

ilium Temvet 90-Day Multidose Injection

Troy Laboratories Pty Ltd

Chemwatch: 9638-82

Version No: 3.1

Safety Data Sheet according to Work Health and Safety Regulations (Hazardous Chemicals) 2023 and ADG requirements

Chemwatch Hazard Alert Code: 2

Initial Date: 08/09/2026

Revision Date: 18/09/2026

Print Date: 22/09/2026

L.GHS.AUS.EN.E

SECTION 1 Identification of the substance / mixture and of the company / undertaking

Product Identifier

Product name	ilium Temvet 90-Day Multidose Injection
Chemical Name	Not Applicable
Synonyms	APVMA number 67612
Chemical formula	Not Applicable
Other means of identification	Not Available

Relevant identified uses of the substance or mixture and uses advised against

Relevant identified uses	For peri-operative and post-operative analgesia in cats. For post-operative analgesia and potentiation of the sedative. effects of centrally acting agents in dogs. To be used as directed on product label. Use according to manufacturer's directions.
--------------------------	---

Details of the manufacturer or importer of the safety data sheet

Registered company name	Troy Laboratories Pty Ltd
Address	37 Glendenning Road Glendenning NSW 2761 Australia
Telephone	(02) 8808 3600
Fax	(02) 9677 9300
Website	www.Troylab.com.au
Email	sales@troylab.com.au

Emergency telephone number

Association / Organisation	Troy Laboratories Pty Ltd
Emergency telephone number(s)	(02) 8808 3600 (8am – 4pm, Monday to Friday)
Other emergency telephone number(s)	Not Available

SECTION 2 Hazards identification

Classification of the substance or mixture

Poisons Schedule	S8
Classification [1]	Non hazardous
Legend:	1. Classified by Chemwatch; 2. Classification drawn from HCIS; 3. Classification drawn from Regulation (EU) No 1272/2008 - Annex VI

Label elements

Hazard pictogram(s)	Not Applicable
---------------------	----------------

Signal word | Not Applicable

Hazard statement(s)

Not Applicable

Precautionary statement(s) Prevention

Not Applicable

Precautionary statement(s) Response

Not Applicable

Precautionary statement(s) Storage

Not Applicable

Precautionary statement(s) Disposal

Not Applicable

No further product hazard information.

SECTION 3 Composition / information on ingredients**Substances**

See section below for composition of Mixtures

Mixtures

CAS No	%[weight]	Name
53152-21-9	<1	<u>buprenorphine hydrochloride</u>
Not Available	Balance	Ingredients determined not to be hazardous

Legend: 1. Classified by Chemwatch; 2. Classification drawn from HCIS; 3. Classification drawn from Regulation (EU) No 1272/2008 - Annex VI; 4. Classification drawn from C&L; * EU IOELVs available

SECTION 4 First aid measures**Description of first aid measures**

Eye Contact	If this product comes in contact with eyes: - Wash out immediately with water. - If irritation continues, seek medical attention. - Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.
Skin Contact	If skin or hair contact occurs: - Flush skin and hair with running water (and soap if available). - Seek medical attention in event of irritation.
Inhalation	- If fumes, aerosols or combustion products are inhaled remove from contaminated area. - Other measures are usually unnecessary.
Ingestion	- For advice, contact a Poisons Information Centre or a doctor at once. - Urgent hospital treatment is likely to be needed. - If swallowed do NOT induce vomiting. - 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. - Transport to hospital or doctor without delay.

Indication of any immediate medical attention and special treatment needed

Treat symptomatically for a narcotic analgesic.

A vigorous program of symptomatic and supportive therapy has saved many victims of poisoning. 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 antagonises the respiratory depression, coma and hypotension from overdoses of morphine, codeine, all semi-synthetics and almost all synthetic narcotics.

GOSSELIN 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

Continued...

As in all cases of suspected poisoning, follow the ABCDEs of emergency medicine (airway, breathing, circulation, disability, exposure), then the ABCDEs of toxicology (antidotes, basics, change absorption, change distribution, change elimination).

For poisons (where specific treatment regime is absent):

BASIC TREATMENT

- Establish a patent airway with suction where necessary.
- Watch for signs of respiratory insufficiency and assist ventilation as necessary.
- Administer oxygen by non-rebreather mask at 10 to 15 L/min.
- Monitor and treat, where necessary, for pulmonary oedema.
- Monitor and treat, where necessary, for shock.
- Anticipate seizures.
- **DO NOT** use emetics. Where ingestion is suspected rinse mouth and give up to 200 ml water (5 ml/kg recommended) for dilution where patient is able to swallow, has a strong gag reflex and does not drool.

ADVANCED TREATMENT

- Consider orotracheal or nasotracheal intubation for airway control in unconscious patient or where respiratory arrest has occurred.
- Positive-pressure ventilation using a bag-valve mask might be of use.
- Monitor and treat, where necessary, for arrhythmias.
- Start an IV D5W TKO. If signs of hypovolaemia are present use lactated Ringers solution. Fluid overload might create complications.
- Drug therapy should be considered for pulmonary oedema.
- Hypotension with signs of hypovolaemia requires the cautious administration of fluids. Fluid overload might create complications.
- Treat seizures with diazepam.
- Proparacaine hydrochloride should be used to assist eye irrigation.

BRONSTEIN, A.C. and CURRANCE, P.L.

EMERGENCY CARE FOR HAZARDOUS MATERIALS EXPOSURE: 2nd Ed. 1994

SECTION 5 Firefighting measures

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.

Special hazards arising from the substance or mixture

Fire Incompatibility	None known.
----------------------	-------------

Advice for firefighters

Fire Fighting	▸ Alert Fire Brigade and tell them location and nature of hazard. ▸ Wear breathing apparatus plus protective gloves in the event of a fire. ▸ Prevent, by any means available, spillage from entering drains or water courses. ▸ Use fire fighting procedures suitable for surrounding area. ▸ 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. ▸ Equipment should be thoroughly decontaminated after use.
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 (CO). ▸ May emit acrid smoke. Decomposes on heating and produces toxic fumes of: ▸ carbon dioxide (CO₂) ▸ nitrogen oxides (NO_x) ▸ other pyrolysis products typical of burning organic material.
HAZCHEM	Not Applicable

SECTION 6 Accidental release measures

Personal precautions, protective equipment and emergency procedures

See section 8

Environmental precautions

See section 12

Methods and material for containment and cleaning up

Minor Spills	▶ Clean up all spills immediately. ▶ Avoid breathing vapours 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	Minor hazard. ▶ Clear area of personnel. ▶ Alert Fire Brigade and tell them location and nature of hazard. ▶ Control personal contact with the substance, by using protective equipment as required. ▶ Prevent spillage from entering drains or water ways. ▶ Contain spill with sand, earth or vermiculite. ▶ Collect recoverable product into labelled containers for recycling. ▶ Absorb remaining product with sand, earth or vermiculite and place in appropriate containers for disposal. ▶ Wash area and prevent runoff into drains or waterways. ▶ If contamination of drains or waterways occurs, advise emergency services.

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

SECTION 7 Handling and storage

Precautions for safe handling

Safe handling	▶ Limit all unnecessary personal contact. ▶ Wear protective clothing when risk of exposure occurs. ▶ Use in a well-ventilated area. ▶ 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. ▶ Always wash hands with soap and water after handling. ▶ Work clothes should be laundered separately. ▶ Use good occupational work practice. ▶ Observe manufacturer's storage and handling recommendations contained within this SDS. ▶ Atmosphere should be regularly checked against established exposure standards to ensure safe working conditions are maintained.
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. ▶ Keep storage area free from debris, wastes and combustibles. ▶ Keep dry. ▶ Keep containers securely sealed. ▶ Protect containers against physical damage. ▶ Check regularly for spills and leaks.

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	Avoid contamination of water, foodstuffs, feed or seed. None known

SECTION 8 Exposure controls / personal protection

Control parameters

Occupational Exposure Limits (OEL)

INGREDIENT DATA

Not Available

MATERIAL DATA

Exposure controls

Appropriate engineering controls	Enclosed local exhaust ventilation is required at points of dust, fume or vapour generation. HEPA terminated local exhaust ventilation should be considered at point of generation of dust, fumes or vapours. Barrier protection or laminar flow cabinets should be considered for laboratory scale handling. A fume hood or vented balance enclosure is recommended for weighing/ transferring quantities exceeding 500 mg. When handling quantities up to 500 gram in either a standard laboratory with general dilution ventilation (e.g. 6-12 air changes per hour) is preferred. Quantities up to 1 kilogram may require a designated laboratory using fume hood, biological safety cabinet, or approved vented enclosures. Quantities exceeding 1 kilogram should be handled in a designated laboratory or containment laboratory using appropriate barrier/ containment technology. Manufacturing and pilot plant operations require barrier/ containment and direct coupling technologies. Barrier/ containment technology and direct coupling (totally enclosed processes that create a barrier between the equipment and the room) typically use double or split butterfly valves and hybrid unidirectional airflow/ local exhaust ventilation solutions (e.g. powder containment booths). Glove bags, isolator glove box systems are optional. HEPA filtration of exhaust from dry product handling areas is required. Fume-hoods and other open-face containment devices are acceptable when face velocities of at least 1 m/s (200 feet/minute) are achieved. Partitions, barriers, and other partial containment technologies are required to prevent migration of the material to uncontrolled areas. For non-routine emergencies maximum local and general exhaust are necessary. Air contaminants generated in the workplace possess varying "escape" velocities which, in turn, determine the "capture velocities" of fresh circulating air required to effectively remove the contaminant.	
	Type of Contaminant:	Air Speed:
	solvent, vapours, etc. evaporating from tank (in still air)	0.25-0.5 m/s (50-100 f/min.)
	aerosols, fumes from pouring operations, intermittent container filling, low speed conveyer transfers (released at low velocity into zone of active generation)	0.5-1 m/s (100-200 f/min.)
	direct spray, drum filling, conveyer loading, crusher dusts, gas discharge (active generation into zone of rapid air motion)	1-2.5 m/s (200-500 f/min.)
	Within each range the appropriate value depends on:	
	Lower end of the range	Upper end of the range
	1: Room air currents minimal or favourable to capture	1: Disturbing room air currents
	2: Contaminants of low toxicity or of nuisance value only.	2: Contaminants of high toxicity
	3: Intermittent, low production.	3: High production, heavy use
Individual protection measures, such as personal protective equipment	4: Large hood or large air mass in motion	4: Small hood-local control only
	Simple theory shows that air velocity falls rapidly with distance away from the opening of a simple extraction pipe. Velocity generally decreases with the square of distance from the extraction point (in simple cases). Therefore the air speed at the extraction point should be adjusted, accordingly, after reference to distance from the contaminating source. The air velocity at the extraction fan, for example, should be a minimum of 1-2.5 m/s (200-500 f/min.) for extraction of gases discharged 2 meters distant from the extraction point. Other mechanical considerations, producing performance deficits within the extraction apparatus, make it essential that theoretical air velocities are multiplied by factors of 10 or more when extraction systems are installed or used. The need for respiratory protection should also be assessed where incidental or accidental exposure is anticipated: Dependent on levels of contamination, PAPR, full face air purifying devices with P2 or P3 filters or air supplied respirators should be evaluated. The following protective devices are recommended where exposures exceed the recommended exposure control guidelines by factors of: 10; high efficiency particulate (HEPA) filters or cartridges 10-25; loose-fitting (Tyvek or helmet type) HEPA powered-air purifying respirator. 25-50; a full face-piece negative pressure respirator with HEPA filters 50-100; tight-fitting, full face-piece HEPA PAPR 100-1000; a hood-shroud HEPA PAPR or full face-piece supplied air respirator operated in pressure demand or other positive pressure mode.	
Eye and face protection	When handling very small quantities of the material eye protection may not be required.	



Ilium Temvet 90-Day Multidose Injection

	For laboratory, larger scale or bulk handling or where regular exposure in an occupational setting occurs: ▸ Chemical goggles. [AS/NZS 1337.1, EN166 or national equivalent] ▸ Face shield. Full face shield may be required for supplementary but never for primary protection of eyes. ▸ Contact lenses may pose a special hazard; soft contact lenses may absorb and concentrate irritants. A written policy document, describing the wearing of lenses or restrictions on use, should be created for each workplace or task. This should include a review of lens absorption and adsorption for the class of chemicals in use and an account of injury experience. Medical and first-aid personnel should be trained in their removal and suitable equipment should be readily available. In the event of chemical exposure, begin eye irrigation immediately and remove contact lens as soon as practicable. Lens should be removed at the first signs of eye redness or irritation - lens should be removed in a clean environment only after workers have washed hands thoroughly. [CDC NIOSH Current Intelligence Bulletin 59].
Skin protection	See Hand protection below
Hands/feet protection	The selection of suitable gloves does not only depend on the material, but also on further marks of quality which vary from manufacturer to manufacturer. Where the chemical is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application. The exact break through time for substances has to be obtained from the manufacturer of the protective gloves and has to be observed when making a final choice. Personal hygiene is a key element of effective hand care. Gloves must only be worn on clean hands. After using gloves, hands should be washed and dried thoroughly. Application of a non-perfumed moisturiser is recommended. Suitability and durability of glove type is dependent on usage. Important factors in the selection of gloves include: · frequency and duration of contact, · chemical resistance of glove material, · glove thickness and · dexterity Select gloves tested to a relevant standard (e.g. Europe EN 374, US F739, AS/NZS 2161.1 or national equivalent). · When prolonged or frequently repeated contact may occur, 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. · Some glove polymer types are less affected by movement and this should be taken into account when considering gloves for long-term use. · Contaminated gloves should be replaced. As defined in ASTM F-739-96 in any application, gloves are rated as: · Excellent when breakthrough time > 480 min · Good when breakthrough time > 20 min · Fair when breakthrough time < 20 min · Poor when glove material degrades For general applications, gloves with a thickness typically greater than 0.35 mm, are recommended. It should be emphasised that glove thickness is not necessarily a good predictor of glove resistance to a specific chemical, as the permeation efficiency of the glove will be dependent on the exact composition of the glove material. Therefore, glove selection should also be based on consideration of the task requirements and knowledge of breakthrough times. Glove thickness may also vary depending on the glove manufacturer, the glove type and the glove model. Therefore, the manufacturers technical data should always be taken into account to ensure selection of the most appropriate glove for the task. Note: Depending on the activity being conducted, gloves of varying thickness may be required for specific tasks. For example: · Thinner gloves (down to 0.1 mm or less) may be required where a high degree of manual dexterity is needed. However, these gloves are only likely to give short duration protection and would normally be just for single use applications, then disposed of. · Thicker gloves (up to 3 mm or more) may be required where there is a mechanical (as well as a chemical) risk i.e. where there is abrasion or puncture potential Gloves must only be worn on clean hands. After using gloves, hands should be washed and dried thoroughly. Application of a non-perfumed moisturiser is recommended. ▸ Rubber gloves (nitrile or low-protein, powder-free latex, latex/ nitrile). Employees allergic to latex gloves should use nitrile gloves in preference. ▸ Double gloving should be considered. ▸ PVC gloves. ▸ Change gloves frequently and when contaminated, punctured or torn. ▸ Wash hands immediately after removing gloves. ▸ Protective shoe covers. [AS/NZS 2210] ▸ Head covering.
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

Recommended material(s)

GLOVE SELECTION INDEX

Respiratory protection

Type A Filter of sufficient capacity. (AS/NZS 1716 & 1715, EN 143:2000 &

Continued...

Glove selection is based on a modified presentation of the:

"Forsberg Clothing Performance Index".

The effect(s) of the following substance(s) are taken into account in the **computer-generated** selection:

Ilium Temvet 90-Day Multidose Injection

Material	CPI
BUTYL	A
NEOPRENE	A
NATURAL RUBBER	C
PVA	C
PVC	C
VITON	C

* CPI - Chemwatch Performance Index

A: Best Selection

B: Satisfactory; may degrade after 4 hours continuous immersion

C: Poor to Dangerous Choice for other than short term immersion

NOTE: As a series of factors will influence the actual performance of the glove, a final selection must be based on detailed observation. -

* Where the glove is to be used on a short term, casual or infrequent basis, factors such as "feel" or convenience (e.g. disposability), may dictate a choice of gloves which might otherwise be unsuitable following long-term or frequent use. A qualified practitioner should be consulted.

Ansell Glove Selection

Glove — In order of recommendation
AlphaTec® 15-554
AlphaTec® Solvex® 37-185
AlphaTec® 38-612
TouchNTuff® 93-700
AlphaTec® 58-008
AlphaTec® 58-530B
AlphaTec® 58-530W
AlphaTec® 58-735
AlphaTec® 79-700
AlphaTec® Solvex® 37-675

The suggested gloves for use should be confirmed with the glove supplier.

149:2001, ANSI Z88 or national equivalent)

Selection of the Class and Type of respirator will depend upon the level of breathing zone contaminant and the chemical nature of the contaminant. Protection Factors (defined as the ratio of contaminant outside and inside the mask) may also be important.

Required minimum protection factor	Maximum gas/vapour concentration present in air p.p.m. (by volume)	Half-face Respirator	Full-Face Respirator
up to 10	1000	A-AUS / Class1	-
up to 50	1000	-	A-AUS / Class 1
up to 50	5000	Airline *	-
up to 100	5000	-	A-2
up to 100	10000	-	A-3
100+			Airline**

* - Continuous Flow ** - Continuous-flow or positive pressure demand

A(All classes) = Organic vapours, B AUS or B1 = Acid gasses, B2 = Acid gas or hydrogen cyanide(HCN), B3 = Acid gas or hydrogen cyanide(HCN), E = Sulfur dioxide(SO₂), G = Agricultural chemicals, K = Ammonia(NH₃), Hg = Mercury, NO = Oxides of nitrogen, MB = Methyl bromide, AX = Low boiling point organic compounds(below 65 degC)

- Cartridge respirators should never be used for emergency ingress or in areas of unknown vapour concentrations or oxygen content.
- The wearer must be warned to leave the contaminated area immediately on detecting any odours through the respirator. The odour may indicate that the mask is not functioning properly, that the vapour concentration is too high, or that the mask is not properly fitted. Because of these limitations, only restricted use of cartridge respirators is considered appropriate.
- Cartridge performance is affected by humidity. Cartridges should be changed after 2 hr of continuous use unless it is determined that the humidity is less than 75%, in which case, cartridges can be used for 4 hr. Used cartridges should be discarded daily, regardless of the length of time used

SECTION 9 Physical and chemical properties

Information on basic physical and chemical properties

Appearance	Clear, colourless liquid; mixes with water.		
Physical state	Liquid	Relative density (Water = 1)	1.012–1.022
Odour	Not Available	Partition coefficient n-octanol / water	Not Available
Odour threshold	Not Available	Auto-ignition temperature (°C)	Not Applicable
pH (as supplied)	Not Available	Decomposition temperature (°C)	Not Available
Melting point / freezing point (°C)	Not Available	Viscosity (mm ² /s)	Not Available
Initial boiling point and boiling range (°C)	Not Available	Molecular weight (g/mol)	Not Applicable
Flash point (°C)	Not Applicable	Taste	Not Available
Evaporation rate	Not Available	Explosive properties	Not Available
Flammability	Not Applicable	Oxidising properties	Not Available

Upper Explosive Limit (%)	Not Applicable	Surface Tension (dyn/cm or mN/m)	Not Available
Lower Explosive Limit (%)	Not Applicable	Volatile Component (%vol)	Not Available
Vapour pressure (kPa)	Not Available	Gas group	Not Available
Solubility in water	Miscible	pH as a solution (1%)	Not Available
Vapour density (Air = 1)	Not Available	VOC g/L	Not Available
Heat of Combustion (kJ/g)	Not Available	Ignition Distance (cm)	Not Available
Flame Height (cm)	Not Available	Flame Duration (s)	Not Available
Enclosed Space Ignition Time Equivalent (s/m3)	Not Available	Enclosed Space Ignition Deflagration Density (g/m3)	Not Available

SECTION 10 Stability and reactivity

Reactivity	See section 7
Chemical stability	Product is considered stable and hazardous polymerisation will not occur.
Possibility of hazardous reactions	See section 7
Conditions to avoid	See section 7
Incompatible materials	See section 7
Hazardous decomposition products	See section 5

SECTION 11 Toxicological information

Information on toxicological effects

a) Acute Toxicity	Based on available data, the classification criteria are not met.
b) Skin Irritation/Corrosion	Based on available data, the classification criteria are not met.
c) Serious Eye Damage/Irritation	Based on available data, the classification criteria are not met.
d) Respiratory or Skin sensitisation	Based on available data, the classification criteria are not met.
e) Mutagenicity	Based on available data, the classification criteria are not met.
f) Carcinogenicity	Based on available data, the classification criteria are not met.
g) Reproductivity	Based on available data, the classification criteria are not met.
h) STOT - Single Exposure	Based on available data, the classification criteria are not met.
i) STOT - Repeated Exposure	Based on available data, the classification criteria are not met.
j) Aspiration Hazard	Based on available data, the classification criteria are not met.

Inhaled	The material is not classified as causing respiratory irritation under Regulation (EC) No 1272/2008 (CLP), as amended. Nevertheless, good hygiene practice requires that exposure be kept to a minimum and that suitable control measures be implemented in an occupational setting. Not normally a hazard due to non-volatile nature of product
Ingestion	The commonest side-effects of narcotic analgesics (including morphine) are nausea, vomiting, constipation, dizziness, drowsiness, sedation, euphoria and confusion. Urination may be difficult and there may be spasm of the gastrointestinal and biliary tracts. Other symptoms include dry mouth, pin-point pupils, sweating, flushing, vertigo, slow shallow respiration, weak pulse, cyanosis, palpitations, orthostatic hypotension, hypothermia, restlessness, and mood changes. Reports of acute toxicity have also included pulmonary oedema, spasticity, occur. Larger doses may produce respiratory depression and hypotension, with circulatory failure and deepening coma. Death may occur as a result of respiratory failure. As analgesia wears off, there may be an increased sensitivity to pain. High doses may produce muscular rigidity and central nervous system depression may progress to stupor, sedation, unconsciousness, and coma. in which skeletal muscles become flaccid (although positive Babinski reflexes and muscle twitching may be present) and the pupils become breathing, apnea and cyanosis. Pulmonary oedema is relatively common. Other respiratory problems include bronchospasm and aspiration pneumonia. Peripheral vasodilation may result in flushing of the face, neck and upper thorax and fainting resulting from orthostatic hypotension. Serious effects deriving from cardiovascular system toxicity include hypertension, arrhythmias, shock, acute ventricular failure and cardiac arrest. Hypersensitivities may result from histamine-release and may produce rashes, pruritis and, on occasion, haemorrhagic urticaria. Gastrointestinal system effects produce decreased gastric motility, constipation, faecal impaction, cramping and increased muscle tone of the gastrointestinal and biliary tracts. Urinary retention and depressed urine formation have been recorded. Liver function tests may be abnormal and the liver may become enlarged and tender. Mild leukocytosis, lymphocytosis, acidosis and hypoglycaemia may also occur. Anaphylactic reactions to morphine and codeine, following injection, have been reported.

ilium Temvet 90-Day Multidose Injection

	Adverse effects associated with opioids include constipation, nausea, vomiting, urinary retention, sedation, impaired cognition, behavioral restlessness, pruritus, miosis, respiratory depression, and postural hypotension. The most common of these adverse effects include constipation, sedation, nausea, vomiting, and pruritus. Because of the distribution of opioid receptors both within and outside the nervous system, opioid analgesics produce a broad spectrum of adverse effects including dysphoria, euphoria, respiratory depression, suppression of endocrine systems, cardiovascular disorders (e.g., bradycardia), convulsion, pruritus, and miosis. Opioids can cause fatal overdose through respiratory depression, especially when combined with other sedatives such as alcohol and benzodiazepines. The material is not expected to produce harmful effects following ingestion based on the available information. However, the material may still cause adverse health effects following ingestion, particularly in individuals with pre-existing organ damage (e.g. liver or kidney impairment). Gastrointestinal discomfort may occur and may result in nausea and vomiting. In an occupational setting, ingestion of incidental quantities should be avoided, and good hygiene practices should be followed to prevent ingestion.
Skin Contact	The material is not classified as a skin irritant under Regulation (EC) No 1272/2008 (CLP), as amended. Nevertheless, good hygiene practice requires that exposure be kept to a minimum and that suitable gloves be used in an occupational setting. Contact dermatitis has been reported with morphine and other narcotic analgesics.
Eye	Although the liquid is not classified as an eye irritant under Regulation (EC) No 1272/2008 (CLP), as amended, direct contact with the eye may produce transient discomfort characterised by tearing or conjunctival redness (as with windburn).
Chronic	The product is not classified as causing specific target organ toxicity following repeated exposure under Regulation (EC) No 1272/2008 (CLP), as amended. Nevertheless, exposure by all routes should be minimised as a matter of course. Constipation is considered the most common adverse effect associated with chronic opioid use, because opioids have various GI effects such as decrease in motility, secretions, and blood flow. In addition to these, long-term use of opioid analgesia can produce tolerance and in some cases opioid-induced hyperalgesia and/or allodynia. Neuroactive agents may produce tachyphylaxis whereby a high-intensity prolonged stimulus or often-repeated stimulus may bring about a diminished response (also known as desensitization). The symptoms of chronic poisoning or addiction may not be readily apparent. Pin-point pupils and rapid mood changes may be observed on occasion and the addict is usually not socially well integrated. Drug dependence of the morphine-type results from repeated administration and is characterised by an overwhelming need to continue taking the drug or one with similar properties and by a tendency to increase the dose owing to the development of tolerance, and by psychic or physiological and physical dependence on the drug. Physical dependence on morphine-like compounds has been reported in as little as two days whilst tolerance to morphine-like actions may occur over two to three weeks of moderate therapeutic doses. Prolonged therapy or abuse may produce abnormal pulmonary function, increased body temperature, myoglobinuria and renal failure. Some physiological values may not return to normal for several months following the acute withdrawal syndrome. Abrupt withdrawal of the opiates may produce yawning, mydriasis, lachrymation, rhinorrhea, sneezing, muscle tremor, headache, weakness, sweating, anxiety, irritability, disturbed sleep or insomnia, restlessness, orgasm, anorexia, nausea, vomiting, loss of weight, diarrhoea, dehydration, leucocytosis, bone pain, abdominal and muscle cramps, increases in heart-rate, respiratory rate and blood pressure, rise in temperature and gooseflesh and vasomotor disturbance.

ilium Temvet 90-Day Multidose Injection	TOXICITY	IRRITATION
	Not Available	Not Available
buprenorphine hydrochloride	TOXICITY	IRRITATION
	Oral (Rat) LD50: >600 mg/kg ^[2]	Not Available

Legend: 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

BUPRENORPHINE HYDROCHLORIDE	Product: Oral (mouse) LD50: 260-261 mg/kg [Tasmanian Alkaloids] (Behavioural effects) Reproductive effects:- (Effects on Newborn- viability, behavioural, physical) WARNING: Abuse can lead to habituation. Subject to Federal and State Regulations. Narcotic Substance, Schedule I (UN).		
Acute Toxicity	✗	Carcinogenicity	✗
Skin Irritation/Corrosion	✗	Reproductivity	✗
Serious Eye Damage/Irritation	✗	STOT - Single Exposure	✗
Respiratory or Skin sensitisation	✗	STOT - Repeated Exposure	✗
Mutagenicity	✗	Aspiration Hazard	✗

Legend: ✗ – Data either not available or does not fill the criteria for classification
 ✓ – Data available to make classification

SECTION 12 Ecological information

Toxicity

ilium Temvet 90-Day Multidose Injection	Endpoint	Test Duration (hr)	Species	Value	Source
	Not Available	Not Available	Not Available	Not Available	Not Available
buprenorphine hydrochloride	Endpoint	Test Duration (hr)	Species	Value	Source
	Not Available	Not Available	Not Available	Not Available	Not Available
Legend: Extracted from 1. IUCLID Toxicity Data 2. Europe ECHA Registered Substances - Ecotoxicological Information - Aquatic Toxicity 3. US EPA, Ecotox database - Aquatic Toxicity Data 4. ECETOC Aquatic Hazard Assessment Data 5. NITE (Japan) - Bioconcentration Data 6. METI (Japan) - Bioconcentration Data 7. Vendor Data 8. User defined data					

DO NOT discharge into sewer or waterways.

Persistence and degradability

Ingredient	Persistence: Water/Soil	Persistence: Air
	No Data available for all ingredients	No Data available for all ingredients

Bioaccumulative potential

Ingredient	Bioaccumulation
	No Data available for all ingredients

Mobility in soil

Ingredient	Mobility
	No Data available for all ingredients

SECTION 13 Disposal considerations

Waste treatment methods

Product / Packaging disposal	Valuable substance, 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, state and/ or territory. Each user must refer to laws operating in their area. In some areas, certain wastes must be tracked. A Hierarchy of Controls seems to be common - the user should investigate: - Reduction - Reuse - Recycling - Disposal (if all else fails) This material may be recycled if unused, or if it has not been contaminated so as to make it unsuitable for its intended use. If it has been contaminated, it may be possible to reclaim the product by filtration, distillation or some other means. Shelf life considerations should also be applied in making decisions of this type. Note that properties of a material may change in use, and recycling or reuse may not always be appropriate. DO NOT allow wash water from cleaning or process equipment to enter drains. - It may be necessary to collect all wash water for treatment before disposal. - In all cases disposal to sewer may be subject to local laws and regulations and these should be considered first. - Where in doubt contact the responsible authority. - Recycle wherever possible. - Consult manufacturer for recycling options or consult local or regional waste management authority for disposal if no suitable treatment or disposal facility can be identified. - Dispose of by: burial in a land-fill specifically licensed to accept chemical and / or pharmaceutical wastes or incineration in a licensed apparatus (after admixture with suitable combustible material). - Decontaminate empty containers. Observe all label safeguards until containers are cleaned and destroyed.

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

14.7. Maritime transport in bulk according to IMO instruments

14.7.1. Transport in bulk according to Annex II of MARPOL and the IBC code

Not Applicable

14.7.2. Transport in bulk in accordance with MARPOL Annex V and the IMSBC Code

Product name	Group
buprenorphine hydrochloride	Not Applicable

14.7.3. Transport in bulk in accordance with the IGC Code

Product name	Ship Type
buprenorphine hydrochloride	Not Applicable

SECTION 15 Regulatory information

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

buprenorphine hydrochloride is found on the following regulatory lists

Australia Chemicals with non-industrial uses removed from the Australian Inventory of Chemical Substances (old Inventory)
Australia Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) - Schedule 8

Additional Regulatory Information

Not Applicable

National Inventory Status

National Inventory	Status
Australia - AIIC / Australia Non-Industrial Use	Yes
Canada - DSL	No (buprenorphine hydrochloride)
Canada - NDSL	No (buprenorphine hydrochloride)
China - IECSC	No (buprenorphine hydrochloride)
Europe - EINEC / ELINCS / NLP	Yes
Japan - ENCS	No (buprenorphine hydrochloride)
Korea - KECI	No (buprenorphine hydrochloride)
New Zealand - NZIoC	Yes
Philippines - PICCS	No (buprenorphine hydrochloride)
USA - TSCA	No (buprenorphine hydrochloride)
Taiwan - TCSI	Yes
Mexico - INSQ	Yes
Vietnam - NCI	No (buprenorphine hydrochloride)
Russia - FBEPH	No (buprenorphine hydrochloride)
UAE - Control List (Banned/Restricted Substances)	No (buprenorphine hydrochloride)
Legend:	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

Revision Date	18/09/2026
Initial Date	08/09/2026

SDS Version Summary

Version	Date of Update	Sections Updated
3.1	18/09/2026	Hazards identification - Classification

Other information

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
- ▶ PC - STEL: Permissible Concentration-Short Term Exposure Limit
- ▶ IARC: International Agency for Research on Cancer
- ▶ ACGIH: American Conference of Governmental Industrial Hygienists
- ▶ STEL: Short Term Exposure Limit
- ▶ TEEL: Temporary Emergency Exposure Limit,
- ▶ IDLH: Immediately Dangerous to Life or Health Concentrations
- ▶ ES: Exposure Standard
- ▶ OSF: Odour Safety Factor
- ▶ NOAEL: No Observed Adverse Effect Level
- ▶ LOAEL: Lowest Observed Adverse Effect Level
- ▶ TLV: Threshold Limit Value
- ▶ LOD: Limit Of Detection
- ▶ OTV: Odour Threshold Value
- ▶ BCF: BioConcentration Factors
- ▶ BEI: Biological Exposure Index
- ▶ DNEL: Derived No-Effect Level
- ▶ PNEC: Predicted no-effect concentration
- ▶ MARPOL: International Convention for the Prevention of Pollution from Ships
- ▶ IMSBC: International Maritime Solid Bulk Cargoes Code
- ▶ IGC: International Gas Carrier Code
- ▶ IBC: International Bulk Chemical Code

- ▶ AIC: Australian Inventory of Industrial Chemicals
- ▶ DSL: Domestic Substances List
- ▶ NDSL: Non-Domestic Substances List
- ▶ IECSC: Inventory of Existing Chemical Substance in China
- ▶ EINECS: European INventory of Existing Commercial chemical Substances
- ▶ ELINCS: European List of Notified Chemical Substances
- ▶ NLP: No-Longer Polymers
- ▶ ENCS: Existing and New Chemical Substances Inventory
- ▶ KECI: Korea Existing Chemicals Inventory
- ▶ NZIoC: New Zealand Inventory of Chemicals
- ▶ PICCS: Philippine Inventory of Chemicals and Chemical Substances
- ▶ TSCA: Toxic Substances Control Act
- ▶ TCSI: Taiwan Chemical Substance Inventory
- ▶ INSQ: Inventario Nacional de Sustancias Químicas
- ▶ NCI: National Chemical Inventory
- ▶ FBEPH: Russian Register of Potentially Hazardous Chemical and Biological Substances

This document is copyright.

Apart from any fair dealing for the purposes of private study, research, review or criticism, as permitted under the Copyright Act, no part may be reproduced by any process without written permission from CHEMWATCH.

TEL (+61 3) 9572 4700.