



cis-Tramadol-13C,D3 HCl 1.0 mg/mL as free base

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

Issue Date: 18/07/2023

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S.GHS.AUS.EN

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

Product Identifier

| | |
|-------------------------------|--|
| Product name | cis-Tramadol-13C,D3 HCl 1.0 mg/mL as free base |
| Synonyms | Not Available |
| Proper shipping name | METHANOL |
| Other means of identification | T-020 |

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

| | |
|--------------------------|---|
| Relevant identified uses | Laboratory chemicals, Synthesis of substances |
|--------------------------|---|

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. |
|------|--|

SECTION 3 Composition / information on ingredients

Substances

See section below for composition of Mixtures

Mixtures

| CAS No | %[weight] | Name |
|---------------|--|-------------------------|
| 67-56-1 | 100 | methanol |
| Not Available | <0.01 | cis-Tramadol-13C,D3 HCl |
| 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.

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 |
|-----------------------------|--|

Advice for firefighters

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|------------------------------|--|
| Fire Fighting | |
| Fire/Explosion Hazard | <ul style="list-style-type: none"> ▶ Liquid and vapour are highly flammable. ▶ Severe fire hazard when exposed to heat, flame and/or oxidisers. ▶ Vapour may travel a considerable distance to source of ignition. ▶ Heating may cause expansion or decomposition leading to violent rupture of containers. <p>Combustion products include: carbon dioxide (CO₂) formaldehyde other pyrolysis products typical of burning organic material.</p> |
| 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"> ▶ Containers, even those that have been emptied, may contain explosive vapours. ▶ Do NOT cut, drill, grind, weld or perform similar operations on or near containers. ▶ 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. |
|----------------------|--|

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|-------------------|---|
| | <ul style="list-style-type: none"> ▶ DO NOT allow clothing wet with material to stay in contact with skin |
| Other information | <ul style="list-style-type: none"> ▶ Store in original containers in approved flame-proof area. ▶ No smoking, naked lights, heat or ignition sources. ▶ DO NOT store in pits, depression, basement or areas where vapours may be trapped. ▶ Keep containers securely sealed. |

Conditions for safe storage, including any incompatibilities

| | |
|-------------------------|--|
| Suitable container | <ul style="list-style-type: none"> ▶ Glass container is suitable for laboratory quantities ▶ Packing as supplied by manufacturer. ▶ Plastic containers may only be used if approved for flammable liquid. ▶ Check that containers are clearly labelled and free from leaks. ▶ For low viscosity materials (i) : Drums and jerry cans must be of the non-removable head type. (ii) : Where a can is to be used as an inner package, the can must have a screwed enclosure. ▶ For materials with a viscosity of at least 2680 cSt. (23 deg. C) ▶ For manufactured product having a viscosity of at least 250 cSt. |
| 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

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 |
| cis-Tramadol-13C,D3 HCl | Not Available | Not Available |

Exposure controls

| | |
|---|--|
| Appropriate engineering controls | <p>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.</p> <p>The basic types of engineering controls are:</p> <p>Process controls which involve changing the way a job activity or process is done to reduce the risk.</p> <p>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.</p> |
| Individual protection measures, such as personal protective equipment |  |
| Eye and face protection | <ul style="list-style-type: none"> ▶ Safety glasses with side shields. ▶ Chemical goggles. [AS/NZS 1337.1, EN166 or national equivalent] ▶ 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 |

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|------------------------------|---|
| Hands/feet protection | <ul style="list-style-type: none"> Wear chemical protective gloves, e.g. PVC. Wear safety footwear or safety gumboots, e.g. Rubber <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> |
| Body protection | See Other protection below |
| Other protection | <ul style="list-style-type: none"> Overalls. PVC Apron. PVC protective suit may be required if exposure severe. Eyewash unit. Some plastic personal protective equipment (PPE) (e.g. gloves, aprons, overshoes) are not recommended as they may produce static electricity. For large scale or continuous use wear tight-weave non-static clothing (no metallic fasteners, cuffs or pockets). Non sparking safety or conductive footwear should be considered. Conductive footwear describes a boot or shoe with a sole made from a conductive compound chemically bound to the bottom components, for permanent control to electrically ground the foot and shall dissipate static electricity from the body to reduce the possibility of ignition of volatile compounds. |

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:

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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.

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.

| 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 gases, 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)

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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) | Not Available |
| 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 |
| 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>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>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> |

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| | 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. | |
| Eye | Methanol is a mild to moderate eye irritant. High vapor concentration or liquid contact with eyes causes irritation, tearing, and burning. 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. 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. | |
| Chronic | Toxic: danger of serious damage to health by prolonged exposure through inhalation, in contact with skin and if swallowed. 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. Ample evidence exists, from results in experimentation, that developmental disorders are directly caused by human exposure to the material. 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. | |
| cis-Tramadol-13C,D3 HCl 1.0 mg/mL as free base | 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] |
| cis-Tramadol-13C,D3 HCl | 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. | | |
| 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

| | | | | | |
|--|--|--------------------|-------------------------------|------------------|---------------|
| cis-Tramadol-13C,D3 HCl 1.0 mg/mL as free base | 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 |
| cis-Tramadol-13C,D3 HCl | 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.

Continued...

cis-Tramadol-13C,D3 HCl 1.0 mg/mL as free base

Persistence and degradability

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

Bioaccumulative potential

| 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>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. 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. |
|------------------------------|--|

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> </table> | ICAO/IATA Class | 3 | ICAO / IATA Subrisk | 6.1 |
| ICAO/IATA Class | 3 | | | | |
| ICAO / IATA Subrisk | 6.1 | | | | |

cis-Tramadol-13C,D3 HCl 1.0 mg/mL as free base

| | | |
|------------------------------|---|------|
| | ERG Code | 3L |
| Packing group | II | |
| Environmental hazard | Not Applicable | |
| Special precautions for user | Special provisions | A113 |
| | Cargo Only Packing Instructions | 364 |
| | 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 |
| cis-Tramadol-13C,D3 HCl | Not Available |

Transport in bulk in accordance with the IGC Code

| Product name | Ship Type |
|-------------------------|---------------|
| methanol | Not Available |
| cis-Tramadol-13C,D3 HCl | 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 6 |
| Australia Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) - Schedule 5 | Australian Inventory of Industrial Chemicals (AIIC) |
| | Chemical Footprint Project - Chemicals of High Concern List |
| cis-Tramadol-13C,D3 HCl is found on the following regulatory lists | |
| Not Applicable | |

National Inventory Status

| National Inventory | Status |
|---|---------------|
| Australia - AIIC / Australia Non-Industrial Use | Yes |
| Canada - DSL | Yes |
| Canada - NDSL | No (methanol) |
| China - IECSC | Yes |
| Europe - EINEC / ELINCS / NLP | Yes |
| Japan - ENCS | Yes |
| Korea - KECI | Yes |
| New Zealand - NZIoC | Yes |
| Philippines - PICCS | Yes |
| USA - TSCA | Yes |

cis-Tramadol-13C,D3 HCl 1.0 mg/mL as free base

| National Inventory | Status |
|--------------------|--------|
| Taiwan - TCSI | Yes |
| Mexico - INSQ | Yes |
| Vietnam - NCI | Yes |
| Russia - FBEPH | Yes |

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 | 18/07/2023 |
| Initial Date | 18/09/2021 |

SDS Version Summary

| Version | Date of Update | Sections Updated |
|---------|----------------|---|
| 2.3 | 18/07/2023 | Hazards identification - Classification, Composition / information on ingredients - Ingredients, Accidental release measures - Spills (major) |

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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