



SAFETY DATA SHEET

Safety Data Sheet according to Regulation (EC) No. 1907/2006 (REACH)

Issuing Date 17-Feb-2016

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Revision Number 1

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

1.1. Product identifier

Product Name Deutetrabenazine Tablets
Synonyms SD-809 tablet
CAS -
EINECS No information available
Index No No information available
Reach Registration Number No information available

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

Identified Use Pharmaceutical
Uses advised against No information available

1.3. Details of the supplier of the safety data sheet

Manufacturer, Supplier TEVA
1090 Horsham Road
North Wales, PA 19454
BUSINESS PHONE: 215-591-3000 [08:00 AM --> 05:00 PM]

For further information, please contact

E-mail Address TevaSDSRequest@tevapharm.com

1.4. Emergency Telephone Number

Emergency Telephone Number United States/Canada/Puerto Rico: 1-800/424-9300 (Chemtrec) [24-hrs]

SECTION 2: Hazards identification

2.1. - Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008
Exempt from requirements - regulated as a medicinal product.

2.2. Label Elements

Exempt from requirements - regulated as a medicinal product

2.3. Other hazards

None known

SECTION 3: Composition/information on ingredients

3.1. Substances

N.A.

3.2. Mixtures

Chemical Name	EC No.	REACH Reg. No.	CAS-No	Weight %	CLP/GHS classification
9,10-Di-(methoxy-d3)-1,3,4,6,7,11b-hexahydro-3-isobutyl-2H-benzo[a]quinolizin-2-one	-	Not available	1392826-25-3	1-5	Repr. 2 H361f

Full text of phrases reported in section 16.

SECTION 4: First aid measures

4.1. Description of first aid measures

Eye Contact	Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.
Skin Contact	Wash off immediately with soap and plenty of water removing all contaminated clothing and shoes.
Ingestion	Clean mouth with water, only if the person is conscious. Get medical attention.
Inhalation	If breathing is difficult, give oxygen. If not breathing, give artificial respiration. Remove from exposure, lie down.

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

See product insert.

4.3. Indication of immediate medical attention and special treatment needed

Notes to Physician Treat symptomatically.

SECTION 5: Fire-fighting measures

5.1. Extinguishing media

Suitable Extinguishing Media

Water spray. Carbon dioxide (CO₂). Foam. Dry powder.

Unsuitable extinguishing media

No information available.

5.2. Special hazards arising from the substance or mixture

Thermal decomposition can lead to release of irritating gases and vapors. Combustible material.

5.3. Advice for firefighters

Special protective equipment for firefighters

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Use personal protective equipment. Avoid contact with dusts/fumes/mists/vapors.

6.1.1. For non-emergency personnel

Protective equipment See section 8

Emergency procedures Evacuate the danger area and alert emergency team

6.1.2. For emergency responders

See section 8

6.2. Environmental Precautions

Prevent entry into waterways, sewers, basements or confined areas. Prevent further leakage or spillage if safe to do so.

6.3. Methods and materials for containment and cleaning up

6.3.1. Methods for Containment

No information available.

6.3.2. For cleaning up

Take up mechanically and collect in suitable container for disposal.

6.3.3. Other information

No information available

6.4. Reference to other sections

See Sections 8 & 13 for additional information.

SECTION 7: Handling and storage

7.1. Precautions for Safe Handling

Handling

Avoid contact with skin, eyes and clothing. Handle in accordance with good industrial hygiene and safety practice. Do not breathe vapors/dust. Provide appropriate exhaust ventilation at places where dust is formed.

Hygiene Measures

Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Keep containers tightly closed in a dry, cool and well-ventilated place. Keep in properly labeled containers. Store at room temperature. Protect from light.

7.3. Specific end use(s)

Exposure Scenario

No information available.

Other Guidelines

No information available.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Exposure Limits

No occupational exposure limit values have been defined by authorities in production Country.

Biological occupational exposure limits

No information available.

Derived No Effect Level (DNEL)

No information available.

Predicted No Effect Concentration (PNEC)

No information available.

8.2. Exposure controls

Engineering Measures

Appropriate Engineering Controls.

Personal protective equipment

Eye/face protection

Use eye protection appropriate for the task.

Skin protection:

- Body protection

Use protective clothing appropriate for the task.

- Hand protection

Use appropriate protective gloves.

Respiratory Protection

No respiratory protection needed for normal handling of this product.

Environmental exposure controls

No information available.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance	
Physical State	solid
Odor	No information available
Odour Threshold	No information available
pH	No information available
Melting Point/Range	No information available
Boiling Point/Range	No information available
Flash Point	No information available
Evaporation Rate	No information available
Flammability (solid, gas)	No information available
Flammability Limits in Air	
Upper	No information available
Lower	No information available
Vapor Pressure	No information available
Vapor Density	No information available
Relative Density	No information available
Solubility	No information available
Autoignition Temperature	No information available
Decomposition Temperature	No information available
Viscosity	No information available
Explosive Properties	No information available
Oxidizing Properties	No information available

9.2. Other information

No information available

SECTION 10: Stability and reactivity

10.1. Reactivity

No information available.

10.2. Chemical Stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

None under normal processing.

10.4. Conditions to avoid

Excessive heat, Moisture.

10.5. Incompatible materials.

Strong oxidizing agents.

10.6. Hazardous decomposition products

May emit toxic fumes under fire conditions.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

For Deutetrabenazine

acute toxicity	No information available.
skin corrosion/irritation	No information available.
serious eye damage/irritation	No information available.
respiratory or skin sensitization	No information available.
germ cell mutagenicity	No evidence of mutagenicity in non-clinical studies.
carcinogenicity	No studies have been performed.
reproductive toxicity	Some evidence of effects on fertility in animal studies. No evidence of teratogenicity in animal studies.
STOT - single exposure	No information available.
STOT - repeated exposures	No information available.
aspiration hazard	No information available.

Other Information

No information available.

SECTION 12: Ecological information

For Deutetrabenazine

12.1. Toxicity

Ecotoxicity effects

No information available.

12.2. Persistence and degradability

No information available.

12.3. Bioaccumulative potential

For Deutetrabenazine: Expected to bioaccumulate : Log Po/w \geq 3 (EC) or \geq 4 (GHS).

12.4. Mobility in soil

No information available.

12.5. Results of PBT and vPvB assessment

No information available.

12.6. Other adverse effects

Endocrine Disruptor Information

Not available.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste from Residues/Unused

Products

Contaminated Packaging

Dispose of in accordance with local regulations.

Empty containers should be taken for local recycling, recovery or waste disposal.

SECTION 14: Transport information

14.1.
UN-No Not hazardous for transport

14.2.
Proper Shipping Name Not hazardous for transport

14.3. Transport hazard class(es)
ADR / RID / ADN (land transport) Not hazardous for transport
IMDG (sea transport) Not hazardous for transport
IATA / ICAO (air transport) Not hazardous for transport

14.4.
Packing Group Not hazardous for transport

14.5. Environmental hazards
Marine Pollutant No information available

14.6. Special precautions for user
Emergency No. No information available
ADR/RID-Labels No information available

14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Technical name No information available
Ship type No information available
Annex II No information available

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture
- Regulation 1907/2006/EC (REACH) and successive modifications
- Regulation 1272/2008 (CLP) and successive modifications
- D.Lgs. 81/2008 and successive modifications and Dir. 2009/161/EU
- REGULATION (EU) 2015/830

15.2. Chemical Safety Assessment
No information available

SECTION 16: Other information

CLP/GHS - Regulation

Hazard Statements

Full text of H-Statements referred to under sections 2 and 3

H361f - Suspected of damaging fertility

Training appropriate for workers is required to ensure protection of human health and environment.

Application/Drug Class Treatment of chorea associated with Huntington's disease, Tourette's syndrome and tardive dyskinesia.

Source of data

R.T.E.C.S. - REGISTRY OF TOXIC EFFECTS OF CHEMICAL SUBSTANCES
A.C.G.I.H. - AMERICAN CONFERENCE OF INDUSTRIAL HYGIENISTS
H.S.D.B. - HAZARDOUS SUBSTANCES DATA BANK
N.I.O.S.H. - NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH
N.T.P. - NATIONAL TOXICOLOGY PROGRAM
I.A.R.C. - INTERNATIONAL AGENCY FOR RESEARCH ON CANCER
ECHA (European chemicals agency) databases
FDA (Food & Drug administration) database
EMA (European Medicines agency) documents
ChemAdvisor
Chemspider database

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Revision Note

Not applicable

Disclaimer

The information provided on this SDS is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guide for safe handling, use, processing, storage, transportation, and disposal of the designated material and is not to be considered as a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other material or in any process, unless specified in the text.

End of Safety Data Sheet