

SAFETY DATA SHEET (SDS)

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Doc. No.: SDS/FM/022

Effective Date: 10 101/2018

Revision No.: 0.0

Section1: Chemical Product and Company Identification

Product Name: Ursodiol Capsule

Synonyms: --

CAS No.: Mixture

Chemical Formula: Mixture

Molecular Weight: Mixture

NFPA Rating:



Health: -; Flammability: -; Reactivity: -;

Specific Hazard: -.

Contact Information:

Corporate Address: Laurus Labs Limited,

2nd Floor, Serene Chambers, Road No #

7, Banjara Hills, Hyderabad – 500034

Ph: 040 - 3980 4333

Section 2: Hazards Identification

Not considered hazardous when handled under normal conditions with good house keeping.

CAS#	osition/ Information on Ingredients Chemical name	Percent
128-13-2	Ursodeoxycholic Acid	82.19
9005-25-8	Corn Starch (Corn starch 400L NF)#	16.85
112945-52-5, 7631-86-9	Colloidal silicon Dioxide (Aerosil 200)	0.48
557-04-0	Magnesium Stearate (Hyqual, Veg Source)	0.48
None assigned	Empty Hard Gelatin Capsule Size "0"	Q.S

Section 4: First Aid Measures

In case of inhalation:

Remove to fresh air. If not breathing give artificial respiration. If breathing is difficult, give oxygen. Seek medical attention.

In case of contact with skin:

Immediately wash skin with soap and copious amounts of water for at least 15 minutes. If irritation persists, seek medical attention.

In case of contact with eyes:

Immediately flush eyes with copious amounts of water for at least 15 minutes. Seek medical advice.

In case of ingestion:

If swallowed, wash out mouth with water, provided person is conscious. Seek medical advice.

Section 5: Fire and Explosion Data

Extinguishing Media:

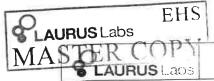
Carbon dioxide, dry chemical powder or appropriate foam. Water spray.

Special fire fighting procedures:

Wear self-contained breathing apparatus and protective clothing to prevent contact with the skin and eyes.

Section 6: Accidental Release Measures

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Ensuring personal safety, mark out contaminated area with signs and prevent unauthorized access. Sweep-up/absorb in suitable material, place in a container and hold for disposal. Avoid raising dust. Ventilate area and wash spill site after pick-up complete.

Section 7: Handling and Storage

Store at 20°C to 25°C (68°F to 77°F). Excursions are permitted between 15°C to 30°C (59°F to 86°F).

Section 8: Exposure Controls/ Personal Protection

Respiratory protection:

Required when dusts are generated.

Eye protection:

Required.

Hand protection:

Required.

Industrial hygiene:

Immediately change contaminated clothing. Wash hands and face after working with substance.

Section 9: Physical and Chemical Properties

Physical State &

Hard shell gelatin Capsules size "0" with a pink colour cap and a white opaque body filled with white to off-white powder.

colour

No data available

Melting Point/ Range :: Flash Point ::

No data available

Flammability

No data available

Autoignition Temp

No data available

Oxidizing Properties :

No data available

Explosive Properties:

Explosion Limits

No data available No data available

Section 10: Stability and Reactivity Data

Conditions to be avoided: Unknown Substances to be avoided: Unknown

Hazardous decomposition products: Unknown

Section 11: Toxicological Information

Toxicology Data

LD50 (In Rats): > 2000mg/Kg for both oral and intraperitoneal administration.

Section 12: Ecological Information

Do not allow product to enter drinking water supplies, waste water or soil!

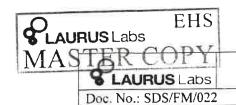
Section 13: Disposal Considerations

Dissolve or mix material with a suitable combustible solvent and incinerate in a chemical incinerator equipped with an afterburner and scrubber.

Material should be disposed of in keeping with all local and national legislation. Packaging should be disposed of in keeping with all local and national legislation. Handle contaminated containers as product.

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Section 14: Transport Information UN number IATA: -IMDG: -ADR/RID: -UN proper shipping name ADR/RID: Not dangerous goods IMDG: Not dangerous goods IATA: Not dangerous goods Transport hazard class(es) IATA: -IMDG: -ADR/RID: -Packaging group IATA: -ADR/RID: -IMDG: -Environmental hazards IATA: no IMDG Marine pollutant: no ADR/RID: no Special precautions for user

Section 15: Other Regulatory Information

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

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

no data available

no data available

Chemical Safety Assessment

no data available

Section 16: Other Information

Disclaimer:

The above information is believed to be correct but does not purport to be all-inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product.

Revision Log:

Revision No.	Reason for revision	Effective Date
0.0	First Issue	श्वीशिवा

Prepared By:

Reviewed By:

Polis

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