SAFETY DATA SHEET

LISDEXAMFETAMINE DIMESYLATE

Safety data sheet according to European Parliament and Council Regulation (EC) No. 1907/2006 (REACH) and Commission Regulation (EU) 2020/878.

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

1.1 Product identifier

Product name
Lisdexamfetamine dimesylate;
L-Lysine-Dextroamphetamine

IUPAC name
(2*S*)-2,6-diamino-*N*-[(1*S*)-1-methyl-2-phenylethyl]-hexanamide, dimethane-sulfonate

CAS no.
608137-33-3

EC no. (EINECS)
-

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

Relevant uses
For industrial and professional use only [SU 3, SU 22].
Active Pharmaceutical Ingredient (API) for the manufacture of medicinal products and use in pharmaceutical research and development under controlled conditions.

Uses advised against
Not intended for consumer use [SU 21].
Not to be used as a finished medicinal product, for self-administration, or for end-use outside regulated facilities.

1.3 Details of the supplier of the safety data sheet

Chr. Olesen Synthesis A/S
Kanalholmen 8-12
2650 Hvidovre
Denmark

Tel:+45 3679 4500
Fax:+45 3834 1572
info@COSynthesis.dk
www.cosynthesis.dk

1.4 Emergency telephone number

National poison information centres
Austria: +43 1 406 43 43 (VIZ), 24/7 service
Belgium: 070 245 245, 24/7 service, free of charge
Bulgaria: +359 2 9154 233, 24/7 service, free of charge
Croatia: +385 1 2348 342, 24/7 service, free of charge
Cyprus: 1401 (Poison Centre), 24/7 service
Czech Republic: +420 224 919 293; +420 224 915 402
Denmark: +45 82 12 12 12, 24/7 service, free of charge
Estonia: 16662; from abroad +372 7943 794
Finland: 0800 147 111, 24/7 service, free of charge
France: +33 (0)1 45 42 59 59 (ORFILA), 24/7 service, free of charge
Greece: +30 210 779 3777, 24/7 service
Hungary: +36 80 201 199, 24/7 service, free of charge
Iceland: +354 543 2222 / +354 543 1000, 24/7 service
Ireland: Public: +353 1 809 2166 (08:00–22:00); HCPs: +353 1 809 2566 (24/7)
Italy: +39 0382 24444 (CAV Pavia), 24/7 service
Latvia: +371 670 42473, 24/7 service
Lithuania: +370 5 2362052
Luxembourg: +352 8002 5500, 24/7 service, free of charge
Netherlands: +31 (0)88 755 8000 (NVIC) — for healthcare professionals only, 24/7
Norway: +47 22 59 13 00, 24/7 service, free of charge
Poland: 112 — poison centre contact via general emergency number
Portugal: +351 800 250 250 (Centro de Informação Antivenenos), 24/7 service
Romania: +40 21 318 3606

Slovakia: +421 2 5477 4166 (NTIC), 24/7 service
Slovenia: 112 — poison centre contact via general emergency number

Spain: +34 91 562 04 20 (Instituto Nacional de Toxicología), 24/7 service
Sweden: 112 — ask for Poisons Information
United Kingdom: NHS 111 (public, 24/7, Tel. 111 or 18001 111 for text relay); NPIS for healthcare professionals: +44 344 892 0111

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

The classification of this substance is based on self-classification in accordance with Regulation (EC) No 1272/2008 (CLP).

Acute Tox. 4 (oral); H302

2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008 [CLP]:

Signal words
Warning

Hazard statements
H302: Harmful if swallowed.

Precautionary statements
P261: Avoid breathing dust.
P301 + P312: IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.

Additional hazard information
None.

2.3 Other hazards

The substance is a potent CNS stimulant – misuse can lead to dependence, but this is not classified under CLP.

This product contains no components considered to be persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

This product does not contain any substances considered to be endocrine disruptors in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605.

SECTION 3: Composition/information on ingredients

3.1 Substances

Substance
Lisdexamfetamine dimesylate (pure substance, stereochemically defined as lisdexamfetamine in its dimesylate salt form, functioning as a prodrug of dexamphetamine).

Chemical formula
$C_{17}H_{33}N_3O_7S_2$

Molecular weight
455.6 g/mol

Component	Identifiers	Purity %	Classification	SCL / M-factors
Lisdexamfetamine dimesylate	CAS: 608137-33-3 EC: - REACH: - Index: -	> 99.9%	Acute Tox. 4 (oral); H302	-

Additional information:
For full text of H-statement, see Section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

Take proper precautions to ensure your own safety before assisting others. Remove exposed individuals from the hazard area. Seek immediate medical attention for any significant exposure. Show this SDS to medical personnel.

In case of inhalation
IF INHALED: Remove person to fresh air and keep comfortable for breathing. Seek medical attention if symptoms worsen or persist.

In case of ingestion
IF SWALLOWED: Rinse mouth thoroughly with water. Do NOT induce vomiting unless instructed by medical personnel. Do not give anything by mouth to an unconscious person. Keep the person calm and under observation; symptoms may include restlessness, rapid heartbeat, or agitation.

Seek immediate medical advice — call a POISON CENTER or doctor right away, and provide information about the substance ingested. If possible, show the container or label to medical personnel.

In case of contact with skin
In case of contact, it is recommended to clean the affected area with plenty of water. DO NOT use solvents or thinners. Remove contaminated clothing and shoes. Ensure to wash exposed skin thoroughly with water and soap. If skin irritation occurs: Get medical advice/attention.

In case of contact with eyes
Rinse eyes with plenty of lukewarm water or saline water, and avoid rubbing or closing the affected person's eyes. In case the affected person wears contact lenses, they should be removed unless they are glued to the eyes. Seek medical assistance and continue flushing during transport.

In case of burns
Not applicable.

4.2 Most important symptoms and effects, both acute and delayed

Acute effects
Ingestion can rapidly cause poisoning. Symptoms of acute exposure may include gastrointestinal irritation (nausea, vomiting, abdominal cramps), extreme restlessness or agitation, tremors, headache, dizziness, tachycardia (rapid heartbeat), hypertension, hyperthermia (elevated body temperature), and possibly confusion or seizures.

Severe overexposure can lead to convulsions, loss of consciousness (coma), and life-threatening complications such as respiratory arrest, cardiac arrhythmias or hemorrhagic stroke.

Onset of symptoms can be rapid due to the substance's potent stimulant effects on the central nervous system.

Inhalation of concentrated dust may also cause irritation of the respiratory tract (coughing, burning sensation) and pulmonary edema in severe cases. Skin or eye contact may cause mild irritation (redness, tearing in eyes) but systemic effects via these routes are less likely with brief exposure.

Delayed effects
Repeated or prolonged exposure to low doses may lead to chronic effects such as insomnia, irritability, loss of appetite and weight, and psychological dependence (addiction). Tolerance can develop with repeated use.

Chronic misuse of amphetamines is known to cause neurotoxicity and potential organ damage (e.g. brain dopamine nerve terminals), but workplace exposure at low levels is unlikely to reach such doses. Some studies suggest possible effects on fertility or fetal development from high doses (see Section 11), so avoid any exposure during pregnancy. There are no specific delayed effects unique to this substance other than those expected from its stimulant action on the nervous system.

4.3 Indication of any immediate medical attention and special treatment needed

If the substance has been ingested or inhaled, seek medical attention immediately. Provide medical personnel with all available information, including the substance name, estimated dose, time of exposure, and the patient's clinical condition, to ensure appropriate treatment.

Notes for the doctor
This substance is a sympathomimetic amine (stimulant). Treatment is primarily supportive and symptomatic. In cases of severe poisoning, consider administration of activated charcoal if the patient is alert and within one hour of ingestion.

There is no specific antidote. For seizures, administer benzodiazepines; for severe hypertension, consider cautiously using intravenous vasodilators. Monitor cardiac function (risk of arrhythmias) and body temperature (risk of hyperthermia).

If inhaled, monitor respiratory function; treat bronchospasm with oxygen and bronchodilators. Due to the risk of sudden CNS stimulation or seizures, avoid stimuli and keep patient calm. Immediate medical intervention is critical given the high acute toxicity. Ensure that medical responders are aware of the substance involved.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media
Use an extinguishing agent appropriate for the surrounding fire. Water spray (fog), dry chemical powder, carbon dioxide, or alcohol-resistant foam can be used.

Unsuitable extinguishing media
Do not use water jet directly, as it may spread burning material.

5.2 Special hazards arising from the substance or mixture

The product is not classified as flammable, but if involved in a fire it can decompose and produce toxic and irritating fumes or smoke.

Fine dust of the substance, if dispersed in air, could potentially form an explosive dust-air mixture in the presence of an ignition source (general caution for organic powders).

Hazardous combustion products
Oxides of carbon (CO, CO_2), oxides of nitrogen (NO_x), oxides of sulfur (SO_x), and other toxic gases. In a fire, the material can contribute toxic smoke; inhalation of combustion products can be very hazardous.

5.3 Advice for firefighters

Evacuate area and fight fire from a safe distance or protected location. Firefighters should wear full protective gear and a self-contained breathing apparatus (SCBA) if there is potential exposure to fumes. Prevent runoff from fire control from entering waterways or drains if possible. Use water spray to keep fire-exposed containers cool. If large quantities of the material are stored, be aware that toxic fumes can accumulate; approach from upwind. Follow standard procedures for chemical fire situations

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel
Evacuate non-essential personnel from the area. Do not breathe dust. Avoid contact with skin, eyes and clothing. Ventilate the area thoroughly.

For emergency responders
Emergency responders should wear appropriate personal protective equipment: gloves, protective clothing, eye protection, and in case of significant dust, a suitable respiratory protection (P3 filter or air-purifying respirator). If material is spilled in an enclosed area, consider using a respirator even for small spills.

Avoid generating airborne dust during cleanup. Remove any ignition sources if fine dust is present (to prevent dust explosion, although this material is not highly flammable, dust clouds of organics can ignite).

6.2 Environmental precautions

Prevent the material from being released into drains, watercourses or soil. Because this compound is pharmaceutically active and toxic, even small quantities could have adverse effects on aquatic life (see Section 12). Contain the spill to avoid environmental contamination. Notify authorities if a large amount enters the environment.

6.3 Methods and material for containment and cleaning up

For containment
For small spills, if possible, dampen the solid dust with water to minimize airborne dispersion. Carefully scoop, sweep, or vacuum (with explosion-proof vacuum) the spilled material into an appropriate closed container for disposal. Use inert absorbent material if needed (for example, wet paper towels or spill pads dampened with water)

to wipe up residues. Avoid dry sweeping which can stir up dust; if sweeping is needed, lightly mist the spill first to suppress dust.

For cleaning up
Collect all contaminated materials (absorbents, used PPE, etc.) in a sealed plastic bag or container for disposal as hazardous waste. After removal of bulk material, wash the spill site with water and detergent to remove any remaining traces. Do not flush wash water into the environment; collect it for proper disposal.

Other information
For larger spills, personnel must wear respiratory protection and follow your organization's chemical spill response plan. Ventilate the area until cleanup is complete.

6.4 Reference to other sections

For more information, see Sections 8 (protective equipment) and 13 (disposal).

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Technical measures
Handle only in a well-ventilated area or fume hood to avoid exposure to dust. Use engineering controls (local exhaust ventilation, closed processes) to minimize dust generation and airborne exposure. All handling should occur in an area with smooth, impermeable surfaces that can be easily cleaned. Keep containers closed when not in use. Handle over spill trays if possible to prevent dispersion of powder. Ensure that only authorized personnel have access, and that handling complies with applicable regulations (controlled drug). Young persons under 18 years should not work with this product.

Measures to prevent fire
Not specifically applicable; substance is not classified as flammable. No special fire prevention measures beyond good housekeeping are required.

Measures to prevent aerosol and dust generation
Handle material in closed systems or under local exhaust ventilation. Avoid open handling and transfer operations that may generate dust. Use spill trays or containment systems to prevent dispersion of powder. Minimize agitation, pouring, or mechanical processes that create airborne particles. Regularly clean work surfaces to avoid accumulation of dust.

Measures to protect the environment
Prevent dispersion of powder outside designated handling areas. Handle over spill trays if possible. Ensure cleaning procedures prevent release to the environment.

Advice on general occupational hygiene
Do not ingest. Avoid contact with skin and eyes – wear appropriate protective equipment (see Section 8). No eating, drinking or smoking in areas where this material is handled or stored. Wash hands and any exposed skin thoroughly with soap and water after handling. Remove and wash contaminated clothing before reuse. Employ good industrial hygiene practices: e.g., keep work areas clean, and periodically clean surfaces to prevent accumulation of powder. Workers should be trained about the hazards and proper handling procedures.

7.2 Conditions for safe storage, including any incompatibilities

Technical measures and storage conditions
Store in the original container, tightly closed, in a secure location. Keep in a cool, dry, and well-ventilated area. Recommended storage temperature: 15–30 °C.

Protect from direct sunlight, moisture/humidity, and physical damage. The substance is slightly hygroscopic; exposure to humid air may cause degradation or clumping. Store away from incompatible materials, especially strong oxidizing agents, strong alkalis/bases, reactive metals, and strong reducing agents. Avoid conditions that may lead to release of dextroamphetamine free base (volatile and flammable). Keep locked up or otherwise secured; access limited to authorized personnel (controlled substance).

Packaging material
Suitable: glass, stainless steel, or high-density polyethylene (HDPE). Ensure containers are labeled, tightly sealed, and intact to prevent leakage.

Requirements for storage rooms and vessels
Storage rooms should be cool, dry, well-ventilated, and secure against unauthorized access. Surfaces and fittings should be resistant to moisture and chemicals. Provide secondary containment or spill trays if possible.

Storage class
According to TRGS 510 (Germany): Storage class 12 (non-combustible solids). National regulations may apply (e.g. controlled drug storage requirements).

7.3 Specific end use(s)

This product is intended for use as an Active Pharmaceutical Ingredient (API) for further processing into finished dosage forms under strictly controlled conditions. It is not intended for direct human or veterinary administration in the provided form.

Use is restricted to professional users familiar with its handling and hazards. Refer to the appropriate technical literature for application details. No other specific uses are advised.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

There are no occupational exposure limit (OEL) values specifically established for lisdexamfetamine dimesylate by EU, OSHA, ACGIH or other major standards.

Internal occupational exposure guideline for similar active pharmaceutical ingredients may exist (e.g., Occupational Exposure Band 2), corresponding to a low microgram per cubic meter range, but no official public limits. Nonetheless, due to the substance's high potency and toxicity, exposure should be kept as low as reasonably achievable (ALARA). Always follow national regulations that may apply for chemical agents at the workplace; there may be a requirement to minimize exposure under directives for hazardous substances.

Monitoring: If available, methods such as air sampling for particulates can be used to confirm control of exposure levels (though no specific analyte method is standardized for amphetamine in air). Biological monitoring is not commonly done for this compound in occupational settings, but any unexpected absorption could theoretically be detected via urinary amphetamine tests.

8.2 Exposure controls

Appropriate engineering controls
Provide adequate general or local exhaust ventilation to keep airborne concentrations below any recommended guidelines and as low as possible. Enclose processes where feasible. If dust is generated (e.g. during weighing or mixing), perform these operations in a fume hood or ventilated enclosure. Use explosion-proof equipment for handling large quantities of fine powder. Implement dust control measures (e.g., use of dust extraction vacuum, wet methods for cleaning) to prevent accumulation of dust on surfaces. Emergency eye wash stations and safety showers should be available in areas where the substance is handled.

Personal protection equipment
Selection of PPE should be in accordance with EN standards and based on risk assessment:

Pictogram	Equipment	Marking	CEN standards	Remarks
	Disposable nitrile gloves Thickness ≥0.4 mm; Breakthrough time >480 min	CE CAT III	EN ISO 374-1:2016; EN ISO 21420:2020	Change immediately if contaminated or torn. Wash hands after removal. Prevent skin absorption.
	Safety goggles with side shields or tightly fitting chemical goggles	CE CAT II	EN 166:2002; EN ISO 4007:2018	Required if dust formation or splashing is possible. Prevents serious eye exposure.
	Half-mask respirator with P3 particulate filter (or full-face if needed)	CE CAT III	EN 140:1998; EN 143:2000/A1:2006; EN 14387:2004+A1:2008	Use if ventilation is inadequate. Protects against fine powder dust.
	Chemical-resistant clothing (e.g. lab coat, disposable coverall, apron)	CE CAT III	EN 13034:2005+A1:2009 (Type 6)	Recommended for bulk handling or risk of spills. Prevents contamination of personal clothes and reduces skin contact risk.

	Closed chemical-resistant footwear (e.g. safety shoes)	CE CAT II	EN ISO 20345:2011	Protects against accidental contamination and ensures safe laboratory/workplace practice.

Environmental exposure controls
Prevent spills or effluents from entering the environment. Use closed systems or secondary containment for processes to reduce the risk of accidental release. Air exhaust from ventilation should be filtered or scrubbed if possible to remove particulate before release.

All waste (solids, solutions) should be collected for proper disposal (see Section 13) rather than discharged. Given the potential ecological effects (see Section 12), even small quantities should be handled with care to avoid environmental contamination.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical and chemical properties

(a) Physical state:	Solid crystalline fine powder or crystals.
(b) Colour:	Typically white or off-white.
(c) Odour:	Odourless (no characteristic odor).
(d) Melting point/freezing point:	194.6 – 195.0 °C.
(e) Boiling point:	Not applicable (solid decomposes before boiling; no boiling point at atmospheric pressure).
(f) Flammability:	Not classified as flammable. The solid can burn if strongly heated, but it does not easily ignite under normal conditions.
(g) Lower and upper explosion limit:	Not applicable (solid material, no flammable vapor; dust explosion limits not determined, treat as any organic dust).
(h) Flash point:	Not applicable (non-volatile solid).
(i) Auto-ignition temperature:	No data available, but not expected to self-ignite. Likely >400 °C if any (organic powder, but no specific data).
(j) Decomposition temperature:	~300 °C (approximate, at which thermal decomposition with darkening and fume generation occurs).
(k) pH:	Not available in pure form. (Aqueous solutions are slightly acidic due to the mesylate; e.g. a 1% solution is expected to have pH in the ~5–6 range, though specific data is not available.)
(l) Kinematic viscosity:	Not applicable (solid).
(m) Solubility:	Very soluble in water. Reported water solubility >200 mg/mL at room temperature. Solubility in ethanol is only slight; practically insoluble in non-polar solvents (ether, chloroform). Soluble in dilute acids.
(n) Partition coefficient: n-octanol/water:	Not available for the salt form. (The free base has an estimated log P around 2.2, but as a dimesylate salt the compound is ionic and will partition into aqueous phase; an octanol-water partition is not meaningful for the ionized form).
(o) Vapour pressure:	Essentially zero at room temperature (solid with negligible vapor pressure). No measurable vapor pressure data available.
(p) Density:	~1.15 (water = 1) at 25 °C. (Specific gravity ~1.15 at 25 °C indicates solid

	crystals are slightly denser than water and will sink in water).
(q) Relative vapour density:	Not applicable (non-volatile solid). (If sublimation occurred, vapor density would be >1 as molecular weight is high, but practically no vapor).
(r) Particle characteristics:	Substance is marketed as a fine crystalline powder (white to off-white). No specific nanoforms are identified. Typical particle size is in the range of 100–500 µm, depending on grade. Product is not intentionally manufactured or supplied as a nanomaterial. Dust may form during handling.
(s) Chemical family:	Alkylated phenethylamine (sympathomimetic amine).
(t) Molecular structure:	Lisdexamfetamine is a covalent conjugate of S-(+)-amphetamine linked to L-lysine via an amide bond. This substance is provided as the dimesylate (bis-methanesulfonate) salt.
(u) Stable isotopic composition:	Contains C, H, N, O, S in natural abundance (no radioactive isotopes).
(v) Surface tension:	Not applicable (solid).
(w) Evaporation rate	Not applicable (non-volatile solid).

9.2 Other information

Information with regard to physical hazard classes

(x) Explosive properties:	Not explosive. The substance does not have chemical groups associated with explosive properties. Note: Finely dispersed dust in air could pose a dust explosion risk in the presence of an ignition source, as is common with organic powders, but this is a physical hazard of dust, not a chemical explosivity rating.
(y) Oxidising properties:	Not oxidizing (does not cause or enhance combustion of other materials).
(z) Corrosive to metals:	The mixture is not classified as corrosive to metals.

Other safety characteristics

No other relevant safety charecteristics.

SECTION 10: Stability and reactivity

10.1 Reactivity

The substance is not considered reactive under normal ambient conditions. It does not undergo hazardous polymerization and is not pyrophoric or water-reactive. It is a stable organic salt that, in the absence of incompatible materials, remains chemically unchanged. No specific reactivity hazards are known with air or water (it is water-soluble but stable in solution).

10.2 Chemical stability

Stable under recommended storage and handling conditions (see Section 7). It can be stored long-term at room temperature if kept dry and protected from light. Gradual degradation may occur on extended exposure to light or heat.

Under normal temperatures and pressures, no significant decomposition occurs.

10.3 Possibility of hazardous reactions

Hazardous polymerization will not occur. The substance is stable under normal conditions of use and storage and is not self-reactive. Contact with strong bases (highly alkaline conditions) may lead to degradation of the amide bond, potentially releasing dextroamphetamine free base, which is a volatile and flammable oily liquid; such decomposition can result in fumes and a flammability hazard.

Strong oxidizing agents (e.g. concentrated nitric acid, perchlorates, permanganates) may react violently with the organic material, causing decomposition or fire. Aside from such extreme conditions, the substance is not expected to undergo hazardous reactions.

10.4 Conditions to avoid

Avoid exposure to high temperatures, open flame, or other ignition sources. Heating above ~150 °C should be avoided except in controlled conditions, as decomposition can begin and hazardous fumes may be emitted at elevated temperatures. Avoid moisture/humidity – the compound absorbs water from air and can degrade or become less stable when wet. Avoid direct sunlight or UV light – prolonged light exposure may cause chemical degradation or discoloration. Also avoid generating dust (as a dust explosion precaution and to avoid inhalation exposure). Any condition causing the formation of aerosols or dust clouds should be controlled.

10.5 Incompatible materials

In general, keep away from reactive chemicals such as strong acids (aside from intentional neutralization), strong bases, oxidizers, and materials that react with amines.

Strong oxidizing agents (e.g. peroxides, perchlorates, nitric acid) can lead to oxidation of the organic material and pose fire/explosion hazard.

Strong bases/alkalis (e.g. sodium or potassium hydroxide, ammonia) can liberate the free amine base and cause exothermic reactions; the free base is a flammable liquid, so strong base contact should be avoided.

10.6 Hazardous decomposition products

When heated to decomposition or combusted, it may produce toxic fumes including nitrogen oxides, sulfur oxides, and carbon monoxide/carbon dioxide. Thermal decomposition may also yield other irritating or harmful vapors such as amines or other organics. In a structure fire, expect dense, acrid smoke containing the above compounds. No hazardous decomposition products are expected under normal storage conditions. In contact with strong base, dextroamphetamine free base (boiling point ~203 °C) may be released as a volatile fume, which is flammable.

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity
Lisdexamfetamine dimesylate is classified as harmful if swallowed (Acute Toxicity Category 4; H302). In non-clinical toxicity studies submitted to regulatory agencies (FDA/EMA), lisdexamfetamine showed relatively low acute toxicity compared with d-amphetamine, as the substance is a prodrug and must be enzymatically converted before exerting stimulant effects.

Single-dose studies in rats did not produce mortality at doses up to several hundred milligrams per kilogram, indicating moderate acute toxicity consistent with the CLP Category 4 classification. Severe toxic signs (agitation, tremor, hyperthermia, convulsions) occurred only at very high doses.

In humans, overdose may cause sympathetic overstimulation, hyperthermia, tachycardia, hypertension, arrhythmias, seizures, rhabdomyolysis and, in extreme cases, death. The onset of severe symptoms may be delayed because lisdexamfetamine requires metabolic conversion.

No experimental data are available for inhalation or dermal LD_{50} values. As a potent active pharmaceutical ingredient in powder form, airborne dust may cause systemic effects if inhaled; therefore, dust generation should be minimized. Prolonged skin contact may result in limited systemic absorption and should be avoided.

Classification: Acute Toxicity Category 4 (H302: Harmful if swallowed)

Oral (LD_{50})	Inhalation (LC_{50})	Dermal (LD_{50})
No data	No data	No data

Skin corrosion/irritation
Based on available data, the classification criteria are not met.

Serious eye damage/irritation
Based on available data, the classification criteria are not met.

Respiratory or skin sensitisation
Based on available data, the classification criteria are not met.

Germ cell mutagenicity
Based on available data, the classification criteria are not met.

Carcinogenicity
Based on available data, the classification criteria are not met.

Reproductive toxicity
Based on available data, the classification criteria are not met.

STOT-single exposure
Based on available data, the classification criteria are not met.

STOT-repeated exposure
Based on available data, the classification criteria are not met.

Aspiration hazard
Based on available data, the classification criteria are not met.

11.2 Information on other hazards

Endocrine disrupting properties
None known.

Other information
None known.

SECTION 12: Ecological information

12.1 Toxicity

Results	
Short-term toxicity to fish -	**Long-term toxicity to fish** -
Short-term toxicity to aquatic invertebrates -	**Long-term toxicity to aquatic invertebrates** -
Toxicity to aquatic algae and cyanobacteria -	**Toxicity to microorganisms** -

No specific ecotoxicity data are available for lisdexamfetamine dimesylate. As an organic amine salt, the substance may cause adverse effects to aquatic organisms at sufficiently high concentrations, but current data are insufficient for classification under CLP. Avoid release to the environment and prevent contamination of surface water and wastewater systems.

12.2 Information on other hazards

BOD5	COD	Biodegradable
No data available	No data available	No data available

No experimental data are available. The substance is expected to undergo biodegradation in the environment based on the based on chemical structure (readily soluble, amine salt and peptide-like amide linkage), but cannot be formally classified as readily biodegradable without test results.

12.3 Bioaccumulative potential

BCF	LogPow	Bioaccumulative potential
No experimental data available	No data for the dimesylate salt (free base ≈ 2.2)	Low

Based on high water solubility and ionic nature, significant bioaccumulation is not expected. The salt form is strongly hydrophilic; effective log Pow is <0. Substance is not expected to bioaccumulate in aquatic organisms.

12.4 Mobility in soil

Koc	Surface tension	Henry's constant
No data available	No data available	No data available

Lisdexamfetamine dimesylate is expected to be highly mobile in the aquatic environment due to its ionic nature and high solubility. It will preferentially remain in the water phase rather than partitioning into soil or air. Significant volatilisation from surfaces is not expected, and adsorption to sediment or soil organic matter is likely to be minimal. Consequently, if released, the compound may migrate with water and could potentially reach groundwater.

12.5 Results of PBT and vPvB assessment

This substance contains no components considered to be persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Endocrine disrupting properties

The product does not contain any components with known endocrine-disrupting properties according to REACH Article 57(f) or Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 in a concentration of 0.1% or higher.

12.7 Other adverse effects

If released, dexamphetamine could potentially disrupt aquatic life behavior due to its stimulant properties (e.g., affecting fish neurologically at sub-lethal doses, though this is not part of standard ecotox metrics).

It is an organic pollutant of emerging concern (pharmaceutical), and in surface waters has been detected (from excreted medications) at low ng/L to µg/L levels in some studies. Even low concentrations might contribute to ecological stress over time (e.g., altering fish behavior or reproduction, as seen with other stimulants), but concrete evidence for amphetamine is limited.

12.8 Additional information

Ozone layer: not ozone-depleting.

Water hazard class (Germany): WGK 3 (severely hazardous to water) – this is a worst-case classification often applied to pharmaceuticals. All releases should be avoided.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Disposal of the product/packaging
Dispose of this material as hazardous chemical waste. Do not discharge to sewer or natural environment. All unused drug substance, spill clean-up materials, and contaminated containers should be disposed of in accordance with local, regional, and national regulations (e.g., EU Directive 2008/98/EC on waste, and pertinent national legislation). Incineration at a licensed hazardous waste incinerator is the preferred method of disposal, as high-temperature incineration will destroy the active ingredient. If incineration is not possible, consult an approved chemical waste disposal contractor for alternatives. When disposing, refer to the material's toxicity – it should be handled by authorized waste disposal personnel.

You may mix the waste with a combustible solvent (if solid) to facilitate incineration. Do not mix this substance with incompatible waste (see Section 10) or general trash. Do not dispose of in household garbage.

Waste codes
Classification according to the European waste catalog (2018/C124/01) depends on the specifics of the disposal situation (contact your waste disposal contractor). A suggested code is shown below.

EWC code	Description	Hazard properties
Wastes from the manufacture, formulation, supply and use (MFSU) of pharmaceuticals		
07 05 13	Solid wastes containing hazardous substances	HP 6 (Acute toxicity)

Information on disposal of the packaging
Dispose of in accordance with Annex I and Annex II (Directive 2008/98/EC). The uncleaned packaging must be disposed of in the same way as the product.
EWC: 15 01 10.

Special precautions for waste treatment
This substance is a controlled drug (Schedule II) in many jurisdictions; waste destruction may need to be documented to meet regulatory requirements. Follow any protocols for destruction of controlled substances (e.g., witnessing by authorized individuals). Ensure that waste is securely stored until disposal to prevent diversion or accidental exposure.

Applicable law
In accordance with Annex II to Regulation (EC) No 1907/2006 of the European Parliament and of the Council (REACH), European and national regulations concerning the handling of waste products are set out below:

EU legislation:	Directives 2008/98/EC and 2014/955/EU. Commission Regulation (EU) No 1357/2014.

SECTION 14: Transport information

14.1 UN or ID number	Not classified as dangerous goods
14.2 UN proper shipping name	-
14.3 Transport hazard class(es)	-
14.4 Packing group	-
14.5 Environmental hazards	None.
14.6 Special precautions for user	Keep away from foodstuffs (including animal feeds). Persons handling the substance should be aware of the toxic nature – avoid handling damaged packages without PPE. In case of accident or spill, emergency responders should use protective equipment and avoid exposure (see Sections 6 and 8).
14.7 Maritime transport in bulk according to IMO instruments	Not applicable – this substance is not transported in bulk cargo form. Typically shipped in packaged form (drums, bottles, etc.). Annex II of MARPOL 73/78 and the IBC Code do not apply (solid, not a bulk liquid).

SECTION 15: Regulatory information

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII)	:	Not listed in REACH Annex XVII with specific restrictions for sale/use (aside from its classification as a controlled drug under narcotics legislation).
REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59)	:	Not applicable (not on the Candidate List).
REACH - List of substances subject to authorisation (Annex XIV)	:	Not listed in Annex XIV.
Regulation (EC) 1005/2009 on substances that deplete the ozone layer	:	Not listed.
Regulation (EU) 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants	:	Not listed.
Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens, mutagens or reproductive toxicants at work	:	Not listed.
Directive 98/24/EC (Chemical Agents Directive)	:	General worker protection requirements apply.

Regulation (EU) No 528/2012 on biocidal products	:	Not applicable; substance is not used as or in a biocidal product.
Regulation (EU) 649/2012 concerning the export and import of hazardous chemical products	:	Not listed in Annex I (PIC list).
Regulation (EU) 2019/1148 on the marketing and use of explosives precursors	:	Not listed as a restricted or reportable precursor.
Directive 2012/18/EU on the control of major-accident hazards involving dangerous substances (Seveso)	:	No Seveso threshold quantities apply to this substance.
Drug Precursors Regulation (273/2004)	:	The substance is a controlled psychostimulant drug, subject to national drug legislation in EU countries. It is not covered by the EU Precursors Regulation.
UN Convention on Psychotropic Substances (1971)	:	Lisdexamfetamine is not mentioned by name in the Annex to the Convention, but is controlled nationally as a psychotropic substance through the regulation of its active metabolite (dexamfetamine), which is covered by the Convention.
Directive 2001/83/EC (Community code for medicinal products)	:	Marketing and use limited to authorised medicinal purposes.
Other applicable legislation	:	National narcotics control legislation applies in all EU Member States. Handling is limited to licensed facilities and authorised personnel; unauthorised handling is prohibited and subject to criminal penalties.

Specific provisions regarding the protection of persons or the environment

The product is covered by the criteria in Council Directive 94/33/EC of 22 June 1994 on the protection of young people at work. Accordingly, young people under the age of 18 should not use or be exposed to the product professionally.

In relation to pregnancy and breastfeeding, the substance is not classified as a reproductive toxicant under current CLP regulations. However, due to the potent pharmacological activity of lisdexamfetamine dimesylate on the central nervous and cardiovascular systems, exposure during pregnancy and breastfeeding should be avoided or strictly minimised as a precautionary measure.

15.2 Chemical safety assessment

No chemical safety assessment has been prepared for this product.

SECTION 16: Other information

Applicable law
This safety data sheet has been prepared in accordance with the European Parliament and Council Regulation (EC) No. 1907/2006 (REACH) and Commission Regulation (EU) 2020/878, and following the official ECHA guidelines. This SDS shall be supplied in an official language of the country where the product is placed on the market.

The safety data sheet has been prepared by

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Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]

Classification	Classification procedure
Acute Tox. 4 (oral)	Based on expert judgement

Key literature references and sources for data

http://echa.europa.eu
http://eur-lex.europa.eu

Revision

This safety data sheet replaces version 4.0 of 27-11-2025. The recommended storage temperature in section 7.2 of the SDS has been updated.

Advice in relation to training

Personnel handling this product must receive appropriate training in chemical safety in accordance with national legislation (e.g. AT-vejledning C.0.11 in Denmark and TRGS 555 in Germany). Also, a good working knowledge of this Safety Data Sheet is essential. Training should cover the hazards of the product, label elements, personal protective equipment, and first aid/emergency procedures.

Hazard statements

H302: Harmful if swallowed.

Abbreviations and acronyms

API Active Pharmaceutical Ingredient
ADR: Agreement concerning the International Carriage of Dangerous Goods by Road
CAS: Chemical Abstracts Service
CLP: Classification, Labelling and Packaging Regulation (EC 1272/2008)
CNS: Central Nervous System
CSA: Chemical Safety Assessment
EC: European Community (Number)
EC50: Effective concentration for 50% of organisms (ecotoxicity)
ECHA: European Chemicals Agency
ERG: Emergency Response Guide
GHS: Globally Harmonized System of Classification and Labelling
IATA: International Air Transport Association
IBC: Intermediate Bulk Container / International Bulk Chemical (Code)
IMDG: International Maritime Dangerous Goods (Code)
LC_{50}: Lethal concentration for 50% of organisms
LD_{50}: Lethal dose for 50% of organisms
OEL: Occupational Exposure Limit
PBT: Persistent, Bioaccumulative, Toxic
PPE: Personal Protective Equipment
REACH: Registration, Evaluation, Authorization and Restriction of Chemicals (EC 1907/2006)
RID: Regulations concerning the International Carriage of Dangerous Goods by Rail
SCBA: Self-Contained Breathing Apparatus
STOT: Specific Target Organ Toxicity (SE: single exposure; RE: repeated exposure)
SVHC: Substance of Very High Concern
vPvB: very Persistent and very Bioaccumulative
WGK: Wassergefährdungsklasse (German Water Hazard Class)