SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878

Public

ORGANON

Mometasone Suspension Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 26.09.2023
4.0	06.04.2024	23608-00025	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 Substance/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, 33nd 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.

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.

Ecological information: 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.

Toxicological information: 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.

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	>= 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 EUH071 ——————— M-Factor (Acute aquatic toxicity):	>= 0,0025 - < 0,025

		100 Acute toxicity estimate Acute oral toxicity: 240 mg/kg Acute inhalation toxicity (dust/mist): 0,0501 mg/l Acute dermal toxicity: 704 mg/kg	

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.
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.

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.

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).

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 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
Mometasone	83919-23-7	TWA	1 µg/m3 (OEB 4)	Internal
	Further information: Skin			
		Wipe limit	10 µg/100 cm²	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/m3
	Consumers	Ingestion	Long-term systemic effects	229 mg/kg bw/day
	Consumers	Inhalation	Long-term local effects	33 mg/m3

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.

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.
Equipment should conform to NS EN 14387

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

Physical state	:	liquid
Colour	:	white to off-white, opaque
Odour	:	odourless
Odour Threshold	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	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
Flash point	:	No data available
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
pH	:	4,3 - 4,9
Viscosity		
Viscosity, kinematic	:	No data available
Solubility(ies)		
Water solubility	:	soluble
Partition coefficient: n-octanol/water	:	Not applicable
Vapour pressure	:	No data available
Relative density	:	No data available

Density	:	1 g/cm³
Relative vapour density	:	No data available
Particle characteristics		
Particle size	:	Not applicable

9.2 Other information

Explosives	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Evaporation rate	:	No data available
Molecular weight	:	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 hazard classes as defined in Regulation (EC) No 1272/2008

Information on likely routes of exposure : Inhalation
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. 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

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 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:

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:

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 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.

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

11.2 Information on other hazards

Endocrine disrupting properties

Product:

Assessment : 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.

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 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

12.3 Bioaccumulative potential

Components:

Mometasone:

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

Benzalkonium chloride:

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

12.4 Mobility in soil

Components:

Mometasone:

Distribution among environmental compartments	:	log Koc: 4,02

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.

12.6 Endocrine disrupting properties

Product:

Assessment : 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.

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.
Do not dispose of waste into sewer.

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.
If not otherwise specified: Dispose of as unused product.

SECTION 14: Transport information

14.1 UN number or ID 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
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 Maritime transport in bulk according to IMO instruments

Remarks : Not applicable for product as supplied.

SECTION 15: Regulatory information

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII) : Conditions of restriction for the following entries should be considered: Number on list 75, 3

Substance(s) or mixture(s) are listed here according to their appearance in the regulation, irrespective of their use/purpose or the conditions of the restriction. Please refer to the conditions in corresponding Regulation to determine whether an entry is applicable to the placing on the market or not.

If you intend to use this product as tattoo ink, please contact your vendor.

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59). : Not applicable

REACH - List of substances subject to authorisation : Not applicable

(Annex XIV)

Regulation (EC) No 1005/2009 on substances that deplete the ozone layer	:	Not applicable
Regulation (EU) 2019/1021 on persistent organic pollutants (recast)	:	Not applicable
Regulation (EU) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals	:	Not applicable

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.

		Quantity 1	Quantity 2
E2	ENVIRONMENTAL HAZARDS	200 t	500 t

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.

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.
EUH071	:	Corrosive to the respiratory tract.

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

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; Regulation (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:		**Classification procedure:**
Aquatic Chronic 2	H411	Calculation method

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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rial 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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