UK REACH Regulations SI 2019/758



### **Dexamethasone (with Ethanol) Formulation**

| Version | Revision Date: | SDS Number:   | Date of last issue: 24.06.2024  |
|---------|----------------|---------------|---------------------------------|
| 6.0     | 28.09.2024     | 9372726-00009 | Date of first issue: 27.08.2021 |

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

| 1.1 | Product identifier<br>Trade name                 | :    | Dexamethasone (with Ethanol) Formulation                              |
|-----|--|------|---|
| 1.2 | Relevant identified uses of th                   | ne s | substance or mixture and uses advised against                         |
|     | Use of the Sub-<br>stance/Mixture                |      | Veterinary product  |
|     | Recommended restrictions on use                  | :    | Not applicable  |
| 1.3 | Details of the supplier of the                   | saf  | ety data sheet  |
|     | Company  | :    | MSD<br>Walton Manor, Walton<br>MK7 7AJ Milton Keynes - United Kingdom |
|     | Telephone  | :    | +1-908-740-4000   |
|     | 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) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)

Not a hazardous substance or mixture.

### 2.2 Label elements

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

No hazard pictogram, no signal word, no hazard statement(s), no precautionary statement(s) required.

EUH210 Safety data sheet available on request.

EUH208 Contains Benzyl alcohol. May produce an allergic reaction.

UK REACH Regulations SI 2019/758



### **Dexamethasone (with Ethanol) Formulation**

| Version | Revision Date: | SDS Number:   | Date of last issue: 24.06.2024  |
|---------|----------------|---------------|---------------------------------|
| 6.0     | 28.09.2024     | 9372726-00009 | Date of first issue: 27.08.2021 |

#### 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.

Vapours may form explosive mixture with air.

### **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) |
|----------------|---|---|--------------------------|
| Ethanol#       | 64-17-5<br>200-578-6<br>603-002-00-5                  | Flam. Liq. 2; H225<br>Eye Irrit. 2; H319<br>specific concentra-<br>tion limit<br>Eye Irrit. 2; H319<br>>= 50 %<br>Eye Irrit. 2; H319<br>>= 50 %                     | >= 1 - < 10              |
| Benzyl alcohol | 100-51-6<br>202-859-9<br>603-057-00-5                 | Acute Tox. 4; H302<br>Eye Irrit. 2; H319<br>Skin Sens. 1B;<br>H317  | >= 0.1 - < 1             |
| Dexamethasone  | 50-02-2<br>200-003-9                                  | Repr. 1B; H360D<br>STOT RE 2; H373<br>(Adrenal gland,<br>Immune system,<br>thymus gland)<br>Aquatic Chronic 1;<br>H410<br>M-Factor (Chronic<br>aquatic toxicity): 1 | >= 0.1 - < 0.25          |

For explanation of abbreviations see section 16. #: Voluntarily-disclosed substance

#### **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



| Version<br>6.0 | Revision Date:<br>28.09.2024 |      | 0S Number:<br>72726-00009   | Date of last issue: 24.06.2024<br>Date of first issue: 27.08.2021   |
|----------------|------------------------------|------|---|---|
|                |                              |      | advice.   |   |
| Prote          | ction of first-aiders        | :    | and use the recor   | ers should pay attention to self-protection,<br>mmended personal protective equipment<br>al for exposure exists (see section 8).                                |
| lf inha        | aled                         | :    | If inhaled, remove<br>Get medical atter                               |   |
| In cas         | se of skin contact           | :    | of water.<br>Remove contamin<br>Get medical atter<br>Wash clothing be |   |
| In cas         | se of eye contact            | :    |   | vater as a precaution.<br>Ition if irritation develops and persists.  |
| lf swa         | llowed                       | :    | Get medical atter   | NOT induce vomiting.<br>Ition.<br>oughly with water.  |
| 4.2 Most i     | mportant symptoms a          | nd e | effects, both acute   | e and delayed   |
| Risks          |                              | :    | May produce an a  | allergic reaction.  |
| 4.3 Indica     | tion of any immediate        | med  | dical attention and   | d special treatment needed  |
| Treat          | ment                         | :    | Treat symptomati  | cally and supportively.   |
| SECTION        | 1 5: Firefighting meas       | sur  | es  |   |
| 5.1 Exting     | uishing media                |      |   |   |
| Suital         | ble extinguishing media      | :    | Water spray<br>Alcohol-resistant<br>Carbon dioxide (C<br>Dry chemical |   |
| Unsui<br>media | itable extinguishing<br>a    | :    | High volume wate  | er jet  |
| 5 2 Specia     | al hazards arising from      | the  | e substance or mi   | xture   |
| -              | fic hazards during fire-     | :    | Do not use a solid<br>fire.<br>Flash back possil<br>Vapours may forr  | d water stream as it may scatter and spread<br>ble over considerable distance.<br>n explosive mixtures with air.<br>bustion products may be a hazard to health. |
| Haza<br>ucts   | rdous combustion prod-       | :    | Carbon oxides   |   |



### **Dexamethasone (with Ethanol) Formulation**

| Version | Revision Date: | SDS Number:   | Date of last issue: 24.06.2024  |
|---------|----------------|---------------|---------------------------------|
| 6.0     | 28.09.2024     | 9372726-00009 | Date of first issue: 27.08.2021 |

### 5.3 Advice for firefighters

| Special protective equipment for firefighters | : | In the event of fire, wear self-contained breathing apparatus.<br>Use personal protective equipment.  |
|---|---|---|
| Specific extinguishing meth-<br>ods           | : | Use extinguishing measures that are appropriate to local cir-<br>cumstances and the surrounding environment.<br>Use water spray to cool unopened containers.<br>Remove undamaged containers from fire area if it is safe to do<br>so.<br>Evacuate area. |

### **SECTION 6:** Accidental release measures

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

| Personal precautions | <ul> <li>Remove all sources of ignition.</li> <li>Use personal protective equipment.</li> <li>Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).</li> </ul> |
|----------------------|---|
|----------------------|---|

### 6.2 Environmental precautions

| Environmental precautions | : | Avoid release to the environment.<br>Prevent further leakage or spillage if safe to do so.<br>Prevent spreading over a wide area (e.g. by containment or oil<br>barriers).<br>Retain and dispose of contaminated wash water.<br>If spillage enters rivers or watercourses, inform the Environ-<br>ment Agency (emergency telephone number 0800 807060). |
|---------------------------|---|---|
|---------------------------|---|---|

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

| Methods for cleaning up | <ul> <li>Non-sparking tools should be used.<br/>Soak up with inert absorbent material.<br/>Suppress (knock down) gases/vapours/mists with a water<br/>spray jet.</li> <li>For large spills, provide dyking or other appropriate contain-<br/>ment to keep material from spreading. If dyked material can<br/>be pumped, store recovered material in appropriate container.<br/>Clean up remaining materials from spill with suitable absor-<br/>bent.</li> <li>Local or national regulations may apply to releases and dis-<br/>posal of this material, as well as those materials and items<br/>employed in the cleanup of releases. You will need to deter-<br/>mine which regulations are applicable.</li> <li>Sections 13 and 15 of this SDS provide information regarding<br/>certain local or national requirements.</li> </ul> |
|-------------------------|---|

#### 6.4 Reference to other sections

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

### SAFETY DATA SHEET According to REACH Regulation (EC) No 1907/2

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



### **Dexamethasone (with Ethanol) Formulation**

| Version | Revision Date: | SDS Number:   | Date of last issue: 24.06.2024  |
|---------|----------------|---------------|---------------------------------|
| 6.0     | 28.09.2024     | 9372726-00009 | Date of first issue: 27.08.2021 |

### **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 eves. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment Keep container tightly closed. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Take precautionary measures against static discharges. Take care to prevent spills, waste and minimize release to the environment. If exposure to chemical is likely during typical use, provide eye Hygiene measures 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 : Keep in properly labelled containers. Keep tightly closed. areas and containers Keep in a cool, well-ventilated place. Store in accordance with the particular national regulations. Keep away from heat and sources of ignition. Do not store with the following product types: Advice on common storage Strong oxidizing agents Self-reactive substances and mixtures Organic peroxides Explosives Gases 7.3 Specific end use(s) Specific use(s) No data available

### **SECTION 8: Exposure controls/personal protection**

### 8.1 Control parameters

### **Occupational Exposure Limits**

| Components | CAS-No. | Value type (Form of exposure) | Control parameters       | Basis   |
|------------|---------|-------------------------------|--------------------------|---------|
| Ethanol    | 64-17-5 | TWA                           | 1,000 ppm<br>1,920 mg/m3 | GB EH40 |

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



## **Dexamethasone (with Ethanol) Formulation**

| Version<br>6.0 |           |                | 8 Number:<br>2726-00009 | Date of last issue: 24.06.2024<br>Date of first issue: 27.08.2021 |          |
|----------------|-----------|----------------|-------------------------|---|----------|
| Dexa           | methasone | 50-02-2        | TWA                     | 10 µg/m3 (OEB 3)  | Internal |
| Further        |           | Further inform | nation: Skin            |   |          |
|                |           |                | Wipe limit              | 100 µg/100 cm <sup>2</sup>  | Internal |

### Derived No Effect Level (DNEL)

| Substance name | End Use   | Exposure routes | Potential health ef-<br>fects | Value               |
|----------------|-----------|-----------------|-------------------------------|---------------------|
| Ethanol        | Workers   | Inhalation      | Long-term systemic<br>effects | 380 mg/m3           |
|                | Workers   | Skin contact    | Long-term systemic<br>effects | 267 mg/kg<br>bw/day |
|                | Consumers | Inhalation      | Long-term systemic<br>effects | 114 mg/m3           |
| Benzyl alcohol | Workers   | Inhalation      | Long-term systemic<br>effects | 22 mg/m3            |
|                | Workers   | Inhalation      | Acute systemic ef-<br>fects   | 110 mg/m3           |
|                | Workers   | Skin contact    | Long-term systemic<br>effects | 8 mg/kg<br>bw/day   |
|                | Workers   | Skin contact    | Acute systemic ef-<br>fects   | 40 mg/kg<br>bw/day  |
|                | Consumers | Inhalation      | Long-term systemic<br>effects | 5.4 mg/m3           |
|                | Consumers | Inhalation      | Acute systemic ef-<br>fects   | 27 mg/m3            |
|                | Consumers | Skin contact    | Long-term systemic effects    | 4 mg/kg<br>bw/day   |
|                | Consumers | Skin contact    | Acute systemic ef-<br>fects   | 20 mg/kg<br>bw/day  |
|                | Consumers | Ingestion       | Long-term systemic<br>effects | 4 mg/kg<br>bw/day   |
|                | Consumers | Ingestion       | Acute systemic ef-<br>fects   | 20 mg/kg<br>bw/day  |

### Predicted No Effect Concentration (PNEC)

| Substance name | Environmental Compartment  | Value                           |
|----------------|----------------------------|---------------------------------|
| Ethanol        | Fresh water                | 0.96 mg/l                       |
|                | Freshwater - intermittent  | 2.75 mg/l                       |
|                | Marine water               | 0.79 mg/l                       |
|                | Sewage treatment plant     | 580 mg/l                        |
|                | Fresh water sediment       | 3.6 mg/kg dry<br>weight (d.w.)  |
|                | Marine sediment            | 2.9 mg/kg dry<br>weight (d.w.)  |
|                | Soil                       | 0.63 mg/kg dry<br>weight (d.w.) |
|                | Oral (Secondary Poisoning) | 380 mg/kg food                  |
| Benzyl alcohol | Fresh water                | 1 mg/l                          |
|                | Marine water               | 0.1 mg/l                        |
|                | Intermittent use/release   | 2.3 mg/l                        |
|                | Sewage treatment plant     | 39 mg/l                         |

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



0.456 mg/kg

### **Dexamethasone (with Ethanol) Formulation**

| Version<br>6.0 | Revision Date: 28.09.2024 | SDS Number:<br>9372726-00009 | Date of last issue: 24.06.20<br>Date of first issue: 27.08.20 |             |
|----------------|---------------------------|------------------------------|---|-------------|
| I              |                           | Fresh water s                | ediment   | 5.27 mg/kg  |
|                |                           | Marine sedim                 | ent   | 0.527 mg/kg |

#### 8.2 Exposure controls

Π

### **Engineering measures**

Minimize workplace exposure concentrations. If sufficient ventilation is unavailable, use with local exhaust ventilation.

Soil

### Personal protective equipment

| Eye/face protection :    |   | Wear the following personal protective equipment:<br>Safety glasses<br>Equipment should conform to BS EN 166  |  |  |
|--------------------------|---|---|--|--|
| Hand protection          |   |   |  |  |
| Material                 | : | Chemical-resistant gloves   |  |  |
| Remarks                  | : | Choose gloves to protect hands against chemicals depending<br>on the concentration and quantity of the hazardous sub-<br>stance and specific to place of work. Breakthrough time is not<br>determined for the product. Change gloves often! For special<br>applications, we recommend clarifying the resistance to<br>chemicals of the aforementioned protective gloves with the<br>glove manufacturer. Take note that the product is flammable,<br>which may impact the selection of hand protection. Wash<br>hands before breaks and at the end of workday. |  |  |
| Skin and body protection | : | Select appropriate protective clothing based on chemical re-<br>sistance data and an assessment of the local exposure poten-<br>tial.<br>Wear the following personal protective equipment:<br>If assessment demonstrates that there is a risk of explosive<br>atmospheres or flash fires, use flame retardant antistatic pro-<br>tective clothing.<br>Skin contact must be avoided by using impervious protective   |  |  |
| Respiratory protection   | : | clothing (gloves, aprons, boots, etc).<br>If adequate local exhaust ventilation is not available or expo-<br>sure assessment demonstrates exposures outside the rec-<br>ommended guidelines, use respiratory protection.<br>Equipment should conform to BS 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

| Appearance<br>Colour<br>Odour<br>Odour Threshold | :: |                   |
|--|----|-------------------|
| рН   | :  | 4.9               |
| Melting point/freezing point                     | :  | No data available |

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



## **Dexamethasone (with Ethanol) Formulation**

| Ver<br>6.0 | ersion Revision Date:<br>0 28.09.2024  |   |   | S Number:<br>72726-00009                                    | Date of last issue: 24.06.2024<br>Date of first issue: 27.08.2021 |
|------------|--|---|---|---|---|
|            | Initial boiling point and boiling range  |   | : |   | 9   |
|            | Flash p  | oint                                    | : | 68 °C   |   |
|            | Evapor   | ation rate                              | : | No data available   | 2   |
|            | Flamma   | ability (solid, gas)                    | : | Not applicable  |   |
|            | Upper explosion limit / Upper flammability limit   |   | : | No data available   | 9   |
|            |  | explosion limit / Lower<br>bility limit | : | No data available   | 9   |
|            | Vapour pressure  |   | : | No data available   | 9   |
|            | Relative vapour density  |   | : | No data available   | 9   |
|            | Density  | ,                                       | : | No data available   | 9   |
|            | Solubility(ies)<br>Water solubility<br>Partition coefficient: n-<br>octanol/water<br>Auto-ignition temperature |   | : | No data available<br>No data available<br>No data available | 9   |
|            | Decom  | position temperature                    | : | No data available   | 9   |
|            | Viscosity<br>Viscosity, kinematic  |   | : | No data available   | 9   |
|            | Explosive properties   |   | : | Not explosive   |   |
|            | Oxidizing properties   |   | : | The substance o   | r mixture is not classified as oxidizing.                         |
| 9.2        | Other in   | formation                               |   |   |   |
|            | Flammability (liquids)   |   | : | Not applicable  |   |
|            | Molecu   | lar weight                              | : | No data available   | 9   |
|            | Particle size  |   | : | No data available   | 9   |

### **SECTION 10: Stability and reactivity**

#### 10.1 Reactivity

Not classified as a reactivity hazard.

### 10.2 Chemical stability

Stable under normal conditions.

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



| Version<br>6.0 | Revision Date: 28.09.2024                         |       | DS Number:<br>72726-00009  | Date of last issue: 24.06.2024<br>Date of first issue: 27.08.2021 |  |  |
|----------------|---|-------|--|---|--|--|
| 10.3 Possi     | bility of hazardous re                            | eacti | ons  |   |  |  |
|                | dous reactions                                    | :     | <ul> <li>Combustible liquid.</li> <li>Vapours may form explosive mixture with air.</li> <li>Can react with strong oxidizing agents.</li> </ul> |   |  |  |
| 10.4 Condi     | itions to avoid                                   |       |  |   |  |  |
| Condit         | tions to avoid                                    | :     | Heat, flames and   | d sparks.   |  |  |
| 10.5 Incom     | patible materials                                 |       |  |   |  |  |
| Materi         | als to avoid                                      | :     | Oxidizing agents   |   |  |  |
| 10.6 Hazar     | dous decomposition                                | pro   | ducts  |   |  |  |
|                | zardous decompositio                              | -     |  |   |  |  |
| SECTION        | 11: Toxicological i                               | nfor  | mation   |   |  |  |
| 44.4 Inform    |   |       | facto  |   |  |  |
|                | nation on toxicologic<br>ation on likely routes o |       |  |   |  |  |
| expos          | •   | . ונ  | Skin contact   |   |  |  |
| - 1            |   |       | Ingestion  |   |  |  |
|                |   |       | Eye contact  |   |  |  |
|                | toxicity  | labla | information  |   |  |  |
|                | assified based on avail<br>onents:                | lable | information.   |   |  |  |
|                |   |       |  |   |  |  |
| Ethan          |   |       |  | <b>7</b> 0  |  |  |
| Acute          | oral toxicity                                     |       | LD50 (Rat): 10,47<br>Method: OECD T  | νυ mg/κg<br>est Guideline 401                                     |  |  |
|                |   |       |  |   |  |  |
| Acute          | inhalation toxicity                               | :     | LC50 (Rat, male)<br>Exposure time: 4   |   |  |  |
|                |   |       | Test atmosphere  |   |  |  |
| Acute          | dermal toxicity                                   | :     | LD50 (Rabbit): >   | 15.800 ma/kg  |  |  |
| II             | ,   |       |  |   |  |  |
|                | l alcohol:  |       |  |   |  |  |
| Acute          | oral toxicity                                     | :     | LD50 (Rat): 1,200  | J mg/kg   |  |  |
| Acute          | inhalation toxicity                               | :     | LC50 (Rat): > 5.4  |   |  |  |
|                |   |       | Exposure time: 4<br>Test atmosphere  |   |  |  |
|                |   |       | Method: OECD T   | est Guideline 403   |  |  |
|                |   |       |  | substance or mixture has no acute inhala-                         |  |  |
|                |   |       | tion toxicity  |   |  |  |
| Dexar          | nethasone:  |       |  |   |  |  |
| Acute          | oral toxicity                                     | :     | LD50 (Rat): > 2,0  | 00 mg/kg  |  |  |
| II             |   |       |  |   |  |  |

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



## **Dexamethasone (with Ethanol) Formulation**

| Version<br>6.0 | Revision Date: 28.09.2024                           |      | OS Number:<br>72726-00009             | Date of last issue: 24.06.2024<br>Date of first issue: 27.08.2021 |
|----------------|---|------|---------------------------------------|---|
| Ш              |   |      | LD50 (Mouse): >                       | 6,500 mg/kg   |
|                | e toxicity (other routes of<br>histration)          | :    | LD50 (Rat): 14 m<br>Application Route |   |
| Skin           | corrosion/irritation                                |      |                                       |   |
|                | lassified based on availa                           | ble  | information.                          |   |
| <u>Com</u>     | ponents:  |      |                                       |   |
| Ethar          |   |      |                                       |   |
| Speci<br>Metho |   | ÷    | Rabbit<br>OECD Test Guide             | aline 404   |
| Resu           |   | :    | No skin irritation                    |   |
| Benz           | yl alcohol:   |      |                                       |   |
| Speci          |   | :    | Rabbit                                |   |
| Metho<br>Resu  |   | ÷    | OECD Test Guide<br>No skin irritation | eline 404   |
| ivesu          | it.   | ·    | NO SKII IIItation                     |   |
| Dexa           | methasone:  |      |                                       |   |
| Speci<br>Resul |   | :    | Rabbit<br>Mild skin irritation        |   |
|                | us eye damage/eye irri<br>lassified based on availa |      |                                       |   |
| -              | oonents:  | DIC  | mormation.                            |   |
| Ethar          | nol:  |      |                                       |   |
| Speci          | es  | :    | Rabbit                                |   |
| Metho          |   | :    | OECD Test Guide                       |   |
| Resu           | lt  | :    | Irritation to eyes,                   | reversing within 21 days  |
| Benz           | yl alcohol:   |      |                                       |   |
| Speci          |   | :    | Rabbit                                |   |
| Metho<br>Resu  |   | :    | OECD Test Guide                       | eline 405<br>reversing within 21 days                             |
| Resu           | it.   | •    | initation to eyes,                    | reversing within 21 days  |
| Dexa           | methasone:  |      |                                       |   |
| Speci          |   | :    | Rabbit                                |   |
| Resu           | It  | :    | Mild eye irritation                   |   |
| Resp           | iratory or skin sensitis                            | atic | on                                    |   |
| Skin           | sensitisation                                       |      |                                       |   |
|                |   |      |                                       |   |

Not classified based on available information.

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



## **Dexamethasone (with Ethanol) Formulation**

| Version | Revision Date: | SDS Number:   | Date of last issue: 24.06.2024  |
|---------|----------------|---------------|---------------------------------|
| 6.0     | 28.09.2024     | 9372726-00009 | Date of first issue: 27.08.2021 |

### Respiratory sensitisation

Not classified based on available information.

### Components:

### Ethanol:

| Test Type         | : | Mouse ear swelling test (MEST) |
|-------------------|---|--------------------------------|
| Exposure routes   | : | Skin contact                   |
| Species           | : | Mouse                          |
| Species<br>Result | : | negative                       |

### **Benzyl alcohol:**

| Test Type<br>Exposure routes<br>Species<br>Result | <ul> <li>Human repeat insult patch test (HRIPT)</li> <li>Skin contact</li> <li>Humans</li> <li>positive</li> </ul> |
|---|--|
| Assessment  | : Probability or evidence of low to moderate skin sensitisation rate in humans                                     |

### Germ cell mutagenicity

Not classified based on available information.

### **Components:**

#### Ethanol:

| Genotoxicity in vitro | : Test Type: Bacterial reverse mutation assay (AMES)<br>Method: OECD Test Guideline 471<br>Result: negative   |
|-----------------------|---|
|                       | Test Type: In vitro mammalian cell gene mutation test<br>Method: OECD Test Guideline 476<br>Result: negative  |
|                       | Test Type: Chromosome aberration test in vitro<br>Result: negative  |
| Genotoxicity in vivo  | : Test Type: Mammalian erythrocyte micronucleus test (in vivo<br>cytogenetic assay)<br>Species: Rat<br>Application Route: Ingestion<br>Result: negative |
| Benzyl alcohol:       |   |
| Genotoxicity in vitro | : Test Type: Bacterial reverse mutation assay (AMES)<br>Result: negative  |
| Genotoxicity in vivo  | : Test Type: Mammalian erythrocyte micronucleus test (in vivo<br>cytogenetic assay)<br>Species: Mouse   |

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



| Version<br>6.0  | Revision Date:<br>28.09.2024                 |       | DS Number:<br>72726-00009   | Date of last issue: 24.06.2024<br>Date of first issue: 27.08.2021                |
|-----------------|--|-------|---|--|
|                 |  |       | Application Route<br>Result: negative                                       | e: Intraperitoneal injection   |
| II<br>Deva      | methasone:                                   |       |   |  |
|                 | toxicity in vitro                            | :     | Test Type: Bacte<br>Result: negative  | erial reverse mutation assay (AMES)  |
|                 |  |       | Test Type: in vitr<br>Test system: mo<br>Result: negative                   | o assay<br>use lymphoma cells  |
| Genot           | toxicity in vivo                             | :     | Test Type: Micro<br>Species: Mouse<br>Application Route<br>Result: negative |  |
|                 | <b>nogenicity</b><br>assified based on avai  | lable | information.  |  |
| Comp            | oonents:                                     |       |   |  |
| Benzy           | yl alcohol:                                  |       |   |  |
| Speci<br>Applic | es<br>cation Route<br>sure time<br>od        | :     | Mouse<br>Ingestion<br>103 weeks<br>OECD Test Guid<br>negative               | leline 451   |
| -               | oductive toxicity<br>assified based on avail | lable | information.  |  |
| Comp            | oonents:                                     |       |   |  |
| Ethan           | nol:   |       |   |  |
| Effect          | s on fertility                               | :     | Test Type: Two-<br>Species: Mouse<br>Application Route<br>Result: negative  | generation reproduction toxicity study<br>e: Ingestion                           |
| Benzy           | yl alcohol:                                  |       |   |  |
|                 | s on fertility                               | :     | Species: Rat<br>Application Route<br>Result: negative                       | ty/early embryonic development<br>e: Ingestion<br>on data from similar materials |
| Effect<br>ment  | s on foetal develop-                         | :     | Test Type: Embr<br>Species: Mouse<br>Application Route<br>Result: negative  | yo-foetal development<br>e: Ingestion  |

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



| Version<br>6.0  | Revision Date:<br>28.09.2024                                      |   | S Number:<br>72726-00009  | Date of last issue: 24.06.2024<br>Date of first issue: 27.08.2021                                    |  |
|-----------------|---|---|---|--|--|
| Dexar           | nethasone:  |   |   |  |  |
| Effects         | Effects on foetal develop-  |   | : Test Type: Development<br>Species: Mouse<br>Application Route: Subcutaneous<br>Developmental Toxicity: LOAEL: 6 mg/kg body weight<br>Result: Specific developmental abnormalities, Cleft palate |  |  |
|                 |   |   |   | e: Intramuscular<br>oxicity: NOAEL: 0.025 mg/kg body weight<br>evelopmental abnormalities            |  |
|                 |   |   |   | e: Intramuscular<br>oxicity: LOAEL: >= 0.062 mg/kg body weight<br>evelopmental abnormalities         |  |
|                 |   |   |   | e: Subcutaneous<br>oxicity: LOAEL: >= 0.02 mg/kg body weight<br>nd visceral variations, Retardations |  |
| Repro<br>sessm  | ductive toxicity - As-<br>nent                                    | :                                       | May damage the  | unborn child.  |  |
| Not cla         | - single exposure<br>assified based on avail                      | lable i                                 | nformation.   |  |  |
|                 | <ul> <li>repeated exposure<br/>assified based on avail</li> </ul> | lable i                                 | nformation.   |  |  |
| <u>Comp</u>     | onents:   |   |   |  |  |
| Dexar           | nethasone:  |   |   |  |  |
| Target          | sure routes<br>t Organs<br>sment                                  | :                                       |   | mune system, thymus gland<br>ge to organs through prolonged or repeated                              |  |
| Repea           | ated dose toxicity  |   |   |  |  |
| <u>Comp</u>     | onents:   |   |   |  |  |
| Ethan           | ol:   |   |   |  |  |
|                 | E   | : | Rat<br>1,730 mg/kg<br>3,200 mg/kg<br>Ingestion<br>90 Days   |  |  |
| Benzy<br>Specie | <b>/I alcohol:</b><br>es  | :                                       | Rat   |  |  |

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



## **Dexamethasone (with Ethanol) Formulation**

| Version<br>6.0 | Revision Date:<br>28.09.2024                   | SDS Number:<br>9372726-00009   | Date of last issue: 24.06.2024<br>Date of first issue: 27.08.2021 |  |  |  |  |
|----------------|--|--|---|--|--|--|--|
|                | cation Route<br>sure time                      | : 28 Days  | : inhalation (dust/mist/fume)                                     |  |  |  |  |
| Dexa           | methasone:                                     |  |   |  |  |  |  |
| Expos          | EL<br>cation Route<br>sure time<br>et Organs   | : Rat<br>: 0.0015 mg/kg<br>: Oral<br>: 7 d<br>: Liver<br>: Significant tox           | icity observed in testing   |  |  |  |  |
| Expos          | EL<br>cation Route<br>sure time<br>et Organs   |  | al gland, thymus gland<br>icity observed in testing               |  |  |  |  |
| Expos          | EL<br>cation Route<br>sure time<br>et Organs   | : Rat<br>: 0.125 mg/kg<br>: Oral<br>: 6 Weeks<br>: Adrenal glanc<br>: Significant to | icity observed in testing   |  |  |  |  |
| Expos          | EL<br>cation Route<br>sure time<br>et Organs   | : Rat<br>: 0.4 mg/kg<br>: Oral<br>: 3 Months<br>: Immune syste<br>: Significant tox  | m<br>icity observed in testing                                    |  |  |  |  |
| Expos          | EL<br>cation Route<br>sure time<br>et Organs   | : Dog<br>: 8 mg/kg<br>: Oral<br>: 3 Months<br>: Immune syste<br>: Significant tox    | em<br>icity observed in testing                                   |  |  |  |  |
| -              | ration toxicity                                |  |   |  |  |  |  |
|                | Not classified based on available information. |  |   |  |  |  |  |
| Expe           | Experience with human exposure                 |  |   |  |  |  |  |

### Components:

#### Dexamethasone:

Ingestion

Target Organs: Immune system Target Organs: Adrenal gland Target Organs: Bone

:

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



## **Dexamethasone (with Ethanol) Formulation**

| Version<br>6.0 | Revision Date: 28.09.2024 | SDS Number:<br>9372726-00009 | Date of last issue: 24.06.2024<br>Date of first issue: 27.08.2021 |  |
|----------------|---------------------------|------------------------------|---|--|
|                |                           |                              |   |  |

## II

Symptoms: muscle weakness

### **SECTION 12: Ecological information**

### 12.1 Toxicity

### Components:

| Ethanol:  |   |   |
|---|---|---|
| Toxicity to fish  | : | LC50 (Pimephales promelas (fathead minnow)): 14,200 mg/l<br>Exposure time: 96 h   |
| Toxicity to daphnia and other aquatic invertebrates                         | : | EC50 (Ceriodaphnia dubia (water flea)): 5,012 mg/l<br>Exposure time: 48 h   |
| Toxicity to algae/aquatic plants  | : | ErC50 (Chlorella vulgaris (Fresh water algae)): 275 mg/l<br>Exposure time: 72 h   |
|   |   | EC10 (Chlorella vulgaris (Fresh water algae)): 11.5 mg/l<br>Exposure time: 72 h   |
| Toxicity to microorganisms  | : | EC50 (Protozoa): 5,800 mg/l<br>Exposure time: 4 h   |
| Toxicity to fish (Chronic tox-<br>icity)                                    | : | NOEC: >= 79 mg/l<br>Exposure time: 100 d<br>Species: Oryzias latipes (Japanese medaka)                                      |
| Toxicity to daphnia and other aquatic invertebrates (Chron-<br>ic toxicity) | : | NOEC: 9.6 mg/l<br>Exposure time: 9 d<br>Species: Daphnia magna (Water flea)   |
| Benzyl alcohol:   |   |   |
| Toxicity to fish  | : | LC50 (Pimephales promelas (fathead minnow)): 460 mg/l<br>Exposure time: 96 h  |
| Toxicity to daphnia and other aquatic invertebrates                         | : | EC50 (Daphnia magna (Water flea)): 230 mg/l<br>Exposure time: 48 h<br>Method: OECD Test Guideline 202                       |
| Toxicity to algae/aquatic plants  | : | EC50 (Pseudokirchneriella subcapitata (green algae)): 770<br>mg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201 |
|   |   | NOEC (Pseudokirchneriella subcapitata (green algae)): 310<br>mg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201 |
| Toxicity to daphnia and other aquatic invertebrates (Chron-                 | : | NOEC: 51 mg/l<br>Exposure time: 21 d  |

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



| Vers<br>6.0 | sion               | Revision Date:<br>28.09.2024 |      | OS Number:<br>72726-00009  | Date of last issue: 24.06.2024<br>Date of first issue: 27.08.2021        |
|-------------|--------------------|------------------------------|------|--|--|
|             | ic toxic           | ity)                         |      |  | a magna (Water flea)<br>est Guideline 211                                |
| 81          | Dexan              | nethasone:                   |      |  |  |
|             | Toxicit            |                              | :    | Exposure time: 4   | nagna (Water flea)): > 56 mg/l<br>8 h<br>est Guideline 202               |
|             | Toxicit<br>plants  | y to algae/aquatic           | :    | mg/l<br>Exposure time: 72  | chneriella subcapitata (green algae)): > 9.2<br>2 h<br>est Guideline 201 |
|             |                    |                              |      | mg/l<br>Exposure time: 72  | rchneriella subcapitata (green algae)): 9.2<br>2 h<br>est Guideline 201  |
|             | Toxicit            | y to microorganisms          | :    | EC50 : > 1,000 m<br>Exposure time: 3<br>Test Type: Respi<br>Method: OECD T | ĥ  |
|             |                    |                              |      | NOEC : 1,000 mg<br>Exposure time: 3<br>Test Type: Respi<br>Method: OECD T  | h  |
|             | Toxicit<br>icity)  | y to fish (Chronic tox-      | :    | NOEC: 0.033 mg<br>Exposure time: 33<br>Species: Pimepha<br>Method: OECD T  |  |
|             | M-Fact<br>toxicity | tor (Chronic aquatic         | :    | 1  |  |
| 12.2        | Persis             | tence and degradabi          | lity |  |  |
|             | Comp               | onents:                      |      |  |  |
|             | Ethan              | ol:                          |      |  |  |
|             | Biodeg             | radability                   | :    | Result: Readily b<br>Biodegradation:<br>Exposure time: 20                  | 84 %   |
|             | Benzy              | l alcohol:                   |      |  |  |
|             |                    | radability                   | :    | Result: Readily b<br>Biodegradation:<br>Exposure time: 14                  | 92 - 96 %  |
| 1           | Dexan              | nethasone:                   |      |  |  |

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



## Dexamethasone (with Ethanol) Formulation

| Version<br>6.0   | Revision Date:<br>28.09.2024                          | -    | DS Number:<br>372726-00009          | Date of last issue: 24.06.2024<br>Date of first issue: 27.08.2021   |
|------------------|---|------|-------------------------------------|---|
| Biodegradability |   | :    | Biodegradation:<br>Exposure time: 3 |   |
| 12.3 Bioa        | ccumulative potential                                 |      |                                     |   |
| Com              | ponents:  |      |                                     |   |
|                  | n <b>ol:</b><br>ion coefficient: n-<br>ol/water       | :    | log Pow: -0.35                      |   |
| Partit           | <b>yl alcohol:</b><br>ion coefficient: n-<br>ol/water | :    | log Pow: 1.05                       |   |
| Partit           | methasone:<br>ion coefficient: n-<br>ol/water         | :    | log Pow: 1.83                       |   |
|                  | l <b>ity in soil</b><br>ata available                 |      |                                     |   |
| 12.5 Resu        | Ilts of PBT and vPvB a                                | isse | ssment                              |   |
| Prod<br>Asse     | <u>uct:</u><br>ssment                                 | :    | to be either persi                  | nixture contains no components considered<br>istent, bioaccumulative and toxic (PBT), or<br>nd very bioaccumulative (vPvB) at levels of |
| 12.6 Othe        | r adverse effects                                     |      |                                     |   |
| Prod             | uct:  |      |                                     |   |
| Endo<br>tial     | crine disrupting poten-                               | :    | ered to have end                    | nixture does not contain components consid-<br>locrine disrupting properties for environment<br>REACH Article 57(f).                    |

### 13.1 Waste treatment methods

| Product                | : | Dispose of in accordance with local regulations.<br>According to the European Waste Catalogue, Waste Codes<br>are not product specific, but application specific.<br>Waste codes should be assigned by the user, preferably in<br>discussion with the waste disposal authorities. |
|------------------------|---|---|
| Contaminated packaging | : | Do not dispose of waste into sewer.<br>Empty containers should be taken to an approved waste han-<br>dling site for recycling or disposal.<br>Empty containers retain residue and can be dangerous.<br>Do not pressurize, cut, weld, braze, solder, drill, grind, or ex-          |

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



## **Dexamethasone (with Ethanol) Formulation**

| Version<br>6.0 | Revision Date: 28.09.2024 | SDS Number:<br>9372726-00009 | Date of last issue: 24.06.2024<br>Date of first issue: 27.08.2021 |   |
|----------------|---------------------------|------------------------------|---|---|
|                |                           |                              |   | _ |

pose such containers to heat, flame, sparks, or other sources of ignition. They may explode and cause injury and/or death. If not otherwise specified: Dispose of as unused product.

### **SECTION 14: Transport information**

### 14.1 UN number

| • •• |                              |   |                                   |
|------|------------------------------|---|-----------------------------------|
|      | ADN                          | : | Not regulated as a dangerous good |
|      | ADR                          | : | Not regulated as a dangerous good |
|      | RID                          | : | Not regulated as a dangerous good |
|      | IMDG                         | : | Not regulated as a dangerous good |
|      | ΙΑΤΑ                         | : | Not regulated as a dangerous good |
| 14.2 | 2 UN proper shipping name    |   |                                   |
|      | ADN                          | : | Not regulated as a dangerous good |
|      | ADR                          | : | Not regulated as a dangerous good |
|      | RID                          | : | Not regulated as a dangerous good |
|      | IMDG                         | : | Not regulated as a dangerous good |
|      | ΙΑΤΑ                         | : | Not regulated as a dangerous good |
| 14.3 | 3 Transport hazard class(es) |   |                                   |
|      | ADN                          | : | Not regulated as a dangerous good |
|      | ADR                          | : | Not regulated as a dangerous good |
|      | RID                          | : | Not regulated as a dangerous good |
|      | IMDG                         | : | Not regulated as a dangerous good |
|      | ΙΑΤΑ                         | : | Not regulated as a dangerous good |
| 14.4 | Packing group                |   |                                   |
|      | ADN                          | : | Not regulated as a dangerous good |
|      | ADR                          | : | Not regulated as a dangerous good |
|      | RID                          | : | Not regulated as a dangerous good |
|      | IMDG                         | : | Not regulated as a dangerous good |
|      | IATA (Cargo)                 | : | Not regulated as a dangerous good |
|      | IATA (Passenger)             | : | 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.



### **Dexamethasone (with Ethanol) Formulation**

| Version | Revision Date: | SDS Number:   | Date of last issue: 24.06.2024  |
|---------|----------------|---------------|---------------------------------|
| 6.0     | 28.09.2024     | 9372726-00009 | Date of first issue: 27.08.2021 |

### **SECTION 15: Regulatory information**

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

Relevant EU provisions transposed through retained EU law

| UK REACH List of restrictions (Annex 17)   | :  | Not applicable |
|--|----|----------------|
| UK REACH Candidate list of substances of very high<br>concern (SVHC) for Authorisation                       | :  | Not applicable |
| The Persistent Organic Pollutants Regulations (retained Regulation (EU) 2019/1021 as amended for Great Brit- | •  | Not applicable |
| ain)   |    |                |
| Regulation (EC) on substances that deplete the ozone laver   | :  | Not applicable |
| UK REACH List of substances subject to authorisation (Annex XIV)   | :  | Not applicable |
| GB Export and import of hazardous chemicals - Prior  | :  | Not applicable |
| Informed Consent (PIC) Regulation  |    |                |
| Control of Major Accident Hazards Regulations 2015 (CO   | MA | .H)            |
| Not applicable   |    |                |

Not applicable

### Other regulations:

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

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

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

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

### 15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

### **SECTION 16: Other information**

H317

| Other information         | : | Items where changes have been made to the previous version<br>are highlighted in the body of this document by two vertical<br>lines. |
|---------------------------|---|--|
| Full text of H-Statements |   |  |
| H225                      | : | Highly flammable liquid and vapour.  |
| H302                      | : | Harmful if swallowed.  |

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



### Dexamethasone (with Ethanol) Formulation

| Version<br>6.0   | Revision Date: 28.09.2024              |      | OS Number:<br>72726-00009 | Date of last issue: 24.06.2024<br>Date of first issue: 27.08.2021 |
|--|--|------|---------------------------|---|
| H319<br>H360D<br>H373<br>H410                          | )                                      | :    | exposure if swalld        | unborn child.<br>ge to organs through prolonged or repeated       |
| Full te  | xt of other abbreviat                  | ions |                           |   |
| Eye Irr<br>Flam. I<br>Repr.<br>Skin S<br>STOT<br>GB EH | c Chronic<br>it.<br>Liq.<br>ens.<br>RE |      | UK. EH40 WEL -            | s<br>city   |

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - 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 - Interna-tional 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 eChem Portal search results and European Chemicals Agen-



### Dexamethasone (with Ethanol) Formulation

| Version | Revision Date: 28.09.2024 | SDS Number:   | Date of last issue: 24.06.2024  |
|---------|---------------------------|---------------|---------------------------------|
| 6.0     |                           | 9372726-00009 | Date of first issue: 27.08.2021 |
|         |                           |               |                                 |

Sheet

cy, http://echa.europa.eu/

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

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.

GB / EN