SAFETY DATA SHEET

Dexamethasone Formulation

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

1.1 Product identifier
Trade name : Dexamethasone Formulation

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
20 Spartan Road
1619 Spartan, South Africa
Telephone : +27119239300
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 1B : H360D: May damage the unborn child.
Long-term (chronic) aquatic hazard, Category 3 : H412: Harmful to aquatic life with long lasting effects.

2.2 Label elements
Labelling (REGULATION (EC) No 1272/2008)
Hazard pictograms :

Signal word : Danger

Hazard statements : H360D May damage the unborn child.
H412 Harmful to aquatic life with long lasting effects.

Precautionary statements : Prevention:
P201 Obtain special instructions before use.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.
Response: P308 + P313  IF exposed or concerned: Get medical advice/attention.

Storage: P405 Store locked up.

Hazardous components which must be listed on the label:
Dexamethasone

2.3 Other hazards
This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No. EC-No. Index-No. Registration number</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzyl alcohol</td>
<td>100-51-6 202-859-9 603-057-00-5</td>
<td>Acute Tox. 4; H302 Acute Tox. 4; H332 Eye Irrit. 2; H319</td>
<td>1.04</td>
</tr>
<tr>
<td>Dexamethasone</td>
<td>50-02-2 200-003-9</td>
<td>Repr. 1B; H360D STOT RE 2; H373 (Adrenal gland, Immune system, thymus gland) Aquatic Chronic 1; H410</td>
<td>0.3</td>
</tr>
</tbody>
</table>

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.

4.3 Indication of any immediate medical attention and special treatment needed
Treatment  :  Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media
Suitable extinguishing media  :  Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO2)  
Dry chemical

Unsuitable extinguishing media  :  None known.

5.2 Special hazards arising from the substance or mixture
Specific hazards during firefighting  :  Exposure to combustion products may be a hazard to health.  
Hazardous combustion products  :  Carbon oxides  
Metal 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.
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.

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.

Remove undamaged containers from fire area if it is safe to do so. Evacuate area.
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.

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:
- Strong oxidizing agents
- Organic peroxides
- Explosives
- Gases

7.3 Specific end use(s)
Specific use(s): No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

**Occupational Exposure Limits**

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dexamethasone</td>
<td>50-02-2</td>
<td>TWA</td>
<td>10 µg/m3 (OEB 3)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>100 µg/100 cm²</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Substance name</th>
<th>End Use</th>
<th>Exposure routes</th>
<th>Potential health effects</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzyl alcohol</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>22 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Inhalation</td>
<td>Acute systemic effects</td>
<td>110 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>8 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Skin contact</td>
<td>Acute systemic effects</td>
<td>40 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>5,4 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Acute systemic effects</td>
<td>27 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>4 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Skin contact</td>
<td>Acute systemic effects</td>
<td>20 mg/kg</td>
</tr>
</tbody>
</table>
Dexamethasone Formulation

**Effects**

| Consumers | Ingestion | Long-term systemic effects | 4 mg/kg bw/day |
| Consumers | Ingestion | Acute systemic effects | 20 mg/kg bw/day |

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

<table>
<thead>
<tr>
<th>Substance name</th>
<th>Environmental Compartment</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium citrate</td>
<td>Fresh water</td>
<td>0.44 mg/l</td>
</tr>
<tr>
<td></td>
<td>Marine water</td>
<td>0.044 mg/l</td>
</tr>
<tr>
<td></td>
<td>Sewage treatment plant</td>
<td>1000 mg/l</td>
</tr>
<tr>
<td></td>
<td>Fresh water sediment</td>
<td>34.6 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Marine water</td>
<td>3.46 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Soil</td>
<td>31.1 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td>Benzyl alcohol</td>
<td>Fresh water</td>
<td>1 mg/l</td>
</tr>
<tr>
<td></td>
<td>Marine water</td>
<td>0.1 mg/l</td>
</tr>
<tr>
<td></td>
<td>Intermittent use/release</td>
<td>2.3 mg/l</td>
</tr>
<tr>
<td></td>
<td>Sewage treatment plant</td>
<td>39 mg/l</td>
</tr>
<tr>
<td></td>
<td>Fresh water sediment</td>
<td>5.27 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Marine sediment</td>
<td>0.527 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Soil</td>
<td>0.456 mg/kg</td>
</tr>
</tbody>
</table>

**8.2 Exposure controls**

**Engineering measures**

Minimize workplace exposure concentrations.

If sufficient ventilation is unavailable, use with local exhaust ventilation.

**Personal protective equipment**

- **Eye protection**: Wear the following personal protective equipment:
  - Safety glasses

- **Hand protection**
  - **Material**: Chemical-resistant gloves
  - **Remarks**: Choose gloves to protect hands against chemicals depending on the concentration and quantity of the hazardous substance and specific to place of work. Breakthrough time is not determined for the product. Change gloves often! For special applications, we recommend clarifying the resistance to chemicals of the aforementioned protective gloves with the glove manufacturer. Wash hands before breaks and at the end of workday.

- **Skin and body protection**: Select appropriate protective clothing based on chemical resistance data and an assessment of the local exposure potential.
  - Skin contact must be avoided by using impervious protective clothing (gloves, aprons, boots, etc).

- **Respiratory protection**: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
  - **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

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>liquid</td>
</tr>
<tr>
<td>Colour</td>
<td>white to off-white</td>
</tr>
<tr>
<td>Odour</td>
<td>No data available</td>
</tr>
<tr>
<td>Odour Threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>7.0 - 7.8</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Initial boiling point and boiling range</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash point</td>
<td>No data available</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Upper explosion limit / Upper flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit / Lower flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapour pressure</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative vapour density</td>
<td>No data available</td>
</tr>
<tr>
<td>Density</td>
<td>No data available</td>
</tr>
<tr>
<td>Solubility(ies)</td>
<td></td>
</tr>
<tr>
<td>Water solubility</td>
<td>No data available</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>No data available</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity</td>
<td></td>
</tr>
<tr>
<td>Viscosity, kinematic</td>
<td>No data available</td>
</tr>
<tr>
<td>Explosive properties</td>
<td>Not explosive</td>
</tr>
<tr>
<td>Oxidizing properties</td>
<td>The substance or mixture is not classified as oxidizing.</td>
</tr>
</tbody>
</table>

9.2 Other information

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flammability (liquids)</td>
<td>No data available</td>
</tr>
<tr>
<td>Molecular weight</td>
<td>No data available</td>
</tr>
<tr>
<td>Particle size</td>
<td>No data available</td>
</tr>
</tbody>
</table>
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 toxicological effects
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 inhalation toxicity : Acute toxicity estimate: > 5 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: Calculation method

Components:
Benzyl alcohol:
Acute oral toxicity : LD50 (Rat): 1.620 mg/kg
Acute toxicity estimate: 1.620 mg/kg
Method: Calculation method

Acute inhalation toxicity : LC50 (Rat): > 4,178 mg/l
Exposure time: 4 h
Dexamethasone Formulation

**Test atmosphere:** dust/mist  
**Method:** OECD Test Guideline 403

### Dexamethasone:
**Acute oral toxicity**  
LD50 (Rat): > 2.000 mg/kg  
LD50 (Mouse): > 6.500 mg/kg

**Acute toxicity (other routes of administration)**  
LD50 (Rat): 14 mg/kg  
Application Route: Subcutaneous

### Skin corrosion/irritation
Not classified based on available information.

#### Components:

**Benzyl alcohol:**
- **Species:** Rabbit  
- **Method:** OECD Test Guideline 404  
- **Result:** No skin irritation

**Dexamethasone:**
- **Species:** Rabbit  
- **Result:** Mild skin irritation

### Serious eye damage/eye irritation
Not classified based on available information.

#### Components:

**Benzyl alcohol:**
- **Species:** Rabbit  
- **Method:** OECD Test Guideline 405  
- **Result:** Irritation to eyes, reversing within 21 days

**Dexamethasone:**
- **Species:** Rabbit  
- **Result:** Mild eye irritation

### Respiratory or skin sensitisation

#### Skin sensitisation
Not classified based on available information.

#### Respiratory sensitisation
Not classified based on available information.

#### Components:

**Benzyl alcohol:**
- **Test Type:** Maximisation Test  
- **Exposure routes:** Skin contact
Species : Guinea pig
Method : OECD Test Guideline 406
Result : negative

**Germ cell mutagenicity**
Not classified based on available information.

**Components:**

**Benzyl alcohol:**
Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Result: negative
Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: Intraperitoneal injection
Result: negative

**Dexamethasone:**
Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Result: negative
Test Type: in vitro assay
Test system: mouse lymphoma cells
Result: negative
Genotoxicity in vivo : Test Type: Micronucleus test
Species: Mouse
Application Route: Oral
Result: negative

**Carcinogenicity**
Not classified based on available information.

**Components:**

**Benzyl alcohol:**
Species : Mouse
Application Route : Ingestion
Exposure time : 103 weeks
Method : OECD Test Guideline 451
Result : negative

**Reproductive toxicity**
May damage the unborn child.

**Components:**

**Benzyl alcohol:**
Effects on fertility : Test Type: Fertility/early embryonic development
Species: Rat
Application Route: Ingestion
SAFETY DATA SHEET

Dexamethasone Formulation

Result: negative
Remarks: Based on data from similar materials

Effects on foetal development:
- Test Type: Embryo-foetal development
- Species: Mouse
- Application Route: Ingestion
- Result: negative

Dexamethasone:
Effects on foetal development:
- Test Type: Development
- Species: Mouse
- Application Route: Subcutaneous
- Developmental Toxicity: LOAEL: 6 mg/kg body weight
- Result: Specific developmental abnormalities, Cleft palate

Species: Rabbit
- Application Route: Intramuscular
- Developmental Toxicity: NOAEL: 0,025 mg/kg body weight
- Result: Specific developmental abnormalities

Species: Rabbit
- Application Route: Intramuscular
- Developmental Toxicity: LOAEL: >= 0,062 mg/kg body weight
- Result: Specific developmental abnormalities

Species: Rat
- Application Route: Subcutaneous
- Developmental Toxicity: NOAEL: >= 0,02 mg/kg body weight
- Result: Skeletal and visceral variations, Retardations

Reproductive toxicity - Assessment:
- May damage the unborn child.

STOT - single exposure
Not classified based on available information.

STOT - repeated exposure
Not classified based on available information.

Components:

Dexamethasone:
- Exposure routes: Oral
- Target Organs: Adrenal gland, Immune system, thymus gland
- Assessment: May cause damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Components:

Benzyl alcohol:
- Species: Rat
- NOAEL: 1,072 mg/l
- Application Route: Inhalation (dust/mist/fume)
<table>
<thead>
<tr>
<th>Exposure time</th>
<th>28 Days</th>
</tr>
</thead>
<tbody>
<tr>
<td>Method</td>
<td>OECD Test Guideline 412</td>
</tr>
</tbody>
</table>

**Dexamethasone:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>0.0015 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>7 d</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Liver</td>
</tr>
<tr>
<td>Remarks</td>
<td>Significant toxicity observed in testing</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOAEL</td>
<td>0.003 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>90 d</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Blood, Adrenal gland, thymus gland</td>
</tr>
<tr>
<td>Remarks</td>
<td>Significant toxicity observed in testing</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>0.125 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>6 Weeks</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Adrenal gland</td>
</tr>
<tr>
<td>Remarks</td>
<td>Significant toxicity observed in testing</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>0.4 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>3 Months</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Immune system</td>
</tr>
<tr>
<td>Remarks</td>
<td>Significant toxicity observed in testing</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Dog</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOAEL</td>
<td>8 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>3 Months</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Immune system</td>
</tr>
<tr>
<td>Remarks</td>
<td>Significant toxicity observed in testing</td>
</tr>
</tbody>
</table>

**Aspiration toxicity**

Not classified based on available information.

**Experience with human exposure**

**Components:**

**Dexamethasone:**

<table>
<thead>
<tr>
<th>Ingestion</th>
<th>Target Organs: Immune system</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Target Organs: Adrenal gland</td>
</tr>
<tr>
<td></td>
<td>Target Organs: Bone</td>
</tr>
<tr>
<td></td>
<td>Symptoms: muscle weakness</td>
</tr>
</tbody>
</table>
SECTION 12: Ecological information

12.1 Toxicity

Components:

**Benzyl alcohol:**
- Toxicity to fish: LC50 (Pimephales promelas (fathead minnow)): 460 mg/l Exposure time: 96 h
- Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): 230 mg/l Exposure time: 48 h Method: OECD Test Guideline 202
- Toxicity to algae/aquatic plants: EC50 (Pseudokirchneriella subcapitata (green algae)): 770 mg/l Exposure time: 72 h Method: OECD Test Guideline 201

**Dexamethasone:**
- Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): > 56 mg/l Exposure time: 48 h Method: OECD Test Guideline 202
- Toxicity to algae/aquatic plants: EC50 (Pseudokirchneriella subcapitata (green algae)): > 9,2 mg/l Exposure time: 72 h Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 310 mg/l Exposure time: 72 h Method: OECD Test Guideline 201

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):
- NOEC: 51 mg/l Exposure time: 21 d Species: Daphnia magna (Water flea) Method: OECD Test Guideline 211

**Toxicity to microorganisms:**
- EC50: > 1,000 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209
- NOEC: 1,000 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209
Toxicity to fish (Chronic toxicity):
   NOEC: 0.033 mg/l
   Exposure time: 32 d
   Species: Pimephales promelas (fathead minnow)
   Method: OECD Test Guideline 210

M-Factor (Chronic aquatic toxicity):
   1

**12.2 Persistence and degradability**

**Components:**

**Benzyl alcohol:**
   Biodegradability:
   Result: Readily biodegradable.
   Biodegradation: 92 - 96%
   Exposure time: 14 d

**Dexamethasone:**
   Biodegradability:
   Result: Not readily biodegradable.
   Biodegradation: 50%
   Exposure time: 3.54 d
   Method: OECD Test Guideline 314

**12.3 Bioaccumulative potential**

**Components:**

**Benzyl alcohol:**
   Partition coefficient: n-octanol/water:
   log Pow: 1.05

**Dexamethasone:**
   Partition coefficient: n-octanol/water:
   log Pow: 1.83

**12.4 Mobility in soil**
No data available

**12.5 Results of PBT and vPvB assessment**

**Product:**
   Assessment:
   This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

**12.6 Other adverse effects**

**Product:**
   Endocrine disrupting potential:
   The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.
SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product: Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.

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

SECTION 14: Transport information

14.1 UN number
Not regulated as a dangerous good

14.2 UN proper shipping name
Not regulated as a dangerous good

14.3 Transport hazard class(es)
Not regulated as a dangerous good

14.4 Packing group
Not regulated as a dangerous good

14.5 Environmental hazards
Not regulated as a dangerous good

14.6 Special precautions for user
Not applicable

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code
Remarks: Not applicable for product as supplied.

SECTION 15: Regulatory information

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

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

AICS: not determined

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
Full text of H-Statements

H302 : Harmful if swallowed.
H319 : Causes serious eye irritation.
H332 : Harmful if inhaled.
H360D : May damage the unborn child.
H373 : May cause damage to organs through prolonged or repeated exposure if swallowed.
H410 : Very toxic to aquatic life with long lasting effects.

Full text of other abbreviations

Acute Tox. : Acute toxicity
Aquatic Chronic : Long-term (chronic) aquatic hazard
Eye Irrit. : Eye irritation
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; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic Substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Further information
Sources of key data used to : Internal technical data, data from raw material SDSs, OECD

**Classification of the mixture:**
- **Repr. 1B**
  - H360D
- **Aquatic Chronic 3**
  - H412

**Classification procedure:**
- 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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