

SAFETY DATA SHEETS

This SDS packet was issued with item:

078941447

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078941443 078941444 078941445 078941448



Safety Data Sheet

Doxepin Hydrochloride Capsules USP, 10mg, 25mg, 50mg, 75mg, 100mg

1. Identification of the Substance/Preparation and of the Company / Undertaking

SDS compliant with regulations – (EC) No 1907/2006 (REACH), (EC) No 1272/2008 (CLP)

1.1: Identification of the substance/mixture and of the company/undertaking

Product Identifier.....	Doxepin Hydrochloride Capsules USP, 10mg, 25mg, 50mg, 75mg, 100mg
Reach Registration number.....	No information available
Product name.....	Doxepin Hydrochloride Capsules USP, 10mg, 25mg, 50mg, 75mg, 100mg
Product type.....	No information available
EC-No.	No information available
Formular.....	No information available

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

Ecology-use.....	No information available
Main use category.....	psychotherapeutic agents
Industrial category.....	No information available

1.3: Company/undertaking identification

Supplier.....	Taro Pharmaceuticals U.S.A., Inc. 3 Skyline Drive, Hawthorne, New York 10532
Company telephone number.....	1-888-TARO-USA
Company fax number.....	
Company contact person.....	

Emergency telephone number.....	1-888-TARO-USA
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2. Hazards Identification

2.1. classification of the substance or mixture

This substance is not classified as dangerous

Classification according to Regulation (EC) No 1272/2008 [EU-GHS/CLP]

Skin Irrit. 2 (H315), Eye irritation cat. 2 (H319), STOT-SE cat. 3 (H335)

Classification according to EU Directives 67/548/EEC or 1999/45/EC

2.2. Label elements

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

Pictogram.....





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Signal word.....	Danger
Hazard statement(s)	
H319	Causes serious eye irritation.
H315	Causes skin irritation.
H335	May cause respiratory irritation
H301	Toxic if swallowed
H302	Harmful if swallowed
Precautionary statement(s)	
P264	Wash {hands} thoroughly after handling.
P280	Wear {protective gloves/protective clothing/eye protection/face protection}.
P261	Avoid breathing dust/fume/gas/mist/vapours/spray.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P304 + P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing
P501	Dispose of contents/container in accordance with local/regional/national/international regulations
P405	Store locked up.
P270	Do not eat, drink or smoke when using this product.
P301+P310	IF SWALLOWED: Immediately call a POISON CENTER/doctor/...

2.3. Other hazards - none

3. Composition/Information on Ingredients

3.1 Mixtures

Synonyms	No information available
Formula	No information available
Molecular Weight	No information available

Dangerous Component		Classification	concentration
Doxepin hydrochloride			
CAS-No.	1229-29-4	H301	19 / 38 %
EC-No.	214-966-8		
Annex I number	N/A		
AMORPHOUS SILICA			
CAS-No.	112945-52-5	H315, H319, H335	<1%



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EC-No.	601-216-3		
Annex I number	N/A		
Sodium dodecyl sulphate			
CAS-No.	151-21-3	H302, H315, H412, H318(M>20%)	<0.1%
EC-No.	205-788-1		
Annex I number	N/A		

For the full text of the H-Statements mentioned in this Section, see Section 16

4. First-Aid Measures

4.1 Description of first aid measures

General advice

Consult a physician. Show this safety data sheet to the doctor in attendance.

Eye Contact.....	Hold eyelids apart and flush eyes with plenty of water for at least 20 minutes. Have eyes examined and tested by medical personnel.
Skin Contact.....	Immediately wash skin with soap and plenty of water for at least 20 minutes. Remove contaminated clothing. Get medical attention if symptoms occur. Wash clothing before reuse.
Inhalation.....	Remove to fresh air. If not breathing, give artificial respiration or give oxygen by trained personnel. Get immediate medical attention.
Ingestion.....	Wash out mouth with water provided person is conscious. Never give anything by mouth to an unconscious person. Get medical attention. Do NOT induce vomiting unless directed to do so by medical personnel.

4.2 Most important symptoms and effects, both acute and delayed

No data available

4.3 Indication of any immediate medical attention and special treatment needed

No data available

5. Fire-Fighting Measures

5.1 Extinguishing media

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



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5.2 Special hazards arising from the substance or mixture

Carbon oxides, Nitrogen oxides (NO_x), Hydrogen chloride gas

5.3 Advice for firefighters

Wear self-contained breathing apparatus for firefighting if necessary.

A solid water stream may be inefficient.

5.4 Further information

Use water spray to cool unopened containers.

6. Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

Avoid dust formation. Avoid breathing vapors, mist, or gas.

6.2 Environmental precautions

Do not let product enter drains.

6.3 Methods and materials for containment and cleaning up

Sweep up and shovel. Keep in suitable, closed containers for disposal.

6.4 Reference to other sections

For disposal see section 13.

7. Handling And Storage

7.1. Handling

Handling.....	Provide appropriate exhaust ventilation at places where dust is formed. Normal measures for preventive fire protection.
Handling temperatures.....	20-25°C (68-77°F)

7.2. storage

Storage.....	Store containers in a cool, dry location, away from direct sunlight, sources of intense heat or other sources of ignition or where freezing is possible. Store at 20-25°C (68-77°F) and away from moisture, humidity and light. Product should be stored in secondary containers or in a diked area, as appropriate. Store away from incompatible materials.
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7.3. special use(s) and requirements

Product transfer/packing requirement.....	Keep the product in its original packing
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Recommended materials.....	system. No information available
Unsuitable materials.....	No information available

8. Exposure Controls / Personal Protection

8.1 Control parameters

Contains no substances with occupational exposure limit values.

8.2 Exposure controls

Personal Protective Equipment:

Hand, Skin and Eye protection.....	Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands. Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166 (EU).
Respiratory Protection.....	Respiratory protection is not required. Where protection from nuisance levels of dusts are desired, use type N95 (US) or type P1 (EN 143) dust masks. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).
Body Protection	Choose body protection in relation to its type, to the concentration and amount of dangerous substances, and to the specific workplace. The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace

9. Physical And Chemical Properties

9.1. general information

Appearance..... solid



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Colour..... White
Odour..... Slight amine-like odor

9.2. important health, safety and environmental information

Initial boiling point and boiling range..... No data available
Melting point..... No data available
Flash point..... No data available
Auto-ignition temperature..... No data available
Upper/lower flammability or explosive limits..... No data available
Relative density..... Blend powder bulk density 0.36 to 0.41 g/ml
Solubility in water..... 31.6 mg/L (at 25 °C)
Other Solubility..... No data available
n-octanol/water partition coefficient (log pow)... No data available
Kinematic viscosity..... No data available
Relative Vapour Density No data available
Vapor pressure..... No data available
Molecular weight..... No data available
PH..... 4.5 – 5.1
Volatility%..... No data available

10. Stability And Reactivity

10.1 Reactivity

No data available

10.2 Chemical stability

Stable under recommended storage temperature conditions

10.3 Possibility of hazardous reactions

No data available

10.4 Conditions to Avoid

Avoid Strong oxidizing agents

10.5 Incompatibilities with Other Materials

No data available

10.6 Hazardous Decomposition Products

Carbon oxides, nitrogen oxides

10.7 Hazardous Polymerization

Hazard polymerization will not occur.

11. Toxicological Information

Acute toxicity – oral..... No data available
Acute toxicity – derma..... No data available

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Acute toxicity – inhalation..... No data available

11.1. Effects and symptoms

Symptoms/injuries after skin contact..... No data available
Symptoms/injuries after inhalation..... No data available
Symptoms/injuries after eye contact..... No data available
Carcinogenicity..... No data available

11.2. other information

Hazchem code..... N/A
Potential health effects..... See Hazard statement(s)

12. Ecological Information

12.1. Ecotoxicity..... No data available
12.2. Environmental Fate..... No data available
12.3. Physical/Chemical..... No data available
12.4. Bio accumulative potential..... No data available

13. Disposal Considerations

13.1. ecological aspects

Ecological general..... No information available

13.2. disposal instructions

Waste disposal..... Observe all federal, state, and local
environmental regulations
Product disposal..... No information available
Container/package disposal..... No information available
Disposal precautions..... No information available

13.3. EU and local legislation

ISRAELI legislation - Licensing of Businesses Regulations (Disposal of Hazardous Wastes),
1990.

EU - Directive 91/689/EEC on hazardous waste



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14. Transport Information

DOT Classification(49 CFR).....	NOT REGULATED
ADR.....	NOT REGULATED
IMDG Code.....	NOT REGULATED
ICAO.....	NOT REGULATED

15. Regulatory Information

This safety datasheet complies with the requirements of Regulation (EC) No. 1907/2006.

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

No information available

15.2. Chemical Safety Assessment

No information available

15.3. compliancy additional legislation

ISRAELI legislation - Hazardous Substances Law, 1993, Licensing of Businesses Regulations (Disposal of Hazardous Wastes), 1990, Hazardous Substances Regulations (Import and Export of Hazardous Wastes), 1994, Licensing of Businesses Regulations (Hazardous Industrial Plants), 1993, transport services law, 1997, Licensing of Businesses Regulations (oil storage), 1976.

16. Other Information

Text of H-code(s) mentioned in Section 3

H319	Causes serious eye irritation.
H315	Causes skin irritation.
H335	May cause respiratory irritation
H301	Toxic if swallowed
H302	Harmful if swallowed

Reach references.....	Not registered
Revision date.....	3.11.2019
Revision information.....	New Addition
Other information.....	Not available

Disclaimer:

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