

Mometasone Suspension Formulation

Version 5.0 Revision Date: 06.04.2024 SDS Number: 23615-00025 Date of last issue: 26.09.2023
Date of first issue: 21.10.2014

SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1 Product identifier**

Trade name : Mometasone Suspension Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Sub-stance/Mixture : Pharmaceutical

Recommended restrictions on use : Not applicable

1.3 Details of the supplier of the safety data sheet

Company : Organon & Co.
30 Hudson Street, 33rd floor
07302 Jersey City, New Jersey, U.S.A

Telephone : +1-551-430-6000

E-mail address of person responsible for the SDS : EHSSTEWARD@organon.com

1.4 Emergency telephone number

+1-215-631-6999

SECTION 2: Hazards identification**2.1 Classification of the substance or mixture****Classification (REGULATION (EC) No 1272/2008)**

Long-term (chronic) aquatic hazard, Category 2 H411: Toxic to aquatic life with long lasting effects.

2.2 Label elements**Labelling (REGULATION (EC) No 1272/2008)**

Hazard pictograms :



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

Precautionary statements :

Prevention:

P273 Avoid release to the environment.

Response:

P391 Collect spillage.

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2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

SECTION 3: Composition/information on ingredients**3.2 Mixtures****Components**

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Mometasone	83919-23-7	Repr. 1B; H360Df STOT RE 2; H373 (Immune system, Liver, Kidney, Skin) Aquatic Chronic 1; H410 M-Factor (Chronic aquatic toxicity): 100	$\geq 0,025 - < 0,1$
Benzalkonium chloride	8001-54-5	Acute Tox. 3; H301 Acute Tox. 2; H330 Acute Tox. 3; H311 Skin Corr. 1; H314 Eye Dam. 1; H318 Aquatic Acute 1; H400 Aquatic Chronic 2; H411 M-Factor (Acute aquatic toxicity): 100	$\geq 0,0025 - < 0,025$

For explanation of abbreviations see section 16.

SECTION 4: First aid measures**4.1 Description of first aid measures**

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

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.

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- 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.

4.2 Most important symptoms and effects, both acute and delayed

None known.

4.3 Indication of any immediate medical attention and special treatment needed

- Treatment : Treat symptomatically and supportively.
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SECTION 5: Firefighting measures

5.1 Extinguishing media

- Suitable extinguishing media : Water spray
Alcohol-resistant foam
Carbon dioxide (CO₂)
Dry chemical

- Unsuitable extinguishing media : None known.

5.2 Special hazards arising from the substance or mixture

- Specific hazards during fire-fighting : Exposure to combustion products may be a hazard to health.
- Hazardous combustion products : Carbon oxides

5.3 Advice for firefighters

- Special protective equipment for firefighters : Wear self-contained breathing apparatus for firefighting if necessary. Use personal protective equipment.
- 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.
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SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

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

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6.2 Environmental precautions

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.

6.3 Methods and material for containment and cleaning up

Methods for 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.

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage**7.1 Precautions for safe 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 assessment
Take care to prevent spills, waste and minimize release to the environment.

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.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers : Keep in properly labelled containers. Store in accordance with the particular national regulations.

Advice on common storage : Do not store with the following product types:
Strong oxidizing agents

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Gases

7.3 Specific end use(s)

Specific use(s) : No data available

SECTION 8: Exposure controls/personal protection**8.1 Control parameters****Occupational Exposure Limits**

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Cellulose	9004-34-6	OEL-RL	10 mg/m ³	ZA OEL
Further information: Occupational Exposure Limits - Restricted Limits For Hazardous Chemical Agents				
Mometasone	83919-23-7	TWA	1 µg/m ³ (OEB 4)	Internal
Further information: Skin				
		Wipe limit	10 µg/100 cm ²	Internal

Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006:

Substance name	End Use	Exposure routes	Potential health effects	Value
Glycerine	Workers	Inhalation	Long-term local effects	56 mg/m ³
	Consumers	Ingestion	Long-term systemic effects	229 mg/kg bw/day
	Consumers	Inhalation	Long-term local effects	33 mg/m ³

Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006:

Substance name	Environmental Compartment	Value
Glycerine	Fresh water	0,885 mg/l
	Marine water	0,0885 mg/l
	Intermittent use/release	8,85 mg/l
	Sewage treatment plant	1000 mg/l
	Fresh water sediment	3,3 mg/kg dry weight (d.w.)
	Marine sediment	0,33 mg/kg dry weight (d.w.)
	Soil	0,141 mg/kg dry weight (d.w.)

8.2 Exposure controls**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.

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Personal protective equipment

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.
Hand protection		
Material	:	Chemical-resistant gloves
Remarks	:	Consider double gloving.
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.
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 (A-P)

SECTION 9: Physical and chemical properties**9.1 Information on basic 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
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

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Density : 1 g/cm³

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.

9.2 Other information

Flammability (liquids) : No data available

Molecular weight : Not applicable

Particle size : Not applicable

SECTION 10: Stability and reactivity

10.1 Reactivity

Not classified as a reactivity hazard.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions : Can react with strong oxidizing agents.

10.4 Conditions to avoid

Conditions to avoid : None known.

10.5 Incompatible materials

Materials to avoid : Oxidizing agents

10.6 Hazardous decomposition products

No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Information on likely routes of : Inhalation

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exposure

Skin contact
Ingestion
Eye contact

Acute toxicity

Not classified based on available information.

Components:**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.
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

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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:**

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:**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

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Genotoxicity in vivo	: Test Type: Mouse Lymphoma Result: negative
Genotoxicity in vivo	: Test Type: Micronucleus test Species: Mouse Application Route: Oral Result: negative
Genotoxicity in vivo	: Test Type: Chromosomal aberration Species: Rat Cell type: Bone marrow Result: negative
Genotoxicity in vivo	: 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
Genotoxicity in vitro	: Test Type: In vitro mammalian cell gene mutation test Method: OECD Test Guideline 476 Result: negative Remarks: Based on data from similar materials
Genotoxicity in vitro	: 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:**Mometasone:**

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

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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:**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
 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

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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.

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.

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Benzalkonium chloride:

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

Repeated dose toxicity**Components:****Mometasone:**

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

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

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

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

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

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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 |
|---------|------------------------------|

SECTION 12: Ecological information**12.1 Toxicity****Components:****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 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 |

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	Exposure time: 3 h
	Test Type: Respiration inhibition
	Method: OECD Test Guideline 209
	Remarks: No toxicity at the limit of solubility
Toxicity to fish (Chronic toxicity)	: NOEC: 0,00014 mg/l Exposure time: 32 d Species: Pimephales promelas (fathead minnow) Method: OECD Test Guideline 210
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	: NOEC: 0,34 mg/l Exposure time: 21 d Species: Daphnia magna (Water flea) Method: OECD Test Guideline 211 Remarks: No toxicity at the limit of solubility
M-Factor (Chronic aquatic toxicity)	: 100

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: 0,032 mg/l Exposure time: 34 d Species: Pimephales promelas (fathead minnow)

12.2 Persistence and degradability**Components:****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
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12.3 Bioaccumulative potential**Components:****Mometasone:**

Bioaccumulation	:	Species: Lepomis macrochirus (Bluegill sunfish) Bioconcentration factor (BCF): 107,1 Method: OECD Test Guideline 305
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Partition coefficient: n-octanol/water	:	log Pow: 4,68
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Benzalkonium chloride:

Bioaccumulation	:	Species: Lepomis macrochirus (Bluegill sunfish) Bioconcentration factor (BCF): < 500 Remarks: Based on data from similar materials
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Partition coefficient: n-octanol/water	:	log Pow: 1,692 Remarks: Calculation
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12.4 Mobility in soil**Components:****Mometasone:**

Distribution among environmental compartments	:	log Koc: 4,02
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12.5 Results of PBT and vPvB assessment**Product:**

Assessment	:	This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.
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12.6 Other adverse effects**Product:**

Endocrine disrupting potential	:	The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.
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SECTION 13: Disposal considerations**13.1 Waste treatment methods**

Product	:	Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.
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Contaminated packaging : Do not dispose of waste into sewer.
 : Empty containers should be taken to an approved waste handling site for recycling or disposal.
 : If not otherwise specified: Dispose of as unused product.

SECTION 14: Transport information**14.1 UN number**

ADN : UN 3082
 ADR : UN 3082
 RID : UN 3082
 IMDG : UN 3082
 IATA : UN 3082

14.2 UN proper shipping name

ADN : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
 (Mometasone, Benzalkonium chloride)
 ADR : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
 (Mometasone, Benzalkonium chloride)
 RID : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
 (Mometasone, Benzalkonium chloride)
 IMDG : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
 (Mometasone, Benzalkonium chloride)
 IATA : Environmentally hazardous substance, liquid, n.o.s.
 (Mometasone, Benzalkonium chloride)

14.3 Transport hazard class(es)

	Class	Subsidiary risks
ADN	: 9	
ADR	: 9	
RID	: 9	
IMDG	: 9	
IATA	: 9	

14.4 Packing group

ADN
 Packing group : III
 Classification Code : M6
 Hazard Identification Number : 90
 Labels : 9
 ADR
 Packing group : III

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Classification Code : M6
 Hazard Identification Number : 90
 Labels : 9
 Tunnel restriction code : (-)

RID

Packing group : III
 Classification Code : M6
 Hazard Identification Number : 90
 Labels : 9

IMDG

Packing group : III
 Labels : 9
 EmS Code : F-A, S-F

IATA (Cargo)

Packing instruction (cargo aircraft) : 964
 Packing instruction (LQ) : Y964
 Packing group : III
 Labels : Miscellaneous

IATA (Passenger)

Packing instruction (passenger aircraft) : 964
 Packing instruction (LQ) : Y964
 Packing group : III
 Labels : Miscellaneous

14.5 Environmental hazards**ADN**

Environmentally hazardous : yes

ADR

Environmentally hazardous : yes

RID

Environmentally hazardous : yes

IMDG

Marine pollutant : yes

IATA (Passenger)

Environmentally hazardous : yes

IATA (Cargo)

Environmentally hazardous : yes

14.6 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.

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Remarks : Not applicable for product as supplied.

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SECTION 15: Regulatory information**15.1 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

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

Other information	:	Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.
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Full text of H-Statements

H301	:	Toxic if swallowed.
H311	:	Toxic in contact with skin.
H314	:	Causes severe skin burns and eye damage.
H318	:	Causes serious eye damage.
H330	:	Fatal if inhaled.
H360Df	:	May damage the unborn child. Suspected of damaging fertility.
H373	:	May cause damage to organs through prolonged or repeated exposure if inhaled.
H400	:	Very toxic to aquatic life.
H410	:	Very toxic to aquatic life with long lasting effects.
H411	:	Toxic to aquatic life with long lasting effects.

Full text of other abbreviations

Acute Tox.	:	Acute toxicity
Aquatic Acute	:	Short-term (acute) aquatic hazard
Aquatic Chronic	:	Long-term (chronic) aquatic hazard
Eye Dam.	:	Serious eye damage
Repr.	:	Reproductive toxicity
Skin Corr.	:	Skin corrosion
STOT RE	:	Specific target organ toxicity - repeated exposure
ZA OEL	:	South Africa. The Regulations for Hazardous Chemical Agents, Occupational Exposure Limits
ZA OEL / OEL-RL	:	Occupational Exposure Limit Restricted limit - 8- hour exposure or equivalent (12 hour shifts)

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regula-

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tion (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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; 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; 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

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/>

Classification of the mixture:

Aquatic Chronic 2 H411

Classification procedure:

Calculation method

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The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

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