

# SAFETY DATA SHEET

according to the Globally Harmonized System



ORGANON

## Mometasone Suspension Formulation

Version 3.7      Revision Date: 26.09.2023      SDS Number: 23600-00023      Date of last issue: 20.03.2023  
Date of first issue: 21.10.2014

---

### 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Mometasone Suspension 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 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

---

### 2. HAZARDS IDENTIFICATION

#### Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

##### Classification

Not classified as hazardous according to criteria laid down in Part I of Schedule-1.

##### GHS Classification

Short-term (acute) aquatic hazard : Category 3

Long-term (chronic) aquatic hazard : Category 2

##### GHS label elements

Hazard pictograms :



Signal word : None

Hazard statements : H402 Harmful to aquatic life.  
H411 Toxic to aquatic life with long lasting effects.

Precautionary statements : **Prevention:**  
P273 Avoid release to the environment.

---

# SAFETY DATA SHEET

according to the Globally Harmonized System



ORGANON

## Mometasone Suspension Formulation

Version 3.7      Revision Date: 26.09.2023      SDS Number: 23600-00023      Date of last issue: 20.03.2023  
Date of first issue: 21.10.2014

### Response:

P391 Collect spillage.

### 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)   |
|-----------------------|------------|-------------------------|
| Cellulose             | 9004-34-6  | $\geq 1 - < 5$          |
| Mometasone            | 83919-23-7 | $\geq 0.025 - < 0.1$    |
| Benzalkonium chloride | 8001-54-5  | $\geq 0.0025 - < 0.025$ |

## 4. FIRST AID MEASURES

If inhaled : If inhaled, remove to fresh air.  
Get medical attention if symptoms occur.

In case of skin contact : Wash with water and soap as a precaution.  
Get medical attention if symptoms occur.

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 if symptoms occur.  
Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and delayed : None known.

Protection of first-aiders : No special precautions are necessary for first aid responders.

Notes to physician : Treat symptomatically and supportively.

## 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.

# SAFETY DATA SHEET

according to the Globally Harmonized System



## Mometasone Suspension Formulation

|         |                |             |                                 |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 20.03.2023  |
| 3.7     | 26.09.2023     | 23600-00023 | Date of first issue: 21.10.2014 |

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 : Wear self-contained breathing apparatus for firefighting if necessary.  
Use personal protective equipment.

### 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures : Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

Environmental precautions : Avoid release to the environment.  
Prevent further leakage or spillage if safe to do so.  
Prevent spreading over a wide area (e.g. by containment or oil barriers).  
Retain and dispose of contaminated wash water.  
Local authorities should be advised if significant spillages cannot be contained.

Methods and materials for containment and cleaning up : Soak up with inert absorbent material.  
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 : Use only with adequate ventilation.

Advice on safe handling : Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment  
Take care to prevent spills, waste and minimize release to the environment.

Conditions for safe storage : Keep in properly labelled containers.  
Store in accordance with the particular national regulations.

Materials to avoid : Do not store with the following product types:  
Strong oxidizing agents

# SAFETY DATA SHEET

according to the Globally Harmonized System



## Mometasone Suspension Formulation

Version 3.7      Revision Date: 26.09.2023      SDS Number: 23600-00023      Date of last issue: 20.03.2023  
Date of first issue: 21.10.2014

### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Components with workplace control parameters

| Components                | CAS-No.    | Value type<br>(Form of exposure) | Control parameters / Permissible concentration | Basis    |
|---------------------------|------------|----------------------------------|--|----------|
| Cellulose                 | 9004-34-6  | TWA                              | 10 mg/m <sup>3</sup>                           | ACGIH    |
| Mometasone                | 83919-23-7 | 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** : 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.

#### 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.

# SAFETY DATA SHEET

according to the Globally Harmonized System



ORGANON

## Mometasone Suspension Formulation

|         |                |             |                                 |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 20.03.2023  |
| 3.7     | 26.09.2023     | 23600-00023 | Date of first issue: 21.10.2014 |

### 9. PHYSICAL AND CHEMICAL PROPERTIES

|  |   |                            |
|--|---|----------------------------|
| Appearance                                       | : | liquid                     |
| Colour   | : | white to off-white, opaque |
| Odour  | : | odourless                  |
| Odour Threshold                                  | : | No data available          |
| pH   | : | 4.3 - 4.9                  |
| 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 applicable             |
| 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  | : | 1 g/cm <sup>3</sup>        |
| Solubility(ies)                                  |   |                            |
| Water solubility                                 | : | soluble                    |
| Partition coefficient: n-octanol/water           | : | Not applicable             |
| Auto-ignition temperature                        | : | No data available          |
| Decomposition temperature                        | : | No data available          |
| Viscosity  |   |                            |
| Viscosity, kinematic                             | : | No data available          |
| Explosive properties                             | : | Not explosive              |

# SAFETY DATA SHEET

according to the Globally Harmonized System



## Mometasone Suspension Formulation

Version 3.7      Revision Date: 26.09.2023      SDS Number: 23600-00023      Date of last issue: 20.03.2023  
Date of first issue: 21.10.2014

Oxidizing properties : The substance or mixture is not classified as oxidizing.  
Molecular weight : Not applicable  
Particle size : Not applicable

### 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 : Inhalation  
Skin contact  
Ingestion  
Eye contact

#### Acute toxicity

Not classified based on available information.

#### Components:

##### Cellulose:

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg  
Acute inhalation toxicity : LC50 (Rat): > 5.8 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Acute dermal toxicity : LD50 (Rabbit): > 2,000 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.  
LC50 (Mouse): > 3.2 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist

Acute toxicity (other routes of exposure) : LD50 (Rat): 300 mg/kg

# SAFETY DATA SHEET

according to the Globally Harmonized System



## Mometasone Suspension Formulation

Version 3.7      Revision Date: 26.09.2023      SDS Number: 23600-00023      Date of last issue: 20.03.2023  
Date of first issue: 21.10.2014

---

administration)      Application Route: Subcutaneous  
Symptoms: Breathing difficulties

### **Benzalkonium chloride:**

Acute oral toxicity      :    LD50 (Rat): 240 mg/kg

Acute inhalation toxicity      :    LC50 (Rat, male): > 0.05 - 0.5 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Method: OECD Test Guideline 403  
Assessment: Corrosive to the respiratory tract.  
Remarks: Based on data from similar materials

Acute dermal toxicity      :    LD50 (Rat, female): 704 mg/kg

### **Skin corrosion/irritation**

Not classified based on available information.

#### **Components:**

##### **Mometasone:**

Species      :    Rabbit  
Result      :    No skin irritation

##### **Benzalkonium chloride:**

Species      :    Human  
Result      :    Corrosive after 4 hours or less of exposure

### **Serious eye damage/eye irritation**

Not classified based on available information.

#### **Components:**

##### **Mometasone:**

Species      :    Rabbit  
Result      :    No eye irritation

##### **Benzalkonium chloride:**

Species      :    Rabbit  
Result      :    Irreversible effects on the eye

### **Respiratory or skin sensitisation**

#### **Skin sensitisation**

Not classified based on available information.

#### **Respiratory sensitisation**

Not classified based on available information.

#### **Components:**

##### **Mometasone:**

# SAFETY DATA SHEET

according to the Globally Harmonized System



## Mometasone Suspension Formulation

Version 3.7      Revision Date: 26.09.2023      SDS Number: 23600-00023      Date of last issue: 20.03.2023  
Date of first issue: 21.10.2014

---

Test Type : Maximisation Test  
Exposure routes : Dermal  
Species : Guinea pig  
Assessment : Does not cause skin sensitisation.  
Result : negative  
Remarks : The results of a test on guinea pigs showed this substance to be a weak skin sensitiser.

### **Benzalkonium chloride:**

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

### **Germ cell mutagenicity**

Not classified based on available information.

### **Components:**

#### **Cellulose:**

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: Ingestion  
Result: negative

#### **Mometasone:**

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



# SAFETY DATA SHEET

according to the Globally Harmonized System



## Mometasone Suspension Formulation

|         |                |             |                                 |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 20.03.2023  |
| 3.7     | 26.09.2023     | 23600-00023 | Date of first issue: 21.10.2014 |

---

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.

### **Benzalkonium chloride:**

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  
Remarks: Based on data from similar materials

Test Type: Chromosome aberration test in vitro  
Method: OECD Test Guideline 473  
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: Ingestion  
Method: OECD Test Guideline 474  
Result: negative  
Remarks: Based on data from similar materials

### **Carcinogenicity**

Not classified based on available information.

### **Components:**

#### **Cellulose:**

Species : Rat  
Application Route : Ingestion  
Exposure time : 72 weeks  
Result : negative

#### **Mometasone:**

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

# SAFETY DATA SHEET

according to the Globally Harmonized System



ORGANON

## Mometasone Suspension Formulation

Version 3.7      Revision Date: 26.09.2023      SDS Number: 23600-00023      Date of last issue: 20.03.2023  
Date of first issue: 21.10.2014

---

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

### **Benzalkonium chloride:**

Species : Rat  
Application Route : Ingestion  
Exposure time : 2 Years  
Method : OECD Test Guideline 453  
Result : negative  
Remarks : Based on data from similar materials

Species : Mouse  
Application Route : Skin contact  
Exposure time : 80 weeks  
Result : negative

Species : Rabbit  
Application Route : Skin contact  
Exposure time : 90 weeks  
Result : negative

### **Reproductive toxicity**

Not classified based on available information.

### **Components:**

#### **Cellulose:**

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

Effects on foetal development : Test Type: Fertility/early embryonic development  
Species: Rat  
Application Route: Ingestion  
Result: negative

#### **Mometasone:**

Effects on fertility : Test Type: Fertility  
Species: Rat  
Application Route: Subcutaneous  
Fertility: NOAEL: 0.015 mg/kg body weight  
Symptoms: Reduced embryonic survival, Reduced foetal weight  
Result: No effects on fertility, Effect on reproduction capacity

Effects on foetal development : Test Type: Embryo-foetal development

# SAFETY DATA SHEET

according to the Globally Harmonized System



ORGANON

## Mometasone Suspension Formulation

|         |                |             |                                 |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 20.03.2023  |
| 3.7     | 26.09.2023     | 23600-00023 | Date of first issue: 21.10.2014 |

ment

Species: Mouse  
Application Route: Subcutaneous  
Embryo-foetal toxicity: LOAEL: 0.06 mg/kg body weight  
Result: Embryotoxic effects., Teratogenicity and developmental toxicity

Test Type: Embryo-foetal development  
Species: Rat  
Application Route: Dermal  
Embryo-foetal toxicity: LOAEL: 0.3 mg/kg body weight  
Result: Embryo-foetal toxicity

Test Type: Embryo-foetal development  
Species: Rabbit  
Application Route: Dermal  
Embryo-foetal toxicity: LOAEL: 0.15 mg/kg body weight  
Result: Embryo-foetal toxicity, Malformations were observed.

Test Type: Embryo-foetal development  
Species: Rat  
Application Route: Subcutaneous  
Embryo-foetal toxicity: LOAEL: 0.15 mg/kg body weight  
Result: Effects on newborn

Test Type: Embryo-foetal development  
Species: Rabbit  
Application Route: Oral  
Embryo-foetal toxicity: LOAEL: 0.7 mg/kg body weight  
Result: Embryo-foetal 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.

### **Benzalkonium chloride:**

Effects on fertility : Test Type: Two-generation reproduction toxicity study  
Species: Rat  
Application Route: Ingestion  
Method: OECD Test Guideline 416  
Result: negative  
Remarks: Based on data from similar materials

Effects on foetal development : Test Type: Embryo-foetal development  
Species: Rabbit  
Application Route: Ingestion  
Method: OECD Test Guideline 414  
Result: negative  
Remarks: Based on data from similar materials

### **STOT - single exposure**

Not classified based on available information.

# SAFETY DATA SHEET

according to the Globally Harmonized System



ORGANON

## Mometasone Suspension Formulation

Version 3.7      Revision Date: 26.09.2023      SDS Number: 23600-00023      Date of last issue: 20.03.2023  
Date of first issue: 21.10.2014

---

### Components:

#### **Mometasone:**

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

#### **STOT - repeated exposure**

Not classified based on available information.

### Components:

#### **Mometasone:**

Exposure routes : inhalation (dust/mist/fume)  
Target Organs : Immune system, Liver, Kidney, Skin  
Assessment : May cause damage to organs through prolonged or repeated exposure.

#### **Benzalkonium chloride:**

Assessment : No significant health effects observed in animals at concentrations of 100 mg/kg bw or less.

### **Repeated dose toxicity**

### Components:

#### **Cellulose:**

Species : Rat  
NOAEL :  $\geq 9,000$  mg/kg  
Application Route : Ingestion  
Exposure time : 90 Days

#### **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

# SAFETY DATA SHEET

according to the Globally Harmonized System



ORGANON

## Mometasone Suspension Formulation

|         |                |             |                                 |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 20.03.2023  |
| 3.7     | 26.09.2023     | 23600-00023 | Date of first issue: 21.10.2014 |

---

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

### **Benzalkonium chloride:**

Species : Rat  
NOAEL : >= 100 mg/kg  
Application Route : Ingestion  
Exposure time : 12 Weeks

### **Aspiration toxicity**

Not classified based on available information.

### **Components:**

#### **Mometasone:**

Not applicable

### **Experience with human exposure**

### **Components:**

#### **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

---

## 12. ECOLOGICAL INFORMATION

### **Ecotoxicity**

### **Components:**

#### **Cellulose:**

Toxicity to fish : LC50 (Oryzias latipes (Japanese medaka)): > 100 mg/l  
Exposure time: 48 h  
Remarks: Based on data from similar materials

#### **Mometasone:**

Toxicity to fish : LC50 (Menidia beryllina (Silverside)): 0.11 mg/l  
Exposure time: 96 h

# SAFETY DATA SHEET

according to the Globally Harmonized System



ORGANON

## Mometasone Suspension Formulation

Version 3.7      Revision Date: 26.09.2023      SDS Number: 23600-00023      Date of last issue: 20.03.2023  
Date of first issue: 21.10.2014

|  |  |
|--|--|
|  | Remarks: No toxicity at the limit of solubility  |
|  | LC50 (Cyprinodon variegatus (sheepshead minnow)): > 5 mg/l<br>Exposure time: 7 d<br>Remarks: No toxicity at the limit of solubility  |
| Toxicity to daphnia and other aquatic invertebrates                    | : EC50 (Daphnia magna (Water flea)): > 5 mg/l<br>Exposure time: 48 h<br>Method: OECD Test Guideline 202<br>Remarks: No toxicity at the limit of solubility                       |
|  | EC50 (Americamysis): > 5 mg/l<br>Exposure time: 96 h<br>Method: US-EPA OPPTS 850.1035<br>Remarks: No toxicity at the limit of solubility   |
| Toxicity to algae/aquatic plants                                       | : EC50 ( Pseudokirchneriella subcapitata (green algae)): > 3.2 mg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201<br>Remarks: No toxicity at the limit of solubility |
| Toxicity to microorganisms   | : EC50: > 1,000 mg/l<br>Exposure time: 3 h<br>Test Type: Respiration inhibition<br>Method: OECD Test Guideline 209<br>Remarks: No toxicity at the limit of solubility            |
|  | NOEC: 1,000 mg/l<br>Exposure time: 3 h<br>Test Type: Respiration inhibition<br>Method: OECD Test Guideline 209<br>Remarks: No toxicity at the limit of solubility                |
| Toxicity to fish (Chronic toxicity)                                    | : NOEC: 0.00014 mg/l<br>Exposure time: 32 d<br>Species: Pimephales promelas (fathead minnow)<br>Method: OECD Test Guideline 210  |
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : NOEC: 0.34 mg/l<br>Exposure time: 21 d<br>Species: Daphnia magna (Water flea)<br>Method: OECD Test Guideline 211<br>Remarks: No toxicity at the limit of solubility            |
| M-Factor (Chronic aquatic toxicity)                                    | : 100  |
| <b>Benzalkonium chloride:</b>  |  |
| Toxicity to fish   | : LC50 (Pimephales promelas (fathead minnow)): 0.28 mg/l<br>Exposure time: 96 h  |
| Toxicity to daphnia and other aquatic invertebrates                    | : EC50 (Daphnia magna (Water flea)): 0.0056 mg/l<br>Exposure time: 48 h  |

# SAFETY DATA SHEET

according to the Globally Harmonized System



ORGANON

## Mometasone Suspension Formulation

|         |                |             |                                 |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 20.03.2023  |
| 3.7     | 26.09.2023     | 23600-00023 | Date of first issue: 21.10.2014 |

---

Toxicity to algae/aquatic plants : ErC50 ( Chlorella pyrenoidosa (algae)): 0.09 mg/l  
Exposure time: 72 h

M-Factor (Acute aquatic toxicity) : 100

Toxicity to fish (Chronic toxicity) : NOEC: 0.032 mg/l  
Exposure time: 34 d  
Species: Pimephales promelas (fathead minnow)

### Persistence and degradability

#### Components:

##### **Cellulose:**

Biodegradability : Result: Readily biodegradable.

##### **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

##### **Benzalkonium chloride:**

Biodegradability : Result: Readily biodegradable.  
Method: OECD Test Guideline 301D  
Remarks: Based on data from similar materials

### Bioaccumulative potential

#### Components:

##### **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

##### **Benzalkonium chloride:**

Bioaccumulation : Species: Lepomis macrochirus (Bluegill sunfish)  
Bioconcentration factor (BCF): < 500  
Remarks: Based on data from similar materials

Partition coefficient: n-octanol/water : log Pow: 1.692  
Remarks: Calculation

# SAFETY DATA SHEET

according to the Globally Harmonized System



## Mometasone Suspension Formulation

Version 3.7      Revision Date: 26.09.2023      SDS Number: 23600-00023      Date of last issue: 20.03.2023  
Date of first issue: 21.10.2014

---

### Mobility in soil

#### Components:

#### Mometasone:

Distribution among environmental compartments : log Koc: 4.02

#### Other adverse effects

No data available

---

## 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.

---

## 14. TRANSPORT INFORMATION

### International Regulations

#### UNRTDG

UN number : UN 3082  
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.  
(Mometasone, Benzalkonium chloride)

Class : 9  
Packing group : III  
Labels : 9  
Environmentally hazardous : yes

#### IATA-DGR

UN/ID No. : UN 3082  
Proper shipping name : Environmentally hazardous substance, liquid, n.o.s.  
(Mometasone, Benzalkonium chloride)

Class : 9  
Packing group : III  
Labels : Miscellaneous  
Packing instruction (cargo aircraft) : 964  
Packing instruction (passenger aircraft) : 964  
Environmentally hazardous : yes

#### IMDG-Code

UN number : UN 3082  
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.  
(Mometasone, Benzalkonium chloride)

---



# SAFETY DATA SHEET

according to the Globally Harmonized System



ORGANON

## Mometasone Suspension Formulation

|         |                |             |                                 |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 20.03.2023  |
| 3.7     | 26.09.2023     | 23600-00023 | Date of first issue: 21.10.2014 |

|                  |            |
|------------------|------------|
| Class            | : 9        |
| Packing group    | : III      |
| Labels           | : 9        |
| EmS Code         | : F-A, S-F |
| Marine pollutant | : yes      |

### Transport in bulk according to IMO instruments

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.

## 15. REGULATORY INFORMATION

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

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

|       |                  |
|-------|------------------|
| AICS  | : not determined |
| DSL   | : not determined |
| IECSC | : not determined |

## 16. OTHER INFORMATION

Revision Date : 26.09.2023

### 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)

ACGIH / TWA : 8-hour, time-weighted average

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 con-

# SAFETY DATA SHEET

according to the Globally Harmonized System



ORGANON

## Mometasone Suspension Formulation

|         |                |             |                                 |
|---------|----------------|-------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 20.03.2023  |
| 3.7     | 26.09.2023     | 23600-00023 | Date of first issue: 21.10.2014 |

---

centration; 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.

IN / EN