

# SAFETY DATA SHEET

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



## Mometasone / Clotrimazole / Gentamicin Formulation

|         |                |              |                                 |
|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number:  | Date of last issue: 14.04.2025  |
| 8.0     | 17.06.2025     | 415344-00030 | Date of first issue: 14.12.2015 |

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

#### 1.1 Product identifier

Trade name : Mometasone / Clotrimazole / Gentamicin Formulation

Other means of identification : MOMETAMAX OINTMENT (52269)

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

Use of the Substance/Mixture : Veterinary product

Recommended restrictions on use : Not applicable

#### 1.3 Details of the supplier of the safety data sheet

Company : MSD  
Kilsheelan  
Clonmel Tipperary, IE

Telephone : 353-51-601000

E-mail address of person responsible for the SDS : EHSDATASTEWARD@msd.com

#### 1.4 Emergency telephone number

+1-908-423-6000

### SECTION 2: Hazards identification

#### 2.1 Classification of the substance or mixture

##### Classification (REGULATION (EC) No 1272/2008)

|                                                |                                                        |
|------------------------------------------------|--------------------------------------------------------|
| Reproductive toxicity, Category 1A             | H360D: May damage the unborn child.                    |
| Short-term (acute) aquatic hazard, Category 1  | H400: Very toxic to aquatic life.                      |
| 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)

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|                          |   |                                                                                                                                                                                                                                                                                                                                                                             |
|--------------------------|---|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Hazard pictograms        | : |                                                                                                                                                                                                                                                                                                                                                                             |
| Signal word              | : | Danger                                                                                                                                                                                                                                                                                                                                                                      |
| Hazard statements        | : | H360D May damage the unborn child.<br>H410 Very toxic to aquatic life with long lasting effects.                                                                                                                                                                                                                                                                            |
| Precautionary statements | : | <b>Prevention:</b><br>P201 Obtain special instructions before use.<br>P273 Avoid release to the environment.<br>P280 Wear protective gloves/ protective clothing/ eye protec-<br>tion/ face protection.<br><b>Response:</b><br>P308 + P313 IF exposed or concerned: Get medical advice/<br>attention.<br>P391 Collect spillage.<br><b>Storage:</b><br>P405 Store locked up. |

Hazardous components which must be listed on the label:  
Gentamicin

### 2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumula-  
tive 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 regu-  
lation (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.<br>EC-No.<br>Index-No.<br>Registration number | Classification | Concentration<br>(% w/w) |
|---------------|-------------------------------------------------------|----------------|--------------------------|
|               |                                                       |                |                          |

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|              |                         |                                                                                                                                                                                                                                                                                                                                                                                      |                     |
|--------------|-------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------|
| clotrimazole | 23593-75-1<br>245-764-8 | Acute Tox. 4; H302<br>Acute Tox. 3; H311<br>Eye Irrit. 2; H319<br>Repr. 2; H361fd<br>STOT RE 2; H373<br>(Liver, Kidney, Ad-<br>renal gland)<br>Aquatic Acute 1;<br>H400<br>Aquatic Chronic 1;<br>H410<br><br>M-Factor (Acute<br>aquatic toxicity): 10<br>M-Factor (Chronic<br>aquatic toxicity): 10<br><br>Acute toxicity esti-<br>mate<br><br>Acute dermal toxic-<br>ity: 923 mg/kg | $\geq 1 - < 2,5$    |
| Gentamicin   | 1403-66-3<br>215-765-8  | Repr. 1A; H360D<br>STOT RE 1; H372<br>(Kidney, inner ear)<br>Aquatic Acute 1;<br>H400<br>Aquatic Chronic 1;<br>H410<br><br>M-Factor (Acute<br>aquatic toxicity):<br>100<br>M-Factor (Chronic<br>aquatic toxicity): 1                                                                                                                                                                 | $\geq 0,3 - < 1$    |
| 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<br><br>M-Factor (Chronic<br>aquatic toxicity):<br>100                                                                                                                                                                                                                   | $\geq 0,1 - < 0,25$ |

For explanation of abbreviations see section 16.

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### 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     | : | Flush eyes with water as a precaution.<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. |
|-------|---|------------------------------|

#### 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<br>Alcohol-resistant foam<br>Carbon dioxide (CO <sub>2</sub> )<br>Dry chemical |
| Unsuitable extinguishing media | : | None known.                                                                                |

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### 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 : 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.  
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.

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### 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.<br>Do not breathe mist or vapours.<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>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

- |                                               |   |                                                                                                                                                                |
|-----------------------------------------------|---|----------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 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.                      |
| Advice on common storage                      | : | Do not store with the following product types:<br>Strong oxidizing agents<br>Self-reactive substances and mixtures<br>Organic peroxides<br>Explosives<br>Gases |

### 7.3 Specific end use(s)

- |                 |   |                   |
|-----------------|---|-------------------|
| Specific use(s) | : | No data available |
|-----------------|---|-------------------|

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### SECTION 8: Exposure controls/personal protection

#### 8.1 Control parameters

##### Occupational Exposure Limits

| Components                    | CAS-No.    | Value type (Form of exposure) | Control parameters            | Basis               |
|-------------------------------|------------|-------------------------------|-------------------------------|---------------------|
| White mineral oil (petroleum) | 8042-47-5  | TWA (Vapour)                  | 50 mg/m <sup>3</sup>          | FOR-2011-12-06-1358 |
|                               |            | TWA (Mist and particles)      | 1 mg/m <sup>3</sup>           | FOR-2011-12-06-1358 |
| clotrimazole                  | 23593-75-1 | TWA                           | 0.2 mg/m <sup>3</sup> (OEB 2) | Internal            |
| Gentamicin                    | 1403-66-3  | TWA                           | 0.1 mg/m <sup>3</sup> (OEB 2) | Internal            |
| Further information: OTO      |            |                               |                               |                     |
| 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

The information below is intended for larger pilot/commercial-scale operations and manufacturing. For smaller scale, clinical, or pharmacy settings, site-specific internal risk assessment practices should be conducted to determine appropriate exposure control measures. The health hazard risks of handling this material are dependent on multiple factors, including but not limited to physical form and quantity handled. If applicable, use process enclosures, local exhaust ventilation (e.g., Biosafety Cabinet, Ventilated Balance Enclosures), or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels as low as reasonably achievable.

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.

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|                        |                                                                                                                                                                                                                                                         |
|------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                        | 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>Filter 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                                   | : suspension         |
| Colour                                           | : white to off-white |
| Odour                                            | : oily               |
| 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                                               | : No data available  |
| Viscosity                                        |                      |
| Viscosity, kinematic                             | : No data available  |
| Solubility(ies)                                  |                      |



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Water solubility : No data available

Partition coefficient: n-octanol/water : Not applicable

Vapour pressure : No data available

Relative density : No data available

Density : No data available

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

## 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

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Information on likely routes of exposure :  
Inhalation  
Skin contact  
Ingestion  
Eye contact

### Acute toxicity

|| Not classified based on available information.

#### Product:

Acute oral toxicity : Acute toxicity estimate: > 2.000 mg/kg  
Method: Calculation method

Acute dermal toxicity : Acute toxicity estimate: > 2.000 mg/kg  
Method: Calculation method

#### Components:

##### **clotrimazole:**

Acute oral toxicity : LD50 (Rat): 708 mg/kg  
LD50 (Mouse): 761 mg/kg  
LD50 (Rabbit): > 1.000 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 0,73 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist

Acute dermal toxicity : LD50 (Mouse): 923 mg/kg

##### **Gentamicin:**

Acute oral toxicity : LD50 (Rat): 8.000 - 10.000 mg/kg  
LD50 (Mouse): 10.000 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 0,2 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Remarks: No mortality observed at this dose.

Acute toxicity (other routes of administration) : LD50 (Rat): 67 - 96 mg/kg  
Application Route: Intravenous  
  
LD50 (Rat): 371 - 384 mg/kg  
Application Route: Intramuscular  
  
LDLo (Monkey): 30 mg/kg  
Application Route: Intravenous

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|                                                 |                                                                                                                                                                                                                  |
|-------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Acute oral toxicity                             | : LD50 (Rat): > 2.000 mg/kg<br>LD50 (Mouse): > 2.000 mg/kg                                                                                                                                                       |
| Acute inhalation toxicity                       | : LC50 (Rat): > 3,3 mg/l<br>Exposure time: 4 h<br>Test atmosphere: dust/mist<br>Remarks: No mortality observed at this dose.<br><br>LC50 (Mouse): > 3,2 mg/l<br>Exposure time: 4 h<br>Test atmosphere: dust/mist |
| Acute toxicity (other routes of administration) | : LD50 (Rat): 300 mg/kg<br>Application Route: Subcutaneous<br>Symptoms: Breathing difficulties                                                                                                                   |

### Skin corrosion/irritation

Not classified based on available information.

#### Components:

##### clotrimazole:

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

##### Gentamicin:

|         |                        |
|---------|------------------------|
| Species | : Rabbit               |
| Result  | : Mild skin irritation |

##### Mometasone:

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

### Serious eye damage/eye irritation

Not classified based on available information.

#### Components:

##### clotrimazole:

|         |                       |
|---------|-----------------------|
| Species | : Rabbit              |
| Result  | : Mild eye irritation |

##### Gentamicin:

|         |                       |
|---------|-----------------------|
| Species | : Rabbit              |
| Result  | : Mild eye irritation |

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

##### Gentamicin:

|         |                     |
|---------|---------------------|
| Remarks | : No data available |
|---------|---------------------|

##### 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:

##### clotrimazole:

|                       |                                                                                                                                                                                                                                                                         |
|-----------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Genotoxicity in vitro | : Test Type: Bacterial reverse mutation assay (AMES)<br>Result: negative<br><br>Test Type: Chromosome aberration test in vitro<br>Result: negative<br><br>Test Type: in vitro micronucleus test<br>Result: negative                                                     |
| Genotoxicity in vivo  | : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)<br>Species: Rat<br>Application Route: Oral<br>Result: negative<br><br>Test Type: Mammalian spermatogonial chromosome aberration test (in vivo)<br>Species: Hamster<br>Result: negative |

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Germ cell mutagenicity- Assessment : Weight of evidence does not support classification as a germ cell mutagen.

### Gentamicin:

Genotoxicity in vitro : Test Type: In vitro mammalian cell gene mutation test  
Result: negative

Test Type: Chromosome aberration test in vitro  
Result: equivocal

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)  
Species: Mouse  
Application Route: Intravenous injection  
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  
Cell type: Liver cells  
Result: negative

Germ cell mutagenicity- Assessment : Weight of evidence does not support classification as a germ cell mutagen.

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### Carcinogenicity

|| Not classified based on available information.

### Components:

#### clotrimazole:

|                   |            |
|-------------------|------------|
| Species           | : Rat      |
| Application Route | : Oral     |
| Exposure time     | : 78 weeks |
| Result            | : negative |

#### Gentamicin:

|                              |                     |
|------------------------------|---------------------|
| Carcinogenicity - Assessment | : No data available |
|------------------------------|---------------------|

#### 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.

### Components:

#### clotrimazole:

|                               |                                                                                                                                                                                                                                                                                                                                                                                                             |
|-------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Effects on fertility          | : Test Type: Fertility/early embryonic development<br>Species: Rat<br>Application Route: Oral<br>Fertility: LOAEL: 50 mg/kg body weight<br>Result: Effects on fertility                                                                                                                                                                                                                                     |
| Effects on foetal development | : Test Type: Embryo-foetal development<br>Species: Rat<br>Application Route: Oral<br>Developmental Toxicity: LOAEL: 100 mg/kg body weight<br>Result: Embryo-foetal toxicity, No teratogenic effects<br><br>Test Type: Embryo-foetal development<br>Species: Rat<br>Application Route: Oral<br>Developmental Toxicity: NOAEL: 50 mg/kg body weight<br>Result: Embryo-foetal toxicity, No teratogenic effects |

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|                                    |   |                                                                                                                                                                                        |
|------------------------------------|---|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                    |   | Test Type: Embryo-foetal development<br>Species: Mouse<br>Application Route: Oral<br>Developmental Toxicity: NOAEL: 200 mg/kg body weight<br>Result: No effects on foetal development  |
|                                    |   | Test Type: Embryo-foetal development<br>Species: Rabbit<br>Application Route: Oral<br>Developmental Toxicity: NOAEL: 180 mg/kg body weight<br>Result: No effects on foetal development |
| Reproductive toxicity - Assessment | : | Some evidence of adverse effects on sexual function and fertility, based on animal experiments., Some evidence of adverse effects on development, based on animal experiments.         |

### Gentamicin:

|                                    |   |                                                                                                                                                                                                                  |
|------------------------------------|---|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Effects on fertility               | : | Test Type: Two-generation reproduction toxicity study<br>Species: Rat<br>Fertility: NOAEL: 20 mg/kg body weight<br>Result: No significant adverse effects were reported                                          |
| Effects on foetal development      | : | Test Type: Embryo-foetal development<br>Species: Rabbit<br>Developmental Toxicity: NOAEL: 3,6 mg/kg body weight<br>Result: No embryo-foetal toxicity                                                             |
|                                    |   | Test Type: Embryo-foetal development<br>Species: Rat<br>Application Route: Intraperitoneal<br>Developmental Toxicity: LOAEL: 75 mg/kg body weight<br>Result: Embryo-foetal toxicity                              |
|                                    |   | Test Type: Embryo-foetal development<br>Species: Mouse<br>Application Route: Intraperitoneal<br>Developmental Toxicity: LOAEL: 10 mg/kg body weight<br>Result: foetal mortality, No malformations were observed. |
|                                    |   | Test Type: Embryo-foetal development<br>Species: Rat<br>Application Route: Intraperitoneal<br>Developmental Toxicity: LOAEL: 50 mg/kg body weight<br>Result: foetal mortality, No malformations were observed.   |
| Reproductive toxicity - Assessment | : | Positive evidence of adverse effects on development from human epidemiological studies.                                                                                                                          |

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### 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<br><br>Test Type: Embryo-foetal development<br>Species: Rat<br>Application Route: Dermal<br>Embryo-foetal toxicity: LOAEL: 0,3 mg/kg body weight<br>Result: Embryo-foetal toxicity<br><br>Test Type: Embryo-foetal development<br>Species: Rabbit<br>Application Route: Dermal<br>Embryo-foetal toxicity: LOAEL: 0,15 mg/kg body weight<br>Result: Embryo-foetal toxicity, Malformations were observed.<br><br>Test Type: Embryo-foetal development<br>Species: Rat<br>Application Route: Subcutaneous<br>Embryo-foetal toxicity: LOAEL: 0,15 mg/kg body weight<br>Result: Effects on newborn<br><br>Test Type: Embryo-foetal development<br>Species: Rabbit<br>Application Route: Oral<br>Embryo-foetal toxicity: LOAEL: 0,7 mg/kg body weight<br>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.



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### STOT - repeated exposure

|| Not classified based on available information.

#### Components:

##### clotrimazole:

|               |                                                                      |
|---------------|----------------------------------------------------------------------|
| Target Organs | : Liver, Kidney, Adrenal gland                                       |
| Assessment    | : May cause damage to organs through prolonged or repeated exposure. |

##### Gentamicin:

|               |                                                                   |
|---------------|-------------------------------------------------------------------|
| Target Organs | : Kidney, inner ear                                               |
| Assessment    | : Causes damage to organs through prolonged or repeated exposure. |

##### 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:

##### clotrimazole:

|                   |                                        |
|-------------------|----------------------------------------|
| Species           | : Rabbit                               |
| LOAEL             | : 5 - 40 mg/kg                         |
| Application Route | : Skin contact                         |
| Exposure time     | : 3 Weeks                              |
| Target Organs     | : Skin                                 |
| Symptoms          | : Oedema, Fissuring, Necrosis, Redness |

|                   |                                |
|-------------------|--------------------------------|
| Species           | : Rat                          |
| LOAEL             | : 10 mg/kg                     |
| Application Route | : Oral                         |
| Exposure time     | : 18 Months                    |
| Target Organs     | : Liver, Kidney, Adrenal gland |

|                   |                                      |
|-------------------|--------------------------------------|
| Species           | : Dog                                |
| LOAEL             | : 25 mg/kg                           |
| Application Route | : Oral                               |
| Exposure time     | : 6 - 12 Months                      |
| Target Organs     | : Adrenal gland                      |
| Symptoms          | : Salivation, Lachrymation, Vomiting |

##### Gentamicin:

|         |       |
|---------|-------|
| Species | : Dog |
|---------|-------|

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|                   |                        |
|-------------------|------------------------|
| LOAEL             | : 3 mg/kg              |
| Application Route | : Intramuscular        |
| Exposure time     | : 12 Months            |
| Target Organs     | : Kidney               |
| Symptoms          | : Vomiting, Salivation |

|                   |                     |
|-------------------|---------------------|
| Species           | : Monkey            |
| LOAEL             | : 50 mg/kg          |
| Application Route | : Subcutaneous      |
| Exposure time     | : 3 Weeks           |
| Target Organs     | : Kidney, inner ear |

|                   |                                   |
|-------------------|-----------------------------------|
| Species           | : Monkey                          |
| LOAEL             | : 6 mg/kg                         |
| Application Route | : Intramuscular                   |
| Exposure time     | : 3 Weeks                         |
| Target Organs     | : Blood, Kidney, inner ear, Liver |

|                   |                 |
|-------------------|-----------------|
| Species           | : Rat           |
| NOAEL             | : 5 mg/kg       |
| LOAEL             | : 10 mg/kg      |
| Application Route | : Intramuscular |
| Exposure time     | : 52 Weeks      |
| Target Organs     | : Kidney, Blood |

|                   |                 |
|-------------------|-----------------|
| Species           | : Rat           |
| NOAEL             | : 12,5 mg/kg    |
| LOAEL             | : 50 mg/kg      |
| Application Route | : Intramuscular |
| Exposure time     | : 13 Weeks      |
| Target Organs     | : Kidney        |

### 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, |

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

## 11.2 Information on other hazards

### Endocrine disrupting properties

|| Not classified based on available information.

### 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:

#### clotrimazole:

|  |              |                                                         |
|--|--------------|---------------------------------------------------------|
|  | Skin contact | : Symptoms: Rash, Itching, Blistering, Oedema, Redness  |
|  | Ingestion    | : Symptoms: Abdominal pain, Nausea, Vomiting, Diarrhoea |

#### Gentamicin:

|  |           |                                                                        |
|--|-----------|------------------------------------------------------------------------|
|  | Ingestion | : Target Organs: Kidney                                                |
|  |           | : Target Organs: inner ear                                             |
|  |           | : Symptoms: Dizziness, Vertigo, hearing loss, tinnitus, fetal deafness |

#### 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                                                                                                                                                           |

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### Further information

#### Components:

##### Mometasone:

Remarks : Dermal absorption possible

## SECTION 12: Ecological information

### 12.1 Toxicity

#### Components:

##### clotrimazole:

|                                                                        |                                                                                                                                                                          |
|------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Toxicity to fish                                                       | : LC50 (Brachydanio rerio (zebrafish)): > 0,29 mg/l<br>Exposure time: 96 h<br>Method: OECD Test Guideline 203                                                            |
| Toxicity to daphnia and other aquatic invertebrates                    | : EC50 (Daphnia magna (Water flea)): 0,02 mg/l<br>Exposure time: 48 h                                                                                                    |
| Toxicity to algae/aquatic plants                                       | : EC50 (Desmodesmus subspicatus (green algae)): 0,268 mg/l<br>Exposure time: 72 h<br><br>NOEC (Desmodesmus subspicatus (green algae)): 0,017 mg/l<br>Exposure time: 72 h |
| M-Factor (Acute aquatic toxicity)                                      | : 10                                                                                                                                                                     |
| Toxicity to microorganisms                                             | : EC50 : > 10.000 mg/l<br>Exposure time: 3 h<br>Test Type: Respiration inhibition<br>Method: OECD Test Guideline 209                                                     |
| Toxicity to fish (Chronic toxicity)                                    | : NOEC: 0,025 mg/l<br>Exposure time: 32 d<br>Species: Oncorhynchus mykiss (rainbow trout)<br>Method: OECD Test Guideline 210                                             |
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : NOEC: 0,01 mg/l<br>Exposure time: 21 d<br>Species: Daphnia magna (Water flea)<br>Method: OECD Test Guideline 211                                                       |
| M-Factor (Chronic aquatic toxicity)                                    | : 10                                                                                                                                                                     |

##### Gentamicin:

|                                                     |                                                                     |
|-----------------------------------------------------|---------------------------------------------------------------------|
| Toxicity to daphnia and other aquatic invertebrates | : EC50 (Daphnia magna (Water flea)): 86 mg/l<br>Exposure time: 48 h |
|-----------------------------------------------------|---------------------------------------------------------------------|

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|                                     |                                                                 |
|-------------------------------------|-----------------------------------------------------------------|
|                                     | Method: OECD Test Guideline 202                                 |
|                                     | LC50 (Americamysis): 30 mg/l                                    |
|                                     | Exposure time: 96 h                                             |
|                                     | Method: US-EPA OPPTS 850.1035                                   |
| Toxicity to algae/aquatic plants    | : EC50 (Pseudokirchneriella subcapitata (green algae)): 10 µg/l |
|                                     | Exposure time: 72 h                                             |
|                                     | Method: OECD Test Guideline 201                                 |
|                                     | NOEC (Pseudokirchneriella subcapitata (green algae)): 1,5 µg/l  |
|                                     | Exposure time: 72 h                                             |
|                                     | Method: OECD Test Guideline 201                                 |
|                                     | EC50 (Anabaena flos-aquae (cyanobacterium)): 4,7 µg/l           |
|                                     | Exposure time: 72 h                                             |
|                                     | Method: OECD Test Guideline 201                                 |
|                                     | NOEC (Anabaena flos-aquae (cyanobacterium)): 1,6 µg/l           |
|                                     | Exposure time: 72 h                                             |
|                                     | Method: OECD Test Guideline 201                                 |
| M-Factor (Acute aquatic toxicity)   | : 100                                                           |
| Toxicity to microorganisms          | : EC50 : 288,7 mg/l                                             |
|                                     | Exposure time: 3 h                                              |
|                                     | Test Type: Respiration inhibition                               |
|                                     | Method: OECD Test Guideline 209                                 |
| M-Factor (Chronic aquatic toxicity) | : 1                                                             |

### 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            |

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|                                                                        |                                                                                                                                                                                                                                                                                                                                                  |
|------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Toxicity to algae/aquatic plants                                       | : EC50 (Pseudokirchneriella subcapitata (green algae)): > 3,2 mg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201<br>Remarks: No toxicity at the limit of solubility                                                                                                                                                                  |
| Toxicity to microorganisms                                             | : EC50 : > 1.000 mg/l<br>Exposure time: 3 h<br>Test Type: Respiration inhibition<br>Method: OECD Test Guideline 209<br>Remarks: No toxicity at the limit of solubility<br><br>NOEC : 1.000 mg/l<br>Exposure time: 3 h<br>Test Type: Respiration inhibition<br>Method: OECD Test Guideline 209<br>Remarks: No toxicity at the limit of solubility |
| Toxicity to fish (Chronic toxicity)                                    | : NOEC: 0,00014 mg/l<br>Exposure time: 32 d<br>Species: Pimephales promelas (fathead minnow)<br>Method: OECD Test Guideline 210                                                                                                                                                                                                                  |
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : NOEC: 0,34 mg/l<br>Exposure time: 21 d<br>Species: Daphnia magna (Water flea)<br>Method: OECD Test Guideline 211<br>Remarks: No toxicity at the limit of solubility                                                                                                                                                                            |
| M-Factor (Chronic aquatic toxicity)                                    | : 100                                                                                                                                                                                                                                                                                                                                            |

### 12.2 Persistence and degradability

#### Components:

##### **clotrimazole:**

|                    |                           |
|--------------------|---------------------------|
| Stability in water | : Hydrolysis: 50 %(242 d) |
|--------------------|---------------------------|

##### **Gentamicin:**

|                  |                                                                                                                 |
|------------------|-----------------------------------------------------------------------------------------------------------------|
| Biodegradability | : Result: rapidly degradable<br>Biodegradation: 100 %<br>Exposure time: 28 d<br>Method: OECD Test Guideline 314 |
|------------------|-----------------------------------------------------------------------------------------------------------------|

##### **Mometasone:**

|                  |                                                                                                                        |
|------------------|------------------------------------------------------------------------------------------------------------------------|
| Biodegradability | : Result: Not readily biodegradable.<br>Biodegradation: 50 %<br>Exposure time: 28 d<br>Method: OECD Test Guideline 314 |
|------------------|------------------------------------------------------------------------------------------------------------------------|

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Stability in water : Hydrolysis: 50 %(12 d)  
Method: OECD Test Guideline 111

### 12.3 Bioaccumulative potential

#### Components:

##### **Gentamicin:**

Partition coefficient: n-  
octanol/water : log Pow: < -2

##### **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 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.

### 12.7 Other adverse effects

No data available

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### 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<br>are not product specific, but application specific.<br>Waste codes should be assigned by the user, preferably in<br>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 han-<br>dling site for recycling or disposal.<br>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,<br>N.O.S.<br>(clotrimazole, Gentamicin) |
| ADR  | : | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,<br>N.O.S.<br>(clotrimazole, Gentamicin) |
| RID  | : | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,<br>N.O.S.<br>(clotrimazole, Gentamicin) |
| IMDG | : | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,<br>N.O.S.<br>(clotrimazole, Gentamicin) |
| IATA | : | Environmentally hazardous substance, liquid, n.o.s.<br>(clotrimazole, Gentamicin)    |

#### 14.3 Transport hazard class(es)

|     | Class | Subsidiary risks |
|-----|-------|------------------|
| ADN | :     | 9                |
| ADR | :     | 9                |
| RID | :     | 9                |



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**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

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### 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 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.

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

REACH - List of substances subject to authorisation (Annex XIV) : Not applicable

Regulation (EU) No 2024/590 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.

|    |                          |                     |                     |
|----|--------------------------|---------------------|---------------------|
| E1 | ENVIRONMENTAL<br>HAZARDS | Quantity 1<br>100 t | Quantity 2<br>200 t |
|----|--------------------------|---------------------|---------------------|

Other regulations:

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Note the Working Environment Act § 4-1 and § 4-2 on requirements for the employer to protect pregnant employees against discomfort and injury as a result of the work situation and the working environment.

Note the regulation on organization, leadership and participation, chapter 12 on the work of children and young people.

### 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

|        |   |                                                                                 |
|--------|---|---------------------------------------------------------------------------------|
| H302   | : | Harmful if swallowed.                                                           |
| H311   | : | Toxic in contact with skin.                                                     |
| H319   | : | Causes serious eye irritation.                                                  |
| H360D  | : | May damage the unborn child.                                                    |
| H360Df | : | May damage the unborn child. Suspected of damaging fertility.                   |
| H361fd | : | Suspected of damaging fertility. Suspected of damaging the unborn child.        |
| H372   | : | Causes damage to organs through prolonged or repeated exposure if swallowed.    |
| H373   | : | May cause damage to organs through prolonged or repeated exposure if inhaled.   |
| H373   | : | May cause damage to organs through prolonged or repeated exposure if swallowed. |
| H400   | : | Very toxic to aquatic life.                                                     |
| H410   | : | Very toxic to aquatic life with long lasting effects.                           |

### Full text of other abbreviations

|                           |   |                                                    |
|---------------------------|---|----------------------------------------------------|
| Acute Tox.                | : | Acute toxicity                                     |
| Aquatic Acute             | : | Short-term (acute) aquatic hazard                  |
| Aquatic Chronic           | : | Long-term (chronic) aquatic hazard                 |
| Eye Irrit.                | : | Eye irritation                                     |
| Repr.                     | : | Reproductive toxicity                              |
| STOT RE                   | : | Specific target organ toxicity - repeated exposure |
| FOR-2011-12-06-1358       | : | Norway. Occupational Exposure limits               |
| FOR-2011-12-06-1358 / TWA | : | Long term exposure limit                           |

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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. 1A          | H360D |
| Aquatic Acute 1   | H400  |
| Aquatic Chronic 2 | H411  |

### Classification procedure:

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

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The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be

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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.

NO / EN