

# **Mometasone Ointment Formulation**



 Version
 Revision Date:
 SDS Number:
 Date of last issue: 10.10.2020

 1.8
 09.04.2021
 1751225-00009
 Date of first issue: 14.06.2017

### SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name : Mometasone Ointment Formulation

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

Use of the Sub- : Pharmaceutical

stance/Mixture

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 : 551-430-6000

E-mail address of person responsible for the SDS

: EHSSTEWARD@organon.com

1.4 Emergency telephone number

215-631-6999

#### **SECTION 2: Hazards identification**

### 2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Skin irritation, Category 2 H315: Causes skin irritation.

Eye irritation, Category 2 H319: Causes serious eye irritation.

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

egory 2

### 2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms :



Signal word : Warning

Hazard statements : H315 Causes skin irritation.

H319 Causes serious eye irritation.

H411 Toxic to aquatic life with long lasting effects.

Precautionary statements : Prevention:

P264 Wash skin thoroughly after handling.P273 Avoid release to the environment.

P280 Wear protective gloves/ eye protection/ face protection.



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Response:

P332 + P313 If skin irritation occurs: Get medical advice/

attention.

P337 + P313 If eye irritation persists: Get medical advice/

attention.

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.

# **SECTION 3: Composition/information on ingredients**

#### 3.2 Mixtures

### Components

Chemical name	CAS-No. EC-No.	Classification	Concentration (% w/w)
	Index-No.		,
2-Methyl-2,4-pentanediol	Registration number 107-41-5 203-489-0 603-053-00-3	Skin Irrit. 2; H315 Eye Irrit. 2; H319	>= 10 - < 20
Mometasone	83919-23-7	Repr. 1B; H360Df STOT RE 2; H373 (Immune system, Liver, Kidney, Skin) Aquatic Chronic 1; H410	>= 0,1 - < 0,25
		M-Factor (Chronic aquatic toxicity):	

For explanation of abbreviations see section 16.

### **SECTION 4: First aid measures**

# 4.1 Description of first aid measures

General advice : In the case of accident or if you feel unwell, seek medical ad-

vice immediately.

When symptoms persist or in all cases of doubt seek medical

advice.

Protection of first-aiders : First Aid responders should pay attention to self-protection,

and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

If inhaled : If inhaled, remove to fresh air.



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Get medical attention.

In case of skin contact In case of contact, immediately flush skin with soap and plenty

of water.

Remove contaminated clothing and shoes.

Get medical attention. Wash clothing before reuse.

Thoroughly clean shoes before reuse.

In case of eye contact In case of contact, immediately flush eyes with plenty of water

for at least 15 minutes.

If easy to do, remove contact lens, if worn.

Get medical attention.

If swallowed If swallowed, DO NOT induce vomiting.

Get medical attention.

Rinse mouth thoroughly with water.

4.2 Most important symptoms and effects, both acute and delayed

Risks Causes skin irritation.

Causes serious eve irritation.

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

Vapours may form explosive mixtures with air.

Exposure to combustion products may be a hazard to health.

Hazardous combustion prod: :

ucts

Carbon oxides

### 5.3 Advice for firefighters

Special protective equipment :

for firefighters

In the event of fire, wear self-contained breathing apparatus.

Use personal protective equipment.

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances and the surrounding environment.

Use water spray to cool unopened containers.



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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 : Use personal protective equipment.

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

tective 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. 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 : Sweep up or vacuum up spillage and collect in suitable con-

tainer for disposal.

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.

### 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 : If sufficient ventilation is unavailable, use with local exhaust

ventilation.

Advice on safe handling : Do not get on skin or clothing.

Do not swallow. Do not get in eyes.

Wash skin thoroughly after handling.

Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure as-

sessment

Keep container tightly closed.

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 contami-



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nated 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. Keep tightly closed. Store in accordance with the particular national regulations.

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

Strong oxidizing agents Organic peroxides Explosives

Explosives 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	Control parameters	Basis
		of exposure)		
2-Methyl-2,4-	107-41-5	TWA OEL-RL	25 ppm	ZA OEL
pentanediol			125 mg/m3	
	Further information: Recommended Limit			
		STEL OEL-RL	25 ppm	ZA OEL
			125 mg/m3	
	Further information: Recommended Limit			
Mometasone	83919-23-7	TWA	1 μg/m3 (OEB 4)	Internal
	Further information: Skin			
		Wipe limit	10 μg/100 cm <sup>2</sup>	Internal

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

Substance name	End Use	Exposure routes	Potential health effects	Value
2-Methyl-2,4- pentanediol	Workers	Inhalation	Long-term systemic effects	44,4 mg/m3
	Workers	Inhalation	Long-term local effects	49 mg/m3
	Workers	Inhalation	Acute local effects	98 mg/m3
	Workers	Skin contact	Long-term systemic effects	42 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	7,8 mg/m3
	Consumers	Inhalation	Long-term local ef- fects	25 mg/m3



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Consumers	Inhalation	Acute local effects	49 mg/m3
Consumers	Skin contact	Long-term systemic effects	15 mg/kg bw/day
Consumers	Ingestion	Long-term systemic effects	1,5 mg/kg bw/day

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

Substance name	Environmental Compartment	Value
Petrolatum	Oral (Secondary Poisoning)	9,33 mg/kg food
2-Methyl-2,4-pentanediol	Fresh water	0,429 mg/l
	Marine water	0,043 mg/l
	Freshwater - intermittent	4,29 mg/l
	Sewage treatment plant	20 mg/l
	Fresh water sediment	1,59 mg/kg dry weight (d.w.)
	Marine sediment	0,159 mg/kg dry weight (d.w.)
	Soil	0,066 mg/kg dry weight (d.w.)

#### 8.2 Exposure controls

# **Engineering measures**

Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., vacuum conveying from a closed system, packout head with inflatable seal from stationary container, ventilated enclosure, etc.).

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.

Personal protective equipment

Eye protection : Wear safety glasses with side shields or goggles.

If the work environment or activity involves dusty conditions,

mists or aerosols, wear the appropriate goggles.

Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or

aerosols.

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 expo-

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection.

Filter type : Combined particulates and organic vapour type (A-P)





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### **SECTION 9: Physical and chemical properties**

9.1 Information on basic physical and chemical properties

Appearance : ointment

Colour : white to off-white
Odour : No data available
Odour Threshold : No data available

pH : No data available

Melting point/freezing point : No data available

Initial boiling point and boiling

range

Flash point : > 93,3 °C

Evaporation rate : No data available

Flammability (solid, gas) : Not classified as a flammability hazard

Upper explosion limit / Upper

flammability limit

No data available

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 : No data available

Solubility(ies)

Water solubility : No data available Partition coefficient: n- : No data available

octanol/water

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) : Not applicable

Molecular weight : No data available



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Particle size : No data available

### **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 : Vapours may form explosive mixture with air.

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 : Skin contact exposure Ingestion

Eye contact

# **Acute toxicity**

Not classified based on available information.

### **Components:**

# 2-Methyl-2,4-pentanediol:

Acute oral toxicity : LD50 (Rat): > 2.000 mg/kg

Acute dermal toxicity : LD50 (Rat): > 2.000 mg/kg

Method: OECD Test Guideline 402

Assessment: The substance or mixture has no acute dermal

toxicity

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



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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

Skin corrosion/irritation

Causes skin irritation.

**Components:** 

2-Methyl-2,4-pentanediol:

Result : Skin irritation

Remarks : Based on harmonised classification in EU regulation

1272/2008, Annex VI

Mometasone:

Species : Rabbit

Result : No skin irritation

Serious eye damage/eye irritation

Causes serious eye irritation.

**Components:** 

2-Methyl-2,4-pentanediol:

Species : Rabbit

Result : Irritation to eyes, reversing within 21 days

Mometasone:

Species : Rabbit

Result : No eye irritation

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

**Components:** 

2-Methyl-2,4-pentanediol:

Test Type : Maximisation Test Exposure routes : Skin contact Species : Guinea pig

Method : OECD Test Guideline 406

Result : negative



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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.

Germ cell mutagenicity

Not classified based on available information.

**Components:** 

2-Methyl-2,4-pentanediol:

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

Test Type: Chromosome aberration test in vitro

Result: negative

Mometasone:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

Test Type: Chromosomal aberration Test system: Chinese hamster lung cells

Result: negative

Test Type: Chromosomal aberration
Test system: Chinese hamster ovary cells

Result: positive

Test Type: Mouse Lymphoma

Result: negative

Genotoxicity in vivo : Test Type: Micronucleus test

Species: Mouse Application Route: Oral Result: negative

Test Type: Chromosomal aberration

Species: Rat

Cell type: Bone marrow Result: negative

Test Type: unscheduled DNA synthesis assay

Species: Rat



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Cell type: Liver cells Result: negative

Germ cell mutagenicity- As-

sessment

Weight of evidence does not support classification as a germ

cell mutagen.

# 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

### Reproductive toxicity

Not classified based on available information.

### **Components:**

### 2-Methyl-2,4-pentanediol:

Effects on fertility : Test Type: Reproduction/Developmental toxicity screening

test

Species: Rat

Application Route: Ingestion Method: OECD Test Guideline 421

Result: negative

Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Rat

Application Route: Ingestion Method: OECD Test Guideline 414

Result: negative

Mometasone:

Effects on fertility : Test Type: Fertility

Species: Rat

Application Route: Subcutaneous

Fertility: NOAEL: 0,015 mg/kg body weight

Symptoms: Reduced embryonic survival, Reduced foetal

weight

Result: No effects on fertility, Effect on reproduction capacity

Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Mouse



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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.

#### 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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### Repeated dose toxicity

### **Components:**

### 2-Methyl-2,4-pentanediol:

Species : Rat

NOAEL : >= 450 mg/kg
Application Route : Ingestion
Exposure time : 90 Days

Method : OECD Test Guideline 408

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

### **Aspiration toxicity**

Not classified based on available information.

#### **Components:**

#### Mometasone:

Not applicable

# Experience with human exposure

### **Components:**

### 2-Methyl-2,4-pentanediol:

Eye contact : Target Organs: Eyes

Symptoms: Irritation



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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

### **SECTION 12: Ecological information**

### 12.1 Toxicity

### **Components:**

2-Methyl-2,4-pentanediol:

Toxicity to fish : LC50 (Gambusia affinis (Mosquito fish)): 8.510 mg/l

Exposure time: 96 h

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Ceriodaphnia dubia (water flea)): 2.800 mg/l

Exposure time: 48 h

Toxicity to algae/aquatic

plants

ErC50 (Pseudokirchneriella subcapitata (green algae)): > 429

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

EC10 (Pseudokirchneriella subcapitata (green algae)): > 429

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Toxicity to microorganisms : NOEC : 200 mg/l

Exposure time: 10 d

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



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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 tox-

icity)

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 (Chron-

ic 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

### 12.2 Persistence and degradability

#### **Components:**

2-Methyl-2,4-pentanediol:

Biodegradability : Result: Readily biodegradable.

Biodegradation: 81 % Exposure time: 28 d

Method: OECD Test Guideline 301F

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

# Public

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### 12.3 Bioaccumulative potential

### **Components:**

2-Methyl-2,4-pentanediol:

Partition coefficient: n-

octanol/water

log Pow: 0

Remarks: Calculation

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

12.4 Mobility in soil

**Components:** 

Mometasone:

Distribution among environ-

mental 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 Other adverse effects

**Product:** 

Endocrine disrupting poten-

tial

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.

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.



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# **SECTION 14: Transport information**

Revision Date:

#### 14.1 UN number

Version

ADN : UN 3077 **ADR** UN 3077 **RID** UN 3077 **IMDG** UN 3077 IATA UN 3077

14.2 UN proper shipping name

ADN ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S.

(Mometasone)

**ADR** ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S.

(Mometasone)

**RID** ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S.

(Mometasone)

**IMDG** ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S.

(Mometasone)

**IATA** Environmentally hazardous substance, solid, n.o.s.

(Mometasone)

### 14.3 Transport hazard class(es)

**ADN** 9 **ADR** 9 RID 9 **IMDG** 9 **IATA** 9

### 14.4 Packing group

ADN

Packing group Ш Classification Code M7 Hazard Identification Number : 90 Labels

ADR

Packing group Ш Classification Code M7 Hazard Identification Number : 90 Labels 9 Tunnel restriction code (-)

**RID** 







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Packing group : III
Classification Code : M7
Hazard Identification Number : 90
Labels : 9

**IMDG** 

Packing group : III Labels : 9

EmS Code : F-A, S-F

IATA (Cargo)

Packing instruction (cargo : 956

aircraft)

Packing instruction (LQ) : Y956
Packing group : III

Labels : Miscellaneous

IATA (Passenger)

Packing instruction (passen: 956

ger aircraft)

Packing instruction (LQ) : Y956
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.

**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



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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**

H315 : Causes skin irritation.

H319 : Causes serious eye irritation.

H360Df : May damage the unborn child. Suspected of damaging fertili-

ty.

H373 : May cause damage to organs through prolonged or repeated

exposure if inhaled.

H410 : Very toxic to aquatic life with long lasting effects.

#### Full text of other abbreviations

Aquatic Chronic : Long-term (chronic) aquatic hazard

Eye Irrit. : Eye irritation

Repr. : Reproductive toxicity

Skin Irrit. : Skin irritation

STOT RE : Specific target organ toxicity - repeated exposure

ZA OEL : South Africa. Hazardous Chemical Substances Regulations,

Occupational Exposure Limits

ZA OEL / TWA OEL-RL : Long term occupational exposure limits - recommended limit ZA OEL / STEL OEL-RL : Short term occupational exposure limits - recommended limit

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European 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)



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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; 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 Agen-

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

### Classification of the mixture: Classification procedure:

Skin Irrit. 2 H315 Calculation method
Eye Irrit. 2 H319 Calculation method
Aquatic Chronic 2 H411 Calculation method

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.

ZA / EN