

SAFETY DATA SHEETS

This SDS packet was issued with item:

078949421



The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078949113

SECTION 1: IDENTIFICATION

| | |
|--|--|
| 1.1 Product identifier | |
| Product name | Torphadine (Butorphanol Tartrate) Injection, 10 mg/mL |
| Chemical name | Not Applicable |
| Synonyms | Not Available |
| Chemical formula | Not Applicable |
| Other means of identification | Not Available |
| 1.2 Recommended use of the chemical and restrictions on use | |
| Relevant identified uses | For the relief of pain associated with colic in adult horses and yearlings |
| 1.3 Details of the supplier of the substance or mixture | |
| Registered company name (US) | Dechra Veterinary Products |
| Address | 7015 College Blvd Suite 525 Overland Park, KS 66211 USA |
| Telephone | 866-933-2472 |
| Fax | Not Available |
| Email | Not Available |
| 1.4 Emergency telephone numbers | |
| Dechra (US) | 866-933-2472 |

SECTION 2: HAZARD(S) IDENTIFICATION

| | |
|---|--|
| 2.1 Classification of the substance or mixture | |
| NFPA 704 diamond  <p>Note: The hazard category numbers found in GHS classification in section 2 of this SDSs are NOT to be used to fill in the NFPA 704 diamond. Blue = Health Red = Fire Yellow = Reactivity White = Special (Oxidizer or water reactive substances)</p> | |
| Classification | Skin Corrosion/Irritation Category 2, Serious Eye Damage/Eye Irritation Category 2A, Specific Target Organ Toxicity - Repeated Exposure Category 2 |
| 2.2 Label elements | |
| Hazard pictogram(s) |  |
| Signal word | Warning |
| Hazard statement(s) | |
| H315 | Causes skin irritation. |
| H319 | Causes serious eye irritation. |
| H373 | May cause damage to organs through prolonged or repeated exposure. |
| Hazard(s) not otherwise classified | |
| Not Applicable | |
| Precautionary statement(s) prevention | |
| P260 | Do not breathe mist/vapors/spray. |
| P280 | Wear protective gloves, protective clothing, eye protection and face protection. |
| P264 | Wash all exposed external body areas thoroughly after handling. |
| Precautionary statement(s) response | |
| P305+P351+P338 | IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. |
| P314 | Get medical advice/attention if you feel unwell. |
| P337+P313 | If eye irritation persists: Get medical advice/attention. |
| P302+P352 | IF ON SKIN: Wash with plenty of water. |
| P332+P313 | If skin irritation occurs: Get medical advice/attention. |
| P362+P364 | Take off contaminated clothing and wash it before reuse. |
| Precautionary statement(s) storage | |
| Not Applicable | |
| Precautionary statement(s) disposal | |
| P501 | Dispose of contents/container to authorised hazardous or special waste collection point in accordance with any local regulation. |

SECTION 3: COMPOSITION / INFORMATION ON INGREDIENTS

| | | |
|--|-------------------|---------------------------------|
| 3.1 Substances | | |
| See section above for composition of Mixtures. | | |
| 3.2 Mixtures | | |
| CAS No. | % [weight] | Name |
| 58786-99-5 | 1-5 | <u>butorphanol tartrate</u> |
| 6132-04-3 | <1 | <u>sodium citrate dihydrate</u> |

| | | |
|--|---------|--|
| 7647-14-5 | <1 | sodium chloride |
| 5949-29-1 | <1 | citric acid, monohydrate |
| 121-54-0 | <1 | benzethonium chloride |
| 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 | Wash out immediately with fresh running water. Ensure complete irrigation of the eye by keeping eyelids apart and away from eye and moving the eyelids by occasionally lifting the upper and lower lids. Seek medical attention without delay; if pain persists or recurs seek medical attention. Removal of contact lenses after an eye injury should only be undertaken by skilled personnel. |
| Skin contact | Immediately remove all contaminated clothing, including footwear. Flush skin and hair with running water (and soap if available). Seek medical attention in event of irritation. |
| Inhalation | If fumes or combustion products are inhaled remove from contaminated area. Lay patient down. Keep warm and rested. Apply artificial respiration if not breathing. Perform CPR if necessary. Transport to hospital, or doctor, without delay. |
| Ingestion | If vomiting occurs, lean patient forward or place on left side (head-down position, if possible) to maintain open airway and prevent aspiration. Observe the patient carefully. Never give liquid to a person showing signs of being sleepy or with reduced awareness; i.e. becoming unconscious. Give water to rinse out mouth, then provide liquid slowly and as much as casualty can comfortably drink. Seek medical advice. |

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

Treat symptomatically for a narcotic analgesic.

The single most important element in therapy is the correction of anoxia by all available means: the maintenance of a patent airway, the administration of oxygen, the use of artificial respiration, and the injection of specific narcotic antagonists such as nalorphine, levallorphan or naloxone promptly antagonizes the respiratory depression, coma and hypotension from overdoses of morphine, codeine, all semi-synthetics and almost all synthetic narcotics. – *GOSSSELIN et al: Clinical Toxicology of Commercial Products*.

In fully conscious patients, remove swallowed poison by thorough gastric lavage and emesis. The chances of removing a significant amount of the drug are better if treatment is started within the first two hours. If the patient is unconscious or depressed, emesis is contraindicated and the dangers of gastric lavage are not justified. – *DREISBACH AND ROBERTSON: Handbook of Poisoning, Appleton & Lange*

SECTION 5: FIRE FIGHTING MEASURES

5.1 Extinguishing media

The product contains a substantial proportion of water, therefore there are no restrictions on the type of extinguishing media which may be used. Choice of extinguishing media should take into account surrounding areas.

Though the material is non-combustible, evaporation of water from the mixture, caused by the heat of nearby fire, may produce floating layers of combustible substances. In such an event consider foam, dry chemical powder, carbon dioxide.

5.2 Special hazards arising from the substance or mixture

| | |
|-----------------------------|------------|
| Fire incompatibility | None known |
|-----------------------------|------------|

5.3 Special protective actions for fire-fighters:

| | |
|--------------------------------|---|
| Firefighting | Wear full body protective clothing with breathing apparatus. Prevent, by any means available, spillage from entering drains or water course. Use firefighting procedures suitable for surrounding area. Avoid spraying water onto liquid pools. DO NOT approach containers suspected to be hot. Cool fire exposed containers with water spray from a protected location. If safe to do so, remove containers from path of fire. |
| Fire / explosion hazard | The material is not readily combustible under normal conditions. However, it will break down under fire conditions and the organic component may burn. Not considered to be a significant fire risk. Heat may cause expansion or decomposition with violent rupture of containers. Decomposes on heating and may produce toxic fumes of carbon monoxide. Decomposes on heating and produces toxic fumes of carbon dioxide, nitrogen oxides, other pyrolysis products typical of burning organic material. May emit poisonous fumes. May emit corrosive fumes. |

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 vapors and contact with skin and eyes. Control personal contact with the substance, by using protective equipment. Contain and absorb spill with sand, earth, inert material or vermiculite. Wipe up. Place in a suitable, labelled container for waste disposal. |
| Major spills | Moderate hazard. Clear area of personnel and move upwind. Alert Fire Brigade and tell them location and nature of hazard. Wear breathing apparatus plus protective gloves. Prevent, by any means available, spillage from entering |

| | |
|--|--|
| | drains or water course. Stop leak if safe to do so. Contain spill with sand, earth or vermiculite. Collect recoverable product into labelled containers for recycling. Neutralise/decontaminate residue. Collect solid residues and seal in labelled drums for disposal. Wash area and prevent runoff into drains. |
| 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 | DO NOT allow clothing wet with material to stay in contact with skin Avoid all personal contact, including inhalation. Wear protective clothing when risk of exposure occurs. Use in a well-ventilated area. Prevent concentration in hollows and sumps. DO NOT enter confined spaces until atmosphere has been checked. DO NOT allow material to contact humans, exposed food or food utensils. Avoid contact with incompatible materials. When handling, DO NOT eat, drink or smoke. Keep containers securely sealed when not in use. Avoid physical damage to containers. Observe manufacturer's storage and handling recommendations. |
| Other information | NOTE: Special security requirements may be mandated under Federal/State Regulation(s). Store in original containers. Store in vault fitted with warning devices or detectors recommended by various Federal/State authorities. Store in vault used only for the purpose of storage of drugs of addiction. Vault must be locked at all times except when the materials stored therein are required. |
| 7.2 Conditions for safe storage, including any incompatibilities | |
| Suitable container | Packaging as recommended by manufacturer. Check that containers are clearly labelled. Tamper-proof containers. Polyethylene or polypropylene containers. Metal drum with sealed plastic liner. Glass container is suitable for laboratory quantities |
| Storage incompatibility | None known |

SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 Control parameters

Occupational exposure limits (OEL)

INGREDIENT DATA
Not Available

Emergency limits

| Ingredient | TEEL-1 | TEEL-2 | TEEL-3 |
|--------------------------|-----------------------|-----------------------|-----------------------|
| sodium citrate dihydrate | 9.3 mg/m ³ | 100 mg/m ³ | 610 mg/m ³ |
| sodium chloride | 0.5 ppm | 2 ppm | 20 ppm |
| Ingredient | Original IDLH | Revised IDLH | |
| butorphanol tartrate | Not Available | Not Available | |
| sodium citrate dihydrate | Not Available | Not Available | |
| sodium chloride | Not Available | Not Available | |
| citric acid, monohydrate | Not Available | Not Available | |
| benzethonium chloride | Not Available | Not Available | |

Occupational Exposure Banding

| Ingredient | Occupational Exposure Band Rating | Occupational Exposure Band Limit |
|--------------------------|-----------------------------------|----------------------------------|
| butorphanol tartrate | E | ≤ 0.01 mg/m ³ |
| sodium chloride | E | ≤ 0.01 mg/m ³ |
| citric acid, monohydrate | E | ≤ 0.01 mg/m ³ |
| benzethonium chloride | E | ≤ 0.01 mg/m ³ |

Notes: Occupational exposure banding is a process of assigning chemicals into specific categories or bands based on a chemical's potency and the adverse health outcomes associated with exposure. The output of this process is an occupational exposure band (OEB), which corresponds to a range of exposure concentrations that are expected to protect worker health.

MATERIAL DATA

Airborne particulate or vapour must be kept to levels as low as is practicably achievable given access to modern engineering controls and monitoring hardware. Biologically active compounds may produce idiosyncratic effects which are entirely unpredictable on the basis of literature searches and prior clinical experience (both recent and past).

8.2 Exposure controls

| | |
|---|---|
| Appropriate engineering controls | Enclosed local exhaust ventilation is required at points of dust, fume or vapor generation. HEPA terminated local exhaust ventilation should be considered at point of generation of dust, fumes or vapors. Barrier protection or laminar flow cabinets should be considered for laboratory scale handling. |
| Personal protection |  |
| Eye and face protection | When handling very small quantities of the material eye protection may not be required. Use safety glasses with side shields or chemical goggles. Contact lenses may pose a special hazard; soft contact lenses may absorb and concentrate irritants. |
| Skin protection | See Hand protection below. |
| Hands/feet protection | Select gloves tested to a relevant standard (e.g. Europe EN 374, US F739, AS/NZS 2161.1 or national equivalent). For a prolonged or frequently repeated, a glove with a protection class of 5 or |

| | |
|-------------------------------|---|
| | higher (breakthrough time greater than 240 minutes according to EN 374, AS/NZS 2161.10.1 or national equivalent) is recommended. When only brief contact is expected, a glove with a protection class of 3 or higher (breakthrough time greater than 60 minutes according to EN 374, AS/NZS 2161.10.1 or national equivalent) is recommended. For general applications, gloves with a thickness typically greater than 0.35 mm, are recommended. |
| Body protection | See Other protection below |
| Other protection | For quantities up to 500 grams a laboratory coat may be suitable. For quantities up to 1 kilogram a disposable laboratory coat or coverall of low permeability is recommended. Coveralls should be buttoned at collar and cuffs. For quantities over 1 kilogram and manufacturing operations, wear disposable coverall of low permeability and disposable shoe covers. For manufacturing operations, air-supplied full body suits may be required for the provision of advanced respiratory protection. Eye wash unit. Ensure there is ready access to an emergency shower. For Emergencies: Vinyl suit |
| Respiratory protection | Type A Filter of sufficient capacity. (AS/NZS 1716 & 1715, EN 143:2000 & 149:2001, ANSI Z88 or national equivalent) |

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

| | |
|--|--|
| Appearance: Clear to light yellow liquid | Vapor density: NA |
| Physical state: Liquid | Auto ignition temperature (°C): NA |
| Odor: No odor | Decomposition temperature (°C): NA |
| Odor threshold: NA | Viscosity (°C): NA |
| pH (as supplied): 3.0-5.5 | Explosive properties: NA |
| Melting point / freezing point (°C): NA | Oxidizing properties: NA |
| Initial boiling point and boiling range: NA | Partition coefficient: NA |
| Flash point: NA | Molecular weight: NA |
| Evaporation rate: NA | Taste: NA |
| Flammability: Flammable | Surface tension: NA |
| Upper/lower flammability or explosive limits: NA | Volatile component (%vol): NA |
| Vapor pressure: NA | Gas group: NA |
| Relative density (at °C): ~1.01 at 20°C | pH as a solution: NA |
| Solubility in water (mg/l): Miscible | VOC g/L: NA |
| | Specific gravity @ 20 °C (water = 1): NA |

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

| | | |
|--|--|-------------------|
| Inhalation | Evidence shows, or practical experience predicts, that the material produces irritation of the respiratory system, if inhaled. Not normally a hazard due to non-volatile nature of product. | |
| Ingestion | Accidental ingestion of the material may be damaging to the health of the individual. The commonest side-effects of narcotic analgesics (including morphine) are nausea, vomiting, constipation, dizziness, drowsiness, sedation, euphoria and confusion. | |
| Skin contact | Evidence exists, or practical experience predicts, that the material either produces inflammation of the skin in a substantial number of individuals following direct contact, and/or produces significant inflammation. | |
| Eye contact | Evidence exists, or practical experience predicts, that the material may cause eye irritation in a substantial number of individuals and/or may produce significant ocular lesions which are present twenty-four hours or more after instillation into the eye(s) of experimental animals. Repeated or prolonged eye contact may cause inflammation characterised by temporary redness (similar to windburn) of the conjunctiva (conjunctivitis); temporary impairment of vision and/or other transient eye damage/ulceration may occur. | |
| Chronic | Repeated or long-term occupational exposure is likely to produce cumulative health effects involving organs or biochemical systems. Long-term exposure to respiratory irritants may result in disease of the airways involving difficult breathing and related systemic problems. | |
| Butorphanol Tartrate Injection, 10 mg/mL | Acute toxicity | Irritation |
| | Not Available | Not Available |
| butorphanol tartrate | Acute toxicity | Irritation |
| | Oral (dog) LD50: >50 mg/kg ^[2] | Not Available |
| sodium citrate dihydrate | Acute toxicity | Irritation |
| | Oral (rat) LD50: >2000 mg/kg ^[1] | Not Available |
| | Oral (mouse) LD50: 5000-6000 mg/kg ^[2] | |
| sodium chloride | Acute toxicity | Irritation |

| | | | |
|--|--|--|---|
| | Dermal (rabbit) LD50: >10000 mg/kg ^[1] Inhalation (rat) LD50: >10.5 mg/kg ^[1] Oral (rat) LD50: 3000 mg/kg ^[2] | Eye (rabbit): 10 mg – moderate Eye (rabbit):100 mg/24h – moderate Skin (rabbit): 500 mg/24h - mild | |
| citric acid, monohydrate | Acute toxicity Oral (mouse) LD50: 5790 mg/kg ^[2] | Irritation Eye (rabbit): 5 mg/30s mild | |
| benzethonium chloride | Acute toxicity Dermal (rabbit) LD50: 3000 mg/kg ^[2] Oral (rat) LD50: 295 mg/kg ^[1] | Irritation Eye (rabbit): 0.03 mg – SEVERE Eye: no adverse effect observed (not irritating) ^[1] Skin (rabbit): SEVERE* Skin: adverse effect observed (corrosive) ^[1] | |
| 1 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 | ✖ |
| Serios 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

| Torphadine (Butorphanol Tartrate) Injection, 10 mg/mL | Endpoint | Test Duration | Species | Value | Source |
|---|---------------|---------------|-------------------------------|------------------|---------------|
| | Not Available | Not Available | Not Available | Not Available | Not Available |
| butorphanol tartrate | Endpoint | Test duration | Species | Value | Source |
| | Not Available | Not Available | Not Available | Not Available | Not Available |
| sodium citrate dihydrate | Endpoint | Test duration | Species | Value | Source |
| | EC50(ECx) | 48h | Crustacea | >50mg/l | 2 |
| | EC50 | 48h | Crustacea | >50mg/l | 2 |
| | EC50 | 96h | Algae or other aquatic plants | >18000-32000mg/l | 1 |
| sodium chloride | Endpoint | Test duration | Species | Value | Source |
| | NOEC50(ECx) | 168h | Crustacea | 0.63mg/l | 4 |
| | EC50 | 72h | Algae or other aquatic plants | 20.76-36.17mg/L | 4 |
| | EC50 | 48h | Crustacea | 340.7-469.2mg/l | 4 |
| | LC50 | 96h | Fish | 3644-4565mg/l | 4 |
| | EC50 | 96h | Algae or other aquatic plants | 1110.36mg/L | 4 |
| citric acid, monohydrate | Endpoint | Test duration | Species | Value | Source |
| | EC10(ECx) | 24h | Algae or other aquatic plants | >1000mg/l | 4 |
| benzethonium chloride | Endpoint | Test duration | Species | Value | Source |
| | EC50 | 72h | Algae or other aquatic plants | 0.12mg/l | 2 |
| | NOEC(Ex) | 72h | Algae or other aquatic plants | 0.038mg/l | 2 |
| | LC50 | 96h | Fish | 1.4-53mg/l | Not Available |
| Extracted from 1. IUCLID Toxicity Data 2. Europe ECHA Registered Substances - Ecotoxicological Information - Aquatic Toxicity 3. EPIWIN Suite V3.12 (QSAR) - Aquatic Toxicity Data (Estimated) 4. US EPA, Ecotox database - Aquatic Toxicity Data 5. ECETOC Aquatic Hazard Assessment Data 6. NITE (Japan) - Bioconcentration Data 7. METI (Japan) - Bioconcentration Data 8. Vendor Data | | | | | |

DO NOT discharge into sewer or waterways.

12.2 Persistence and degradability

| Ingredient | Persistence: Water/Soil | Persistence: Air |
|--------------------------|-------------------------|------------------|
| sodium chloride | LOW | LOW |
| citric acid, monohydrate | LOW | LOW |
| benzethonium chloride | HIGH | HIGH |

12.3 Bioaccumulative potential

| Ingredient | Bioaccumulation |
|--------------------------|------------------------|
| sodium chloride | LOW (LogKOW = 0.5392) |
| citric acid, monohydrate | LOW (LogKOW = -1.64) |
| benzethonium chloride | HIGH (LogKOW = 5.9969) |

12.4 Mobility in soil

| Ingredient | Mobility |
|--------------------------|--------------------|
| sodium chloride | LOW (KOC = 14.3) |
| citric acid, monohydrate | LOW (KOC = 10) |
| benzethonium chloride | LOW (KOC = 443300) |

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

| Product/ packaging disposal | Hold all residues for recovery. Disposal of the material must be carried out in accordance with the requirements of the relevant Federal/State Act(s) or Code(s) regulating the disposal of Drugs of Addiction. Consult manufacturer/supplier for recycling options. Decontaminate empty containers with water; incinerate plastic bags. DO NOT reuse containers. Bury empty containers in an authorised landfill. Legislation addressing waste |
|-----------------------------------|--|
|-----------------------------------|--|

| | |
|--|---|
| | disposal requirements may differ by country. DO NOT allow wash water from cleaning or process equipment to enter drains. |
|--|---|

SECTION 14: TRANSPORT INFORMATION

| | |
|---|------------------|
| Labels required | |
| Marine pollutant | NO |
| Land transport (US: DOT) | |
| Not regulated for transport of dangerous goods | |
| Land transport (ICAO-IATA / DGR) | |
| Not regulated for transport of dangerous goods | |
| Land 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 |
| No Data available for all ingredients | |
| Transport in bulk in accordance with the ICG Code | |
| Product name | Ship type |
| No Data available for all ingredients | |

SECTION 15: REGULATORY INFORMATION

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

Product regulated by FDA as a veterinary product.

butorphanol tartrate is found on the following regulatory lists

Not Applicable

sodium citrate dihydrate is found on the following regulatory lists

US DOE Temporary Emergency Exposure Limits (TEELs), US Toxic Substances Control Act (TSCA) - Chemical Substance Inventory, US TSCA Chemical Substance Inventory - Interim List of Active Substances

sodium chloride is found on the following regulatory lists

US DOE TEELs, US TSCA - Chemical Substance Inventory, US TSCA Chemical Substance Inventory - Interim List of Active Substances

citric acid, monohydrate is found on the following regulatory lists

US TSCA - Chemical Substance Inventory, US TSCA Chemical Substance Inventory - Interim List of Active Substances

benzethonium chloride is found on the following regulatory lists

US TSCA - Chemical Substance Inventory, US TSCA Chemical Substance Inventory - Interim List of Active Substances

Federal Regulations

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Section 311/312 hazard categories

| | |
|--|-----|
| Flammable (Gases, Aerosols, Liquids, or Solids) | No |
| Gas under pressure | No |
| Explosive | No |
| Self-heating | No |
| Pyrophoric (Liquid or Solid) | No |
| Pyrophoric Gas | No |
| Corrosive to metal | No |
| Oxidizer (Liquid, Solid or Gas) | No |
| Organic Peroxide | No |
| Self-reactive | No |
| In contact with water emits flammable gas | No |
| Combustible Dust | No |
| Carcinogenicity | No |
| Acute toxicity (any route of exposure) | No |
| Reproductive toxicity | No |
| Skin Corrosion or Irritation | Yes |
| Respiratory or Skin Sensitization | No |
| Serious eye damage or eye irritation | Yes |
| Specific target organ toxicity (single or repeated exposure) | Yes |
| Aspiration Hazard | No |
| Germ cell mutagenicity | No |
| Simple Asphyxiant | No |
| Hazards Not Otherwise Classified | No |

US. EPA CERCLA Hazardous Substances and Reportable Quantities (40 CFR 302.4)

None reported

| State Regulations | |
|--|---|
| US: California Proposition 65 None reported | |
| National Inventory Status | |
| Australia - AIIC / AustraliaNon-Industrial Use | No (butorphanol tartrate) |
| Canada - DSL | No (butorphanol tartrate) |
| Canada - NDSL | No (butorphanol tartrate; sodium chloride; citric acid, monohydrate; benzethonium chloride) |
| China - IECSC | No (butorphanol tartrate) |
| Europe - EINEC / ELINCS /NLP | Yes |
| Japan - ENCS | No (butorphanol tartrate) |
| Korea - KECI | No (butorphanol tartrate) |
| New Zealand - NZIoC | Yes |
| Philippines - PICCS | No (butorphanol tartrate) |
| USA - TSCA | No (butorphanol tartrate) |
| Taiwan - TCSI | Yes |
| Mexico - INSQ | No (butorphanol tartrate) |
| Vietnam - NCI | No (butorphanol tartrate) |
| Russia - FBEPH | No (butorphanol tartrate) |
| 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: 7 October 2022 – Classification, Ingredients updated

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: Odour Safety Factor |
| IDLH: Immediately Dangerous to Life or Health Concentrations | NOAEL :No Observed Adverse Effect Level |
| AIIC: Australian Inventory of Industrial Chemicals | LOAEL: Lowest Observed Adverse Effect Level |
| IECSC: 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: Odour 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 | NDSL: Non-Domestic Substances List |
| FBEPH: Russian Register of Potentially Hazardous Chemical and Biological Substances | NLP: No-Longer Polymers |
| NZIoC: New Zealand Inventory of Chemicals | KECI: Korea Existing Chemicals Inventory |
| | TSCA: Toxic Substances Control Act |
| | TCSI: Taiwan Chemical Substance Inventory |

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