SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

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
   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 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.
Dexamethasone Formulation

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.

Ecological 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.

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

<table>
<thead>
<tr>
<th>Components</th>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>EC-No.</th>
<th>Index-No.</th>
<th>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>Acute toxicity estimate</td>
<td>Acute oral toxicity: 1,620 mg/kg</td>
<td>1.04</td>
<td></td>
<td></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 M-Factor (Chronic aquatic toxicity): 1</td>
<td>0.3</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
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.
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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. 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 spills 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.

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>Further information: Skin</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>100 µg/100 cm²</td>
<td>Internal</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>
</table>
Benzyl alcohol

Workers

Inhalation

Long-term systemic effects

22 mg/m³

Workers

Inhalation

Acute systemic effects

110 mg/m³

Workers

Skin contact

Long-term systemic effects

8 mg/kg bw/day

Workers

Skin contact

Acute systemic effects

40 mg/kg bw/day

Consumers

Inhalation

Long-term systemic effects

5.4 mg/m³

Consumers

Inhalation

Acute systemic effects

27 mg/m³

Consumers

Skin contact

Long-term systemic effects

4 mg/kg bw/day

Consumers

Skin contact

Acute systemic effects

20 mg/kg bw/day

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
Equipment should conform to I.S. EN 166

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.

Equipment should conform to I.S. 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 | liquid |
| Colour | white to off-white |
| Odour | No data available |
| 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 | 7.0 - 7.8 |
| Viscosity | |
| Viscosity, kinematic | No data available |
| Solubility(ies) | |
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Water solubility : No data available
Partition coefficient: n-octanol/water : No data available
Vapour pressure : No data available
Density : No data available
Relative vapour density : No data available
Particle characteristics
   Particle size : No data available

9.2 Other information
   Explosives : Not explosive
   Oxidizing properties : The substance or mixture is not classified as oxidizing.
   Evaporation rate : No data available
   Molecular weight : 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
   Information on likely routes of exposure
      Inhalation
      Skin contact
      Ingestion
      Eye contact
## Dexamethasone Formulation

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date</th>
<th>SDS Number</th>
<th>Date of last issue</th>
<th>Date of first issue</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.6</td>
<td>27.08.2021</td>
<td>1843087-00009</td>
<td>09.04.2021</td>
<td>20.07.2017</td>
</tr>
</tbody>
</table>

### Acute toxicity

Not classified based on available information.

**Product:**

<table>
<thead>
<tr>
<th>Toxicity Type</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute oral toxicity</td>
<td>Acute toxicity estimate: &gt; 2,000 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Method: Calculation method</td>
</tr>
<tr>
<td>Acute inhalation toxicity</td>
<td>Acute toxicity estimate: &gt; 5 mg/l</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 4 h</td>
</tr>
<tr>
<td></td>
<td>Test atmosphere: dust/mist</td>
</tr>
<tr>
<td></td>
<td>Method: Calculation method</td>
</tr>
</tbody>
</table>

### Components:

**Benzyl alcohol:**

<table>
<thead>
<tr>
<th>Component</th>
<th>Toxicity Type</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Acute oral toxicity</td>
<td>LD50 (Rat): 1,620 mg/kg</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Acute toxicity estimate: 1,620 mg/kg</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Method: Calculation method</td>
</tr>
<tr>
<td></td>
<td>Acute inhalation toxicity</td>
<td>LC50 (Rat): &gt; 4.178 mg/l</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Exposure time: 4 h</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Test atmosphere: dust/mist</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Method: OECD Test Guideline 403</td>
</tr>
</tbody>
</table>

**Dexamethasone:**

<table>
<thead>
<tr>
<th>Component</th>
<th>Toxicity Type</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Acute oral toxicity</td>
<td>LD50 (Rat): &gt; 2,000 mg/kg</td>
</tr>
<tr>
<td></td>
<td></td>
<td>LD50 (Mouse): &gt; 6,500 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Acute toxicity (other routes of administration)</td>
<td>LD50 (Rat): 14 mg/kg</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Application Route: Subcutaneous</td>
</tr>
</tbody>
</table>

### Skin corrosion/irritation

Not classified based on available information.

**Components:**

**Benzyl alcohol:**

<table>
<thead>
<tr>
<th>Component</th>
<th>Toxicity Type</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Species</td>
<td>Rabbit</td>
</tr>
<tr>
<td></td>
<td>Method</td>
<td>OECD Test Guideline 404</td>
</tr>
<tr>
<td></td>
<td>Result</td>
<td>No skin irritation</td>
</tr>
</tbody>
</table>

**Dexamethasone:**

<table>
<thead>
<tr>
<th>Component</th>
<th>Toxicity Type</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Species</td>
<td>Rabbit</td>
</tr>
<tr>
<td></td>
<td>Result</td>
<td>Mild skin irritation</td>
</tr>
</tbody>
</table>
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
Carcinogenicity
Not classified based on available information.

Components:

Benzyl alcohol:
Species: Mouse
Application Route: Oral
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
Result: negative
Remarks: Based on data from similar materials

Effects on foetal development:
Species: Mouse
Application Route: Ingestion
Result: negative

Dexamethasone:
Effects on foetal 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: LOAEL: >= 0.02 mg/kg body weight
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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)
- Exposure time: 28 Days
- Method: OECD Test Guideline 412

Dexamethasone:
- Species: Rat
- NOAEL: 0.0015 mg/kg
- Application Route: Oral
- Exposure time: 7 d
- Target Organs: Liver
- Remarks: Significant toxicity observed in testing

- Species: Rat
- LOAEL: 0.003 mg/kg
- Application Route: Oral
- Exposure time: 90 d
- Target Organs: Blood, Adrenal gland, thymus gland
- Remarks: Significant toxicity observed in testing

- Species: Rat
- LOAEL: 0.125 mg/kg
- Application Route: Oral
- Exposure time: 6 Weeks
- Target Organs: Adrenal gland
- Remarks: Significant toxicity observed in testing

- Species: Rat
- LOAEL: 0.4 mg/kg
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Application Route: Oral
Exposure time: 3 Months
Target Organs: Immune system
Remarks: Significant toxicity observed in testing

Species: Dog
LOAEL: 8 mg/kg
Application Route: Oral
Exposure time: 3 Months
Target Organs: Immune system
Remarks: Significant toxicity observed in testing

Aspiration toxicity
Not classified based on available information.

11.2 Information on other hazards
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.

Experience with human exposure
Components:
Dexamethasone:
Ingestion: Target Organs: Immune system
Target Organs: Adrenal gland
Target Organs: Bone
Symptoms: muscle weakness

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

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

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)): 9.2 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

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
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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 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

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.
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according to Regulation (EC) No. 1907/2006

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SECTION 14: Transport information

14.1 UN number or ID 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 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, preparations and articles (Annex XVII):
Conditions of restriction for the following entries should be considered:
Number on list 3

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

Regulation (EC) No 1005/2009 on substances that deplete the ozone layer:
Not applicable

Regulation (EU) 2019/1021 on persistent organic pollutants (recast):
Not applicable

Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals:
Not applicable

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

Not applicable

Other regulations:
Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.
Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

The components of this product are reported in the following inventories:
AICS: not determined
SAFETY DATA SHEET
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Dexamethasone Formulation

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DSL: not determined
IECSC: not determined

15.2 Chemical safety assessment
A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

Other information: Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

Full text of H-Statements
H302: Harmful if swallowed.
H319: Causes serious eye irritation.
H332: Hazardous to the respiratory system.
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); ERx - 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; KECl - 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 sub-
Sources of key data used to compile the Safety Data Sheet:

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