

## Mometasone Suspension Formulation

Version 4.1      Revision Date: 2023/09/26      SDS Number: 23597-00024      Date of last issue: 2023/03/20  
Date of first issue: 2014/10/21

---

**1. PRODUCT AND COMPANY IDENTIFICATION**

Product name : Mometasone Suspension Formulation

**Manufacturer or supplier's details**

Company : Organon & Co.

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

Telephone : +1-551-430-6000

Emergency telephone number : +1-215-631-6999

E-mail address : EHSSTEWARD@organon.com

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

Recommended use : Pharmaceutical

Restrictions on use : Not applicable

---

**2. HAZARDS IDENTIFICATION****GHS Classification**

Long-term (chronic) aquatic hazard : Category 2

**GHS label elements**

Hazard pictograms :



Signal word : None

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

Precautionary statements :

**Prevention:**

P273 Avoid release to the environment.

**Response:**

P391 Collect spillage.

**Disposal:**

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

## Mometasone Suspension Formulation

Version 4.1      Revision Date: 2023/09/26      SDS Number: 23597-00024      Date of last issue: 2023/03/20  
Date of first issue: 2014/10/21

**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	< 10
Mometasone	83919-23-7	>= 0.025 -< 0.25
Benzalkonium chloride	8001-54-5	>= 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.  
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.

## Mometasone Suspension Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/03/20
4.1	2023/09/26	23597-00024	Date of first issue: 2014/10/21

**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

**8. EXPOSURE CONTROLS/PERSONAL PROTECTION****Components with workplace control parameters**

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Cellulose	9004-34-6	NAB	10 mg/m <sup>3</sup>	ID OEL

## Mometasone Suspension Formulation

Version 4.1      Revision Date: 2023/09/26      SDS Number: 23597-00024      Date of last issue: 2023/03/20  
Date of first issue: 2014/10/21

		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.

**9. PHYSICAL AND CHEMICAL PROPERTIES**

**Appearance** : liquid

# SAFETY DATA SHEET



## Mometasone Suspension Formulation



Version 4.1      Revision Date: 2023/09/26      SDS Number: 23597-00024      Date of last issue: 2023/03/20  
Date of first issue: 2014/10/21

---

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

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

## Mometasone Suspension Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/03/20
4.1	2023/09/26	23597-00024	Date of first issue: 2014/10/21

---

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

**Mometasone Suspension Formulation**

Version            Revision Date:            SDS Number:            Date of last issue: 2023/03/20  
4.1                  2023/09/26              23597-00024            Date of first issue: 2014/10/21

---

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.

## Mometasone Suspension Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/03/20
4.1	2023/09/26	23597-00024	Date of first issue: 2014/10/21

---

**Components:****Mometasone:**

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



## Mometasone Suspension Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/03/20
4.1	2023/09/26	23597-00024	Date of first issue: 2014/10/21

---

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.

**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 Suspension Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/03/20
4.1	2023/09/26	23597-00024	Date of first issue: 2014/10/21

---

**Mometasone:**

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

**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

## Mometasone Suspension Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/03/20
4.1	2023/09/26	23597-00024	Date of first issue: 2014/10/21

---

- 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  
 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

## Mometasone Suspension Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/03/20
4.1	2023/09/26	23597-00024	Date of first issue: 2014/10/21

---

Method: OECD Test Guideline 414  
 Result: negative  
 Remarks: Based on data from similar materials

**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:**

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

## Mometasone Suspension Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/03/20
4.1	2023/09/26	23597-00024	Date of first issue: 2014/10/21

---

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

**Benzalkonium chloride:**

Species : Rat  
NOAEL :  $\geq 100$  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

## Mometasone Suspension Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/03/20
4.1	2023/09/26	23597-00024	Date of first issue: 2014/10/21

---

## 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  
 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  
 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

## Mometasone Suspension Formulation

Version	Revision Date:	SDS Number:	Date of last issue:
4.1	2023/09/26	23597-00024	2023/03/20
			Date of first issue: 2014/10/21

---

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

**Benzalkonium chloride:**

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 0.28 mg/l  
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 0.0056 mg/l  
Exposure time: 48 h

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 (Pimephales promelas (fathead minnow)): 0.032 mg/l  
Exposure time: 34 d

**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:**

## Mometasone Suspension Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/03/20
4.1	2023/09/26	23597-00024	Date of first issue: 2014/10/21

---

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

**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 Suspension Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2023/03/20
4.1	2023/09/26	23597-00024	Date of first issue: 2014/10/21

---

(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)

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.

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

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

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

Hazardous substances that must be registered : Not applicable

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

Hazardous substances approved for use : Glycerine

Prohibited substances : Not applicable

Restricted substances : Not applicable

## Mometasone Suspension Formulation

Version	Revision Date:	SDS Number:	Date of last issue:
4.1	2023/09/26	23597-00024	2023/03/20
			Date of first issue: 2014/10/21

---

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

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

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

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

AICS : not determined

DSL : not determined

IECSC : not determined

---

**16. OTHER INFORMATION**

Revision Date : 2023/09/26

**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 : yyyy/mm/dd

**Full text of other abbreviations**

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

ID OEL : Indonesia. Occupational Exposure Limits

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

ID OEL / NAB : Long term exposure limit

AIC - 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

**Mometasone Suspension Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 2023/03/20
4.1	2023/09/26	23597-00024	Date of first issue: 2014/10/21

---

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.

ID / EN