

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



 **ORGANON**

## Mometasone Dry Powder Inhaler Formulation

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 30.09.2023  |
| 4.2     | 06.04.2024     | 9372577-00007 | Date of first issue: 27.08.2021 |

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

#### 1.1 Product identifier

Trade name : Mometasone Dry Powder Inhaler 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.  
Shotton Lane  
NE23 3JU Cramlington NU - Great Britain

Telephone : +44 1 670 59 32 05

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

#### 1.4 Emergency telephone number

+1-215-631-6999

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### SECTION 2: Hazards identification

#### 2.1 Classification of the substance or mixture

**Classification (REGULATION (EC) No 1272/2008) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)**

Reproductive toxicity, Category 1B

H360Df: May damage the unborn child. Suspected of damaging fertility.

Specific target organ toxicity - repeated exposure, Category 2

H373: May cause damage to organs through prolonged or repeated exposure.

Long-term (chronic) aquatic hazard, Category 1

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

#### 2.2 Label elements

**Labelling (REGULATION (EC) No 1272/2008) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)**

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|                          |   |                                                                                                                                                                                                                                                                                                                                                                                        |
|--------------------------|---|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Hazard pictograms        | : |                                                                                                                                                                                                                      |
| Signal word              | : | Danger                                                                                                                                                                                                                                                                                                                                                                                 |
| Hazard statements        | : | H360Df      May damage the unborn child. Suspected of damaging fertility.<br>H373      May cause damage to organs through prolonged or repeated exposure.<br>H410      Very toxic to aquatic life with long lasting effects.                                                                                                                                                           |
| Precautionary statements | : | <b>Prevention:</b><br>P201      Obtain special instructions before use.<br>P260      Do not breathe dust.<br>P273      Avoid release to the environment.<br>P280      Wear protective gloves/ protective clothing/ eye protection/ face protection.<br><br><b>Response:</b><br>P308 + P313      IF exposed or concerned: Get medical advice/ attention.<br>P391      Collect spillage. |

Hazardous components which must be listed on the label:  
Mometasone

### 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.  
Dust contact with the eyes can lead to mechanical irritation.  
Contact with dust can cause mechanical irritation or drying of the skin.  
May form explosive dust-air mixture during processing, handling or other means.

## SECTION 3: Composition/information on ingredients

### 3.2 Mixtures

#### Components

| Chemical name | CAS-No.<br>EC-No.<br>Index-No.<br>Registration number | Classification                                                                                               | Concentration<br>(% w/w) |
|---------------|-------------------------------------------------------|--------------------------------------------------------------------------------------------------------------|--------------------------|
| Mometasone    | 83919-23-7                                            | Repr. 1B; H360Df<br>STOT RE 2; H373<br>(Immune system,<br>Liver, Kidney, Skin)<br>Aquatic Chronic 1;<br>H410 | >= 10 - < 20             |

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|  |  |                                             |  |
|--|--|---------------------------------------------|--|
|  |  | M-Factor (Chronic aquatic toxicity):<br>100 |  |
|--|--|---------------------------------------------|--|

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 advice immediately.<br>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.<br>Get medical attention.                                                                                                                                                            |
| In case of skin contact    | : | In case of contact, immediately flush skin with soap and plenty of water.<br>Remove contaminated clothing and shoes.<br>Get medical attention.<br>Wash clothing before reuse.<br>Thoroughly clean shoes before reuse. |
| In case of eye contact     | : | If in eyes, rinse well with water.<br>Get medical attention if irritation develops and persists.                                                                                                                      |
| If swallowed               | : | If swallowed, DO NOT induce vomiting.<br>Get medical attention.<br>Rinse mouth thoroughly with water.                                                                                                                 |

#### 4.2 Most important symptoms and effects, both acute and delayed

- |       |   |                                                                                                                                                                                                                                                                                      |
|-------|---|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Risks | : | May damage the unborn child. Suspected of damaging fertility.<br>May cause damage to organs through prolonged or repeated exposure.<br><br>Contact with dust can cause mechanical irritation or drying of the skin.<br>Dust contact with the eyes can lead to mechanical irritation. |
|-------|---|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

#### 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 (CO<sub>2</sub>)  
Dry chemical

Unsuitable extinguishing media : None known.

#### 5.2 Special hazards arising from the substance or mixture

Specific hazards during fire-fighting : Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.  
Exposure to combustion products may be a hazard to health.

Hazardous combustion products : Carbon oxides  
Chlorine compounds

#### 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 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 : Use personal protective equipment.  
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.  
Retain and dispose of contaminated wash water.  
If spillage enters rivers or watercourses, inform the Environment Agency (emergency telephone number 0800 807060).

#### 6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Sweep up or vacuum up spillage and collect in suitable container for disposal.

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Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).  
Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration.  
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      | : | Static electricity may accumulate and ignite suspended dust causing an explosion.<br>Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.                                                                                                                                                                                                                                                                                                                                                                            |
| Local/Total ventilation | : | If sufficient ventilation is unavailable, use with local exhaust ventilation.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| Advice on safe handling | : | Do not get on skin or clothing.<br>Do not breathe dust.<br>Do not swallow.<br>Avoid contact with eyes.<br>Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment<br>Keep container tightly closed.<br>Minimize dust generation and accumulation.<br>Keep container closed when not in use.<br>Keep away from heat and sources of ignition.<br>Take precautionary measures against static discharges.<br>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.<br>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

- |                                               |   |                                                                                                                                           |
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| Requirements for storage areas and containers | : | Keep in properly labelled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national regulations. |
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Advice on common storage : Do not store with the following product types:  
Strong oxidizing agents  
Self-reactive substances and mixtures  
Organic peroxides  
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

|                  |                                                                                                   |
|------------------|---------------------------------------------------------------------------------------------------|
| dust of any kind | 10 mg/m <sup>3</sup><br>Value type (Form of exposure): TWA (Inhalable)<br>Basis: GB EH40          |
|                  | 4 mg/m <sup>3</sup><br>Value type (Form of exposure): TWA (Respirable fraction)<br>Basis: GB EH40 |

| Components | CAS-No.                   | Value type (Form of exposure) | Control parameters          | Basis    |
|------------|---------------------------|-------------------------------|-----------------------------|----------|
| Mometasone | 83919-23-7                | TWA                           | 1 µg/m <sup>3</sup> (OEB 4) | Internal |
|            | Further information: Skin |                               |                             |          |
|            |                           | Wipe limit                    | 10 µg/100 cm <sup>2</sup>   | Internal |

### 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/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

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|                          |   |                                                                                                                                                                                                                                                                                             |
|--------------------------|---|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Material                 | : | Chemical-resistant gloves                                                                                                                                                                                                                                                                   |
| Remarks                  | : | Consider double gloving.                                                                                                                                                                                                                                                                    |
| Skin and body protection | : | Work uniform or laboratory coat.<br>Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.<br>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.<br>Equipment should conform to BS EN 143                                                                               |
| Filter type              | : | Particulates type (P)                                                                                                                                                                                                                                                                       |

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### SECTION 9: Physical and chemical properties

#### 9.1 Information on basic physical and chemical properties

|                                                  |   |                                                                                 |
|--------------------------------------------------|---|---------------------------------------------------------------------------------|
| Appearance                                       | : | powder                                                                          |
| Colour                                           | : | 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          | : | No data available                                                               |
| Flash point                                      | : | Not applicable                                                                  |
| Evaporation rate                                 | : | No data available                                                               |
| Flammability (solid, gas)                        | : | May form explosive dust-air mixture during processing, handling or other means. |
| Upper explosion limit / Upper flammability limit | : | No data available                                                               |
| Lower explosion limit / Lower flammability limit | : | No data available                                                               |
| Vapour pressure                                  | : | No data available                                                               |
| Relative vapour density                          | : | No data available                                                               |
| Relative density                                 | : | No data available                                                               |
| Density                                          | : | No data available                                                               |
| Solubility(ies)                                  | : |                                                                                 |

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|                                        |   |                                                          |
|----------------------------------------|---|----------------------------------------------------------|
| Water solubility                       | : | No data available                                        |
| Partition coefficient: n-octanol/water | : | No data available                                        |
| 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       | : | No data available |
| 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 | : | May form explosive dust-air mixture during processing, handling or other means.<br>Can react with strong oxidizing agents. |
|---------------------|---|----------------------------------------------------------------------------------------------------------------------------|

### 10.4 Conditions to avoid

|                     |   |                                                   |
|---------------------|---|---------------------------------------------------|
| Conditions to avoid | : | Heat, flames and sparks.<br>Avoid dust formation. |
|---------------------|---|---------------------------------------------------|

### 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. |
|                                                 |   | 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

Not classified based on available information.

### Components:

#### Mometasone:

|         |   |                    |
|---------|---|--------------------|
| Species | : | Rabbit             |
| Result  | : | No skin irritation |

### Serious eye damage/eye irritation

Not classified based on available information.

### Components:

#### 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.

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### 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. |

#### **Germ cell mutagenicity**

Not classified based on available information.

### Components:

#### **Mometasone:**

|                                    |                                                                                                          |
|------------------------------------|----------------------------------------------------------------------------------------------------------|
| Genotoxicity in vitro              | : Test Type: Bacterial reverse mutation assay (AMES)<br>Result: negative                                 |
|                                    | Test Type: Chromosomal aberration<br>Test system: Chinese hamster lung cells<br>Result: negative         |
|                                    | Test Type: Chromosomal aberration<br>Test system: Chinese hamster ovary cells<br>Result: positive        |
|                                    | Test Type: Mouse Lymphoma<br>Result: negative                                                            |
| Genotoxicity in vivo               | : Test Type: Micronucleus test<br>Species: Mouse<br>Application Route: Oral<br>Result: negative          |
|                                    | Test Type: Chromosomal aberration<br>Species: Rat<br>Cell type: Bone marrow<br>Result: negative          |
|                                    | Test Type: unscheduled DNA synthesis assay<br>Species: Rat<br>Cell type: Liver cells<br>Result: negative |
| Germ cell mutagenicity- Assessment | : Weight of evidence does not support classification as a germ cell mutagen.                             |

#### **Carcinogenicity**

Not classified based on available information.

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### 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**

May damage the unborn child. Suspected of damaging fertility.

### Components:

#### **Mometasone:**

|                      |                                                                                                                                                                                                                                                           |
|----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Effects on fertility | : Test Type: Fertility<br>Species: Rat<br>Application Route: Subcutaneous<br>Fertility: NOAEL: 0.015 mg/kg body weight<br>Symptoms: Reduced embryonic survival, Reduced foetal weight<br>Result: No effects on fertility, Effect on reproduction capacity |
|----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

|                               |                                                                                                                                                                                                                                 |
|-------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Effects on foetal development | : Test Type: Embryo-foetal development<br>Species: Mouse<br>Application Route: Subcutaneous<br>Embryo-foetal toxicity: LOAEL: 0.06 mg/kg body weight<br>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

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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.

### 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

May cause damage to organs through prolonged or repeated exposure.

#### 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.

### 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

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|                   |   |                                                                                     |
|-------------------|---|-------------------------------------------------------------------------------------|
| 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:

#### 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<br>Exposure time: 96 h<br>Remarks: No toxicity at the limit of solubility<br><br>LC50 (Cyprinodon variegatus (sheepshead minnow)): > 5 mg/l<br>Exposure time: 7 d<br>Remarks: No toxicity at the limit of solubility |
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (Daphnia magna (Water flea)): > 5 mg/l<br>Exposure time: 48 h                                                                                                                                                                                                    |

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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

### 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

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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

Partition coefficient: n-octanol/water : log Pow: 4.68

### 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 Other adverse effects

#### Product:

Endocrine disrupting potential : This substance/mixture does not contain components considered to have endocrine disrupting properties for environment according to UK REACH Article 57(f).

---

## SECTION 13: Disposal considerations

### 13.1 Waste treatment methods

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

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## SECTION 14: Transport information

### 14.1 UN number

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|      |   |         |
|------|---|---------|
| 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,<br>N.O.S.<br>(Mometasone) |
| ADR  | : | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,<br>N.O.S.<br>(Mometasone) |
| RID  | : | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,<br>N.O.S.<br>(Mometasone) |
| IMDG | : | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,<br>N.O.S.<br>(Mometasone) |
| IATA | : | Environmentally hazardous substance, solid, n.o.s.<br>(Mometasone)    |

### 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          | : | M7  |
| Hazard Identification Number | : | 90  |
| Labels                       | : | 9   |
| ADR                          |   |     |
| Packing group                | : | III |
| Classification Code          | : | M7  |
| Hazard Identification Number | : | 90  |
| Labels                       | : | 9   |
| Tunnel restriction code      | : | (-) |
| RID                          |   |     |
| Packing group                | : | III |

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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 aircraft) : 956  
Packing instruction (LQ) : Y956  
Packing group : III  
Labels : Miscellaneous

### IATA (Passenger)

Packing instruction (passenger aircraft) : 956  
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

Relevant EU provisions transposed through retained EU law

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|                                                                                                                 |                       |                     |                     |
|-----------------------------------------------------------------------------------------------------------------|-----------------------|---------------------|---------------------|
| UK REACH List of restrictions (Annex 17)                                                                        | :                     | Not applicable      |                     |
| UK REACH Candidate list of substances of very high concern (SVHC) for Authorisation                             | :                     | Not applicable      |                     |
| The Persistent Organic Pollutants Regulations (retained Regulation (EU) 2019/1021 as amended for Great Britain) | :                     | Not applicable      |                     |
| Regulation (EC) No 1005/2009 on substances that deplete the ozone layer                                         | :                     | Not applicable      |                     |
| UK REACH List of substances subject to authorisation (Annex XIV)                                                | :                     | Not applicable      |                     |
| GB Export and import of hazardous chemicals - Prior Informed Consent (PIC) Regulation                           | :                     | Not applicable      |                     |
| Control of Major Accident Hazards Regulations 2015 (COMAH)                                                      | :                     |                     |                     |
| E1                                                                                                              | ENVIRONMENTAL HAZARDS | Quantity 1<br>100 t | Quantity 2<br>200 t |

### Other regulations:

Take note of The Management of Health and Safety at Work Regulations 1999 (requirements relating to new and expectant mothers at work contained in Regulation 16 to 18) and of the Pregnant Workers Directive 92/85/EEC.

Take note of The Management of Health and Safety at Work Regulations 1999 (requirements relating to protection of young people at work contained in Regulation 19) and of Directive 94/33/EC on the protection of young people at work.

### 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

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

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|               |                                                          |
|---------------|----------------------------------------------------------|
| Repr.         | : Reproductive toxicity                                  |
| STOT RE       | : Specific target organ toxicity - repeated exposure     |
| GB EH40       | : UK. EH40 WEL - Workplace Exposure Limits               |
| GB EH40 / TWA | : Long-term exposure limit (8-hour TWA reference period) |

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

|                   |        |
|-------------------|--------|
| Repr. 1B          | H360Df |
| STOT RE 2         | H373   |
| Aquatic Chronic 1 | H410   |

### Classification procedure:

|                    |
|--------------------|
| Calculation method |
| Calculation method |
| 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

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