| SECTION 1: IDENTIFICATION | |
|---|---|
| **1.1 Product identifier** | |
| **Product name:** | Prednidale® (5mg and 25mg tablets) |
| **Synonyms:** | Not Available |
| **Proper Shipping name:** | Not Available |
| **Other means of identification:** | None |
| **1.2 Relevant identified uses of the substances or mixture and uses advised against** | |
| **Recommended uses:** | For the treatment of inflammatory and allergic diseases, including some autoimmune diseases and some neoplastic conditions in cats and dogs. Inflammatory, allergic and autoimmune processes may be involved in cutaneous, alimentary, respiratory, musculo-skeletal and haematological manifestations of disease. |
| **Uses advised against:** | Not for human use.<br>Do not use in animals with renal insufficiency, diabetes mellitus or corneal ulceration.<br>Do not use in animals receiving vaccines containing live organisms.<br>Do not use in pregnant animals. |
| **1.3 Details of the supplier of the substance or mixture** | |
| **Registered company name:** | Dechra Ltd |
| **Address:** | Snaygill Industrial Estate<br>Keighley Road<br>Skipton<br>North Yorkshire<br>BD23 2RW<br>UK |
| **Telephone:** | +44 (0) 1756 791311 |
| **Fax:** | +44 (0) 1756 798604 |
| **Email:** | Not available |
| **1.4 Emergency Telephone Numbers** | |
| | +44 (0) 1756 791311 |

| SECTION 2: HAZARDS IDENTIFICATION | |
|---|---|
| **2.1 Classification of the substance or mixture** | |
| **DSD Classification (EU):** | Not Available |
| **DPD Classification (EU)[1]:** | Not Available |
| **Classification according to regulation (EC) No 1272/2008 [CLP] (EU)[1]:** | Not Available |
| **2.2 Label Elements** | |
| **Signal Word:** | NOT AVAILABLE |
| **Hazard Statement(s)** | |
| Not available | |
| **Precautionary Statement(s) Prevention:** | |
| Not available | |
| **Precautionary Statement(s) Response:** | |
| Not available | |
| **Precautionary Statement(s) Storage:** | |
| Not available | |
| **Precautionary Statement(s) Disposal:** | |
| Not available | |
| **2.3 Other Hazard Information**<br>Not available | |

| SECTION 3: INFORMATION ON THE INGREDIENTS |
|---|
| **3.1 Substances** |
| See section below for composition of mixtures |

| **3.2 Mixtures** | | | |
|---|---|---|---|
| **1.CAS No<br>2.EC Number<br>3.Index Number<br>4.REACH Number** | **% w/v** | **Name** | **Classification according to regulations (EC) No 1272/2008 [CLP] (EU)** |
| 1. 50-24-8<br>2. 200-021-7<br>3. Not Available | 0.5 - 2 | Prednisolone | Acute toxicity (oral) category 4, H302[1] |

| | | | |
|---|---|---|---|
| 4. 01-2119560581-40-XXXX | | | |
| N/a | Proprietary | Other ingredients determined not to be hazardous | N/a |
| **Legend:** | *1. Classified by Chemwatch* | | |

## SECTION 4: FIRST AID MEASURES

**4.1 Description of first aid measures**

| | |
|---|---|
| **Eye contact:** | In case of accidental contact of the product with the eyes rinse abundantly with fresh water. Seek medical attention if irritation occurs, showing the package leaflet or the label to the medical practitioner. |
| **Skin contact:** | In case of accidental contact of the product with the skin, rinse with fresh water. Seek medical attention if irritation occurs, showing the package leaflet or the label to the medical practitioner. |
| **Inhalation:** | If difficulty in breathing develops or persists, seek medical attention. |
| **Ingestion:** | Following accidental ingestion, rinse out mouth and drink bland fluids; do not induce vomiting. In the event of |

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

See Section 11

**4.3 Indication of immediate medical attention and special treatment needed**

N/a

## SECTION 5: FIRE FIGHTING MEASURES

**5.1 Extinguishing media**

| | |
|---|---|
| **Suitable:** | All systems can be used. |
| **Unsuitable:** | None. |

**5.2 Special hazards arising from the substance or mixture**

| | |
|---|---|
| **Fire incompatibility:** | None known |

**5.3 Special protective actions for fire-fighters:**

| | |
|---|---|
| **Firefighting:** | Alert Fire Brigade and tell them location and nature of hazard. Wear full breathing apparatus and self-contained breathing apparatus. |
| **Fire / explosion hazard:** | May be combustible at high temperatures. |

| SECTION 6: ACCIDENTAL RELEASE MEASURES | |
|---|---|
| **6.1 Personal precautions, protective equipment and emergency procedures** | |
| For information on protective equipment, see section 8. | |
| **6.2 Environmental Precautions** | |
| Do not allow product to reach drains, sewage systems or any waterways.<br>Do not allow to enter sewers/surface or ground water. | |
| **6.3 Methods and material for containment and cleaning up** | |
| **Minor Spills:** | Flush/wash residues and small spillages to a suitable container with copious quantities of water |
| **Major Spills:** | Clean up all spills immediately.<br>Larger spills should be dammed off, and pumped into a container for waste disposal.<br>Control personal contact with the substance, by using protective equipment such as gloves and eye protection. |

| SECTION 7: HANDLING AND STORAGE | |
|---|---|
| **7.1 Precautions for safe handling** | |
| **Safe Handling:** | Gloves should be worn to administer the product and you should wash hands immediately after administration of the product.<br>When handling, **DO NOT** eat, drink or smoke.<br>Observe manufacturer's storage and handling recommendations. |
| **Other Information:** | Keep out of the reach and sight of children. |
| **7.2 Conditions for safe storage, including any incompatibilities** | |
| **Suitable Container:** | Do not store above 25°C.<br>Store in tightly closed original container.<br>Store in a dry place.<br>Shelf life: 2 years. |
| **Storage incompatibility:** | None known. |
| **7.3 Specific end uses** | |
| Not available | |

| SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION |
|---|
| **8.1 Control parameters** |
| **DERIVED NO EFFECT LEVEL - DNEL** |
| Not Available |
| **PREDICTED NO EFFECT LEVEL - PNEC** |
| Not Available |
| **OCCUPATIONAL EXPOSURE LIMITS (OEL)** |

| **INGREDIENT DATA:** | | | | |
|---|---|---|---|---|
| Not Available | | | | |
| **EMERGENCY LIMITS:** | | | | |
| **Ingredient** | **Material Name** | **TEEL-1** | **TEEL-2** | **TEEL-3** |
| Not Available | | | | |
| **Ingredient** | **Original IDLH** | **Revised IDLH** | | |
| Not Available | | | | |
| **8.2 Exposure controls** | | | | |
| **Appropriate engineering controls:** | The basic types of engineering controls are:<br>Process controls which involve changing the way a job activity or process is done to reduce the particular risk. | | | |
| **Personal protection:** |  | | | |
| **Eye and face protection:** | Safety glasses with side shields / chemical goggles | | | |
| **Skin protection:** | See hand protection below | | | |
| **Hands/ feet protection:** | No special equipment needed when handling small quantities.<br>OTHERWISE: Wear chemical protective gloves | | | |
| **Body protection:** | Wear appropriate clothing | | | |
| **Other protection:** | No special equipment needed when handling small quantities | | | |
| **Thermal hazards:** | Not applicable | | | |
| **Respiratory protection:** | Not applicable | | | |
| **8.3 Environmental exposure controls**<br>See Section 12 | | | | |

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

### 9.1 Information on basic physical and chemical properties

**Appearance:** Prednidale®: White, circular, flat faced tablets with a breakline and PL5 imprinted on one face and CP or DP on the reverse.
Prednisolone**:** Solid crystalline powder.
**Container:** Polypropylene tubs with a low density polyethylene cap (push-fit) with a tamper evident ring, containing 500 or 1000 tablets.
**Physical state:** Liquid
**Odour:** Not available
**Odour Threshold:** Not available
**pH (as supplied):** Not available
**Melting point / freezing point (degrees C):** Prednisolone decomposes at 237-239°C
**Initial boiling point and boiling range:** Not available
**Flash Point:** Not available
**Evaporation rate:** Not available
**Flammability:** Not available
**Upper/lower flammability or explosive limits:** Not available
**Vapour pressure:** Not available
**Relative Density (at degrees C):** Not available
**Solubility in water and solvents (mg/l):** Prednisolone: very slightly soluble in cold water
**Vapour density:** Not available
**Auto ignition temperature (degrees C):** Not available
**Decomposition temperature (degrees C):** Not available
**Viscosity: (degrees C):** Not available
**Explosive properties:** Not available
**Oxidising properties:** Not available
**Partition Coefficient:** Not available
**Molecular weight:** Prednisolone: 360.45 g/mole
**Taste:** Not available
**Surface tension:** Not available
**Volative component:** Not available
**Gas group:** Not available
**pH as a solution:** Not available
**VOC g/L:** Not available

### 9.2 Other information

Not Available

## 10: REACTIVITY AND STABILITY

| | |
|---|---|
| **10.1 Reactivity:** | See Section 7. |
| **10.2 Chemical stability:** | Product is considered stable. |
| **10.3 Possibility of hazardous reactions:** | Stable under normal temperatures and conditions. |
| **10.4 Conditions to avoid:** | Avoid excess heat and moisture. |

| | |
|---|---|
| **10.5 Incompatible materials:** | See section 7. |
| **10.6 Hazardous decomposition:** | See Section 5. |

## SECTION 11: TOXICOLOGICAL INFORMATION

| | |
|---|---|
| **Inhalation:** | Dust may cause respiratory tract irritation. |
| **Ingestion:** | May cause gastrointestinal tract irritation. May also affect behaviour (toxic psychosis), metabolism, and urinary system. The material is readily absorbed from the gastrointestinal tract. Ingestion of a massive single dose is unlikely to cause adverse effects. Prolonged or repeated exposure may cause allergic reaction (possible hypersensitization). |
| **Skin contact:** | May cause skin irritation. May be absorbed through the skin. Prolonged or repeated exposure may cause allergic reaction (possible hypersensitisation). |
| **Eye contact:** | Dust may cause eye irritation. Prolonged or repeated exposure may cause allergic reaction (possible hypersensitization). |
| **Chronic:** | Administration of single high doses are generally tolerated well, but medium to long-term use may provoke reactions.<br>Corticosteroid therapy may lead to increased time in the healing of wounds and to a reduction in the ability of the body to resist infection. Appropriate anti-infective therapy may be required. |

| **Prednidale®:** | **Acute toxicity** | **Irritation** |
|---|---|---|
| | Not Available | Not Available |
| **Prednisolone:** | **Acute toxicity** | **Irritation** |
| | Oral (rat) $LD_{50}$: 3857 mg/kg[1] | Not Available |

*1.* Value obtained from manufacturer's SDS. Unless otherwise specified, data extracted from RTECS - Register of Toxic Effect of chemical Substances.*

**Skin corrosion / irritation:**

Not expected to cause skin corrosion or irritation.

**Serious eye damage / irritation:**

May cause allergic reaction or hypersensitization.

**Respiratory or skin sensitization:**

May cause allergic reaction or hypersensitization.

**Germ cell mutagenicity:**

Not thought to produce any mutagenic potential.

| SECTION 11: TOXICOLOGICAL INFORMATION |
|---|
| **Carcinogenicity:** |
| Not thought to produce any carcinogenic potential. |
| **Reproductive toxicity:** |
| Studies in laboratory animals have shown that administration during early pregnancy may cause foetal abnormalities. Administration during the later stages of pregnancy may cause abortion or early parturition.<br>Insignificant amounts of prednisolone are generally eliminated in the milk of lactating animals, and therefore such use is not contra-indicated. |
| **STOT – single exposure:** |
| Not available |
| **STOT–repeated exposure:** |
| Systemic poisoning may occur. |
| **Aspiration hazard:** |
| Not available |

| SECTION 12: ECOLOGICAL INFORMATION | | |
|---|---|---|
| **12.1 Toxicity** | | |
| Not Available | | |
| **12.2 Persistence and degradability** | | |
| **Ingredient** | **Persistence: Water/soil** | **Persistence: Air** |
| Prednisolone | HIGH | HIGH |
| **12.3 Bioaccumulative potential** | | |
| **Ingredient** | **Bioaccumulation** | |
| Prednisolone | LOW (LogKOW = 1.62) | |
| **12.4 Mobility in Soil** | | |
| **Ingredient** | **Mobility** | |
| Prednisolone | LOW (KOC = 36.36) | |

| **12.5 Results of PBT and vPvB assessment** |
|---|
| Not Available |
| **12.6 Other adverse effects** |
| Not Available |

| **SECTION 13: DISPOSAL CONSIDERATIONS** | |
|---|---|
| **13.1 Waste treatment methods** | |
| **Product / packaging disposal:** | Any unused veterinary medicinal product or waste material derived from such veterinary medicinal products should be disposed of in accordance with national requirements.<br><br>Legislation addressing waste disposal requirements may differ by country, state and/ or territory. Each user must refer to laws operating in their area.<br><br>Ensure that the disposal of material is carried out in accordance with Hazardous Substances (Disposal) Regulations 2001. |
| **Waste Treatment Options:** | Not Available |
| **Sewage Disposal Options:** | Not Available |

| **SECTION 14: TRANSPORT INFORMATION** | | |
|---|---|---|
| **Labels required:** | None | |
| **Marine pollutant:** | NO | |
| **Hazchem:** | Not Applicable | |
| **Land transport (ADR):** | | |
| **14.1 UN Number** | N/a | |
| **14.2 UN Proper Shipping Name** | N/a | |
| **14.3 Transport hazard class(es)** | Class | N/a |
| | Sub risk | N/a |
| **14.4 Packing group** | N/a | |
| **14.5 Environmental hazards** | N/a | |
| **14.6 Special** | Special provisions | N/a |

| | | |
|---|---|---|
| **precautions for user** | Classification code | N/a |
| | Hazard Label | N/a |
| | Special provisions | N/a |
| | Limited quantity | N/a |

| | | |
|---|---|---|
| **14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code** | N/a | |
| **Air transport (ICAO-IATA / DGR):** | | |
| **14.1 UN Number** | N/a | |
| **14.2 UN Proper Shipping Name** | N/a | |
| **14.3 Transport hazard class(es)** | ICAO/IATA Class | N/a |
| | ICAO / IATA Sub risk | N/a |
| | ERG Code | N/a |
| **14.4 Packing group** | N/a | |
| **14.5 Environmental hazards** | N/a | |
| **14.6 Special precautions for user** | Special provisions | N/a |
| | Cargo only packing instructions | N/a |
| | Cargo only maximum qty/pack | N/a |
| | Passenger and cargo packaging instructions | N/a |
| | Passenger and cargo maximum qty/pack | N/a |
| | Passenger and cargo limited quantity packing instructions | N/a |
| | Passenger and cargo limited maximum qty/pack | N/a |

| | |
|---|---|
| **14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code** | N/a |
| **Sea transport (IMDG-Code / GGVSee):** | |
| **14.1 UN Number** | N/a |

| | | |
|---|---|---|
| **14.2 UN Proper Shipping Name** | N/a | |
| **14.3 Transport hazard class(es)** | IMDG Class | N/a |
| | IMDG Sub risk | N/a |
| **14.4 Packing group** | N/a | |
| **14.5 Environmental hazards** | N/a | |
| **14.6 Special precautions for user** | EMS Number | N/a |
| | Special provisions | N/a |
| | Limited quantities | N/a |
| **14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code** | N/a | |
| **Inland waterways transport (ADN):** | | |
| **14.1 UN Number** | N/a | |
| **14.2 UN Proper Shipping Name** | N/a | |
| **14.3 Transport hazard class(es)** | N/a | N/a |
| **14.4 Packing group** | N/a | |
| **14.5 Environmental hazard** | N/a | |

| | | |
|---|---|---|
| **14.6 Special precautions for user** | Classification Code | N/a |
| | Special provisions | N/a |
| | Limited quantity | N/a |
| | Equipment required | N/a |
| | Fire cones number | N/a |
| **14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code** | N/a | |

## SECTION 15: REGULATORY INFORMATION

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

**PREDNISOLONE (50-24-8) IS FOUND ON THE FOLLOWING REGULATORY LISTS:**

- European Customs Inventory of Chemical Substances ECICS (English)
- European Union - European Inventory of Existing Commercial Chemical Substances (EINECS) (English)

**15.2 Chemical Safety Assessment**

**ECHA SUMMARY**

| Ingredient | CAS number | Index Number | ECHA Dossier |
|---|---|---|---|
| Pethidine hydrochloride | 50-24-8 | Not Available | 01-2119560581-40-XXXX |

| Harmonization (C&L Inventory) | Hazard Class and Category Code(s) | Pictograms Signal Word Code(s) | Hazard Statement Code(s) |
|---|---|---|---|
| 1 | Acute Tox. 4 | GHS07, Wng | H302, H312, H332 |
| 2 | Repr. 1B, Acute Tox. 4, Repr. 1A, STOT RE 2, Repr. 2, Muta. 2, Carc. 1B, Skin Irrit. 2, Eye Irrit. 2, STOT SE 3 | GHS08, Dgr | H302, H312, H332, H360Df, H341, H350, H373, H315, H319, H335, H400 |
| 1 | Repr. 1A, STOT RE 2 | GHS08, Dgr | H360, H373 |
| 2 | Repr. 1A, STOT RE 2 | GHS08, Dgr | H360, H373 |
| Harmonization Code 1 = The most prevalent classification. Harmonization Code 2 = The most severe classification | | | |

| | |
|---|---|
| Australia - AICS | Y |
| Canada - DSL | Y |
| Canada - NDSL | N (prednisolone) |
| China - IECSC | Y |
| Europe - EINEC / ELINCS / NLP | Y |
| Japan - ENCS | N (prednisolone) |
| Korea - KECI | Y |
| New Zealand - NZIoC | Y |
| Philippines - PICCS | Y |
| USA - TSCA | Y |
| ***Legend:*** | *Y = All ingredients are on the inventory*<br>*N = Not determined or one or more ingredients are not on the inventory and are not exempt from listing(see specific ingredients in brackets)* |

## SECTION 16: OTHER INFORMATION

The SDS is written in accordance to guidelines specified by REACH, GHS and ECHA.

For detailed advice on Personal Protective Equipment, refer to the following EU CEN Standards:
EN 166 Personal eye-protection
EN 340 Protective clothing
EN 374 Protective gloves against chemicals and micro-organisms
EN 13832 Footwear protecting against chemicals
EN 133 Respiratory protective devices

**Definitions and abbreviations**
PC—TWA: Permissible Concentration-Time Weighted Average
PC—STEL: Permissible Concentration-Short Term Exposure Limit
STEL: Short Term Exposure Limit
TEEL: Temporary Emergency Exposure Limit
IDLH: Immediately Dangerous to Life or Health Concentrations

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