

Lisdexamfetamine dimesylate solution Novachem Pty Ltd

Version No: 1.1

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

Chemwatch Hazard Alert Code: 4

Issue Date: 21/01/2024 Print Date: 21/01/2024 S.GHS.AUS.EN

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

Product Identifier	
Product name	Lisdexamfetamine dimesylate solution
Synonyms	Not Available
Proper shipping name	METHANOL
Other means of identification	L-026

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.

 Version No: 1.1
 Page 2 of 11
 Issue Date: 21/01/2024

 Print Date: 21/01/2024
 Print Date: 21/01/2024

Lisdexamfetamine dimesylate solution

H331	Toxic if inhaled.
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	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	99.9	methanol
608137-33-3	0.1	lisdexamfetamine dimesylate
Legend:	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: 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	If skin or hair contact occurs: Cuickly 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	 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.

- 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.

If swallowed do NOT induce vomiting.

Monthly occurs, lea

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.
- Ingestion 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.

Version No: **1.1** Page **3** of **11** Issue Date: **21/01/2024**

Lisdexamfetamine dimesylate solution

Print Date: 21/01/2024

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 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.

The management of overdose with amphetamines generally involves supportive and symptomatic therapy. Sedation is usually sufficient. Forced acid diuresis has been advocated to increase amphetamine excretion but should only be considered in severely poisoned patients and requires close supervision and monitoring. MARTINDALE: The Extra Pharmacopoeia, 27th Ed.

Amphetamines may be monoamine oxidase inhibitors (MAOIs). Monoamine oxidase inhibitors produce postural hypotension, dizziness, drowsiness, weakness and fatigue, dryness of the mouth, constipation and other gastrointestinal disturbances (including nausea and vomiting) and oedema. Other symptoms may include agitation and tremors, insomnia and restless sleep, blurred vision, difficulty in urinating, convulsions, skin rashes, leucopenia, sexual disturbances and weight gain with inappropriate appetite. Psychotic episodes may be characterised by hypomanic behavior, confusion and hallucinations. Jaundice has been reported and infrequently this may lead to fatal progressive hepatocellular necrosis. 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		

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.
Fire/Explosion Hazard	 ▶ 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). Combustion products include: carbon dioxide (CO2) formaldehyde other pyrolysis products typical of burning organic material. 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

- ▶ 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.

Version No: **1.1** Page **4** of **11** Issue Date: **21/01/2024**

Lisdexamfetamine dimesylate solution

Print Date: 21/01/2024

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

- 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

Suitable containe

NOTE: Special security requirements may be mandated under Federal/State Regulation(s).

- Store in original containers.
- ▶ Store in vault fitted with warning devices or detectors recommended by various Federal/State authorities.
- ▶ Store in vault used only for the purpose of storage of drugs of addiction.

Conditions for safe storage, including any incompatibilities

- 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

For low viscosity materials

- 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.

For materials with a viscosity of at least 2680 cSt. (23 deg. C) and solids (between 15 C deg. and 40 deg C.):

- ▶ Removable head packaging;
- Cans with friction closures and
- low pressure tubes and cartridges

may be used.

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.

Methanol

- 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.

Static induced flash fires have happened when filling plastic containers with methanol / water solutions with as low as 30% methanol content Alcohols

- ▶ 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, dialkylzincs, 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)

Storage incompatibility

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	
ingredient	Original IDEH		Revised IDLH	
methanol	6,000 ppm		Not Available	
lisdexamfetamine dimesylate	Not Available		Not Available	

Version No: **1.1** Page **5** of **11** Issue Date: **21/01/2024**

Lisdexamfetamine dimesylate solution

Ingredient	Occupational Exposure Band Rating	Occupational Exposure Band Limit	
lisdexamfetamine dimesylate	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

For potent pharmacological agents:

Solutions Handling:

- 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.

Unless written procedures, specific to the workplace are available, the following is intended as a guide:

- 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

Appropriate engineering

controls











Eye and face protection

- ▶ 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

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.

Hands/feet protection
Personal hygiene is a key element of effective hand care.

- 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

- 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:

Lisdexamfetamine dimesylate solution

Material	СРІ
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	В
NAT+NEOPR+NITRILE	С
NATURAL RUBBER	С
NATURAL+NEOPRENE	С
NEOPRENE/NATURAL	С

Respiratory protection

Type AX Filter of sufficient capacity. (AS/NZS 1716 & 1715, EN 143:2000 & 149:2001, ANSI 288 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.

Print Date: 21/01/2024

 Version No: 1.1
 Page 6 of 11
 Issue Date: 21/01/2024

 Print Date: 21/01/2024
 Print Date: 21/01/2024

Lisdexamfetamine dimesylate solution

NITRILE	С
PVA	С
PVC	С

- * 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.

- 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.

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

SECTION 9 Physical and chemical properties

Information on basic physical and chemical properties

Appearance	Not Available		
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)	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	 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

Version No: **1.1** Page **7** of **11** Issue Date: **21/01/2024**

Lisdexamfetamine dimesylate solution

Print Date: 21/01/2024

Conditions to avoid	See section 7
Incompatible materials	See section 7
Hazardous decomposition products	See section 5

SECTION 11 Toxicological information

Inhaled

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 vertico.

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.

WARNING: Methanol is only slowly eliminated from the body and should be regarded as a cumulative poison which cannot be made non-harmful [CCINFO]

Ingestion

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.

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.

Phenethylamines are structurally similar to amphetamines

Side effects of amphetamine treatment are associated with overstimulation of the central nervous system and include sleeplessness, nervousness, restlessness, irritability and a feeling of well-being, followed by fatigue and depression. There may be dry mouth, poor appetite, abdominal cramps and other gastrointestinal disturbances, headache, dizziness, tremor, sweating, fast heartbeat, palpitations, increased blood pressure, difficulty urinating, altered sex drive and impotence. Psychotic reactions and muscle damage (associated with kidney complications)

Phenethylamines produce effects similar to amphetamines. They excite the nervous system, causing shortness of breath, cough, narrowing of the airways and throat spasms.

Swallowing of the liquid may cause aspiration into the lungs with the risk of chemical pneumonitis; serious consequences may result. (ICSC13733)

Skin Contact

Skin contact with the material may produce toxic effects; systemic effects may result following absorption.

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.

There is strong evidence to suggest that this material, on a single contact with skin, can cause serious, irreversible damage of organs.

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 use of amphetamines can lead to tolerance developing to some of its effects, leading to an urge to increase dose and habituation. However, amphetamines generally do not cause physical dependence.

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.

Chronic exposure to phenethylamines excite the central nervous system and induce tolerance; in extreme cases they produce amphetamine-like responses including personality changes, compulsive and stereotyped behaviour and may induce psychosis with auditory and visual hallucinations and paranoid delusions.

Lisdexamfetamine dimesylate 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]

Version No: 1.1 Page 8 of 11 Issue Date: 21/01/2024

Lisdexamfetamine dimesylate solution

Print Date: 21/01/2024

lisdexamfetamine dimesylate	TOXICITY Not Available	IRRITATION Not Available	
Legend:	Nalue obtained from Europe ECHA Registered Subspecified data extracted from RTECS - Register of To.		ined from manufacturer's SDS. Unless otherwise
METHANOL	The material may cause skin irritation after prolonged vesicles, scaling and thickening of the skin.	or repeated exposure and may produ	ce on contact skin redness, swelling, the production of
LISDEXAMFETAMINE DIMESYLATE	Animal reproduction studies have shown adverse effe	cts on the foetus. No significant acute	toxicological data identified in literature search.
Acute Toxicity	~	Carcinogenicity	×
Skin Irritation/Corrosion	×	Reproductivity	✓
Serious Eye Damage/Irritation	✓	STOT - Single Exposure	✓
Respiratory or Skin sensitisation	×	STOT - Repeated Exposure	~

Legend:

X - Data either not available or does not fill the criteria for classification

Data available to make classification

SECTION 12 Ecological information

Toxicity

isdexamfetamine dimesylate	Endpoint Test D		Test Duration (hr)		Species Value			Source	ource	
solution	Not Available Not Available			Not Available	Not Available		Not Available			
	Endpoint	Tes	t Duration (hr)	Species			Value		Source	
	EC50	48h	1	Crustace	ea		>10000mg/l		2	
methanol	EC50	C50 96h		Algae or	Algae or other aquatic plants		14.11-20.623mg/l		4	
	LC50	96h	1	Fish			290mg/l		2	
	NOEC(ECx) 720h		Fish	Fish		0.007mg/L		4		
:	Endpoint		Test Duration (hr)		Species	Value		Source		
isdexamfetamine dimesylate	Not Available	Available Not Available			Not Available	vailable Not Avail		ailable Not Available		
Legend:			Toxicity Data 2. Europe Toxicity Data 5. ECET		ered Substances - Ec	otoxicological l				

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

Ingredient	Bioaccumulation
methanol	LOW (BCF = 10)

Mobility in soil

Ingredient	Mobility
methanol	HIGH (KOC = 1)

SECTION 13 Disposal considerations

Waste treatment methods

- ▶ Containers may still present a chemical hazard/ danger when empty.
- ▶ Return to supplier for reuse/ recycling if possible. Otherwise:

Product / Packaging disposal

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

Version No: **1.1** Page **9** of **11** Issue Date: **21/01/2024**

Lisdexamfetamine dimesylate solution

Print Date: 21/01/2024

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.

Valuable substance, hold all residues for recovery. Disposal of the material must be carried out in accordance with the requirements of the relevant Federal/State Act(s) or Code(s) regulating the disposal of Drugs of Addiction.

- Consult manufacturer/supplier for recycling options.
- ▶ Decontaminate empty containers with water; incinerate plastic bags.

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.

- ▶ 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.

SECTION 14 Transport information

Labels Required





Marine Pollutant	NO
HAZCHEM	•2WE

Land transport (ADG)

14.1. UN number or ID number	1230
14.2. UN proper shipping name	METHANOL
14.3. Transport hazard class(es)	Class 3 Subsidiary Hazard 6.1
14.4. Packing group	II
14.5. Environmental hazard	Not Applicable
14.6. Special precautions for user	Special provisions 279 Limited quantity 1 L

Air transport (ICAO-IATA / DGR)

·	•				
14.1. UN number	1230				
14.2. UN proper shipping name	Methanol				
	ICAO/IATA Class	3			
14.3. Transport hazard class(es)	ICAO / IATA Subsidiary Hazard	ICAO / IATA Subsidiary Hazard 6.1			
ciass(cs)	ERG Code	3L			
14.4. Packing group	II				
14.5. Environmental hazard	Not Applicable				
	Special provisions		A113		
	Cargo Only Packing Instructions		364		
	Cargo Only Maximum Qty / Pack		60 L		
14.6. Special precautions for user	Passenger and Cargo Packing In	structions	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)

14.1. UN number	1230
14.2. UN proper shipping name	METHANOL

 Version No: 1.1
 Page 10 of 11
 Issue Date: 21/01/2024

 Print Date: 21/01/2024
 Print Date: 21/01/2024

Lisdexamfetamine dimesylate solution

IMDG Class 3 14.3. Transport hazard class(es) IMDG Subsidiary Hazard 6.1 14.4. Packing group 14.5 Environmental hazard Not Applicable **EMS Number** F-E, S-D 14.6. Special precautions for Special provisions user Limited Quantities 1 L

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

Not Applicable

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

Product name	Group
methanol	Not Available
lisdexamfetamine dimesylate	Not Available

14.7.3. Transport in bulk in accordance with the IGC Code

Product name	Ship Type
methanol	Not Available
lisdexamfetamine dimesylate	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

 $\label{eq:australia} \textbf{Australia Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) - Schedule \ 6}$

Australian Inventory of Industrial Chemicals (AIIC)

Chemical Footprint Project - Chemicals of High Concern List

lisdexamfetamine dimesylate is found on the following regulatory lists

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

Additional Regulatory Information

Not Applicable

National Inventory Status

National Inventory	Status
Australia - AIIC / Australia Non-Industrial Use	No (lisdexamfetamine dimesylate)
Canada - DSL	No (lisdexamfetamine dimesylate)
Canada - NDSL	No (methanol; lisdexamfetamine dimesylate)
China - IECSC	No (lisdexamfetamine dimesylate)
Europe - EINEC / ELINCS / NLP	No (lisdexamfetamine dimesylate)
Japan - ENCS	No (lisdexamfetamine dimesylate)
Korea - KECI	No (lisdexamfetamine dimesylate)
New Zealand - NZIoC	No (lisdexamfetamine dimesylate)
Philippines - PICCS	No (lisdexamfetamine dimesylate)
USA - TSCA	No (lisdexamfetamine dimesylate)
Taiwan - TCSI	No (lisdexamfetamine dimesylate)
Mexico - INSQ	No (lisdexamfetamine dimesylate)
Vietnam - NCI	No (lisdexamfetamine dimesylate)
Russia - FBEPH	No (lisdexamfetamine dimesylate)
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	21/01/2024
Initial Date	21/01/2024

Other information

Version No: **1.1** Page **11** of **11** Issue Date: **21/01/2024**

Lisdexamfetamine dimesylate solution

Print Date: 21/01/2024

committee using available literature references.

The SDS is a Hazard Communication tool and should be used to assist in the Risk Assessment. Many factors determine whether the reported Hazards are Risks in the workplace or other settings. Risks may be determined by reference to Exposures Scenarios. Scale of use, frequency of use and current or available engineering controls must be considered.

Definitions and abbreviations

- ▶ PC TWA: Permissible Concentration-Time Weighted Average
- ▶ PC STEL: Permissible Concentration-Short Term Exposure Limit
- ► IARC: International Agency for Research on Cancer
- ACGIH: American Conference of Governmental Industrial Hygienists
- STEL: Short Term Exposure Limit
- ► TEEL: Temporary Emergency Exposure Limit,
- IDLH: Immediately Dangerous to Life or Health Concentrations
- ES: Exposure Standard
- OSF: Odour Safety Factor
- ▶ NOAEL: No Observed Adverse Effect Level
- ► LOAEL: Lowest Observed Adverse Effect Level
- ► TLV: Threshold Limit Value
- ► LOD: Limit Of Detection
- ► OTV: Odour Threshold Value
- ▶ BCF: BioConcentration Factors
- BEI: Biological Exposure Index
- ► DNEL: Derived No-Effect Level
- ▶ PNEC: Predicted no-effect concentration
- ▶ 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

Powered by AuthorITe, from Chemwatch.