according to GB/T 16483 and GB/T 17519



Mometasone Suspension Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 2020/03/23

 3.1
 2020/10/16
 23592-00017
 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 : 30 Hudson Street, 33nd floor

Jersey City, New Jersey, U.S.A 07302

Telephone : 551-430-6000

Emergency telephone number : 215-631-6999

E-mail address : EHSSTEWARD@organon.com

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical

2. HAZARDS IDENTIFICATION

Emergency Overview

Appearance : liquid

Colour : white to off-white, opaque

Odour : odourless

Harmful to aquatic life. Toxic to aquatic life with long lasting effects.

GHS Classification

Short-term (acute) aquatic

hazard

Category 3

Long-term (chronic) aquatic

hazard

Category 2

GHS label elements

Hazard pictograms :

¥2>

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.

Response:

P391 Collect spillage.

according to GB/T 16483 and GB/T 17519



Mometasone Suspension Formulation

Version Revision Date: SDS Number: Date of last issue: 2020/03/23 3.1 2020/10/16 23592-00017 Date of first issue: 2014/10/21

Disposal:

P501 Dispose of contents/ container to an approved waste

disposal plant.

Physical and chemical hazards

Not classified based on available information.

Health hazards

Not classified based on available information.

Environmental hazards

Harmful to aquatic life. Toxic to aquatic life with long lasting effects.

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	>= 1 -< 10
Mometasone	83919-23-7	>= 0.025 -< 0.1
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. None known.

Most important symptoms

and effects, both acute and

delayed

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 (CO2)

Dry chemical

Unsuitable extinguishing

media

None known.

Specific hazards during fire-

fighting

Exposure to combustion products may be a hazard to health.

2/18

according to GB/T 16483 and GB/T 17519



Mometasone Suspension Formulation

Version SDS Number: Date of last issue: 2020/03/23 Revision Date: 3.1 2020/10/16 23592-00017 Date of first issue: 2014/10/21

Hazardous combustion prod: :

Carbon oxides

Specific extinguishing meth-

Use extinguishing measures that are appropriate to local cir-

cumstances and the surrounding environment. Use water spray to cool unopened containers.

Remove undamaged containers from fire area if it is safe to do

Evacuate area.

Special protective equipment

for firefighters

Wear self-contained breathing apparatus for firefighting if nec-

essary.

Use personal protective equipment.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protec- : tive equipment and emer-

gency procedures

Follow safe handling advice (see section 7) and personal pro-

tective equipment recommendations (see section 8).

Avoid release to the environment. **Environmental precautions**

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 absor-

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 deter-

mine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

7. HANDLING AND STORAGE

Handling

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 as-

sessment

Take care to prevent spills, waste and minimize release to the

environment.

Avoidance of contact Oxidizing agents

according to GB/T 16483 and GB/T 17519



Mometasone Suspension Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 2020/03/23

 3.1
 2020/10/16
 23592-00017
 Date of first issue: 2014/10/21

Storage

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

Packaging material : Unsuitable material: None known.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	CAS-No.	Value type (Form of	Control parame- ters / Permissible	Basis	
		exposure)	concentration		
Cellulose	9004-34-6	PC-TWA	10 mg/m3	CN OEL	
		TWA	10 mg/m3	ACGIH	
Mometasone	83919-23-7	TWA	1 μg/m3 (OEB 4)	Internal	
	Further information: Skin				
		Wipe limit	10 μg/100 cm ²	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 expo-

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection.

Filter type : Combined particulates and organic vapour type

Eye/face 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, dis-

posable suits) to avoid exposed skin surfaces.

Use appropriate degowning techniques to remove potentially

contaminated clothing.

Hand protection

Material : Chemical-resistant gloves

Remarks : Consider double gloving.

Hygiene measures : If exposure to chemical is likely during typical use, provide

according to GB/T 16483 and GB/T 17519



Mometasone Suspension Formulation

Version Revision Date: SDS Number: Date of last issue: 2020/03/23 3.1 2020/10/16 23592-00017 Date of first issue: 2014/10/21

eye flushing systems and safety showers close to the work-

ing 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

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/cm3

Solubility(ies)

Water solubility : soluble

Partition coefficient: n-

octanol/water

Not applicable

according to GB/T 16483 and GB/T 17519



Mometasone Suspension Formulation

Version Revision Date: SDS Number: Date of last issue: 2020/03/23 3.1 2020/10/16 23592-00017 Date of first issue: 2014/10/21

Auto-ignition temperature : No data available

Decomposition temperature : No data available

Viscosity

Viscosity, kinematic : No data available

Explosive properties : Not explosive

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

Molecular weight : 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 reac-

tions

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

Exposure routes : 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

according to GB/T 16483 and GB/T 17519



Mometasone Suspension Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 2020/03/23

 3.1
 2020/10/16
 23592-00017
 Date of first issue: 2014/10/21

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 :

administration)

LD50 (Rat): 300 mg/kg

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

according to GB/T 16483 and GB/T 17519



Mometasone Suspension Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 2020/03/23

 3.1
 2020/10/16
 23592-00017
 Date of first issue: 2014/10/21

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

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

according to GB/T 16483 and GB/T 17519



Mometasone Suspension Formulation

Version Revision Date: SDS Number: Date of last issue: 2020/03/23 3.1 2020/10/16 23592-00017 Date of first issue: 2014/10/21

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.

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

according to GB/T 16483 and GB/T 17519



Mometasone Suspension Formulation

Version **Revision Date:** SDS Number: Date of last issue: 2020/03/23 3.1 2020/10/16 23592-00017 Date of first issue: 2014/10/21

72 weeks Exposure time Result negative

Mometasone:

Species Rat **Application Route** Inhalation Exposure time 2 Years

0.067 mg/kg body weight Dose

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 Skin contact **Application Route** 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 develop-

Test Type: Fertility/early embryonic development ment

Species: Rat

Application Route: Ingestion

Result: negative

Mometasone:

according to GB/T 16483 and GB/T 17519



Mometasone Suspension Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 2020/03/23

 3.1
 2020/10/16
 23592-00017
 Date of first issue: 2014/10/21

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

weiaht

Result: No effects on fertility, Effect on reproduction capacity

Effects on foetal develop-

ment

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 developmen-

tal 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 - As-

sessment

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 develop-

ment

Test Type: Embryo-foetal development

Species: Rabbit

according to GB/T 16483 and GB/T 17519



Mometasone Suspension Formulation

Version Revision Date: SDS Number: Date of last issue: 2020/03/23 3.1 2020/10/16 23592-00017 Date of first issue: 2014/10/21

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.

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 concentra-

tions of 100 mg/kg bw or less.

Repeated dose toxicity

Components:

Cellulose:

Species : Rat

NOAEL : >= 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

according to GB/T 16483 and GB/T 17519



Mometasone Suspension Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 2020/03/23

 3.1
 2020/10/16
 23592-00017
 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 : >= 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 res-

piratory 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:

according to GB/T 16483 and GB/T 17519



Mometasone Suspension Formulation

Version Revision Date: SDS Number: Date of last issue: 2020/03/23 3.1 2020/10/16 23592-00017 Date of first issue: 2014/10/21

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 tox-

icity)

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 (Chron-

ic 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

according to GB/T 16483 and GB/T 17519



Mometasone Suspension Formulation

Version Revision Date: SDS Number: Date of last issue: 2020/03/23 3.1 2020/10/16 23592-00017 Date of first issue: 2014/10/21

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 (aglae)): 0.09 mg/l

Exposure time: 72 h

100

M-Factor (Acute aquatic tox-

icity)

Toxicity to fish (Chronic tox-:

icity)

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:

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

according to GB/T 16483 and GB/T 17519



Mometasone Suspension Formulation

Version Revision Date: SDS Number: Date of last issue: 2020/03/23 3.1 2020/10/16 23592-00017 Date of first issue: 2014/10/21

Partition coefficient: n- : log Pow: 1.692 octanol/water 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 : Dispose of in accordance with local regulations.

Contaminated packaging : Empty containers should be taken to an approved waste han-

dling 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

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 (passen-

ger aircraft)

964

Environmentally hazardous :

: yes

IMDG-Code

UN number : UN 3082

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.

(Mometasone, Benzalkonium chloride)

according to GB/T 16483 and GB/T 17519



Mometasone Suspension Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 2020/03/23

 3.1
 2020/10/16
 23592-00017
 Date of first issue: 2014/10/21

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.

National Regulations

GB 6944/12268

UN number : UN 3082

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.

(Mometasone, Benzalkonium chloride)

Class : 9
Packing group : III
Labels : 9

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

National regulatory information

Law on the Prevention and Control of Occupational Diseases

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

AICS : not determined

DSL : not determined

IECSC : not determined

16. OTHER INFORMATION

Further information

Sources of key data used to

compile the Safety Data Sheet Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen-

cy, http://echa.europa.eu/

Date format : yyyy/mm/dd

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

CN OEL : Occupational exposure limits for hazardous agents in the

workplace - Chemical hazardous agents.

according to GB/T 16483 and GB/T 17519



Mometasone Suspension Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 2020/03/23

 3.1
 2020/10/16
 23592-00017
 Date of first issue: 2014/10/21

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

CN OEL / PC-TWA : Permissible concentration - 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 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; 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

Disclaimer

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.

CN / EN