

| SECTION 1: IDENTIFICATION | |
|--|---|
| 1.1 Product identifier | |
| Product name | Redivom 1 mg/mL Solution for Injection |
| Synonyms | None |
| Proper shipping name | Not Available |
| Other means of identification | Not Available |
| 1.2 Recommended use of the chemical and restrictions on use | |
| Relevant identified uses | Induction of emesis in dogs |
| Uses advised against | Not for human use. |
| 1.3 Details of the supplier of the substance or mixture | |
| Registered company name (US) | Dechra Veterinary Products (Australia) Pty Ltd |
| Address | 2 Cal Close Somersby NSW 2250 Australia |
| Telephone | (02) 4372 1661 1300 015 825 |
| Fax | (02) 4372 1668 |
| Website | http://www.dechra.com.au/ |
| 1.4 Emergency telephone numbers | |
| Dechra | (02) 4372 1661 1300 015 825 |

| SECTION 2: HAZARD(S) IDENTIFICATION | |
|---|--|
| 2.1 Classification of the substance or mixture | |
| Poisons Schedule | S4 – PRESCRIPTION ANIMAL REMEDY |
| Classification^[1] | Not Applicable |
| 1. Classified by Chemwatch; 2. Classification drawn from Regulation (EU) No 1272/2008 - Annex VI | |
| 2.2 Label elements | |
| Hazard pictogram(s) | Not Applicable |
| Signal word | Not Applicable |
| Hazard statement(s) | |
| H301 | Toxic if swallowed |
| H302 | Harmful if swallowed. |
| Precautionary statement(s) Prevention | |
| P270 | Do not eat, drink or smoke when using this product. |
| P280 | Wear protective gloves/protective clothing/eye protection/face protection. |
| Precautionary statement(s) Response | |
| Not Applicable | |
| Precautionary statement(s) storage | |
| P405 | Store locked up. |
| P403+P233 | Store in a well-ventilated place. Keep container tightly closed. |
| Precautionary statement(s) disposal | |
| P501 | Dispose of contents/container to authorised hazardous or special waste collection point in accordance with any local regulation. |
| 2.3 Other hazard information | |
| Apomorphine has been shown to have teratogenic effects in laboratory animals and is excreted in human milk. Pregnant or lactating women should avoid handling the veterinary medicinal product. | |

| SECTION 3: COMPOSITION / INFORMATION ON INGREDIENTS | | |
|--|------------------|--|
| 3.1 Substances | | |
| See section below for composition of Mixtures | | |
| 3.2 Mixtures | | |
| CAS No | %[weight] | Name |
| 41372-20-7 | 0.1 | apomorphine hydrochloride |
| Not Available | balance | Ingredients determined not to be hazardous |
| The specific chemical identity and/or exact percentage (concentration) of composition has been withheld as a trade secret. | | |

| SECTION 4: FIRST AID MEASURES | |
|---|--|
| 4.1 Description of first aid measures | |
| Eye contact | In cases of accidental eye contact, immediately rinse the affected area with large amounts of clean water until advised to stop by a doctor or for at least 15 minutes. Seek medical advice. |
| Skin contact | In the event of eye or skin contact, remove contaminated clothing, rinse the affected area with large amounts of clean water and if irritation occurs, seek medical attention. |
| Inhalation | If fumes or combustion products are inhaled, remove from contaminated area. Other measures are usually unnecessary. |
| Ingestion | If accidentally swallowed, seek medical aid immediately and show the package leaflet or SDS to the medical practitioner. |
| 4.3 Indication of immediate medical attention and special treatment needed | |
| Treat symptomatically. | |

SECTION 5: FIRE FIGHTING MEASURES

5.1 Extinguishing media

There is no restriction on the type of extinguisher which may be used.

5.2 Special hazards arising from the substance or mixture

| | |
|-----------------------------|---|
| Fire incompatibility | Avoid contamination with oxidising agents i.e. nitrates, oxidising acids, chlorine bleaches, pool chlorine etc. as ignition may result. |
|-----------------------------|---|

5.3 Special protective actions for fire-fighters:

| | |
|--------------------------------|---|
| Firefighting | Alert Fire Brigade and tell them location/nature of hazard. Wear breathing apparatus plus protective gloves. Prevent, by any means available, spillage from entering drains or water courses. |
| Fire / explosion hazard | No combustible. May decompose to produce toxic fumes of sulfur oxides |
| HAZCHEM | Not Applicable |

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

See section 8.

6.2 Environmental precautions

See Section 12

6.3 Methods and material for containment and cleaning up

| | |
|---------------------|---|
| Minor spills | Clean up all spills immediately. Avoid breathing vapours and contact with skin and eyes. Wear protective clothing, gloves, safety glasses and dust respirator. Use dry clean up procedures and avoid generating dust. |
| Major spills | Clear area of personnel and move upwind. Alert Fire Brigade and tell them location and nature of the hazard. Control personal contact by wearing protective clothing. |

Personal Protective Equipment advice is contained in Section 8 of the SDS.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

| | |
|--------------------------|--|
| Safe handling | When handling, DO NOT eat, drink or smoke. Always wash hands with water after handling. 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 | Clear Type I glass vials containing 5, 10 or 20 ml, closed with a coated bromobutyl rubber stopper and sealed with an aluminium cap. Each vial is packed into a cardboard box. |
| Storage incompatibility | None known |

SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 Control parameters

Occupational exposure limits (OEL)

INGREDIENT DATA

| Source | Ingredient | Material name | TWA | STEL | Peak | Notes |
|----------------------------------|------------|---------------|-----|------|------|-------|
| Not Available for any ingredient | | | | | | |

Emergency limits

| Ingredient | TEEL-1 | TEEL-2 | TEEL-3 |
|----------------------------------|--------|--------|--------|
| Not Available for any ingredient | | | |

| Ingredient | Original IDLH | Revised IDLH |
|----------------------------------|---------------|--------------|
| Not Available for any ingredient | | |

MATERIAL DATA

8.2 Exposure controls

8.2.1. Appropriate engineering controls The basic types of engineering controls are: process controls which involve changing the way a job activity or process is done to reduce the particular risk.

8.2.2. Personal protection



| | |
|--------------------------------|---|
| Eye and face protection | Safety glasses with side shields / chemical goggles |
| Skin protection | See hand protection below |
| Hands/feet protection | Protective gloves |
| Body protection | Wear appropriate clothing |
| Other protection | Not Applicable |
| Respiratory protection | Not Applicable |

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

| | |
|---|---|
| Appearance: Clear solution practically free from particles | Vapor density: Not Available |
| Physical state: Liquid | Auto ignition temperature (°C): Not Available |
| Odor: Not Available | Decomposition temperature (°C): Not Available |
| Odor threshold: Not Available | Viscosity (°C): Not Available |
| pH (as supplied): 2.5 – 4.0 | Explosive properties: Not Available |
| Melting point / freezing point (°C): Not Available | Oxidizing properties: Not Available |
| Initial boiling point and boiling range: Not Available | Partition coefficient: Not Available |
| Flash point (°C): Not Available | Molecular weight: Not Available |
| Evaporation rate: Not Available | Taste: Not Available |
| Flammability: Not Available | Surface tension: Not Available |
| Upper/lower flammability or explosive limits: Not Available | Volatile component (%vol): Not Available |
| Vapor pressure: Not Available | Gas group: Not Available |
| Relative density (Water = 1): 1.003 | pH as a solution: Not Available |
| Solubility in water (mg/l): Miscible | VOC g/L: Not Available |
| | Specific gravity @ 20 °C (water = 1): Not Available |

SECTION 10: STABILITY AND REACTIVITY

| | |
|---|--|
| Reactivity | See Section 7 |
| Chemical stability | Unstable in the presence of incompatible materials. Product is considered stable. Hazardous polymerization will not occur. |
| Possibility of hazardous reactions | See Section 7 |
| Conditions to avoid | See Section 7 |
| Incompatible materials | See Section 7 |
| Hazardous composition | See Section 5 |

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

| | | | |
|---|--|--------------------------|---|
| Inhalation | Not expected to cause adverse health effects or respiratory irritation | | |
| Ingestion | Not expected to be harmful for ingestion | | |
| Skin contact | May cause skin irritation and hypersensitivity. | | |
| Eye contact | May cause eye irritation. | | |
| Chronic | May cause hypersensitivity | | |
| Redivom 1 mg/mL Solution for Injection | Acute toxicity | Irritation | |
| | Not Available | Not Available | |
| apomorphine hydrochloride | Acute toxicity | Irritation | |
| | Oral (mouse) LD ₅₀ : 300 mg/kg ^[2] | May cause irritation | |
| 1. Value obtained from Europe ECHA Registered Substances - Acute toxicity 2. Value obtained from manufacturer's SDS. Unless otherwise specified data extracted from RTECS - Register of Toxic Effect of chemical Substances | | | |
| Acute Toxicity | * | Carcinogenicity | * |
| Skin Irritation/Corrosion | * | Reproductivity | * |
| Serious Eye Damage/Irritation | * | STOT – Single Exposure | * |
| Respiratory or Skin Sensitization | * | STOT – Repeated Exposure | * |
| Mutagenicity | * | Aspiration Hazard | * |
| * - Data either not available or does not fill the criteria for classification, ✓ - Data available to make classification. | | | |

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

| Redivom 1 mg/mL Solution for Injection | Endpoint | Test Duration | Species | Value | Source |
|--|---------------|---------------|---------------|---------------|---------------|
| | Not Available |
| apomorphine hydrochloride | Endpoint | Test Duration | Species | Value | Source |
| | LC50 | 96h | Fish | 12.989mg/l | 3 |

Extracted from 3 EPIWIN Suite V3.12 (QSAR) - Aquatic Toxicity Data (Estimated)

DO NOT discharge into sewer or waterways.

12.2 Persistence and degradability

| Ingredient | Persistence: Water/Soil | Persistence: Air |
|---------------------------|-------------------------|------------------|
| apomorphine hydrochloride | HIGH | HIGH |

12.3 Bioaccumulative potential

| Ingredient | Bioaccumulation |
|---------------------------|--------------------|
| apomorphine hydrochloride | LOW (LogKOW = 2.3) |

12.4 Mobility in soil

| Ingredient | Mobility |
|---------------------------|--------------------|
| apomorphine hydrochloride | LOW (KOC = 245300) |

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. Legislation addressing waste disposal requirements may differ by country, state and/ or territory. Each user must refer to laws operating in their area. Ensure that the disposal of material is carried out in accordance with Hazardous Substances (Disposal) Regulations 2001. DO NOT allow wash water from cleaning or process equipment to enter drains. |
|------------------------------------|---|

SECTION 14: TRANSPORT INFORMATION

Labels required

| | |
|---|----------------------------------|
| Marine pollutant | NO |
| HAZCHEM | Not Applicable |
| Land transport (ADG): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS | |
| Air transport (ICAO-IATA / DGR): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS | |
| Sea transport (IMDG-Code / GGVSee): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS | |
| Transport in bulk according to Annex II of MARPOL and the IBC code Not Applicable | |
| Transport in bulk in accordance with MARPOL Annex V and the IMSBC Code | |
| Product name | Group |
| | Not available for any ingredient |
| Transport in bulk in accordance with ICG Code | |
| Product name | Group |
| | Not available for any ingredient |

SECTION 15: REGULATORY INFORMATION

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

apomorphine hydrochloride is found on the following regulatory lists

Poisons Schedule: S4

National Inventory Status

| | |
|--|--------------------------------|
| Australia - AIIIC / Australia Non-Industrial Use | Yes |
| Canada - DSL | No (apomorphine hydrochloride) |
| Canada - NDSL | Yes |
| China - IECS | No (apomorphine hydrochloride) |
| Europe - EINEC / ELINCS / NLP | Yes |
| Japan - ENCS | No (apomorphine hydrochloride) |
| Korea - KECI | No (apomorphine hydrochloride) |
| New Zealand - NZIoC | Yes |
| Philippines - PICCS | No (apomorphine hydrochloride) |
| USA - TSCA | Yes |
| Taiwan - TCSI | Yes |
| Mexico - INSQ | No (apomorphine hydrochloride) |
| Vietnam - NCI | No (apomorphine hydrochloride) |
| Russia - FBEPH | No (apomorphine hydrochloride) |

Yes = All CAS declared ingredients are on the inventory

No = One or more of the CAS listed ingredients are not on the inventory. These ingredients may be exempt or will require registration

SECTION 16: OTHER INFORMATION

Initial date: September 2023

Classification of the preparation and its individual components has drawn on official and authoritative sources as well as independent review by the Chemwatch Classification committee using available literature references. The SDS is a Hazard Communication tool and should be used to assist in the Risk Assessment. Many factors determine whether the reported Hazards are Risks in the workplace or other settings. Risks may be determined by reference to Exposures Scenarios. Scale of use, frequency of use and current or available engineering controls must be considered.

Definitions and abbreviations

| | |
|---|---|
| PC—TWA: Permissible Concentration-Time Weighted Average | STEL: Short Term Exposure Limit |
| PC—STEL: Permissible Concentration-Short Term Exposure Limit | TEEL: Temporary Emergency Exposure Limit |
| IARC: International Agency for Research on Cancer | ES: Exposure Standard |
| ACGIH: American Conference of Governmental Industrial Hygienists | OSF: Odor Safety Factor |
| IDLH: Immediately Dangerous to Life or Health Concentrations | NOAEL: No Observed Adverse Effect Level |
| AIIIC: Australian Inventory of Industrial Chemicals | LOAEL: Lowest Observed Adverse Effect Level |
| IECS: Inventory of Existing Chemical Substance in China | TLV: Threshold Limit Value |
| EINECS: European Inventory of Existing Commercial chemical Substances | LOD: Limit Of Detection |
| ELINCS: European List of Notified Chemical Substances | OTV: Odor Threshold Value |
| ENCS: Existing and New Chemical Substances Inventory | BCF: BioConcentration Factors |
| PICCS: Philippine Inventory of Chemicals and Chemical Substances | BEI: Biological Exposure Index |
| INSQ: Inventario Nacional de Sustancias Químicas | DSL: Domestic Substances List |



NCI: National Chemical Inventory
FBEPH: Russian Register of Potentially Hazardous Chemical and
Biological Substances
NZIoC: New Zealand Inventory of Chemicals

NDSL: Non-Domestic Substances List
NLP: No-Longer Polymers
KECI: Korea Existing Chemicals Inventory
TSCA: Toxic Substances Control Act
TCSI: Taiwan Chemical Substance Inventory

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