

SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of: Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision date 13-Jun-2023 Revision Number 1

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

1.1. Product identifier

Product Code(s) CAT 1063

Product Name Zolpidem Tartrate

Form Not applicable

NOTE [8] - No registration number is given for this substance because it is under the threshold in REACH Article 6(1) and not subject to the registration requirements according to REACH Title II

EC No (EU Index No) 629-694-9

CAS No 99294-93-6

Chemical name Zolpidem Hemitartrate

Pure substance/mixture Substance

Formula C38-H42-N6-O2.C8-H12-O12

Molecular weight 764.86

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

Recommended use Laboratory use

Uses advised against No information available

1.3. Details of the supplier of the safety data sheet

Supplier

British Pharmacopoeia Commission MHRA 10 South Colonnade Canary Wharf London E14 4PU United Kingdom

Tel: +44 (0)20 3080 6561 eMail: bpcrs@mhra.gov.uk

EGHS / EN Page 1/16



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For further information, please contact

E-mail address bpcrs@mhra.gov.uk

1.4. Emergency telephone number

Emergency Telephone +44 (0)20 3080 6561 (Monday - Friday: 8am - 5pm)

Emergency Telephone - §45 - (EC)1272/2008				
Europe	112			
Austria	No information available			
Bulgaria				
Croatia				
Cyprus				
Czech Republic				
Denmark				
France				
Hungary				
Ireland				
Italy				
Lithuania				
Luxembourg				
Netherlands				
Norway				
Portugal				
Romania				
Slovakia				
Slovenia				
Spain				
Sweden				
Switzerland				

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Regulation (EC) No 1272/2008

Acute toxicity - Oral	Category 4 - (H302)
Reproductive toxicity	Category 2 - (H361)
Specific target organ toxicity — single exposure	Category 3 - (H336)
Chronic aquatic toxicity	Category 3 - (H412)

2.2. Label elements



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Contains Zolpidem Hemitartrate



Signal word Warning

Hazard statements

H302 - Harmful if swallowed

H336 - May cause drowsiness or dizziness

H361d - Suspected of damaging the unborn child

H412 - Harmful to aquatic life with long lasting effects

Precautionary Statements - EU (§28, 1272/2008)

P201 - Obtain special instructions before use

P261 - Avoid breathing dust/fume/gas/mist/vapours/spray

P264 - Wash face, hands and any exposed skin thoroughly after handling

P280 - Wear protective gloves/protective clothing/eye protection/face protection

P312 - Call a POISON CENTER or doctor if you feel unwell

P501 - Dispose of contents/ container to an approved waste disposal plant

2.3. Other hazards

Harmful to aquatic life.

This substance does not meet the PBT/vPvB criteria of REACH, annex XIII.

Endocrine Disruptor Information	This product does not contain any known or suspected endocrine disruptors.			
Chemical name	EU - REACH (1907/2006) - Article 59(1) EU - REACH (1907/2006) - Endocrir			
	- Candidate List of Substances of Very Disruptor Assessment List of			
	High Concern (SVHC) for Authorisation Substances			
Zolpidem Hemitartrate				

SECTION 3: Composition/information on ingredients

3.1 Substances

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ſ	Chemical name	Weight-%	REACH registration	EC No (EU	Classification according	Specific	M-Factor	M-Factor



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		number	Index No)	to Regulation (EC) No. 1272/2008 [CLP]	concentration limit (SCL)	(long-term)
Zolpidem Hemitartrate 99294-93-6	90 - 100%	-	629-694-9	Acute Tox. 4 (H302) Repr. 2 (H361d) STOT SE 3 (H336) Aquatic Chronic 3 (H412)		

Full text of H- and EUH-phrases: see section 16

Acute Toxicity Estimate

If LD50/LC50 data is not available or does not correspond to the classification category, then the appropriate conversion value from CLP Annex I, Table 3.1.2, is used to calculate the acute toxicity estimate (ATEmix) for classifying a mixture based on its components

Chemical name	Oral LD50 mg/kg		Inhalation LC50 - 4 hour - dust/mist - mg/L	Inhalation LC50 - 4 hour - vapour - mg/L	Inhalation LC50 - 4 hour - gas - ppm
Zolpidem Hemitartrate 99294-93-6	2700	No data available	No data available	No data available	No data available

This product does not contain candidate substances of very high concern at a concentration >=0.1% (Regulation (EC) No. 1907/2006 (REACH), Article 59)

SECTION 4: First aid measures

4.1. Description of first aid measures

General advice Show this safety data sheet to the doctor in attendance.

Inhalation Remove to fresh air. IF exposed or concerned: Get medical advice/attention.

Eye contact Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids.

Consult a doctor.

Skin contactWash skin with soap and water. In the case of skin irritation or allergic reactions see a

doctor.

Ingestion Call a doctor. Do NOT induce vomiting. Rinse mouth. Never give anything by mouth to an

unconscious person.

4.2. Most important symptoms and effects, both acute and delayed



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Symptoms Inhalation of high vapour concentrations may cause symptoms like headache, dizziness,

tiredness, nausea and vomiting.

4.3. Indication of any immediate medical attention and special treatment needed

Note to doctorsTreat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

surrounding environment.

Large Fire CAUTION: Use of water spray when fighting fire may be inefficient.

Unsuitable extinguishing mediaDo not scatter spilled material with high pressure water streams.

5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the

chemical

No information available.

5.3. Advice for firefighters

Special protective equipment and precautions for fire-fighters

Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear.

Use personal protection equipment.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions Ensure adequate ventilation. Use personal protective equipment as required. Evacuate

personnel to safe areas.

Other information Refer to protective measures listed in Sections 7 and 8.

6.2. Environmental precautions

Environmental precautionsSee Section 12 for additional Ecological Information.

6.3. Methods and material for containment and cleaning up



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Methods for containment Prevent further leakage or spillage if safe to do so.

Methods for cleaning upTake up mechanically, placing in appropriate containers for disposal.

Prevention of secondary hazards Clean contaminated objects and areas thoroughly observing environmental regulations.

6.4. Reference to other sections

Reference to other sectionsSee section 8 for more information. See section 13 for more information.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Advice on safe handling Handle in accordance with good industrial hygiene and safety practice. Avoid contact with

skin, eyes or clothing. Do not eat, drink or smoke when using this product. Remove contaminated clothing and shoes. Ensure adequate ventilation. Avoid breathing vapours or

mists. In case of insufficient ventilation, wear suitable respiratory equipment.

General hygiene considerations Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this

product. Wash hands before breaks and after work. Wear suitable gloves and eye/face protection. Wash hands before breaks and immediately after handling the product.

7.2. Conditions for safe storage, including any incompatibilities

Storage Conditions Please refer to the manufacturer's certificate for specific storage and transport temperature

conditions. Store only in the original receptacle unless other advice is given on the CoA. Store locked up. Keep containers tightly closed in a dry, cool and well-ventilated place.

Keep out of the reach of children.

7.3. Specific end use(s)

Risk Management Methods (RMM) The information required is contained in this Safety Data Sheet.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Exposure Limits This product, as supplied, does not contain any hazardous materials with occupational

exposure limits established by the region specific regulatory bodies.



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Biological occupational exposure limits

This product, as supplied, does not contain any hazardous materials with biological limits established by the region specific regulatory bodies

Derived No Effect Level (DNEL)
Predicted No Effect Concentration
(PNEC)

No information available. No information available.

8.2. Exposure controls

Personal protective equipment

Eye/face protection Avoid contact with eyes. Wear safety glasses with side shields (or goggles).

Hand protection The protective gloves to be used must comply with the specifications of EC Directive

89/686/EEC and the related standard EN374. Wear protective nitrile rubber gloves. Wear

suitable gloves.

Skin and body protection Wear suitable protective clothing.

Respiratory protection No protective equipment is needed under normal use conditions. If exposure limits are

exceeded or irritation is experienced, ventilation and evacuation may be required.

General hygiene considerations Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this

product. Wash hands before breaks and after work. Wear suitable gloves and eye/face protection. Wash hands before breaks and immediately after handling the product.

Environmental exposure controls Do not allow into any sewer, on the ground or into any body of water.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state Solid
Appearance Solid
Colour white
Odour Odourless.

Odour threshold No information available

Property Values Remarks • Method

Melting point / freezing point 185 °C None known



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Initial boiling point and boiling rangeNo data available

No data available

None known

None known

Flammability Limit in Air

None known

Upper flammability or explosive No data available

limits
Lower flammability or explosive No data available

limits

Flash point No data available None known Autoignition temperature No data available None known Decomposition temperature None known

pH No data available None known
pH (as aqueous solution) No data available No information available

Kinematic viscosity No data available None known No data available **Dynamic viscosity** None known No data available Water solubility None known Solubility(ies) No data available None known **Partition coefficient** No data available None known Vapour pressure No data available None known No data available Relative density None known

Bulk density
No data available
No data available

Relative vapour density No data available None known

Particle characteristics

Particle SizeNo information availableParticle Size DistributionNo information available

9.2. Other information

Molecular weight 764.86

Molecular formula C38-H42-N6-O2.C8-H12-O12

9.2.1. Information with regards to physical hazard classes Not applicable

9.2.2. Other safety characteristics No information available

SECTION 10: Stability and reactivity

10.1. Reactivity

Reactivity No information available.

10.2. Chemical stability

Stability Stable under normal conditions.



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Explosion data

Sensitivity to mechanical impact None. Sensitivity to static discharge None.

10.3. Possibility of hazardous reactions

Possibility of hazardous reactions
None under normal processing.

10.4. Conditions to avoid

Conditions to avoid None known based on information supplied.

10.5. Incompatible materials

Incompatible materialsNone known based on information supplied.

Hazardous decomposition products None known based on information supplied.

SECTION 11: Toxicological information

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

Information on likely routes of exposure

Product Information

Inhalation May cause drowsiness or dizziness.

Eye contact Specific test data for the substance or mixture is not available.

Skin contact Specific test data for the substance or mixture is not available.

Ingestion Specific test data for the substance or mixture is not available. Harmful if swallowed. (based

on components).

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms Inhalation of high vapour concentrations may cause symptoms like headache, dizziness,

tiredness, nausea and vomiting.

Numerical measures of toxicity

Acute toxicity



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Component Information

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Zolpidem Hemitartrate	= 2700 mg/kg (Rat)		

Delayed and immediate effects as well as chronic effects from short and long-term exposure

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

Serious eye damage/eye irritation No information available.

Respiratory or skin sensitisation No information available.

Germ cell mutagenicity No information available.

Carcinogenicity No information available.

Reproductive toxicity Contains a known or suspected reproductive toxin. Classification based on data available

for ingredients. Suspected of damaging fertility or the unborn child.

STOT - single exposure May cause drowsiness or dizziness.

STOT - repeated exposure No information available.

Aspiration hazard No information available.

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Endocrine disrupting properties No information available.



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11.2.2. Other information

Other adverse effects No information available.

SECTION 12: Ecological information

12.1. Toxicity

Ecotoxicity Harmful to aquatic life with long lasting effects.

Chemical name	Algae/aquatic plants	Fish	Toxicity to	Crustacea
			microorganisms	
Zolpidem Hemitartrate	-	LC50: 22 mg/l (Fish, 96h)	-	-

12.2. Persistence and degradability

Persistence and degradability No information available.

12.3. Bioaccumulative potential

Bioaccumulation There is no data for this product.

Component Information

Chemical name	Partition coefficient
Zolpidem Hemitartrate	2.42

12.4. Mobility in soil

Mobility in soil No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment No information available.

12.6. Endocrine disrupting properties

Endocrine disrupting properties No information available.

12.7. Other adverse effects

No information available.

SECTION 13: Disposal considerations



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13.1. Waste treatment methods

Waste from residues/unused

products

Dispose of in accordance with local regulations. Dispose of waste in accordance with

environmental legislation.

Contaminated packaging Do not reuse empty containers.

SECTION 14: Transport information

IATA

14.1 UN number or ID numberNot regulated14.2 UN proper shipping nameNot regulated14.3 Transport hazard class(es)Not regulated14.4 Packing groupNot regulated14.5 Environmental hazardsNot applicable

14.6 Special precautions for user

Special Provisions None

Special Flovisions

IMDG

14.1 UN number or ID numberNot regulated14.2 UN proper shipping nameNot regulated14.3 Transport hazard class(es)Not regulated14.4 Packing groupNot regulated14.5 Marine pollutantNot applicable

14.6 Special precautions for user

Special Provisions
14.7 Maritime transport in bulk

according to IMO instruments

None No information available

No information available

RID

14.1UN number or ID numberNot regulated14.2UN proper shipping nameNot regulated14.3Transport hazard class(es)Not regulated14.4Packing groupNot regulated14.5Environmental hazardsNot applicable

14.6 Special precautions for user

Special Provisions None

ADR

ADK	
14.1 UN number or ID number	Not regulated
14.2 UN proper shipping name	Not regulated
14.3 Transport hazard class(es)	Not regulated
14.4 Packing group	Not regulated
14.5 Environmental hazards	Not applicable



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14.6 Special precautions for user Special Provisions

None

SECTION 15: Regulatory information

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

National regulations

RemarksThis substance is considered a controlled drug in some countries and needs to be treated

according to the applicable regulations

Germany

Water hazard class (WGK) obviously hazardous to water (WGK 2)

Poland

SDS created according to the following Polish regulation: Act of February 25, 2011 on chemical substances and their mixtures (Journal of Laws of 2018, item 143, as amended). Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing the European Chemicals Agency (EC) as amended. Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labeling and packaging of substances and mixtures, as amended. Regulation of the Minister of Health of 10 August 2012 on the criteria and method of classifying chemical substances and their mixtures (Journal of Laws of 2012, item 1018). Regulation of the Minister of Health of 20 April 2012 on labeling packaging of hazardous substances and mixtures and some mixtures (Journal of Laws of 2012, item 445). Regulation of the Minister of Family, Labor and Social Policy of 12 June 2018 on the maximum allowable concentrations and intensities of factors harmful to health in the work environment (Journal of Laws of 2018, item 1286). Announcement of the Minister of Economy, Labor and Social Policy of August 28, 2003 on the publication of the unified text of the Ordinance of the Minister of Labor and Social Policy on general health and safety at work regulations (Journal of Laws of 2003, No. 169, item 1650) . Regulation of the Minister of Health of 30 December 2004 on occupational safety and health related to the presence of chemical agents in the workplace (Journal of Laws of 2005, No. 11, item 86). Act of December 14, 2012 on waste (Journal of Laws of 2013, item 21) Regulation of the Minister of Health of December 30, 2004 on occupational health and safety related to the presence of chemical agents in the workplace (Journal U. of 2005, No. 11, item 86). Waste Act of December 14, 2012 (Journal of Laws of 2013, item 21). Act of 13 June 2013 on the management of packaging and packaging waste, Journal of Laws 2013, item 888). Government statement of September 24, 2002 - European Agreement on the International Carriage of Dangerous Goods by Road (ADR) (Journal of Laws No. 194,



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item 1629 and Journal of Laws of 2003, No. 207, item 2013 and 2014).

European Union

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work.

Authorisations and/or restrictions on use:

This product does not contain substances subject to authorisation (Regulation (EC) No. 1907/2006 (REACH), Annex XIV) This product does not contain substances subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

DIRECTIVE (EU) 2021/1187 on the marketing and use of explosives precursors

Not applicable

Persistent Organic Pollutants

Not applicable

Ozone-depleting substances (ODS) regulation (EC) 1005/2009

Not applicable

International Inventories

TSCA Complies under research and development exemption or is regulated by a different

government agency.

DSL/NDSL
Contact supplier for inventory compliance status
IECSC
Contact supplier for inventory compliance status
KECL
Contact supplier for inventory compliance status
Contact supplier for inventory compliance status
Contact supplier for inventory compliance status
AllC
Contact supplier for inventory compliance status

Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

ENCS - Japan Existing and New Chemical Substances

IECSC - China Inventory of Existing Chemical Substances

KECL - Korean Existing and Evaluated Chemical Substances

PICCS - Philippines Inventory of Chemicals and Chemical Substances

AICS - Australian Inventory of Chemical Substances



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15.2. Chemical safety assessment

Chemical Safety Report A Chemical Safety Assessment is not required for this substance

SECTION 16: Other information

Key or legend to abbreviations and acronyms used in the safety data sheet

Full text of H-Statements referred to under section 3

H302 - Harmful if swallowed

H336 - May cause drowsiness or dizziness

H361d - Suspected of damaging the unborn child

H412 - Harmful to aquatic life with long lasting effects

Legend

SVHC: Substances of Very High Concern for Authorisation:

Legend Section 8: Exposure controls/personal protection

TWA TWA (time-weighted average) STEL STEL (Short Term Exposure Limit)

Ceiling Maximum limit value * Skin designation

Classification procedure	
Classification procedure Classification according to Regulation (EC) No. 1272/2008 [CLP]	Method Used
Acute oral toxicity	Calculation method
Acute dermal toxicity	Calculation method
Acute inhalation toxicity - gas	Calculation method
Acute inhalation toxicity - Vapour	Calculation method
Acute inhalation toxicity - dust/mist	Calculation method
Skin corrosion/irritation	Calculation method
Serious eye damage/eye irritation	Calculation method
Respiratory sensitisation	Calculation method
Skin sensitisation	Calculation method
Mutagenicity	Calculation method
Carcinogenicity	Calculation method
STOT - single exposure	Calculation method
STOT - repeated exposure	Calculation method
Acute aquatic toxicity	Calculation method
Chronic aquatic toxicity	Calculation method
Aspiration hazard	Calculation method
Ozone	Calculation method

Key literature references and sources for data used to compile the SDS

Agency for Toxic Substances and Disease Registry (ATSDR)



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U.S. Environmental Protection Agency ChemView Database

European Food Safety Authority (EFSA)

EPA (Environmental Protection Agency)

Acute Exposure Guideline Level(s) (AEGL(s))

U.S. Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act

U.S. Environmental Protection Agency High Production Volume Chemicals

Food Research Journal

Hazardous Substance Database

International Uniform Chemical Information Database (IUCLID)

Japan GHS Classification

Australian National Industrial Chemicals Notification and Assessment Scheme (NICNAS)

NIOSH (National Institute for Occupational Safety and Health)

National Library of Medicine's ChemID Plus (NLM CIP)

National Library of Medicine's PubMed database (NLM PUBMED)

National Toxicology Program (NTP)

New Zealand's Chemical Classification and Information Database (CCID)

Organisation for Economic Co-operation and Development Environment, Health, and Safety Publications

Organisation for Economic Co-operation and Development High Production Volume Chemicals Programme

Organisation for Economic Co-operation and Development Screening Information Data Set

World Health Organization

Revision date

13-Jun-2023

This material safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006 Disclaimer

The information in this safety data sheet (SDS) has been prepared with due care and is true and accurate to the best of our knowledge. The user must determine the suitability of the information for its particular purpose, ensure compliance with existing laws and regulations, and be aware that other or additional safety or performance considerations may arise when using, handling and/ or storing the material. The information in this SDS does not purport to be all inclusive or a guarantee as to the properties of the material supplied, and should be used only as a guide. British Pharmacopoeia Commission Office makes no warranties or representations as to the accuracy and completeness of the information contained herein, shall not be heldresponsible for the suitability of this information for the user's intended purposes or the consequences of such use, and shall not be liable for any damage or loss, howsoever arising, direct or otherwise.

End of Safety Data Sheet