

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830 and according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

Date of issue: 25/02/2011 Revision date: 09/08/2022 Supersedes: 22/10/2019 Version: 2.3

CLM-7491

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

1.1. Product identifier

Product form : Substance

Substance name : CIS-(+/-)-TRAMADOL:HCL (METHOXY-13C, 99%)

EC-No. : 252-950-2

CAS-No. : 36282-47-0 (Unlabeled)

Product code : CLM-7491

Formula : *CC15H25NO2-HCI

Synonyms : (±)-cis-2-(Dimethylaminomethyl)-1-(3-methoxyphenyl)cyclohexanol hydrochloride

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

1.2.1. Relevant identified uses

Main use category : Professional use

Industrial/Professional use spec : For professional use only

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Cambridge Isotope Laboratories, Inc.

50 Frontage Road Andover, MA 01810

USA

USA: 1-800-322-1174 Int: 1-978-749-8000 <u>cilsales@isotope.com</u> www.isotope.com

Emergency telephone number

Emergency numbers:

Chemtrec: 1-800-424-9300 (24 hours) International: 1-703-741-5970 (24 hours)

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 Aquatic Chronic 2 H411

Full text of hazard classes and H-statements : see section 16

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

Xn; R22 N; R51/53

Full text of R-phrases: see section 16

GHS-US classification

Acute Tox. 4 (Oral) H302 Aquatic Acute 2 H401 Aquatic Chronic 2 H411

Full text of H statements : see section 16

Adverse physicochemical, human health and environmental effects

No additional information available

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2.2. Label elements

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

Hazard pictograms (CLP)

Precautionary statements (CLP)





GHS07

Marning

Signal word (CLP) : Warning

Hazard statements (CLP) : H302 - Harmful if swallowed.

H411 - Toxic to aquatic life with long lasting effects.

P264 - Wash Both hands thoroughly after handling.

P270 - Do not eat, drink or smoke when using this product.

P273 - Avoid release to the environment.

P301+P312 - IF SWALLOWED: Call a POISON CENTER or doctor if you feel unwell.

P330 - Rinse mouth. P391 - Collect spillage.

P501 - Dispose of contents/container to Comply with applicable regulations

GHS-US labelling

Hazard pictograms (GHS-US)





GHS07

GHS09

Signal word (GHS-US) : Warning

Hazard statements (GHS-US) : H302 - Harmful if swallowed.

H401 - Toxic to aquatic life

H411 - Toxic to aquatic life with long lasting effects.

Precautionary statements (GHS-US)

P264 - Wash Both hands thoroughly after handling.

P270 - Do not eat, drink or smoke when using this product.

P273 - Avoid release to the environment.

P301+P312 - If swallowed: Call a poison center/doctor/... if you feel unwell

P330 - Rinse mouth. P391 - Collect spillage.

P501 - Dispose of contents/container to Comply with applicable regulations

2.3. Other hazards

No additional information available

SECTION 3: Composition/information on ingredients

3.1. Substances

Name	Product identifier	%	Classification according to Directive 67/548/EEC
CIS-(+/-)-TRAMADOL:HCL (METHOXY-13C, 99%)	(CAS-No.) 36282-47-0 (Unlabeled) (EC-No.) 252-950-2	100	Xn; R22 N; R51/53
Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]

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

Name	Product identifier	%	GHS-US classification
CIS-(+/-)-TRAMADOL:HCL (METHOXY-13C, 99%) (Main constituent)	(CAS-No.) 36282-47-0 (Unlabeled)	100	Acute Tox. 4 (Oral), H302 Aquatic Acute 2, H401 Aquatic Chronic 2, H411

Full text of H-statements: see section 16

3.2. Mixtures

Not applicable

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SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general : Move out of dangerous area. Consult a physician and show this safety data sheet.

First-aid measures after inhalation : If breathed in, move person to fresh air. If not breathing, give artificial respiration. Consult a

physician.

First-aid measures after skin contact : Wash with soap and plenty of water. Consult a physician.

First-aid measures after eye contact : Flush eye with water for 15 minutes. Get medical attention.

First-aid measures after ingestion : Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a

physician.

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

Symptoms/effects after inhalation : May be harmful if inhaled. May cause respiratory tract irritation.

Symptoms/effects after skin contact : May be harmful if absorbed through skin. May cause skin irritation.

Symptoms/effects after eye contact : Causes eye irritation. Symptoms/effects after ingestion : Toxic if swallowed.

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 : Use water spray, alcohol-resistant foam, dry chemical, or carbon dioxide.

5.2. Special hazards arising from the substance or mixture

No additional information available

5.3. Advice for firefighters

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

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Emergency procedures : Use personal protective equipment. Avoid dust formation. Avoid breathing dust. Ensure

adequate ventilation.

6.1.2. For emergency responders

No additional information available

6.2. Environmental precautions

Prevent further leakage or spillage if safe to do so. Do not let product enter drains.

6.3. Methods and material for containment and cleaning up

For containment : Pick up and arrange disposal without creating dust. Keep in suitable, closed containers for

disposal.

6.4. Reference to other sections

No additional information available

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Additional hazards when processed : Avoid contact with skin and eyes. Avoid formation of dust and aerosols. Provide appropriate

exhaust ventilation at places where dust is formed. Normal measures for preventive fire

protection.

Hygiene measures : Handle in accordance with good industrial hygiene and safety practice. Wash hands before

breaks and at the end of workday.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store at room temperature away from light and moisture.

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No additional information available

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8.2. Exposure controls

Personal protective equipment : Gloves. Protective clothing. Protective goggles. Self-contained breathing apparatus.



Eye protection : Wear safety glasses with side shields (or goggles) and a face shield.

: No data available

Skin and body protection : Choose body protection according to the amount and concentration of the dangerous

substance at the work place.

Respiratory protection : When appropriate, use NIOSH/CEN approved respirator.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Solid
Appearance : Solid
Molecular mass : 300.8 g/mol
Colour : White

Odour : No data available
Odour threshold : No data available

pH : 5.0 - 6.0 at 10 g/l at 20 °C (68 °F)

Relative evaporation rate (butylacetate=1) : No data available

Melting point : 178 - 181 °C (352 - 358 °F)

: No data available Freezing point Boiling point No data available Flash point : No data available Auto-ignition temperature : No data available Decomposition temperature : No data available Flammability (solid, gas) No data available : No data available Vapour pressure Relative vapour density at 20 °C : No data available Relative density No data available Solubility Water: 100 % Log Pow : No data available Log Kow : No data available : No data available Viscosity, kinematic Viscosity, dynamic No data available : No data available Explosive properties Oxidising properties : No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

Explosive limits

No additional information available

10.2. Chemical stability

Stable if stored under recommended conditions.

10.3. Possibility of hazardous reactions

No additional information available

10.4. Conditions to avoid

No additional information available

10.5. Incompatible materials

Strong oxidizing agents.

10.6. Hazardous decomposition products

Under fire conditions: Carbon oxides, Nitrogen oxides, Hydrogen chloride gas.

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SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Oral: Harmful if swallowed.

CIS-(+/-)-TRAMADOL:HCL (METHOXY-13C, 99%) (36282-47-0 (Unlabeled))	
LD50 oral rat	303 mg/kg
LD50 dermal rabbit	> 500 mg/kg
ATE CLP (oral)	303.000 mg/kg bodyweight

Skin corrosion/irritation : Not classified

Skin - rabbit - No skin irritation

pH: 5.0 - 6.0 at 10 g/l at 20 °C (68 °F)

Serious eye damage/irritation : Not classified

Eyes - rabit - Mild eye irritation pH: 5.0 - 6.0 at 10 g/l at 20 °C (68 °F)

Respiratory or skin sensitisation : Not classified
Germ cell mutagenicity : Not classified
Carcinogenicity : Not classified
Reproductive toxicity : Not classified
STOT-single exposure : Not classified
STOT-repeated exposure : Not classified

Potential adverse human health effects and

symptoms

Aspiration hazard

: The chemical, physical, and toxicological properties have not been thoroughly investigated.

Symptoms/effects after inhalation : May be harmful if inhaled. May cause respiratory tract irritation.

Symptoms/effects after skin contact : May be harmful if absorbed through skin. May cause skin irritation.

: Not classified

Symptoms/effects after eye contact : Causes eye irritation.
Symptoms/effects after ingestion : Toxic if swallowed.

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general : Toxic to aquatic life with long lasting effects.

CIS-(+/-)-TRAMADOL:HCL (METHOXY-13C, 99	%) (36282-47-0 (Unlabeled))
LC50 fish 1	6.2 mg/l - 96 h, Carassius auratus (goldfish) -

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

CIS-(+/-)-TRAMADOL:HCL (METHOXY-13C, 99%) (36282-47-0 (Unlabeled))	
Bioaccumulative potential	Not available.

12.4. Mobility in soil

CIS-(+/-)-TRAMADOL:HCL (METHOXY-13C, 99	%) (36282-47-0 (Unlabeled))
Ecology - soil	Not available.

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Other adverse effects

Other adverse effects : An environmental hazard cannot be excluded in the event of unprofessional handling or disposal. Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic

environment.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Regional legislation (waste) : Waste materials should be disposed of under conditions which meet Federal, State, and Local environmental control regulations.

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SECTION 14: Transport information

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

14.1. UN number

UN-No.(DOT) : UN3077
DOT NA no. UN3077

14.2. UN proper shipping name

Proper Shipping Name (DOT) : Environmentally hazardous substances, solid, n.o.s.

(trans-(+/-)-2-[(Dimethylamino)methyl]-1-(3-methoxyphenyl)cyclohexan-1-ol hydrochloride)

Class (DOT) : 9 - Class 9 - Miscellaneous hazardous material 49 CFR 173.140

Hazard labels (DOT) : 9 - Class 9 (Miscellaneous dangerous materials)



DOT Symbols : G - Identifies PSN requiring a technical name

Packing group (DOT) : III - Minor Danger

DOT Special Provisions (49 CFR 172.102) : 8 - A hazardous substance that is not a hazardous waste may be shipped under the shipping description "Other regulated substances, liquid or solid, n.o.s.", as appropriate. In addition, for

solid materials, special provision B54 applies.

146 - This description may be used for a material that poses a hazard to the environment but does not meet the definition for a hazardous waste or a hazardous substance, as defined in 171.8 of this subchapter, or any hazard class as defined in Part 173 of this subchapter, if it is designated as environmentally hazardous by the Competent Authority of the country of origin, transit or destination.

335 - Mixtures of solids that are not subject to this subchapter and environmentally hazardous liquids or solids may be classified as "Environmentally hazardous substances, solid, n.o.s," UN3077 and may be transported under this entry, provided there is no free liquid visible at the time the material is loaded or at the time the packaging or transport unit is closed. Each transport unit must be leakproof when used as bulk packaging.

A112 - Notwithstanding the quantity limits shown in Column (9A) and (9B) for this entry, the following IBCs are authorized for transportation aboard passenger and cargo-only aircraft. Each IBC may not exceed a maximum net quantity of 1,000 kg:

a. Metal: 11A, 11B, 11N, 21A, 21B and 21N

b. Rigid plastics: 11H1, 11H2, 21H1 and 21H2

c. Composite with plastic inner receptacle: 11HZ1, 11HZ2, 21HZ1 and 21HZ2

d. Fiberboard: 11G

e. Wooden: 11C, 11D and 11F (with inner liners)

f. Flexible: 13H2, 13H3, 13H4, 13H5, 13L2, 13L3, 13L4, 13M1 and 13M2 (flexible IBCs must be sift-proof and water resistant or must be fitted with a sift-proof and water resistant liner).

B54 - Open-top, sift-proof rail cars are also authorized.

IB8 - Authorized IBCs: Metal (11A, 11B, 11N, 21A, 21B, 21N, 31A, 31B and 31N); Rigid plastics (11H1, 11H2, 21H1, 21H2, 31H1 and 31H2); Composite (11HZ1, 11HZ2, 21HZ1, 21HZ2, 31HZ1 and 31HZ2); Fiberboard (11G); Wooden (11C, 11D and 11F); Flexible (13H1, 13H2, 13H3, 13H4, 13H5, 13L1, 13L2, 13L3, 13L4, 13M1 or 13M2).

IP3 - Flexible IBCs must be sift-proof and water-resistant or must be fitted with a sift-proof and water-resistant liner.

N20 - A 5M1 multi-wall paper bag is authorized if transported in a closed transport vehicle. T1 - 1.5 178.274(d)(2) Normal...... 178.275(d)(2)

TP33 - The portable tank instruction assigned for this substance applies for granular and powdered solids and for solids which are filled and discharged at temperatures above their melting point which are cooled and transported as a solid mass. Solid substances transported or offered for transport above their melting point are authorized for transportation in portable tanks conforming to the provisions of portable tank instruction T4 for solid substances of packing group III or T7 for solid substances of packing group II, unless a tank with more stringent requirements for minimum shell thickness, maximum allowable working pressure, pressure-relief devices or bottom outlets are assigned in which case the more stringent tank instruction and special provisions shall apply. Filling limits must be in accordance with portable tank special provision TP3. Solids meeting the definition of an elevated temperature material must be transported in accordance with the applicable requirements of this subchapter.

DOT Packaging Exceptions (49 CFR 173.xxx) : 155
DOT Packaging Non Bulk (49 CFR 173.xxx) : 213
DOT Packaging Bulk (49 CFR 173.xxx) : 240

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Marine pollutant : No



14.3. Additional information

Other information : No supplementary information available.

Special transport precautions : DOT: Not dangerous goods.

Overland transport

Packing group (ADR) : III

Class (ADR) : 9 - Miscellaneous dangerous substances and articles

Hazard identification number (Kemler No.) : 90
Classification code (ADR) : M7

Danger labels (ADR) : 9 - Miscellaneous dangerous substances and articles



Orange plates

90

Tunnel restriction code (ADR) : E
Limited quantities (ADR) 5kg
EAC code : 2Z
Excepted quantities (ADR) : E1

Transport by sea

DOT Vessel Stowage Location : A - The material may be stowed "on deck" or "under deck" on a cargo vessel and on a

passenger vessel.

MFAG-No : 171

Air transport

DOT Quantity Limitations Passenger aircraft/rail : No limit

(49 CFR 173.27)

DOT Quantity Limitations Cargo aircraft only (49 : No limit

CFR 175.75)

Civil Aeronautics Law : Miscellaneous dangerous substances & articles(Hazardous materials notice Appended Table 1

Article 194 of the Enforcement Regulations)

14.4. Environmental hazards

Dangerous for the environment



Other information : No supplementary information available.

14.5. Special precautions for user

Special transport precautions : DOT: Not dangerous goods.

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

Not applicable

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SECTION 15: Regulatory information

15.1. US Federal regulations

CIS-(+/-)-TRAMADOL:HCL (METHOXY-13C, 99%) (36282-47-0 (Unlabeled))	
SARA Section 302 Threshold Planning Quantity (TPQ)	Not subject to reporting requirements of the United States SARA Section 302
SARA Section 311/312 Hazard Classes	Immediate (acute) health hazard
SARA Section 313 - Emission Reporting	Not subject to reporting requirements of the United States SARA Section 313

15.2. International regulations

CANADA

CIS-(+/-)-TRAMADOL:HCL (METHOXY-13C, 99%) (36282-47-0 (Unlabeled))

Not listed on the Canadian DSL (Domestic Substances List)

National regulations

No additional information available

15.3. US State regulations

CIS-(+/-)-TRAMADOL:HCL (METHOXY-13C, 99%)(36282-47-0 (Unlabeled))	
U.S California - Proposition 65 - Carcinogens List	No
U.S California - Proposition 65 - Developmental Toxicity	No
U.S California - Proposition 65 - Reproductive Toxicity - Female	No
U.S California - Proposition 65 - Reproductive Toxicity - Male	No
State or local regulations	RTK - U.S Pennsylvania - RTK (Right to Know) List RTK - U.S New Jersey - Right to Know Hazardous Substance List

SECTION 16: Other information

Other information

: This product is not radioactive. The data given for this product are those of the corresponding unlabeled compound, unless specifically indicated otherwise. Health and safety data for labeled compounds are generally not available, but are assumed to be similar or identical to the corresponding unlabeled compound.

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

Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Aquatic Chronic 2	Hazardous to the aquatic environment — Chronic Hazard, Category 2
H302	Harmful if swallowed.
H411	Toxic to aquatic life with long lasting effects.
R22	Harmful if swallowed
R51/53	Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment
N	Dangerous for the environment
Xn	Harmful

NFPA health hazard

: 2 - Materials that, under emergency conditions, can cause

temporary incapacitation or residual injury.

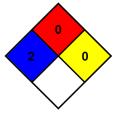
NFPA fire hazard

: 0 - Materials that will not burn under typical fire conditions, including intrinsically noncombustible materials such as

concrete, stone, and sand.

NFPA reactivity

: 0 - Material that in themselves are normally stable, even under fire conditions.



HMIS III Rating

Health : 2 Moderate Hazard - Temporary or minor injury may occur

: 0 Minimal Hazard Flammability Physical : 0 Minimal Hazard

CIL Substance SDS

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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