



Tapentadol hydrochloride solution

Novachem Pty Ltd

Version No: 3.3

Safety Data Sheet according to WHS Regulations (Hazardous Chemicals) Amendment 2020 and ADG requirements

Chemwatch Hazard Alert Code: 4

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S.GHS.AUS.EN

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

Product Identifier

Product name	Tapentadol hydrochloride solution
Synonyms	T-058-1ML
Proper shipping name	METHANOL
Other means of identification	T-058

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

Relevant identified uses	Laboratory chemicals, Synthesis of substances
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Details of the manufacturer or supplier of the safety data sheet

Registered company name	Novachem Pty Ltd	Novachem Pty Ltd
Address	25 Crissane Road, Heidelberg West Victoria 3081 Australia	25 Crissane Road, Heidelberg West Victoria 3081 Australia
Telephone	+61384151255	+61384151255
Fax	+61386250088	+61386250088
Website	www.novachem.com.au	www.novachem.com.au
Email	novachem@novachem.com.au	novachem@novachem.com.au

Emergency telephone number

Association / Organisation	Victorian Poisons Information Centre	Victorian Poisons Information Centre
Emergency telephone numbers	13 11 26	13 11 26
Other emergency telephone numbers	Not Available	Not Available

SECTION 2 Hazards identification

Classification of the substance or mixture

Poisons Schedule	Not Applicable
Classification [1]	Flammable Liquids Category 2, Acute Toxicity (Oral) Category 3, Acute Toxicity (Dermal) Category 3, Serious Eye Damage/Eye Irritation Category 2B, Acute Toxicity (Inhalation) Category 3, Reproductive Toxicity Category 1B, Specific Target Organ Toxicity - Single Exposure Category 1, Specific Target Organ Toxicity - Repeated Exposure Category 2
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)	
Signal word	Danger

Hazard statement(s)

H225	Highly flammable liquid and vapour.
H301	Toxic if swallowed.
H311	Toxic in contact with skin.
H320	Causes eye irritation.
H331	Toxic if inhaled.

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H360D	May damage the unborn child.
H370	Causes damage to organs.
H373	May cause damage to organs through prolonged or repeated exposure.

Precautionary statement(s) Prevention

P201	Obtain special instructions before use.
P210	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P260	Do not breathe mist/vapours/spray.
P264	Wash all exposed external body areas thoroughly after handling.

Precautionary statement(s) Response

P301+P310	IF SWALLOWED: Immediately call a POISON CENTER/doctor/physician/first aider.
P308+P311	IF exposed or concerned: Call a POISON CENTER/doctor/physician/first aider.
P330	Rinse mouth.
P370+P378	In case of fire: Use alcohol resistant foam or normal protein foam to extinguish.

Precautionary statement(s) Storage

P403+P235	Store in a well-ventilated place. Keep cool.
P405	Store locked up.

Precautionary statement(s) Disposal

P501	Dispose of contents/container to authorised hazardous or special waste collection point in accordance with any local regulation.
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SECTION 3 Composition / information on ingredients

Substances

See section below for composition of Mixtures

Mixtures

CAS No	%[weight]	Name
67-56-1	99.9	<u>methanol</u>
175591-09-0	0.1	<u>tapentadol hydrochloride</u>
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	<p>If this product comes in contact with the eyes:</p> <ul style="list-style-type: none">▶ Immediately hold eyelids apart and flush the eye continuously with 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.▶ Continue flushing until advised to stop by the Poisons Information Centre or a doctor, or for at least 15 minutes.▶ Transport to hospital or doctor without delay.▶ Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.
Skin Contact	<p>If skin or hair contact occurs:</p> <ul style="list-style-type: none">▶ Quickly but gently, wipe material off skin with a dry, clean cloth.▶ Immediately remove all contaminated clothing, including footwear.▶ Wash skin and hair with running water. Continue flushing with water until advised to stop by the Poisons Information Centre.▶ Transport to hospital, or doctor.
Inhalation	<ul style="list-style-type: none">▶ If fumes or combustion products are inhaled remove from contaminated area.▶ Lay patient down. Keep warm and rested.▶ Prostheses such as false teeth, which may block airway, should be removed, where possible, prior to initiating first aid procedures.▶ Apply artificial respiration if not breathing, preferably with a demand valve resuscitator, bag-valve mask device, or pocket mask as trained. Perform CPR if necessary.▶ Transport to hospital, or doctor, without delay.
Ingestion	<ul style="list-style-type: none">▶ 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.▶ Avoid giving milk or oils.▶ Avoid giving alcohol.▶ If spontaneous vomiting appears imminent or occurs, hold patient's head down, lower than their hips to help avoid possible aspiration of vomitus.

Indication of any immediate medical attention and special treatment needed

Any material aspirated during vomiting may produce lung injury. Therefore emesis should not be induced mechanically or pharmacologically. Mechanical means should be used if it is

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considered necessary to evacuate the stomach contents; these include gastric lavage after endotracheal intubation. If spontaneous vomiting has occurred after ingestion, the patient should be monitored for difficult breathing, as adverse effects of aspiration into the lungs may be delayed up to 48 hours.

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.

GOSELIN 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

For noradrenaline reuptake inhibitors (NRIs).

Recommended treatment of overdoses include activated charcoal treatment to prevent further absorption of the drug

The primary pharmacological action of the NRIs is to inhibit noradrenalin reuptake and thereby increase the concentration of noradrenalin in the synaptic cleft, and increase the stimulation of noradrenalin alpha-1, noradrenalin-alpha-2 and noradrenalin-beta receptors.

Noradrenalin may be more involved in the symptoms of anergia, fatigue and loss of drive in depression, and 5-HT may be more involved in the alteration in subjective mood and anxiety, but there is as yet no consistent evidence that a particular clinical pattern of depressive illness is more likely to benefit from an NRI than from an SSR.

Many NRIs are also monoamine oxidase inhibitors (MAOIs):

Special care should be taken with any drug therapy in view of the many hazards of monoamine oxidase inhibitor interactions. In particular metaraminol and other sympathomimetic agents are not suitable for the treatment of hypotension, which should be managed with intravenous fluids and, in severe shock, intravenous hydrocortisone

Reboxetine, is a model selective NRI antidepressant. It has a wide margin of safety and is well-tolerated at therapeutic doses. To date, reboxetine has no clinically significant drug-drug or drug-food interactions. The combination or reboxetine with other sympathomimetic agents, however, could produce synergistic hyperadrenergic effects. Although experience is limited, the clinical effects that result from reboxetine overdose are likely to be mild to moderate in severity and manifest as an exaggeration of pharmacologic effects. If they occur, toxic effects should be evident within a few hours of acute ingestion and are likely to be characterized by mydriasis, diaphoresis, anxiety, mild hypertension, sinus tachycardia, and tremor. Timely supportive care should prevent death in the overwhelming majority of patients with reboxetine poisoning

Treatment is primarily supportive and should allow for complete recovery when provided in a timely fashion for the vast majority of patients. Sinus tachycardia and asymptomatic hypertension, when present, do not require any specific treatment. When hypertension is associated with end-organ dysfunction (e.g., confusion, agitation, chest pain, electrocardiographic changes, and pulmonary edema), intravenous sodium nitroprusside or phentolamine is recommended. Phentolamine is pharmacologically attractive due to its ability to block alpha-adrenergic receptors and antagonize the effects of NE. As for other sympathomimetic intoxications, liberal doses of benzodiazepines (e.g., diazepam or lorazepam) are recommended as first-line therapy for patients with neuromuscular hyperactivity, agitation, and seizures associated with reboxetine intoxication or adverse interaction. Gastrointestinal decontamination should be initiated as soon as possible after patient stabilization. For the vast majority of patients, the administration of a single dose of activated charcoal with or without a cathartic is the preferred method of decontamination following reboxetine overdose.

For acute and short term repeated exposures to methanol:

- Toxicity results from accumulation of formaldehyde/formic acid.
- Clinical signs are usually limited to CNS, eyes and GI tract. Severe metabolic acidosis may produce dyspnea and profound systemic effects which may become intractable. All symptomatic patients should have arterial pH measured. Evaluate airway, breathing and circulation.
- Stabilise obtunded patients by giving naloxone, glucose and thiamine.
- Decontaminate with ipecac or lavage for patients presenting 2 hours post-ingestion. Charcoal does not absorb well; the usefulness of cathartic is not established.
- Forced diuresis is not effective; haemodialysis is recommended where peak methanol levels exceed 50 mg/dL (this correlates with serum bicarbonate levels below 18 mEq/L).
- Ethanol, maintained at levels between 100 and 150 mg/dL, inhibits formation of toxic metabolites and may be indicated when peak methanol levels exceed 20 mg/dL. An intravenous solution of ethanol in D5W is optimal.
- Folate, as leucovorin, may increase the oxidative removal of formic acid. 4-methylpyrazole may be an effective adjunct in the treatment. 8-Phenytoin may be preferable to diazepam for controlling seizure.

[Ellenhorn Barceloux: Medical Toxicology]

Methanol poisoning can be treated with fomepizole, or if unavailable, ethanol. Both drugs act to reduce the action of alcohol dehydrogenase on methanol by means of competitive inhibition. Ethanol, the active ingredient in alcoholic beverages, acts as a competitive inhibitor by more effectively binding and saturating the alcohol dehydrogenase enzyme in the liver, thus blocking the binding of methanol. Methanol is excreted by the kidneys without being converted into the very toxic metabolites formaldehyde and formic acid. Alcohol dehydrogenase instead enzymatically converts ethanol to acetaldehyde, a much less toxic organic molecule. Additional treatment may include sodium bicarbonate for metabolic acidosis, and hemodialysis or hemodiafiltration to remove methanol and formate from the blood. Folinic acid or folic acid is also administered to enhance the metabolism of formate.

BIOLOGICAL EXPOSURE INDEX - BEI

Determinant	Index	Sampling Time	Comment
1. Methanol in urine	15 mg/l	End of shift	B, NS
2. Formic acid in urine	80 mg/gm creatinine	Before the shift at end of workweek	B, NS

B: Background levels occur in specimens collected from subjects **NOT** exposed.

NS: Non-specific determinant - observed following exposure to other materials.

SECTION 5 Firefighting measures

Extinguishing media

Water may be an ineffective extinguishing media for methanol fires; static explosions are reported for aqueous solutions as dilute as 30%. Water may be used to cool containers.

- ▶ Alcohol stable foam.
- ▶ Dry chemical powder.
- ▶ BCF (where regulations permit).
- ▶ Carbon dioxide.

Special hazards arising from the substrate or mixture

Fire Incompatibility	▶ Avoid contamination with oxidising agents i.e. nitrates, oxidising acids, chlorine bleaches, pool chlorine etc. as ignition may result
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Advice for firefighters

Fire Fighting	<ul style="list-style-type: none"> ▶ 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.
Fire/Explosion Hazard	<ul style="list-style-type: none"> ▶ Combustible. ▶ Slight fire hazard when exposed to heat or flame. ▶ Heating may cause expansion or decomposition leading to violent rupture of containers. ▶ On combustion, may emit toxic fumes of carbon monoxide (CO). <p>Combustion products include: carbon dioxide (CO₂) formaldehyde other pyrolysis products typical of burning organic material.</p>

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	May emit poisonous fumes.
HAZCHEM	•2WE

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	<ul style="list-style-type: none"> Remove all ignition sources. Clean up all spills immediately. Avoid breathing vapours and contact with skin and eyes. Control personal contact with the substance, by using protective equipment.
Major Spills	

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

SECTION 7 Handling and storage

Precautions for safe handling

Safe handling	<ul style="list-style-type: none"> 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 allow clothing wet with material to stay in contact with skin
Other information	<p>NOTE: Special security requirements may be mandated under Federal/State Regulation(s).</p> <ul style="list-style-type: none"> 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.

Conditions for safe storage, including any incompatibilities

Suitable container	<ul style="list-style-type: none"> Packaging as recommended by manufacturer. Check that containers are clearly labelled. Tamper-proof containers. Polyethylene or polypropylene containers. Glass container is suitable for laboratory quantities <p>For low viscosity materials</p> <ul style="list-style-type: none"> Drums and jerricans must be of the non-removable head type. Where a can is to be used as an inner package, the can must have a screwed enclosure. <p>For materials with a viscosity of at least 2680 cSt. (23 deg. C) and solids (between 15 C deg. and 40 deg C.):</p> <ul style="list-style-type: none"> Removable head packaging; Cans with friction closures and low pressure tubes and cartridges <p>may be used.</p> <p>All inner and sole packagings for substances that have been assigned to Packaging Groups I or II on the basis of inhalation toxicity criteria, must be hermetically sealed.</p>
Storage incompatibility	<p>Methanol:</p> <ul style="list-style-type: none"> reacts violently with strong oxidisers, acetyl bromide, alkyl aluminium salts, beryllium dihydride, bromine, chromic acid, 1-chloro-3,3-difluoro-2-methoxycyclopropene, cyanuric chloride, diethylzinc, isophthaloyl chloride, nitric acid, perchloric acid, potassium-tert-butoxide, potassium sulfur diimide, Raney nickel catalysts, 2,4,6-trichlorotriazine, triethylaluminium, 1,3,3-trifluoro-2-methoxycyclopropene is incompatible with strong acids, strong caustics, alkaline earth and alkali metals, aliphatic amines, acetaldehyde, benzoyl peroxide, 1,3-bis(di-n-cyclopentadienyl iron)-2-propen-1-one, calcium carbide, chloroform, chromic anhydride, chromium trioxide, dialkylzinc, dichlorine oxide, dichloromethane, ethylene oxide, hypochlorous acid, isocyanates, isopropyl chlorocarbonate, lithium tetrahydroaluminate, magnesium, methyl azide, nitrogen dioxide, palladium, pentafluoroguanidine, perchloryl fluoride, phosphorus pentasulfide, phosphorus trioxide, potassium, tangerine oil, triisobutylaluminium mixtures with lead perchlorate, sodium hypochlorite are explosive may react with metallic aluminium at high temperatures slowly corrodes lead and aluminium may generate electrostatic charges, due to low conductivity, on flow or agitation attacks some plastics, rubber and coatings. <p>Static induced flash fires have happened when filling plastic containers with methanol / water solutions with as low as 30% methanol content</p> <p>Alcohols</p> <ul style="list-style-type: none"> are incompatible with strong acids, acid chlorides, acid anhydrides, oxidising and reducing agents. reacts, possibly violently, with alkaline metals and alkaline earth metals to produce hydrogen react with strong acids, strong caustics, aliphatic amines, isocyanates, acetaldehyde, benzoyl peroxide, chromic acid, chromium oxide, dialkylzinc, dichlorine oxide, ethylene oxide, hypochlorous acid, isopropyl chlorocarbonate, lithium tetrahydroaluminate, nitrogen dioxide, pentafluoroguanidine, phosphorus halides, phosphorus pentasulfide, tangerine oil, triethylaluminium, triisobutylaluminium should not be heated above 49 deg. C. when in contact with aluminium equipment Avoid storage with reducing agents.

SECTION 8 Exposure controls / personal protection

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Control parameters

Occupational Exposure Limits (OEL)

INGREDIENT DATA

Source	Ingredient	Material name	TWA	STEL	Peak	Notes
Australia Exposure Standards	methanol	Methyl alcohol	200 ppm / 262 mg/m3	328 mg/m3 / 250 ppm	Not Available	Not Available

Emergency Limits

Ingredient	TEEL-1	TEEL-2	TEEL-3
methanol	Not Available	Not Available	Not Available


Ingredient	Original IDLH	Revised IDLH
methanol	6,000 ppm	Not Available
tapentadol hydrochloride	Not Available	Not Available

Occupational Exposure Banding

Ingredient	Occupational Exposure Band Rating	Occupational Exposure Band Limit
tapentadol hydrochloride	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.
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Exposure controls

Appropriate engineering controls	<p>For potent pharmacological agents:</p> <p>Solutions Handling:</p> <ul style="list-style-type: none">Solutions can be handled outside a containment system or without local exhaust ventilation during procedures with no potential for aerosolisation. If the procedures have a potential for aerosolisation, an air-purifying respirator is to be worn by all personnel in the immediate area.Solutions used for procedures where aerosolisation may occur (e.g., vortexing, pumping) are to be handled within a containment system or with local exhaust ventilation.In situations where this is not feasible (may include animal dosing), an air-purifying respirator is to be worn by all personnel in the immediate area. <p>Unless written procedures, specific to the workplace are available, the following is intended as a guide:</p> <ul style="list-style-type: none">For Laboratory-scale handling of Substances assessed to be toxic by inhalation. Quantities of up to 25 grams may be handled in Class II biological safety cabinets *; Quantities of 25 grams to 1 kilogram may be handled in Class II biological safety cabinets* or equivalent containment systems; Quantities exceeding 1 kg may be handled either using specific containment, a hood or Class II biological safety cabinet*,HEPA terminated local exhaust ventilation should be considered at point of generation of dust, fumes or vapours.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.
Individual protection measures, such as personal protective equipment	
Eye and face protection	<ul style="list-style-type: none">Chemical protective goggles with full seal. [AS/NZS 1337.1, EN166 or national equivalent]Shielded mask (gas-type).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.
Skin protection	See Hand protection below
Hands/feet protection	<p>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.</p> <p>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.</p> <p>Personal hygiene is a key element of effective hand care.</p> <ul style="list-style-type: none">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.
Body protection	See Other protection below
Other protection	<ul style="list-style-type: none">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.

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: Tapentadol hydrochloride solution

Respiratory protection

Type AX Filter of sufficient capacity. (AS/NZS 1716 & 1715, EN 143:2000 & 149:2001, ANSI Z88 or national equivalent)

Where the concentration of gas/particulates in the breathing zone, approaches or exceeds the "Exposure Standard" (or ES), respiratory protection is required. Degree of protection varies with both face-piece and Class of filter; the nature of protection varies with Type of filter.

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Material	CPI
BUTYL	A
BUTYL/NEOPRENE	A
PE/EVAL/PE	A
PVDC/PE/PVDC	A
SARANEX-23	A
SARANEX-23 2-PLY	A
TEFLON	A
VITON/NEOPRENE	A
NEOPRENE	B
NAT+NEOPR+NITRILE	C
NATURAL RUBBER	C
NATURAL+NEOPRENE	C
NEOPRENE/NATURAL	C
NITRILE	C
PVA	C
PVC	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.

Required Minimum Protection Factor	Half-Face Respirator	Full-Face Respirator	Powered Air Respirator
up to 5 x ES	AX-AUS / Class 1	-	AX-PAPR-AUS / Class 1
up to 25 x ES	Air-line*	AX-2	AX-PAPR-2
up to 50 x ES	-	AX-3	-
50+ x ES	-	Air-line**	-

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

^ - Full-face

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

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	AX-AUS / Class 1	-
up to 50	1000	-	AX-AUS / Class 1
up to 50	5000	Airline *	-
up to 100	5000	-	AX-2
up to 100	10000	-	AX-3
100+		-	Airline**

** - 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 deg C)

SECTION 9 Physical and chemical properties

Information on basic physical and chemical properties

Appearance	Not Available		
Physical state	Liquid	Relative density (Water = 1)	0.791
Odour	Not Available	Partition coefficient n-octanol / water	Not Available
Odour threshold	Not Available	Auto-ignition temperature (°C)	Not Available
pH (as supplied)	Not Available	Decomposition temperature (°C)	Not Available
Melting point / freezing point (°C)	Not Available	Viscosity (cSt)	Not Available
Initial boiling point and boiling range (°C)	64-65	Molecular weight (g/mol)	257.80
Flash point (°C)	9.7	Taste	Not Available
Evaporation rate	Not Available	Explosive properties	Not Available
Flammability	HIGHLY FLAMMABLE.	Oxidising properties	Not Available
Upper Explosive Limit (%)	36	Surface Tension (dyn/cm or mN/m)	Not Available
Lower Explosive Limit (%)	6	Volatile Component (%vol)	Not Available

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Vapour pressure (kPa)	Not Available	Gas group	Not Available
Solubility in water	Not Available	pH as a solution (1%)	Not Available
Vapour density (Air = 1)	Not Available	VOC g/L	Not Available

SECTION 10 Stability and reactivity

Reactivity	See section 7
Chemical stability	<ul style="list-style-type: none"> ▶ Static induced flash fires have happened when filling plastic containers with methanol / water solutions with as low as 30% methanol content. ▶ 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	<p>Inhalation of vapours or aerosols (mists, fumes), generated by the material during the course of normal handling, may produce toxic effects. The material is not thought to produce respiratory irritation (as classified by EC Directives using animal models). Nevertheless inhalation of vapours, fumes or aerosols, especially for prolonged periods, may produce respiratory discomfort and occasionally, distress. Inhalation of vapours may cause drowsiness and dizziness. This may be accompanied by sleepiness, reduced alertness, loss of reflexes, lack of co-ordination, and vertigo.</p> <p>Minor but regular methanol exposures may effect the central nervous system, optic nerves and retinae. Symptoms may be delayed, with headache, fatigue, nausea, blurring of vision and double vision. Continued or severe exposures may cause damage to optic nerves, which may become severe with permanent visual impairment even blindness resulting.</p> <p>WARNING: Methanol is only slowly eliminated from the body and should be regarded as a cumulative poison which cannot be made non-harmful [CCINFO]</p>
Ingestion	<p>Toxic effects may result from the accidental ingestion of the material; animal experiments indicate that ingestion of less than 40 gram may be fatal or may produce serious damage to the health of the individual.</p> <p>Noradrenaline (norepinephrine) reuptake inhibitors (NRI, NERI) or adrenergic reuptake inhibitors (ARI) cause increased concentrations of noradrenaline and adrenaline outside the cell, and therefore an increase in adrenergic neurotransmission.</p> <p>NRIs are used to treat attention-deficit hyperactivity disorder (ADHD) and fatigue or lethargy as stimulants. They are also used as weight-loss medications, antidepressants, decongestants for blocked nose or sinuses, treatment for bed wetting, low blood pressure and to offset the side effects of other drugs (for example, sexual dysfunction caused by selective serotonin reuptake inhibitors).</p> <p>NRIs can cause a wide range of psychological and physical effects, including the following:</p> <p>Psychological: General and subjective altered consciousness; stimulation, arousal and hyperactivity; increased alertness, awareness and wakefulness; increased energy and endurance; agitation or restlessness; increased attention, concentration and motivation; improved cognition, memory and learning; improved mood; irritability, aggression and anger; anxiety, negativity, paranoia and/or panic attacks; general unwellness and tiredness, and increased sex drive.</p> <p>Morphine and other analgesics cause nausea, vomiting, constipation, drowsiness and confusion. Urination can be difficult, and the bowel and bile ducts can spasm.</p> <p>Methanol may produce a burning or painful sensation in the mouth, throat, chest, and stomach. This may be accompanied by nausea, vomiting, headache, dizziness, shortness of breath, weakness, fatigue, leg cramps, restlessness, confusion, drunken behaviour, visual disturbance, drowsiness, coma and death. 60-200 ml of methanol is a fatal dose for most adults with as little as 10 ml producing blindness. In massive overdose, liver, kidney, heart and muscle injury have been described.</p> <p>Swallowing of the liquid may cause aspiration into the lungs with the risk of chemical pneumonitis; serious consequences may result. (ICSC13733)</p>
Skin Contact	<p>Skin contact with the material may produce toxic effects; systemic effects may result following absorption.</p> <p>Contact dermatitis has been reported with morphine and other narcotic analgesics.</p> <p>Open cuts, abraded or irritated skin should not be exposed to this material</p> <p>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.</p> <p>There is strong evidence to suggest that this material, on a single contact with skin, can cause serious, irreversible damage of organs.</p> <p>There is some evidence to suggest that the material may cause moderate inflammation of the skin either following direct contact or after a delay of some time. Repeated exposure can cause contact dermatitis which is characterised by redness, swelling and blistering.</p>
Eye	<p>Methanol is a mild to moderate eye irritant. High vapor concentration or liquid contact with eyes causes irritation, tearing, and burning.</p> <p>Direct contact of the eye with ethanol may cause immediate stinging and burning with reflex closure of the lid and tearing, transient injury of the corneal epithelium and hyperaemia of the conjunctiva.</p> <p>There is some evidence that material may produce eye irritation in some persons and produce eye damage 24 hours or more after instillation. Moderate inflammation may be expected with redness; conjunctivitis may occur with prolonged exposure.</p>
Chronic	<p>Toxic: danger of serious damage to health by prolonged exposure through inhalation, in contact with skin and if swallowed.</p> <p>This material can cause serious damage if one is exposed to it for long periods. It can be assumed that it contains a substance which can produce severe defects.</p> <p>Ample evidence exists, from results in experimentation, that developmental disorders are directly caused by human exposure to the material.</p> <p>Chronic morphine poisoning or addiction causes pin-point pupils, rapid mood changes and poor social adaptation. As dependence and tolerance occurs, there is an overwhelming need to continue taking the drug or similar drugs and to increase the dose.</p>

Continued...

Tapentadol hydrochloride solution

	Long-term exposure to methanol vapour, at concentrations exceeding 3000 ppm, may produce cumulative effects characterised by gastrointestinal disturbances (nausea, vomiting), headache, ringing in the ears, insomnia, trembling, unsteady gait, vertigo, conjunctivitis and clouded or double vision. Liver and/or kidney injury may also result.	
Tapentadol hydrochloride solution	TOXICITY	IRRITATION
	Not Available	Not Available
methanol	TOXICITY	IRRITATION
	Dermal (rabbit) LD50: 15800 mg/kg ^[2]	Eye (rabbit): 100 mg/24h-moderate
	Inhalation(Rat) LC50: 64000 ppm4h ^[2]	Eye (rabbit): 40 mg-moderate
	Oral (Rat) LD50: 5628 mg/kg ^[2]	Eye: no adverse effect observed (not irritating) ^[1]
		Skin (rabbit): 20 mg/24 h-moderate
		Skin: no adverse effect observed (not irritating) ^[1]
tapentadol hydrochloride	TOXICITY	IRRITATION
	Not Available	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	

METHANOL	The material may cause skin irritation after prolonged or repeated exposure and may produce on contact skin redness, swelling, the production of vesicles, scaling and thickening of the skin.		
TAPENTADOL HYDROCHLORIDE	No significant acute toxicological data identified in literature search. Side effects of treatment with mhu (mu) opioid agonists such as morphine may include nausea, vomiting, sedation, constriction of the pupils, irritability, pallor, slow heart rate, low blood pressure, and sweating. Respiratory depression, psychological dependence and other disturbing psychotic effects have been recorded. Approved mu opioid antagonists for use in the treatment of these adverse effects include naloxone and naltrexone. Naloxone, in contrast to naltrexone may be addictive.		
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					
Tapentadol hydrochloride solution	Endpoint	Test Duration (hr)	Species	Value	Source
	Not Available	Not Available	Not Available	Not Available	Not Available
methanol	Endpoint	Test Duration (hr)	Species	Value	Source
	EC50	48h	Crustacea	>10000mg/l	2
	EC50	96h	Algae or other aquatic plants	14.11-20.623mg/l	4
	LC50	96h	Fish	290mg/l	2
	NOEC(ECx)	720h	Fish	0.007mg/L	4
tapentadol 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 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				

For Methanol: Log Kow: -0.82 to -0.66; Koc: 1; Henry s Law Constant: 4.55x10-6 atm-cu m/mole; Vapor Pressure: 127 mm Hg; BCF: < 10.
Atmospheric Fate: Methanol is expected to exist solely as a vapor in the ambient atmosphere. Vapor-phase methanol is broken down in the atmosphere by reactions with hydroxyl radicals; the half-life for this reaction in air is estimated to be 17 days.
Terrestrial Fate: Methanol is expected to have very high mobility in soil.
DO NOT discharge into sewer or waterways.

Persistence and degradability

Ingredient	Persistence: Water/Soil	Persistence: Air
methanol	LOW	LOW

Bioaccumulative potential

Tapentadol hydrochloride solution

Ingredient	Bioaccumulation
methanol	LOW (BCF = 10)

Mobility in soil

Ingredient	Mobility
methanol	HIGH (KOC = 1)

SECTION 13 Disposal considerations

Waste treatment methods

Product / Packaging disposal	<ul style="list-style-type: none"> Containers may still present a chemical hazard/ danger when empty. Return to supplier for reuse/ recycling if possible. <p>Otherwise:</p> <ul style="list-style-type: none"> If container can not be cleaned sufficiently well to ensure that residuals do not remain or if the container cannot be used to store the same product, then puncture containers, to prevent re-use, and bury at an authorised landfill. Where possible retain label warnings and SDS and observe all notices pertaining to the product. <p>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.</p> <ul style="list-style-type: none"> Consult manufacturer/supplier for recycling options. Decontaminate empty containers with water; incinerate plastic bags. <p>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.</p> <p>A Hierarchy of Controls seems to be common - the user should investigate:</p> <ul style="list-style-type: none"> Reduction Reuse Recycling Disposal (if all else fails) <p>This material may be recycled if unused, or if it has not been contaminated so as to make it unsuitable for its intended use.</p> <ul style="list-style-type: none"> 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.
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SECTION 14 Transport information

Labels Required

	 
Marine Pollutant	NO
HAZCHEM	*2WE

Land transport (ADG)

UN number or ID number	1230				
UN proper shipping name	METHANOL				
Transport hazard class(es)	<table> <tr> <td>Class</td><td>3</td></tr> <tr> <td>Subsidiary risk</td><td>6.1</td></tr> </table>	Class	3	Subsidiary risk	6.1
Class	3				
Subsidiary risk	6.1				
Packing group	II				
Environmental hazard	Not Applicable				
Special precautions for user	<table> <tr> <td>Special provisions</td><td>279</td></tr> <tr> <td>Limited quantity</td><td>1 L</td></tr> </table>	Special provisions	279	Limited quantity	1 L
Special provisions	279				
Limited quantity	1 L				

Air transport (ICAO-IATA / DGR)

UN number	1230						
UN proper shipping name	Methanol						
Transport hazard class(es)	<table> <tr> <td>ICAO/IATA Class</td><td>3</td></tr> <tr> <td>ICAO / IATA Subrisk</td><td>6.1</td></tr> <tr> <td>ERG Code</td><td>3L</td></tr> </table>	ICAO/IATA Class	3	ICAO / IATA Subrisk	6.1	ERG Code	3L
ICAO/IATA Class	3						
ICAO / IATA Subrisk	6.1						
ERG Code	3L						
Packing group	II						
Environmental hazard	Not Applicable						
Special precautions for user	<table> <tr> <td>Special provisions</td><td>A113</td></tr> <tr> <td>Cargo Only Packing Instructions</td><td>364</td></tr> </table>	Special provisions	A113	Cargo Only Packing Instructions	364		
Special provisions	A113						
Cargo Only Packing Instructions	364						

Tapentadol hydrochloride solution

	Cargo Only Maximum Qty / Pack	60 L
	Passenger and Cargo Packing Instructions	352
	Passenger and Cargo Maximum Qty / Pack	1 L
	Passenger and Cargo Limited Quantity Packing Instructions	Y341
	Passenger and Cargo Limited Maximum Qty / Pack	1 L

Sea transport (IMDG-Code / GGVSee)

UN number	1230		
UN proper shipping name	METHANOL		
Transport hazard class(es)	IMDG Class	3	
	IMDG Subrisk	6.1	
Packing group	II		
Environmental hazard	Not Applicable		
Special precautions for user	EMS Number	F-E, S-D	
	Special provisions	279	
	Limited Quantities	1 L	

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
methanol	Not Available
tapentadol hydrochloride	Not Available

Transport in bulk in accordance with the IGC Code

Product name	Ship Type
methanol	Not Available
tapentadol hydrochloride	Not Available

SECTION 15 Regulatory information

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

methanol is found on the following regulatory lists

Australia Hazardous Chemical Information System (HCIS) - Hazardous Chemicals
Australia Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) - Schedule 5

Australia Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) - Schedule 6
Australian Inventory of Industrial Chemicals (AIIC)
Chemical Footprint Project - Chemicals of High Concern List

tapentadol hydrochloride is found on the following regulatory lists

Australia Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) - Schedule 8

National Inventory Status

National Inventory	Status
Australia - AIIC / Australia Non-Industrial Use	No (tapentadol hydrochloride)
Canada - DSL	No (tapentadol hydrochloride)
Canada - NDSL	No (methanol; tapentadol hydrochloride)
China - IECSC	No (tapentadol hydrochloride)
Europe - EINEC / ELINCS / NLP	No (tapentadol hydrochloride)
Japan - ENCS	No (tapentadol hydrochloride)
Korea - KECI	No (tapentadol hydrochloride)
New Zealand - NZIoC	No (tapentadol hydrochloride)
Philippines - PICCS	No (tapentadol hydrochloride)
USA - TSCA	No (tapentadol hydrochloride)
Taiwan - TCSI	No (tapentadol hydrochloride)
Mexico - INSQ	No (tapentadol hydrochloride)
Vietnam - NCI	No (tapentadol hydrochloride)
Russia - FBEPH	No (tapentadol 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.

Tapentadol hydrochloride solution

SECTION 16 Other information

Revision Date	12/07/2023
Initial Date	27/07/2021

SDS Version Summary

Version	Date of Update	Sections Updated
2.3	12/07/2023	Hazards identification - Classification, Identification of the substance / mixture and of the company / undertaking - Synonyms

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

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