEL : 0,5 mg/kg
 Application Route : Oral
 Exposure time : 30 d
 Target Organs : Lymph nodes, Liver, Adrenal gland, Skin, thymus gland

Species : Rat
 NOAEL : 0,00013 mg/l
 Application Route : inhalation (dust/mist/fume)
 Exposure time : 90 d
 Target Organs : Adrenal gland, Lungs, Lymph nodes, spleen, Bone marrow, Kidney, Liver, thymus gland

Species : Dog
 NOAEL : 0,0005 mg/l
 Application Route : inhalation (dust/mist/fume)
 Exposure time : 90 d
 Target Organs : Adrenal gland, Lungs, Lymph nodes, spleen, Bone marrow, Kidney, thymus gland, Liver

Aspiration toxicity

Not classified based on available information.

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Components:**Mometasone:**

Not applicable

Experience with human exposure**Components:****2-Methyl-2,4-pentanediol:**

Eye contact : Target Organs: Eyes
Symptoms: Irritation

Mometasone:

Inhalation : Symptoms: allergic rhinitis, Headache, pharyngitis, upper respiratory tract infection, sinusitis, oral candidiasis, Back pain, musculoskeletal pain, immune system effects, indigestion

Skin contact : Symptoms: Dermatitis, Itching

Further information**Components:****Mometasone:**

Remarks : Dermal absorption possible

SECTION 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

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Remarks: Based on data from similar materials

2-Methyl-2,4-pentanediol:

- Toxicity to fish : LC50 (*Gambusia affinis* (Mosquito fish)): 8.510 mg/l
Exposure time: 96 h
- Toxicity to daphnia and other aquatic invertebrates : EC50 (*Ceriodaphnia dubia* (water flea)): 2.800 mg/l
Exposure time: 48 h
- Toxicity to algae/aquatic plants : ErC50 (*Raphidocelis subcapitata* (freshwater green alga)): > 429 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
- EC10 (*Raphidocelis subcapitata* (freshwater green alga)): > 429 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)): 25 mg/l
Exposure time: 21 d
Method: OECD Test Guideline 211
- Toxicity to microorganisms : NOEC (Bacteria): 200 mg/l
Exposure time: 10 d

Mometasone:

- Toxicity to fish : LC50 (*Menidia beryllina* (Silverside)): 0,11 mg/l
Exposure time: 96 h
Remarks: No toxicity at the limit of solubility.
- LC50 (*Cyprinodon variegatus* (sheepshead minnow)): > 5 mg/l
Exposure time: 7 d
Remarks: No toxicity at the limit of solubility.
- Toxicity to daphnia and other aquatic invertebrates : EC50 (*Daphnia magna* (Water flea)): > 5 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202
Remarks: No toxicity at the limit of solubility.
- EC50 (*Americamysis*): > 5 mg/l
Exposure time: 96 h
Method: US-EPA OPPTS 850.1035
Remarks: No toxicity at the limit of solubility.
- Toxicity to algae/aquatic plants : EC50 (*Pseudokirchneriella subcapitata* (green algae)): > 3,2 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)): 0,00014 mg/l
Exposure time: 32 d

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Method: OECD Test Guideline 210

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 0,34 mg/l
 Exposure time: 21 d
 Method: OECD Test Guideline 211
 Remarks: No toxicity at the limit of solubility.

M-Factor (Chronic aquatic toxicity) : 100

Toxicity to microorganisms : EC50: > 1.000 mg/l
 Exposure time: 3 h
 Test Type: Respiration inhibition
 Method: OECD Test Guideline 209
 Remarks: No toxicity at the limit of solubility.

NOEC: 1.000 mg/l
 Exposure time: 3 h
 Test Type: Respiration inhibition
 Method: OECD Test Guideline 209
 Remarks: No toxicity at the limit of solubility.

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

2-Methyl-2,4-pentanediol:

Biodegradability : Result: Readily biodegradable.
 Biodegradation: 81 %
 Exposure time: 28 d
 Method: OECD Test Guideline 301F

Mometasone:

Biodegradability : Result: Not readily biodegradable.
 Biodegradation: 50 %
 Exposure time: 28 d
 Method: OECD Test Guideline 314

Stability in water : Hydrolysis: 50 %(12 d)
 Method: OECD Test Guideline 111

Bioaccumulative potential**Components:****2-Methyl-2,4-pentanediol:**

Partition coefficient: n- : log Pow: < 4

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octanol/water Remarks: Calculation

Mometasone:

Bioaccumulation : Species: Lepomis macrochirus (Bluegill sunfish)
Bioconcentration factor (BCF): 107,1
Method: OECD Test Guideline 305

Partition coefficient: n-octanol/water : log Pow: 4,68

Mobility in soil

Components:

Mometasone:

Distribution among environmental compartments : log Koc: 4,02

Other adverse effects

No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : Do not dispose of waste into sewer.
Dispose of in accordance with local regulations.
Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.
If not otherwise specified: Dispose of as unused product.

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG

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

IATA-DGR

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

SAFETY DATA SHEET



Mometasone Ointment Formulation



Version 3.1 Revision Date: 30.09.2023 SDS Number: 1758815-00014 Date of last issue: 04.04.2023
Date of first issue: 14.06.2017

Environmentally hazardous : yes

IMDG-Code

UN number : UN 3077
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,
N.O.S.
(Mometasone)
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.

SECTION 15. REGULATORY INFORMATION

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

Argentina. Carcinogenic Substances and Agents Registry. : Not applicable

Control of precursors and essential chemicals for the preparation of drugs. : Not applicable

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

AICS : not determined

DSL : not determined

IECSC : not determined

SECTION 16. OTHER INFORMATION

Revision Date : 30.09.2023
Date format : dd.mm.yyyy

Further information

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

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

SAFETY DATA SHEET



Mometasone Ointment Formulation



| | | | |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 04.04.2023 |
| 3.1 | 30.09.2023 | 1758815-00014 | Date of first issue: 14.06.2017 |

| | | |
|--------------------|---|---|
| AR OEL | : | Argentina. Occupational Exposure Limits |
| ACGIH / TWA | : | 8-hour, time-weighted average |
| ACGIH / STEL | : | Short-term exposure limit |
| AR OEL / CMP | : | TLV (Threshold Limit Value) |
| AR OEL / CMP - CPT | : | STEL (Short Term Limit Value) |
| AR OEL / CMP-C | : | Ceiling value |

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 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.

AR / Z8