

Zopiclone

Safety Data Sheet

according to Regulation (EC) No. 453/2010
Date of issue: 29/07/2015 Revision date:

Version: 1.0

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

1.1. Product identifier

Product form : Substance
Substance name : Zopiclone
EC no : 256-138-9
CAS No : 43200-80-2
Product code : 900817
Synonyms : Somnol, Zimovane, Limovane, Amoban, Imovane, Sopivan, Ximovan
Product group : Raw material

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

1.2.1. Relevant identified uses

Main use category : Pharmaceutical industry
Use of the substance/mixture : Active ingredient for the preparation of pharmaceuticals

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Duchefa FARMA BV
A. Hofmanweg 71
2031BH Haarlem - Nederland
T +31(0)23-5319093 - F +31(0)23-5318027
info@ducheffa.com - www.ducheffa.com

1.4. Emergency telephone number

Country	Organisation/Company	Address	Emergency number
UNITED KINGDOM	Guy's & St Thomas' Poisons Unit Medical Toxicology Unit, Guy's & St Thomas' Hospital Trust	Avonley Road SE14 5ER London	0870 243 2241

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Acute Tox. 4 (Oral) H302
Acute Tox. 4 (Dermal) H312
Acute Tox. 4 (Inhalation:gas) H332

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Eye Irrit. 2	H319
Repr. 2	H361f
Aquatic Chronic 2	H411

Full text of H-phrases: see section 16

Classification according to Directive 67/548/EEC [DSD] or 1999/45/EC [DPD]

Repr.Cat.3; R62

Xn; R20/21/22

Xi; R36/37/38

N; R51/53

Full text of R-phrases: see section 16

2.2. Label elements

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

Hazard pictograms (CLP)

:



GHS07



GHS08



GHS09

Signal word (CLP)

: Warning

Hazard statements (CLP)

: H302+H312+H332 - Harmful if swallowed, in contact with skin or if inhaled
H319 - Causes serious eye irritation
H361f - Suspected of damaging fertility
H411 - Toxic to aquatic life with long lasting effects

Precautionary statements (CLP)

: P261 - Avoid breathing dust
P301+P312 - IF SWALLOWED: call a POISON CENTER or doctor/physician if you feel unwell
P305 - IF IN EYES:
P351 - Rinse cautiously with water for several minutes
P304+P340 - IF INHALED: remove victim to fresh air and keep at rest in a position comfortable for breathing
P302+P352 - IF ON SKIN: Wash with plenty of soap and water

2.3. Other hazards

Adverse physicochemical, human health and environmental effects

: Damage to central nervous system.

SECTION 3: Composition/information on ingredients

3.1. Substance

Name	: Zopiclone
CAS No	: 43200-80-2
EC no	: 256-138-9

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Name	Product identifier	%	Classification according to Directive 67/548/EEC	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Zopiclone	(CAS No) 43200-80-2 (EC no) 256-138-9	98,5 - 100,5	Repr.Cat.3; R62 Xn; R20/21/22 Xi; R36/37/38 N; R51/53	Acute Tox. 4 (Oral), H302 Acute Tox. 4 (Dermal), H312 Acute Tox. 4 (Inhalation:gas), H332 Eye Irrit. 2, H319 Repr. 2, H361f Aquatic Chronic 2, H411

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

3.2. Mixture

Not applicable

SECTION 4: First aid measures

4.1. Description of first aid measures

- First-aid measures general : Never give anything by mouth to an unconscious person.
- First-aid measures after inhalation : Remove victim to fresh air and keep at rest in a position comfortable for breathing. Call a POISON CENTER or doctor/physician if you feel unwell. Give oxygen or artificial respiration as needed.
- First-aid measures after skin contact : Gently wash with plenty of soap and water. Immediately call a POISON CENTER or doctor/physician.
- First-aid measures after eye contact : Immediately flush eyes thoroughly with water for at least 15 minutes.
- First-aid measures after ingestion : Immediately call a POISON CENTER or doctor/physician. Rinse mouth. Do not induce vomiting.

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

- Symptoms/injuries after inhalation : Dizziness. Irritation of the respiratory tract and the other mucous membranes. Sore throat.
- Symptoms/injuries after skin contact : Redness, pain.
- Symptoms/injuries after eye contact : Redness, pain. Lacrimation.
- Symptoms/injuries after ingestion : Headache. Vomiting. Unconsciousness. Nausea.

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

No additional information available

SECTION 5: Firefighting measures

5.1. Extinguishing media

- Suitable extinguishing media : dry chemical powder, alcohol-resistant foam, carbon dioxide (CO₂).
- Unsuitable extinguishing media : Do not use a heavy water stream.

5.2. Special hazards arising from the substance or mixture

- Fire hazard : Vapours are heavier than air and may spread along floors. Under fire conditions, hazardous fumes will be present.
- Hazardous decomposition products in case of fire : Toxic and irritating gases are released.

5.3. Advice for firefighters

- Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection.

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SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Protective equipment : Wear recommended personal protective equipment.
Emergency procedures : Only qualified personnel equipped with suitable protective equipment may intervene.

6.1.2. For emergency responders

Protective equipment : Wear respiratory protection. Protective gloves. Wear suitable protective clothing and eye/face protection.

6.2. Environmental precautions

Prevent entry to sewers and public waters.

6.3. Methods and material for containment and cleaning up

For containment : Avoid raising dust. Ensure adequate ventilation.
Methods for cleaning up : Soak up with inert absorbent material (for example sand, sawdust, a universal binder, silica gel). Store away from other materials. This material and its container must be disposed of in a safe way, and as per local legislation.

6.4. Reference to other sections

Reference to other sections (8, 13).

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Only accessible to trained personnel. Avoid contact with skin and eyes.
Hygiene measures : Always wash hands after handling the product. Contaminated work clothing should not be allowed out of the workplace.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Keep container tightly closed. Store in a dry place. Store in a well-ventilated place. Store in a closed container.
Incompatible materials : Direct sunlight. Sources of ignition.
Storage temperature : 15 - 25 °C

7.3. Specific end use(s)

Pharmaceutical industry.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Additional information : < 0.01 mg/m³/8h

8.2. Exposure controls

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Appropriate engineering controls	: Handle in accordance with good industrial hygiene and safety practice. Technical measures and appropriate working operations should have priority over the use of personal protective equipment.
Hand protection	: Chemical resistant gloves (according to European standard NF EN 374 or equivalent)
Eye protection	: Safety glasses (to European standard EN 166 or equivalent)
Skin and body protection	: Protective clothing (with elasticated cuffs and closed neck)
Respiratory protection	: Dustmask with filtertype P3

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Solid
Appearance	: Crystalline powder.
Molecular mass	: 388,8 g/mol
Colour	: white to slightly yellow.
Odour	: odourless.
Odour threshold	: No data available
pH	: No data available
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: 177 °C
Freezing point	: No data available
Boiling point	: 580 °C
Flash point	: 305 °C
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Flammability (solid, gas)	: No data available
Vapour pressure	: No data available
Relative vapour density at 20 °C	: No data available
Relative density	: No data available
Density	: 1,54 g/cm ³
Solubility	: Poorly soluble in water. Soluble in dichloromethane.
Log Pow	: No data available
Log Kow	: 1,54
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available

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Explosive properties : No data available

Oxidising properties : No data available

Explosive limits : No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

No additional information available

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No additional information available

10.4. Conditions to avoid

Sources of ignition. Direct sunlight. Avoid dust formation.

10.5. Incompatible materials

Strong oxidizing agents.

10.6. Hazardous decomposition products

Carbon oxides (CO, CO₂). Nitrogen oxides. Hydrogen chloride.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Oral: Harmful if swallowed. Dermal: Harmful in contact with skin.
Inhalation:gas: Harmful if inhaled.

Zopiclone (43200-80-2)	
LD50 oral rat	827 mg/kg
LD50 oral	2174 mouse

Skin corrosion/irritation : Not classified

Serious eye damage/irritation : Causes serious eye irritation.

Respiratory or skin sensitisation : Not classified

Germ cell mutagenicity : Not classified

Carcinogenicity : Not classified

Reproductive toxicity : Suspected of damaging fertility.

Specific target organ toxicity (single exposure) : Not classified

Specific target organ toxicity (repeated exposure) : Not classified

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Aspiration hazard : Not classified

SECTION 12: Ecological information

12.1. Toxicity

No additional information available

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

Zopiclone (43200-80-2)	
Log Kow	1,54
Bioaccumulative potential	unlikely.

12.4. Mobility in soil

Zopiclone (43200-80-2)	
Ecology - soil	Poorly soluble in water.

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Regional legislation (waste) : Disposal must be done according to official regulations.
Waste disposal recommendations : Dispose of contaminated material at an authorized site.

SECTION 14: Transport information

In accordance with ADR / RID / IMDG / IATA / ADN

14.1. UN number

UN-No. (ADR) : 3077
UN-No. (IMDG) : 3077
UN-No.(IATA) : 3077
UN-No.(ADN) : 3077
UN-No. (RID) : 3077

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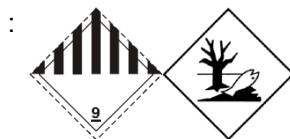
14.2. UN proper shipping name

Proper Shipping Name (ADR)	: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
Proper Shipping Name (IMDG)	: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
Proper Shipping Name (IATA)	: Environmentally hazardous substance, solid, n.o.s.
Proper Shipping Name (ADN)	: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
Proper Shipping Name (RID)	: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
Transport document description (ADR)	: UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S., 9, III, (E)
Transport document description (IMDG)	: UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S., 9, III, MARINE POLLUTANT/ENVIRONMENTALLY HAZARDOUS

14.3. Transport hazard class(es)

ADR

Transport hazard class(es) (ADR)	: 9
Danger labels (ADR)	: 9



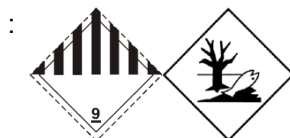
IMDG

Transport hazard class(es) (IMDG)	: 9
Danger labels (IMDG)	: 9



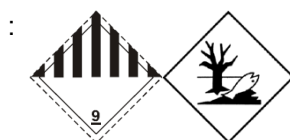
IATA

Transport hazard class(es) (IATA)	: 9
Hazard labels (IATA)	: 9



ADN

Transport hazard class(es) (ADN)	: 9
Danger labels (ADN)	: 9



RID

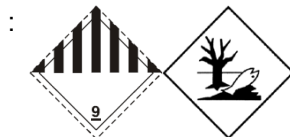
Transport hazard class(es) (RID)	: 9
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Danger labels (RID) : 9



14.4. Packing group


Packing group (ADR) : III
Packing group (IMDG) : III
Packing group (IATA) : III
Packing group (ADN) : III
Packing group (RID) : III

14.5. Environmental hazards

Dangerous for the environment : Yes
Marine pollutant : Yes
Other information : No supplementary information available

14.6. Special precautions for user

- Overland transport

Classification code (ADR) : M7
Special provisions (ADR) : 274, 335, 601
Limited quantities (ADR) : 5kg
Excepted quantities (ADR) : E1
Packing instructions (ADR) : P002, IBC08, LP02, R001
Special packing provisions (ADR) : PP12, B3
Mixed packing provisions (ADR) : MP10
Portable tank and bulk container instructions (ADR) : T1, BK1, BK2
Portable tank and bulk container special provisions (ADR) : TP33
Tank code (ADR) : SGAV, LGBV
Vehicle for tank carriage : AT
Transport category (ADR) : 3
Special provisions for carriage - Packages (ADR) : V13
Special provisions for carriage - Bulk (ADR) : VV1
Special provisions for carriage - Loading, unloading and handling (ADR) : CV13
Hazard identification number (Kemler No.) : 90
Orange plates : 
Tunnel restriction code (ADR) : E
EAC code : 2Z

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- Transport by sea

Special provisions (IMDG)	: 274, 335, 966, 967
Limited quantities (IMDG)	: 5 kg
Excepted quantities (IMDG)	: E1
Packing instructions (IMDG)	: P002, LP02
Special packing provisions (IMDG)	: PP12
IBC packing instructions (IMDG)	: IBC08
IBC special provisions (IMDG)	: B3
Tank instructions (IMDG)	: T1, BK1, BK2, BK3
Tank special provisions (IMDG)	: TP33
EmS-No. (Fire)	: F-A
EmS-No. (Spillage)	: S-F
Stowage category (IMDG)	: A

- Air transport

PCA Excepted quantities (IATA)	: E1
PCA Limited quantities (IATA)	: Y956
PCA limited quantity max net quantity (IATA)	: 30kgG
PCA packing instructions (IATA)	: 956
PCA max net quantity (IATA)	: 400kg
CAO packing instructions (IATA)	: 956
CAO max net quantity (IATA)	: 400kg
Special provisions (IATA)	: A97, A158, A179, A197
ERG code (IATA)	: 9L

- Inland waterway transport

Classification code (ADN)	: M7
Special provisions (ADN)	: 274, 335, 61
Limited quantities (ADN)	: 5 kg
Excepted quantities (ADN)	: E1
Carriage permitted (ADN)	: T* B**
Equipment required (ADN)	: PP, A
Number of blue cones/lights (ADN)	: 0
Additional requirements/Remarks (ADN)	: * Only in the molten state. ** For carriage in bulk see also 7.1.4.1. *** Only in the case of transport in bulk.
Carriage prohibited (ADN)	: No
Not subject to ADN	: No

- Rail transport

Classification code (RID)	: M7
Special provisions (RID)	: 274, 335, 601
Limited quantities (RID)	: 5kg
Excepted quantities (RID)	: E1
Packing instructions (RID)	: P002, IBC08, LP02, R001
Special packing provisions (RID)	: PP12, B3
Mixed packing provisions (RID)	: MP10
Portable tank and bulk container instructions (RID)	: T1, BK1, BK2

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Portable tank and bulk container special provisions (RID)	: TP33
Tank codes for RID tanks (RID)	: SGAV, LGBV
Transport category (RID)	: 3
Special provisions for carriage – Packages (RID)	: W13
Special provisions for carriage – Bulk (RID)	: VW1
Special provisions for carriage - Loading, unloading and handling (RID)	: CW13, CW31
Colis express (express parcels) (RID)	: CE11
Hazard identification number (RID)	: 90
Carriage prohibited (RID)	: No

14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable

SECTION 15: Regulatory information

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

15.1.1. EU-Regulations

No REACH Annex XVII restrictions

Zopiclone is not on the REACH Candidate List

Zopiclone is not on the REACH Annex XIV List

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Indication of changes:

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

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Data sources

: REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. Supplier.

Full text of R-, H- and EUH-phrases:

Acute Tox. 4 (Dermal)	Acute toxicity (dermal), Category 4
Acute Tox. 4 (Inhalation:gas)	Acute toxicity (inhalation:gas) Category 4
Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Aquatic Chronic 2	Hazardous to the aquatic environment — Chronic Hazard, Category 2
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
Repr. 2	Reproductive toxicity, Category 2
H302	Harmful if swallowed
H312	Harmful in contact with skin
H319	Causes serious eye irritation
H332	Harmful if inhaled
H361f	Suspected of damaging fertility
H411	Toxic to aquatic life with long lasting effects
R20/21/22	Harmful by inhalation, in contact with skin and if swallowed
R36/37/38	Irritating to eyes, respiratory system and skin
R51/53	Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment
R62	Possible risk of impaired fertility
N	Dangerous for the environment
Xi	Irritant
Xn	Harmful

SDS EU (REACH Annex II) Duchefa

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