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Droleptan®, Droperidol 2.5mg in 1ml, Injection

Phebra Pty Ltd

Chemwatch Hazard Alert Code: **1**

Chemwatch: **24-8048**
Version No: **3.1**
Safety Data Sheet according to WHS Regulations (Hazardous Chemicals) Amendment 2020 and ADG requirements

Issue Date: **01/11/2019**
Print Date: **08/09/2022**
S.GHS.AUS.EN.E

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

Product Identifier

Product name	Droleptan®, Droperidol 2.5mg in 1ml, Injection
Chemical Name	Not Applicable
Synonyms	Not Available
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	ANAESTHESIA DROLEPTAN® INJECTION is indicated to produce tranquillisation and to reduce the incidence of nausea and vomiting in surgical and diagnostic procedures; for premedication, induction, and as an adjunct in the maintenance of general and regional anaesthesia; in neuroleptanalgesia in which DROLEPTAN® INJECTION is given concurrently with a narcotic analgesic, to aid in producing tranquillity and decreasing anxiety and pain. PSYCHIATRY The management of severe agitation, hyperactivity, or aggressiveness in psychotic disorders, including schizophrenic reaction and the manic type of manic depressive illness, or in disturbed states, such as some types of acute brain syndrome and in nonpsychotic acute excitation states.

Details of the manufacturer or supplier of the safety data sheet

Registered company name	**Phebra**
Address	17-19 Orion Road Lane Cove West NSW 2066 Australia
Telephone	+61 2 9420 9199|1800 720 020
Fax	+61 2 9420 9177
Website	www.phebra.com
Email	msds@phebra.com

Emergency telephone number

Association / Organisation	**Phebra**
Emergency telephone numbers	+61 401 264 004
Other emergency telephone numbers	N/A

SECTION 2 Hazards identification

Classification of the substance or mixture

HAZARDOUS CHEMICAL. NON-DANGEROUS GOODS. According to the WHS Regulations and the ADG Code.

ChemWatch Hazard Ratings

	Min	Max
Flammability	0	
Toxicity	1	
Body Contact	1	
Reactivity	0	
Chronic	0	

0 = Minimum
1 = Low
2 = Moderate
3 = High
4 = Extreme

Poisons Schedule	S4
Classification [1]	Serious Eye Damage/Eye Irritation Category 2B
Legend:	*1. Classified by Chemwatch; 2. Classification drawn from HCIS; 3. Classification drawn from Regulation (EU) No 1272/2008 - Annex VI*

Page 1 continued...

Label elements

Hazard pictogram(s)	Not Applicable
Signal word	**Warning**

Hazard statement(s)

H320	Causes eye irritation.

Precautionary statement(s) Prevention

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.
P337+P313	If eye irritation persists: Get medical advice/attention.

Precautionary statement(s) Storage

Not Applicable

Precautionary statement(s) Disposal

Not Applicable

SECTION 3 Composition / information on ingredients

Substances

See section below for composition of Mixtures

Mixtures

CAS No	%[weight]	Name
69-65-8	<5	mannitol
548-73-2	0-1	droperidol
87-69-4	0-1	tartaric acid
7732-18-5	>90	water
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 the eyes: ▸ 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	If skin contact occurs: ▸ 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, aerosols or combustion products are inhaled remove from contaminated area. ▸ Other measures are usually unnecessary. If you feel unwell contact Doctor or Poisons Information Centre. (Show the label if possible).
Ingestion	▸ 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. ▸ Seek medical advice.

Indication of any immediate medical attention and special treatment needed

Treat symptomatically.
Neuroleptic malignant syndrome (NMS) is a life-threatening idiosyncratic reaction to antipsychotic drugs characterized by fever, altered mental status, muscle rigidity, and autonomic dysfunction. It has been associated with virtually all neuroleptics, including newer atypical antipsychotics, as well as a variety of other medications that affect central dopaminergic neurotransmission. Although uncommon, NMS remains a critical consideration in the differential diagnosis of patients presenting with fever and mental status changes because it requires prompt recognition to prevent significant morbidity and death. Treatment includes immediately stopping the offending agent and implementing supportive measures, as well as pharmacological interventions in more severe cases. Maintaining vigilant awareness of the clinical features of NMS to diagnose and treat the disorder early, however, remains the most important strategy by which physicians can keep mortality rates low and improve patient outcomes.
Neuroleptic malignant syndrome in hospitalized patients is considered a neurologic emergency as a delay in treatment or withholding of therapeutic measures can potentially lead to serious morbidity or death. As such, some consider it prudent to treat for NMS even if there is doubt about the diagnosis
The management of NMS (Neuroleptic Malignant syndrome) should include:
· immediate discontinuation of antipsychotic drugs and other drugs not essential to concurrent therapy;
· intensive symptomatic treatment and medical monitoring and
· treatment of any concomitant serious medical problems for which specific treatments are available.
· There is no general agreement about specific pharmacological regimes for NMS.

Continued...

The key step in the management of NMS is the initiation of supportive medical therapy. Aggressive hydration is often required, especially if highly elevated CPK levels threaten to damage the kidneys, and treatment of hyperthermia with cooling blankets or ice packs to the axillae and groin may be needed. Metabolic abnormalities may need to be corrected, and bicarbonate loading should be considered in some cases as it may be beneficial in preventing renal failure.
Patients with NMS may be at increased risk of morbidity due to renal failure and disseminated intravascular coagulation (DIC) secondary to rhabdomyolysis, deep venous thrombosis and pulmonary embolism resulting from dehydration and immobilization, aspiration pneumonia because of difficulty swallowing combined with an altered mental status, as well as other medical complications including cardiopulmonary failure, seizures, arrhythmias, myocardial infarction, and sepsis, and so many cases require intensive care monitoring and support.
The use of neuroleptic agents has been associated with a variety of adverse motor effects including parkinsonism, acute dystonia, acute akathisia, tremor, and tardive dyskinesia, and several other classes of drugs at toxic levels may cause symptoms resembling NMS such as serotinergic agents, anticholinergics, monoamine oxidase inhibitors, tricyclics and lithium (as examples.
The underlying pathophysiologic mechanisms of NMS are complex and elements still debated among experts, but most agree that a marked and sudden reduction in central dopaminergic activity resulting from D2 dopamine receptor blockade within the nigrostriatal, hypothalamic, and mesolimbic/cortical pathways helps explain the clinical features of NMS including rigidity, hyperthermia, and altered mental status, respectively. D2 dopamine receptor antagonism, however, does not explain all the presenting signs and symptoms of NMS, nor does it explain its occurrence with antipsychotic medications with lower D2 activity and medications without known antidopaminergic activity.
Following recent ingestion of an overdose of phenothiazine sedatives, the stomach should be emptied by gastric lavage, and aspiration. Management should include intensive symptomatic, and supportive therapy. In particular attention should be paid to the maintenance of respiratory and renal function and to the maintenance of electrolyte balance.
Phenothiazine-induced hypotension should **NOT** be managed with adrenalin or other sympathomimetics with beta-adrenergic agonist properties since the alpha-blocking effects of phenothiazines impair vasoconstriction and these agents may exacerbate hypotension. MARTINDALE: The Extra Pharmacopoeia, 29th Edition.
Phenothiazines are contraindicated in severe central nervous system depression or comatose states from any cause including drug induced central nervous system depression.. It should also be noted that hypertensive or hypotensive heart disease of extreme degree is a contraindication of phenothiazine administration.
In overdose:
Primarily involvement of the extrapyramidal mechanism produce certain dystonic reactions.
Signs and Symptoms

· Effects and clinical complications of acute overdose involving phenothiazines may include:
· Cardiovascular: Cardiac arrhythmias, hypotension, shock, ECG changes, increased QT and PR intervals, non-specific ST and T wave changes, bradycardia, sinus tachycardia, atrioventricular block, ventricular tachycardia, ventricular fibrillation, Torsade de pointes, myocardial depression.
· Central Nervous System: Sedation, extrapyramidal effects, confusion, agitation, hypothermia, hyperthermia, restlessness, seizures, areflexia, coma.
· Autonomic Nervous System: Mydriasis, miosis, dry skin, dry mouth, nasal congestion, urinary retention, blurred vision.
· Respiratory: Respiratory depression, apnea, pulmonary edema.
· Gastrointestinal: Hypomotility, constipation, ileus.
· Renal: Oliguria, uremia.
· Toxic dose and blood concentration ranges for the phenothiazines have not been firmly established.

Treatment

· An airway must be established and maintained. Adequate oxygenation and ventilation must be ensured.
· Cardiovascular monitoring should commence immediately and should include continuous electrocardiographic monitoring to detect possible arrhythmias. Treatment may include one or more of the following therapeutic interventions: correction of electrolyte abnormalities and acid-base balance, lidocaine, phenytoin, isoproterenol, ventricular pacing, and defibrillation. Disopyramide, procainamide, and quinidine may produce additive QT-prolonging effects when administered to patients with acute overdosage). Caution must be exercised when administering lidocaine, as it may increase the risk of developing seizures.
· Treatment of hypotension may require intravenous fluids and vasopressors. Phenylephrine, levarterenol, or metaraminol are the appropriate pressor agents for use in the management of refractory hypotension. The potent a adrenergic blocking properties of the phenothiazines makes the use of vasopressors with mixed alpha and beta adrenergic agonist properties inappropriate, including epinephrine and dopamine. Paradoxical vasodilation may result.
· In managing overdosage, the physician should always consider the possibility of multiple drug involvement. Gastric lavage and repeated doses of activated charcoal should be considered. Induction of emesis is less preferable to gastric lavage because of the risk of dystonia and the potential for aspiration of vomitus. Emesis should not be induced in patients expected to deteriorate rapidly, or those with impaired consciousness.
· Acute extrapyramidal symptoms may be treated with diphenhydramine hydrochloride or benztropine mesylate.
· Avoid the use of barbiturates when treating seizures, as they may potentiate phenothiazine-induced respiratory depression.
· Forced diuresis, hemoperfusion, hemodialysis and manipulation of urine pH are of unlikely benefit in the treatment of phenothiazine overdose due to their large volume of distribution and extensive plasma protein binding.
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· Forced diuresis, hemoperfusion, hemodialysis and manipulation of urine pH are of unlikely benefit in the treatment of phenothiazine overdose due to their large volume of distribution and extensive plasma protein binding.
· Treatment is essentially symptomatic and supportive.
· Early gastric lavage is helpful.
· Keep patient under observation and maintain an open airway, since involvement of the extrapyramidal mechanism may produce dysphagia and respiratory difficulty in severe overdosage.
· Do not attempt to induce emesis because a dystonic reaction of the head or neck may develop that could result in aspiration of vomitus.
· Extrapyramidal symptoms may be treated with anti-parkinsonism drugs, barbiturates or Benadryl. Care should be taken to avoid increasing respiratory depression.
· If administration of a stimulant is desirable, amphetamine, dextroamphetamine or caffeine with sodium benzoate is recommended. Stimulants that may cause convulsions (e.g., picrotoxin or pentylenetetrazol) should be avoided.
· If hypotension occurs, the standard measures for managing circulatory shock should be initiated. If it is desirable to administer a vasoconstrictor, Levophed and Neo-Synephrine are most suitable. Other pressor agents, including epinephrine, are not recommended because phenothiazine derivatives may reverse the usual elevating action of these agents and cause a further lowering of blood pressure.
· Limited experience indicates that phenothiazines are not dialyzable.

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.

Continued...

Special hazards arising from the substrate 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 (CO_2) other pyrolysis products typical of burning organic material. May emit poisonous fumes. May emit corrosive fumes.
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	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.

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

SECTION 7 Handling and storage

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.
Other information	▸ Store in original containers. ▸ Keep containers securely sealed. ▸ Store in a cool, dry, well-ventilated area. ▸ Store away from incompatible materials and foodstuff containers. ▸ Protect containers against physical damage and check regularly for leaks. ▸ Observe manufacturer's storage and handling recommendations contained within this SDS.

Conditions for safe storage, including any incompatibilities

Suitable container	amber glass ampoule ▸ Glass container is suitable for laboratory quantities ▸ Polyethylene or polypropylene container. ▸ Packing as recommended by manufacturer. ▸ Check all containers are clearly labelled and free from leaks.

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Storage incompatibility	None known

SECTION 8 Exposure controls / personal protection

Control parameters

Occupational Exposure Limits (OEL)

INGREDIENT DATA

Not Available

Emergency Limits

Ingredient	TEEL-1	TEEL-2	TEEL-3
tartaric acid	1.6 mg/m3	17 mg/m3	100 mg/m3

Ingredient	Original IDLH	Revised IDLH
mannitol	Not Available	Not Available
droperidol	Not Available	Not Available
tartaric acid	Not Available	Not Available
water	Not Available	Not Available

Occupational Exposure Banding

Ingredient	Occupational Exposure Band Rating	Occupational Exposure Band Limit
droperidol	E	≤ 0.01 mg/m³
tartaric acid	E	≤ 0.01 mg/m³
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.*	

Exposure controls

Appropriate engineering controls	Engineering controls are used to remove a hazard or place a barrier between the worker and the hazard. Well-designed engineering controls can be highly effective in protecting workers and will typically be independent of worker interactions to provide this high level of protection. The basic types of engineering controls are: Process controls which involve changing the way a job activity or process is done to reduce the risk. Enclosure and/or isolation of emission source which keeps a selected hazard "physically" away from the worker and ventilation that strategically "adds" and "removes" air in the work environment. Ventilation can remove or dilute an air contaminant if designed properly. The design of a ventilation system must match the particular process and chemical or contaminant in use. Employers may need to use multiple types of controls to prevent employee overexposure. General exhaust is adequate under normal operating conditions.
Personal protection	
Eye and face protection	▸ Safety glasses with side shields. ▸ Chemical goggles. ▸ 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.
Skin protection	See Hand protection below
Hands/feet protection	▸ Wear chemical protective gloves, e.g. PVC. ▸ Wear safety footwear or safety gumboots, e.g. Rubber 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.
Body protection	See Other protection below
Other protection	▸ Overalls. ▸ P.V.C apron. ▸ Barrier cream. ▸ Skin cleansing cream. ▸ Eye wash unit.

Recommended material(s)

GLOVE SELECTION INDEX

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:

Respiratory protection

- 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

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Droleptan®, Droperidol 2.5mg in 1ml, Injection

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

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. Droleptan injection is an aqueous solution of 1mL in an amber glass ampoule.

Physical state	Liquid	**Relative density (Water = 1)**	Not Available
Odour	Not Available	**Partition coefficient n-octanol / water**	Not Available
Odour threshold	Not Available	**Auto-ignition temperature (°C)**	Not Available
pH (as supplied)	3.0-3.8	**Decomposition temperature (°C)**	Not Available
Melting point / freezing point (°C)	Not Available	**Viscosity (cSt)**	Not Available
Initial boiling point and boiling range (°C)	Not Available	**Molecular weight (g/mol)**	Not Applicable
Flash point (°C)	Not Available	**Taste**	Not Available
Evaporation rate	Not Available	**Explosive properties**	Not Available
Flammability	Not Available	**Oxidising properties**	Not Available
Upper Explosive Limit (%)	Not Available	**Surface Tension (dyn/cm or mN/m)**	Not Available
Lower Explosive Limit (%)	Not Available	**Volatile Component (%vol)**	Not Available
Vapour pressure (kPa)	Not Available	**Gas group**	Not Available
Solubility in water	Miscible	**pH as a solution (Not Available%)**	Not Available
Vapour density (Air = 1)	Not Available	**VOC g/L**	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 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

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. Antipsychotics or neuroleptics are a group of drugs used to treat psychosis (including schizophrenia). Psychoses (in particular schizophrenia) are very complex diseases involving positive symptoms (hallucinations, delusions, inappropriate behaviour, aggressiveness) and negative symptoms (reduced speech and expression, indifference, carelessness). Antipsychotics improve these symptoms, especially the former. It affects a number of receptors in the brain. Side effects, which are often specific to the individual drug, include sedation, drowsiness, confusion, apathy and depression, increased production of saliva, increased susceptibility to seizures, constipation, low blood pressure on standing up, heartbeat disturbances, high prolactin levels (causing unwanted milk production, breast development in males, loss of periods in women, loss of

Continued...

	sex drive and impotence), weight gain (especially with the atypical agents), extremely low white cell count, tardive dyskinesia (involuntary repetitive writhing movements), akathisia (restlessness), and worsening of psychiatric symptoms. Sufficiently high doses may affect short-term memory. All antipsychotic drugs block dopamine receptors and this appears to be the main mechanism of their effect. Antipsychotics do not cause psychological addiction.
Skin Contact	Open cuts, abraded or irritated skin should not be exposed to this material Entry into the blood-stream, through, for example, cuts, abrasions or lesions, may produce systemic injury with harmful effects. Examine the skin prior to the use of the material and ensure that any external damage is suitably protected. Irritation and skin reactions are possible with sensitive skin
Eye	There is some evidence to suggest that this material can cause eye irritation and damage in some persons.
Chronic	Substance accumulation, in the human body, may occur and may cause some concern following repeated or long-term occupational exposure. An increase in the incidence of breast and pancreas cancer may be common adverse effects of dopamine antagonists. Antipsychotic drugs have been shown, in animal experiments, to increase the rate of breast tumours. However, the relevance of this in humans is not known.

Droleptan®, Droperidol 2.5mg in 1ml, Injection	**TOXICITY**	**IRRITATION**
	Not Available	Not Available
mannitol	**TOXICITY**	**IRRITATION**
	Oral (Rat) LD50; 13500 mg/kg[2]	Not Available
droperidol	**TOXICITY**	**IRRITATION**
	Oral (Rat) LD50; 750 mg/kg[2]	Not Available
tartaric acid	**TOXICITY**	**IRRITATION**
	dermal (rat) LD50: >2000 mg/kg[1]	Not Available
	Oral (Rat) LD50; >=2000<=5000 mg/kg[1]	
water	**TOXICITY**	**IRRITATION**
	Oral (Rat) LD50; >90000 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*	

DROPERIDOL	Oral (human) TDLo: 0.223 mg/kg/12d - I Nil reported Wakefulness, tremor, muscle weakness, coma, convulsions, dyspnea, somnolence, convulsions recorded. Although atypical antipsychotics (also known as second generation antipsychotics) are thought to be safer than typical antipsychotics, they still have severe side effects, including tardive dyskinesia (a serious movement disorder), neuroleptic malignant syndrome, and increased risk of stroke, sudden cardiac death, blood clots, and diabetes. Significant weight gain may occur. Critics have argued that "the time has come to abandon the terms first-generation and second-generation antipsychotics, as they do not merit this distinction". Extrapyramidal and/or withdrawal symptoms, including agitation, hypertonia, hypotonia, tremour, somnolence, respiratory distress and feeding disorder have been reported in neonates who were exposed to antipsychotic drugs during the third trimester of pregnancy. These symptoms have varied in severity. Some neonates recovered within hours or days without specific treatment; others required prolonged hospitalization. Monitor neonates for extrapyramidal and/or withdrawal symptoms and manage symptoms appropriately. There are published reports of sedation, failure to thrive, jitteriness, and extrapyramidal symptoms (tremors and abnormal muscle movements) in breastfed infants exposed to antipsychotics Symptoms of dystonia, prolonged abnormal contractions of muscle groups, may occur in susceptible individuals during the first few days of treatment. Dystonic symptoms include: spasm of the neck muscles, sometimes progressing to tightness of the throat, swallowing difficulty, difficulty breathing, and/or protrusion of the tongue. Although these symptoms can occur at low doses, they occur more frequently and with greater severity with high potency and higher doses of first-generation antipsychotic drugs. An elevated risk of acute dystonia is observed in males and younger age groups. Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. Dopamine receptors are implicated in many neurological processes, including motivation, pleasure, cognition, memory, learning, and fine motor control, as well as modulation of neuroendocrine signaling. Abnormal dopamine receptor signaling and dopaminergic nerve function is implicated in several neuropsychiatric disorders.Thus, dopamine receptors are common neurologic drug targets; antipsychotics are often dopamine receptor antagonists while psychostimulants are typically indirect agonists of dopamine receptors. The neurotransmitter dopamine is the primary endogenous ligand for dopamine receptors Dopamine receptors are a class of G protein-coupled receptors that are prominent in the vertebrate central nervous system (CNS). Dopamine receptors activate different effectors through not only G-protein coupling, but also signaling through different protein (dopamine receptor-interacting proteins) interactions. For G-protein inhibitors:/ antagonists/ modulators. G protein-coupled receptors (GPCRs) are essential cell membrane signaling molecules and represent the most important class of drug targets. Some signaling pathways downstream of a GPCR may be responsible for drug adverse effects, while others mediate therapeutic efficacy. Biased ligands preferentially activate only a subset of all GPCR signaling pathways. They hold great potential to become next-generation GPCR drugs with less side effects due to their potential to exclusively activate desired signaling pathways. GPCR ligands include odorants, tastants, and neurotransmitters, and vary in size and properties. Dramatic chemical diversity may occur even among ligands of the same receptor. Chemical variability of antagonists significantly correlates with the binding site hydrophobicity and anti-correlates with the number of hydrogen bond donors in the binding site. The number of disulfide bridges in the extracellular region of a receptor anti-correlates with the range of molecular weights of its antagonists, highlighting the role of the entrance pathway in determining the size selectivity for GPCR antagonists.
TARTARIC ACID	Convulsions, haemorrhage recorded. For simple alpha-hydroxy carbolic acids and their salts: Experimental data available for members of this group shows that they have low acute, repeat-dose, reproductive and developmental toxicity. They are eye and skin irritants, but are not expected to be skin sensitisers. Testing shows they have little or no potential to cause mutations or cancer.
Droleptan®, Droperidol 2.5mg in 1ml, Injection & WATER	No significant acute toxicological data identified in literature search.

Continued...

Droleptan®, Droperidol 2.5mg in 1ml, Injection & TARTARIC ACID	Asthma-like symptoms may continue for months or even years after exposure to the material ends. This may be due to a non-allergic condition known as reactive airways dysfunction syndrome (RADS) which can occur after exposure to high levels of highly irritating compound. Main criteria for diagnosing RADS include the absence of previous airways disease in a non-atopic individual, with sudden onset of persistent asthma-like symptoms within minutes to hours of a documented exposure to the irritant. Other criteria for diagnosis of RADS include a reversible airflow pattern on lung function tests, moderate to severe bronchial hyperreactivity on methacholine challenge testing, and the lack of minimal lymphocytic inflammation, without eosinophilia. RADS (or asthma) following an irritating inhalation is an infrequent disorder with rates related to the concentration of and duration of exposure to the irritating substance. On the other hand, industrial bronchitis is a disorder that occurs as a result of exposure due to high concentrations of irritating substance (often particles) and is completely reversible after exposure ceases. The disorder is characterized by difficulty breathing, cough and mucus production.

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

Droleptan®, Droperidol 2.5mg in 1ml, Injection

Endpoint	Test Duration (hr)	Species	Value	Source
Not Available	Not Available	Not Available	Not Available	Not Available

mannitol

Endpoint	Test Duration (hr)	Species	Value	Source
EC10(ECx)	168h	Algae or other aquatic plants	4773.64mg/L	4

droperidol

Endpoint	Test Duration (hr)	Species	Value	Source
Not Available	Not Available	Not Available	Not Available	Not Available

tartaric acid

Endpoint	Test Duration (hr)	Species	Value	Source
NOEC(ECx)	72h	Algae or other aquatic plants	3.125mg/l	2
EC50	72h	Algae or other aquatic plants	51.404mg/l	2
EC50	48h	Crustacea	93.313mg/l	2
LC50	96h	Fish	>100mg/l	2
EC50	96h	Algae or other aquatic plants	23616mg/L	2

water

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 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.

Persistence and degradability

Ingredient	Persistence: Water/Soil	Persistence: Air
mannitol	LOW	LOW
droperidol	HIGH	HIGH
tartaric acid	LOW	LOW
water	LOW	LOW

Bioaccumulative potential

Ingredient	Bioaccumulation
mannitol	LOW (LogKOW = -3.0108)
droperidol	LOW (LogKOW = 3.5)
tartaric acid	LOW (LogKOW = -1.0017)

Mobility in soil

Ingredient	Mobility
mannitol	LOW (KOC = 10)
droperidol	LOW (KOC = 26220)
tartaric acid	HIGH (KOC = 1)

Continued...

SECTION 13 Disposal considerations

Waste treatment methods

Product / Packaging disposal	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

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
mannitol	Not Available
droperidol	Not Available
tartaric acid	Not Available
water	Not Available

Transport in bulk in accordance with the ICG Code

Product name	Ship Type
mannitol	Not Available
droperidol	Not Available
tartaric acid	Not Available
water	Not Available

SECTION 15 Regulatory information

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

mannitol is found on the following regulatory lists

Australian Inventory of Industrial Chemicals (AIIC)

droperidol 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 4
FEI Equine Prohibited Substances List - Banned Substances
FEI Equine Prohibited Substances List (EPSL)

tartaric acid is found on the following regulatory lists

Australian Inventory of Industrial Chemicals (AIIC)

water is found on the following regulatory lists

Australian Inventory of Industrial Chemicals (AIIC)

National Inventory Status

Continued...

National Inventory	Status
Australia - AIIC / Australia Non-Industrial Use	Yes
Canada - DSL	No (droperidol)
Canada - NDSL	No (mannitol; droperidol; tartaric acid; water)
China - IECSC	No (droperidol)
Europe - EINEC / ELINCS / NLP	Yes
Japan - ENCS	No (droperidol)
Korea - KECI	No (droperidol)
New Zealand - NZIoC	No (droperidol)
Philippines - PICCS	No (droperidol)
USA - TSCA	No (droperidol)
Taiwan - TCSI	Yes
Mexico - INSQ	No (droperidol)
Vietnam - NCI	No (droperidol)
Russia - FBEPH	No (droperidol)
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	01/11/2019
Initial Date	01/11/2009

SDS Version Summary

Version	Date of Update	Sections Updated
2.1	13/09/2010	First Aid (inhaled), Ingredients
3.1	01/11/2019	One-off system update. NOTE: This may or may not change the GHS 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
AIIC: 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

Continued...