

# SAFETY DATA SHEET

According to 13 December 2014, No:29204, "Ministry of Environment and Urbanization; Regulation on Safety data sheets regarding hazardous substances and mixtures; Part I".



## Gentamicin / Posaconazole / Mometasone Suspension Formulation

Version 2.2      Revision Date: 23.03.2020      SDS Number: 2548428-00005      Date of last issue: 13.09.2019  
Date of first issue: 23.02.2018

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

#### 1.1 Product identifier

Trade name : Gentamicin / Posaconazole / Mometasone Suspension Formulation  
Product code : Mometamax Single

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

Use of the Substance/Mixture : Veterinary product

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

Company : MSD  
Balıkhisar Mah. Köyiçi Küme Evleri No: 765/A  
Çubuk Yolu 2. Km  
Akyurt / Ankara / TÜRKİYE  
Telephone : +90 312 840 53 00  
E-mail address of person responsible for the SDS : EHSDATASTEWARD@msd.com

#### 1.4 Emergency telephone number

National Poison Control Center (UZEM): 114  
Emergency: 1-908-423-6000

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### SECTION 2: Hazards identification

#### 2.1 Classification of the substance or mixture

##### Classification T.R. SEA No 28848

Reproductive toxicity, Category 1A  
Short-term (acute) aquatic hazard, Category 1  
Long-term (chronic) aquatic hazard, Category 2

H360D: May damage the unborn child.  
H400: Very toxic to aquatic life.  
H411: Toxic to aquatic life with long lasting effects.

#### 2.2 Label elements

##### Labelling T.R. SEA No 28848

Hazard pictograms :



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|   |   |   |
|---|---|---|
| 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 protection/ face protection.<br><b>Response:</b><br>P308 + P313 IF exposed or concerned: Get medical advice/ 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

None known.

## 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) |
|---------------|---|--|--------------------------|
| Gentamicin    | 1403-66-3<br>215-765-8                                | Repr.1A; H360D<br>STOT RE1; H372<br>Aquatic Acute1;<br>H400<br>Aquatic Chronic1;<br>H410<br><br>M-Factor (Acute aquatic toxicity): 100<br>M-Factor (Chronic aquatic toxicity): 1 | >= 0,3 - < 1             |
| Posaconazole  | 171228-49-2   | Repr.2; H361d<br>STOT RE1; H372<br>Aquatic Acute1;   | >= 0,25 - < 1            |

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|            |            |   |                 |
|------------|------------|---|-----------------|
|            |            | H400<br>Aquatic Chronic1;<br>H410<br><br>M-Factor (Acute aquatic toxicity): 1<br>M-Factor (Chronic aquatic toxicity): 1 |                 |
| Mometasone | 83919-23-7 | Repr.1B; H360Df<br>STOT RE2; H373<br>Aquatic Chronic1;<br>H410<br><br>M-Factor (Chronic aquatic toxicity): 100          | >= 0,1 - < 0,25 |

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.  
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.  
Get medical attention.

In case of skin contact : In case of contact, immediately flush skin with soap and plenty of water.  
Remove contaminated clothing and shoes.  
Get medical attention.  
Wash clothing before reuse.  
Thoroughly clean shoes before reuse.

In case of eye contact : Flush eyes with water as a precaution.  
Get medical attention if irritation develops and persists.

If swallowed : If swallowed, DO NOT induce vomiting.  
Get medical attention.  
Rinse mouth thoroughly with water.

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

Risks : May damage the unborn child.

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### 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 : 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.

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## SECTION 6: Accidental release measures

### 6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Use personal protective equipment.  
Follow safe handling advice and personal protective equipment recommendations.

### 6.2 Environmental precautions

Environmental precautions : Discharge into the environment must be avoided.  
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

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cannot be contained.

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

Methods for cleaning up : Soak up with inert absorbent material. For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absorbent. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

### 6.4 Reference to other sections

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

## SECTION 7: Handling and storage

### 7.1 Precautions for safe handling

Technical measures : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation : If sufficient ventilation is unavailable, use with local exhaust ventilation.

Advice on safe handling : Do not get on skin or clothing. Do not breathe vapours or spray mist. Do not swallow. Avoid contact with eyes. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment. Keep container tightly closed. Take care to prevent spills, waste and minimize release to the environment.

Hygiene measures : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use. The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

### 7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers : Keep in properly labelled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national

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regulations.

Advice on common storage : Do not store with the following product types:  
Strong oxidizing agents  
Organic peroxides  
Explosives  
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    |
|---------------------------|-------------|-------------------------------|-------------------------------|----------|
| Gentamicin                | 1403-66-3   | TWA                           | 0.1 mg/m <sup>3</sup> (OEB 2) | Internal |
| Posaconazole              | 171228-49-2 | TWA                           | 300 µg/m <sup>3</sup> (OEB 2) | Internal |
| 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

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 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.

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|                          |   |
|--------------------------|---|
| 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 TS EN 14387   |
| Filter type              | : Combined particulates and organic vapour type (A-P)   |

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## SECTION 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

|  |                           |
|--|---------------------------|
| Appearance                                       | : viscous liquid          |
| Colour   | : white to off-white      |
| Odour  | : No data available       |
| Odour Threshold                                  | : No data available       |
| pH   | : No data available       |
| Melting point/freezing point                     | : No data available       |
| Initial boiling point and boiling range          | : No data available       |
| Flash point                                      | : No data available       |
| Evaporation rate                                 | : No data available       |
| Flammability (solid, gas)                        | : Not applicable          |
| Upper explosion limit / Upper flammability limit | : No data available       |
| Lower explosion limit / Lower flammability limit | : No data available       |
| Vapour pressure                                  | : No data available       |
| Relative vapour density                          | : No data available       |
| Relative density                                 | : No data available       |
| Density  | : 0,874 g/cm <sup>3</sup> |
| Solubility(ies)                                  |                           |
| Water solubility                                 | : No data available       |
| Partition coefficient: n-octanol/water           | : Not applicable          |

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|                           |   |  |
|---------------------------|---|--|
| 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          | : | Not applicable    |

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## 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.

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## SECTION 11: Toxicological information

### 11.1 Information on toxicological effects

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

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### Acute toxicity

Not classified based on available information.

### Components:

#### **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

#### **Posaconazole:**

Acute oral toxicity : LD50 (Rat): > 5.000 mg/kg  
LD50 (Mouse): > 3.000 mg/kg

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

#### **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

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### Skin corrosion/irritation

Not classified based on available information.

#### Components:

##### **Gentamicin:**

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

##### **Posaconazole:**

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

##### **Mometasone:**

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

### Serious eye damage/eye irritation

Not classified based on available information.

#### Components:

##### **Gentamicin:**

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

##### **Posaconazole:**

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

##### **Mometasone:**

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

### Respiratory or skin sensitisation

#### **Skin sensitisation**

Not classified based on available information.

#### **Respiratory sensitisation**

Not classified based on available information.

#### Components:

##### **Gentamicin:**

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

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### **Posaconazole:**

Test Type : Magnusson-Kligman-Test  
Exposure routes : Skin contact  
Species : Guinea pig  
Result : negative

### **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:**

#### **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

#### **Posaconazole:**

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative  
  
Test Type: Chromosomal aberration  
Result: negative  
  
Genotoxicity in vivo : Test Type: Micronucleus test  
Species: Mouse  
Cell type: Bone marrow  
Application Route: Intravenous  
Result: negative

#### **Mometasone:**

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

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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.

### Carcinogenicity

Not classified based on available information.

### Components:

#### **Gentamicin:**

Carcinogenicity - Assessment : No data available

#### **Posaconazole:**

|                   |   |  |
|-------------------|---|--|
| Species           | : | Rat  |
| Application Route | : | oral (feed)  |
| Exposure time     | : | 2 Years  |
| Result            | : | positive   |
| Remarks           | : | The mechanism or mode of action is not relevant in humans. |

  

|                   |   |          |
|-------------------|---|----------|
| Species           | : | Mouse    |
| Application Route | : | Oral     |
| Exposure time     | : | 2 Years  |
| Result            | : | positive |

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Remarks : The mechanism or mode of action is not relevant in humans.

### **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:**

#### **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 - As : Positive evidence of adverse effects on development from

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essment human epidemiological studies.

### Posaconazole:

Effects on fertility : Test Type: Fertility/early embryonic development  
Species: Rat, male  
General Toxicity - Parent: NOAEL: 180 mg/kg body weight  
Symptoms: No effects on mating performance  
Result: negative

Test Type: Fertility/early embryonic development  
Species: Rat, female  
General Toxicity - Parent: NOAEL: 45 mg/kg body weight  
Symptoms: No effects on mating performance  
Result: negative

Effects on foetal development : Test Type: Embryo-foetal development  
Species: Rat, female  
Application Route: Oral  
Frequency of Treatment: 6 - 15 days  
Developmental Toxicity: LOAEL: 29 mg/kg body weight  
Result: Fetotoxicity, Malformations were observed.

Test Type: Embryo-foetal development  
Species: Rabbit, female  
Frequency of Treatment: 7 - 19 days  
Developmental Toxicity: LOAEL: 40 mg/kg body weight  
Result: Fetotoxicity

Reproductive toxicity - Assessment : Some evidence of adverse effects on development, based on animal experiments.

### Mometasone:

Effects on fertility : Test Type: Fertility  
Species: Rat  
Application Route: Subcutaneous  
Fertility: NOAEL: 0,015 mg/kg body weight  
Symptoms: Reduced embryonic survival, Reduced foetal weight  
Result: No effects on fertility, Effect on reproduction capacity

Effects on foetal development : Test Type: Embryo-foetal development  
Species: Mouse  
Application Route: Subcutaneous  
Embryo-foetal toxicity: LOAEL: 0,06 mg/kg body weight  
Result: Embryotoxic effects., Teratogenicity and developmental toxicity

Test Type: Embryo-foetal development  
Species: Rat

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According to 13 December 2014, No:29204, "Ministry of Environment and Urbanization; Regulation on Safety data sheets regarding hazardous substances and mixtures; Part I".



## Gentamicin / Posaconazole / Mometasone Suspension Formulation

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Application Route: Dermal  
Embryo-foetal toxicity: LOAEL: 0,3 mg/kg body weight  
Result: Embryo-foetal toxicity

Test Type: Embryo-foetal development  
Species: Rabbit  
Application Route: Dermal  
Embryo-foetal toxicity: LOAEL: 0,15 mg/kg body weight  
Result: Embryo-foetal toxicity, Malformations were observed.

Test Type: Embryo-foetal development  
Species: Rat  
Application Route: Subcutaneous  
Embryo-foetal toxicity: LOAEL: 0,15 mg/kg body weight  
Result: Effects on newborn

Test Type: Embryo-foetal development  
Species: Rabbit  
Application Route: Oral  
Embryo-foetal toxicity: LOAEL: 0,7 mg/kg body weight  
Result: Embryo-foetal toxicity, Malformations were observed.

Reproductive toxicity - Assessment : Clear evidence of adverse effects on development, based on animal experiments., Some evidence of adverse effects on sexual function and fertility, based on animal experiments.

### STOT - single exposure

Not classified based on available information.

### Components:

#### **Mometasone:**

Remarks : Based on available data, the classification criteria are not met.

### STOT - repeated exposure

Not classified based on available information.

### Components:

#### **Gentamicin:**

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

#### **Posaconazole:**

Exposure routes : Ingestion  
Target Organs : Adrenal gland, Bone marrow, Kidney, Liver, Reproductive organs, Nervous system  
Assessment : Causes damage to organs through prolonged or repeated

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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:**

#### **Gentamicin:**

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

#### **Posaconazole:**

|         |   |             |
|---------|---|-------------|
| Species | : | Rat, female |
| LOAEL   | : | 5 mg/kg     |

# SAFETY DATA SHEET

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|                    |   |   |
|--------------------|---|---|
| Application Route  | : | Oral  |
| Exposure time      | : | 6 Months  |
| Target Organs      | : | Adrenal gland, Lungs, Heart, Liver, spleen, Kidney, Ovary   |
| Species            | : | Dog   |
| LOAEL              | : | 3 mg/kg   |
| Application Route  | : | Oral  |
| Exposure time      | : | 392 Days  |
| Target Organs      | : | Lungs, Liver, Brain, small intestine, Adrenal gland, Spinal cord, lymphoid tissue                 |
| Species            | : | Monkey  |
| LOAEL              | : | 15 mg/kg  |
| Application Route  | : | Oral  |
| Exposure time      | : | 1 Months  |
| Target Organs      | : | Bone marrow, Adrenal gland, Lymph nodes, Blood  |
| Species            | : | Dog   |
| LOAEL              | : | 3 mg/kg   |
| Application Route  | : | Oral  |
| Exposure time      | : | 56 Weeks  |
| Target Organs      | : | Adrenal gland, Bone marrow, Kidney, Nervous system, spleen, thymus gland, Testis, lymphoid tissue |
| Species            | : | Monkey  |
| LOAEL              | : | 180 mg/kg   |
| Application Route  | : | Oral  |
| Exposure time      | : | 12 Months   |
| Target Organs      | : | Blood, Gastrointestinal tract, spleen   |
| Species            | : | Monkey  |
| LOAEL              | : | 8 mg/kg   |
| Application Route  | : | Intravenous   |
| Exposure time      | : | 1 Months  |
| Target Organs      | : | Cardio-vascular system, Lungs, Adrenal gland, Blood   |
| <b>Mometasone:</b> |   |   |
| 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   |

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|                   |   |   |
|-------------------|---|---|
| Species           | : | Rat   |
| NOAEL             | : | 0,00013 mg/l  |
| Application Route | : | inhalation (dust/mist/fume)   |
| Exposure time     | : | 90 d  |
| Target Organs     | : | Adrenal gland, Lungs, Lymph nodes, spleen, Bone marrow, Kidney, Liver, thymus gland |
| Species           | : | Dog   |
| NOAEL             | : | 0,0005 mg/l   |
| Application Route | : | inhalation (dust/mist/fume)   |
| Exposure time     | : | 90 d  |
| Target Organs     | : | Adrenal gland, Lungs, Lymph nodes, spleen, Bone marrow, Kidney, thymus gland, Liver |

### Aspiration toxicity

Not classified based on available information.

### Components:

#### **Mometasone:**

Not applicable

### Experience with human exposure

### Components:

#### **Gentamicin:**

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

#### **Posaconazole:**

|           |   |  |
|-----------|---|--|
| Ingestion | : | Symptoms: Cough, Headache, Nausea, Vomiting, Fever, Liver effects, Rash, pruritis, Diarrhoea, hypertension, neutropenia, electrolyte imbalance |
|-----------|---|--|

#### **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 |
|---------|---|----------------------------|

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### SECTION 12: Ecological information

#### 12.1 Toxicity

##### Components:

###### **Gentamicin:**

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

###### **Posaconazole:**

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): > 0,95 mg/l  
Exposure time: 96 h  
Method: OECD Test Guideline 203  
Remarks: No toxicity at the limit of solubility

Toxicity to daphnia and other : EC50 (Daphnia magna (Water flea)): 0,276 mg/l

# SAFETY DATA SHEET

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|  |  |
|--|--|
| aquatic invertebrates  | Exposure time: 48 h<br>Method: OECD Test Guideline 202   |
| Toxicity to algae/aquatic plants                                       | : EC50 (Pseudokirchneriella subcapitata (green algae)): > 0,509 mg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201   |
|  | NOEC (Pseudokirchneriella subcapitata (green algae)): 0,041 mg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201   |
| M-Factor (Acute aquatic toxicity)                                      | : 1  |
| Toxicity to microorganisms   | : EC50 (Natural microorganism): > 1.000 mg/l<br>Exposure time: 3 h<br>Test Type: Respiration inhibition<br>Method: OECD Test Guideline 209                             |
| Toxicity to fish (Chronic toxicity)                                    | : NOEC: 0,206 mg/l<br>Exposure time: 33 d<br>Species: Pimephales promelas (fathead minnow)<br>Method: OECD Test Guideline 210  |
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : NOEC: 0,244 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)                                    | : 1  |
| <b>Mometasone:</b>   |  |
| 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   |
|  | 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<br>Method: OECD Test Guideline 202<br>Remarks: No toxicity at the limit of solubility             |
|  | EC50 (Americamysis): > 5 mg/l<br>Exposure time: 96 h   |

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|  |   |   |
|--|---|---|
|  |   | Method: US-EPA OPPTS 850.1035<br>Remarks: No toxicity at the limit of solubility  |
| 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          |
|  |   | 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:

##### **Gentamicin:**

Biodegradability : Result: rapidly degradable  
Biodegradation: 100 %  
Exposure time: 28 d  
Method: OECD Test Guideline 314

##### **Posaconazole:**

Biodegradability : Result: Not readily biodegradable.  
Biodegradation: 50 %  
Exposure time: 28 h  
Method: OECD Test Guideline 314

# SAFETY DATA SHEET

According to 13 December 2014, No:29204, "Ministry of Environment and Urbanization; Regulation on Safety data sheets regarding hazardous substances and mixtures; Part I".



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Stability in water : Degradation half life (DT50): > 30 d  
Method: OECD Test Guideline 111

### **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

### 12.3 Bioaccumulative potential

#### Components:

##### **Gentamicin:**

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

##### **Posaconazole:**

Bioaccumulation : Species: Lepomis macrochirus (Bluegill sunfish)  
Bioconcentration factor (BCF): 20  
Method: OECD Test Guideline 305

Partition coefficient: n-octanol/water : log Pow: 4,15

##### **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:

##### **Posaconazole:**

Distribution among environmental compartments : log Koc: 5,52

##### **Mometasone:**

Distribution among environmental compartments : log Koc: 4,02

### 12.5 Results of PBT and vPvB assessment

Not relevant

# SAFETY DATA SHEET

According to 13 December 2014, No:29204, "Ministry of Environment and Urbanization; Regulation on Safety data sheets regarding hazardous substances and mixtures; Part I".



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### 12.6 Other adverse effects

No data available

## 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. |
| 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.   |

## SECTION 14: Transport information

### 14.1 UN number

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

### 14.2 UN proper shipping name

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

### 14.3 Transport hazard class(es)

|     |     |
|-----|-----|
| ADN | : 9 |
| ADR | : 9 |

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**RID** : 9

**IMDG** : 9

**IATA** : 9

### 14.4 Packing group

#### ADN

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

#### ADR

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

#### RID

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

#### IMDG

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

#### IATA (Cargo)

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

#### IATA (Passenger)

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

### 14.5 Environmental hazards

#### ADN

Environmentally hazardous : yes

#### ADR

Environmentally hazardous : yes

#### RID

Environmentally hazardous : yes

## SAFETY DATA SHEET

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### 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

|  |  |                     |
|--|--|---------------------|
| KKDIK (30105 (Bis)) - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex 17) | : Conditions of restriction for the following entries should be considered: Number on list 3 |                     |
| Regulation on Persistent Organic Pollutants (Number 30595)   | : Not applicable   |                     |
| Regulation on prevention of major industrial accidents. Reg number 30702   | Quantity 1<br>100 t  | Quantity 2<br>200 t |
| E1   | ENVIRONMENTAL<br>HAZARDS   |                     |

### Other regulations:

According to 13 December 2014, No:29204, "Ministry of Environment and Urbanization; Regulation on Safety data sheets regarding hazardous substances and mixtures; Part I".  
Regulation on Classification, Labelling and Packaging of Substances and Mixtures. Dated 11 December 2013, Numbered 28848 (Bis) Ministry of Environment and Forestry.  
Regulation on Health and Safety Measures Of Working with Chemicals Substances Dated 12.08.13, numbered 28733 Ministry of Labour and Social Security.

### The components of this product are reported in the following inventories:

|       |                  |
|-------|------------------|
| AICS  | : not determined |
| DSL   | : not determined |
| IECSC | : not determined |

---

## SECTION 16: Other information

# SAFETY DATA SHEET

According to 13 December 2014, No:29204, "Ministry of Environment and Urbanization; Regulation on Safety data sheets regarding hazardous substances and mixtures; Part I".



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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

H360D : May damage the unborn child.  
H360Df : May damage the unborn child. Suspected of damaging fertility.  
H361d : 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.  
H400 : Very toxic to aquatic life.  
H410 : Very toxic to aquatic life with long lasting effects.

**The Turkish SDS has been prepared according to the Regulation on Safety Data Sheets for Hazardous Substances and Mixtures No. 29204.**

### Full text of other abbreviations

Aquatic Acute : Short-term (acute) aquatic hazard  
Aquatic Chronic : Long-term (chronic) aquatic hazard  
Repr. : Reproductive toxicity  
STOT RE : Specific target organ toxicity - repeated exposure

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AICS - Australian Inventory of Chemical Substances; 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,

# SAFETY DATA SHEET

According to 13 December 2014, No:29204, "Ministry of Environment and Urbanization; Regulation on Safety data sheets regarding hazardous substances and mixtures; Part I".



## Gentamicin / Posaconazole / Mometasone Suspension Formulation

|                |                              |                              |   |
|----------------|------------------------------|------------------------------|---|
| Version<br>2.2 | Revision Date:<br>23.03.2020 | SDS Number:<br>2548428-00005 | Date of last issue: 13.09.2019<br>Date of first issue: 23.02.2018 |
|----------------|------------------------------|------------------------------|---|

tion, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

### Further information

Sources of key data used to compile the Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals 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 |

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

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