Alembic Pharmaceuticals Limited

Safety Data Sheet
According to Regulation (EC) No. 1907/2006
Updated on 23-08-2017

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

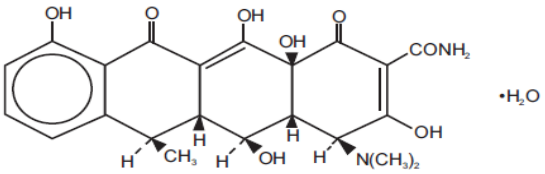
Product name	:	Doxycycline Capsules, 100 mg and 75 mg
CAS No.	:	564-25-0
Identified uses	:	Doxycycline, USP is a broad-spectrum antibacterial synthetically derived from Oxytetracycline. Doxycycline is indicated for treatment of infections.
Company	:	Alembic Pharmaceuticals Limited Alembic Road, Vadodara, Gujarat, INDIA-390 003
Telephone	:	+91 - 265 - 228 0550
Fax	:	+91 - 265 - 228 1508
Emergency Phone #	:	

2. HAZARDS IDENTIFICATION

Classification of the substance or mixture
Fire & Explosion: Combustible solid which burns but propagates flame with difficulty.
Health:
Environment: No information is available about the potential of this product to produce adverse environmental effects.
Other hazards -
Warning: The use of drugs of the tetracycline class, including doxycycline, during tooth development (last half of pregnancy, infancy and childhood to the age of 8 years) may cause permanent discoloration of the teeth (yellow-gray-brown). This adverse reaction is more common during long-term use of the drugs, but it has been observed following repeated short-term courses. Enamel hypoplasia has also been reported. Use of doxycycline in pediatric patients 8 years of age or less only when the potential benefits are expected to outweigh the risks in severe or life-threatening conditions (e.g. anthrax, Rocky Mountain spotted fever), particularly when there are no alternative therapies.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Doxycycline Capsules Synonyms: alpha-6-deoxy-5-oxytetracycline
Doxycycline Capsules: $C_{22}H_{24}N_2O_8 \bullet H_2O_8$
Doxycycline Capsules Weight : 462.45
Doxycycline Capsules chemical structure :



Chemical Name	CAS-No.	Concentration	Oral LD_{50} (Rat)	Dermal LD_{50}	Inhalation LC_{50}
Doxycycline Capsules	564-25-0	>98 %	--	--	--

4. FIRST AID MEASURES

Description of first aid measures
General advice - Consult a physician. Show this safety data sheet to the doctor in attendance.
Ingestion: Accidental ingestion of the material may be harmful
If inhaled - The material is not thought to produce either adverse health effects or irritation of the respiratory tract following inhalation. Nevertheless, adverse systemic effects have been produced following exposure of animals by at least one other route and good hygiene practice requires that exposure be kept to a minimum and that suitable control measures be used in an occupational setting.
In case of skin contact- The material is not thought to be a skin irritant. Abrasive damage however, may result from prolonged exposures. Good hygiene practice requires that exposure be kept to a minimum and that suitable gloves be used in an occupational setting.

In case of eye contact - Although the material is not thought to be an irritant (as classified by EC Directives), direct contact with the eye may cause transient discomfort characterised by tearing or conjunctival redness (as with windburn). Slight abrasive damage may also result. The material may produce foreign body irritation in certain individuals.

Most important symptoms and effects, both acute and delayed - To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

OVERDOSAGE:

In case of overdosage, discontinue medication, treat symptomatically and institute supportive measures. Dialysis does not alter serum half-life, and it would not be of benefit in treating cases of overdosage.

5. FIRE-FIGHTING MEASURES

Fire and Explosion Hazards: Combustible solid which burns but propagates flame with difficulty; it is estimated that most organic dusts are combustible (circa 70%) - according to the circumstances under which the combustion process occurs, such materials may cause fires and / or dust explosions.

Suitable extinguishing media

Foam, Dry chemical powder, BCF (where regulations permit), Carbon dioxide, Water spray or fog - Large fire only.

Advice for firefighters

Wear breathing apparatus plus protective gloves. Prevent, by any means available, spillage from entering drains or water courses. Use water delivered as a fine spray to control fire and cool adjacent area. Do not approach containers suspected to be hot. Cool fire exposed containers with water spray from a protected location. Equipment should be thoroughly decontaminated after use.

Further information - No data available

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Use personal protective equipment. Avoid dust formation. Avoid breathing vapors, mist or gas and contact with skin or eyes. Ensure adequate ventilation. Evacuate personnel to safe areas.

Environmental precautions

Prevent further leakage or spillage if safe to do so. Do not let product enter drains. Discharge into the environment must be avoided.

Methods and materials for containment and cleaning up

Pick up and arrange disposal without creating dust. Sweep up and shovel. Keep in suitable, closed containers for disposal.

Reference to other sections - For disposal see section 13.

7. HANDLING AND STORAGE

Precautions for safe handling: No special control measures required for the normal handling of this product. Avoid contact with skin and eyes. Provide appropriate exhaust ventilation at places where dust is formed.

Conditions for safe storage, including any incompatibilities: Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature]. Dispense in a tight light-resistant container as defined in the USP/NF.

Specific end uses

no data available

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters
Components with workplace control parameters
Exposure controls
Appropriate engineering controls
Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.
Personal protective equipment
Eye/face protection
Chemical goggles, Face shield should be used while handling. Contact lenses may pose a special hazard; soft contact lenses may absorb and concentrate irritants. A written policy document, describing the wearing of lenses or restrictions on use, should be created for each workplace or task. This should include a review of lens absorption and adsorption for the class of chemicals in use and an account of injury experience. Medical and first-aid personnel should be trained in their removal and suitable equipment should be readily available. In the event of chemical exposure, begin eye irrigation immediately and remove contact lens as soon as practicable. Lens should be removed at the first signs of eye redness or irritation - lens should be removed in a clean environment only after workers have washed hands thoroughly. [CDC NIOSH Current Intelligence Bulletin 59], [AS/NZS 1336 or national equivalent]
Skin 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. Select gloves tested to a relevant standard (e.g. Europe EN 374, US F739, AS/NZS 2161.1 or national equivalent).
Other protection
For quantities up to 500 grams a laboratory coat may be suitable.
For quantities up to 1 kilogram a disposable laboratory coat or coverall of low permeability is recommended. Coveralls should be buttoned at collar and cuffs.
For quantities over 1 kilogram and manufacturing operations, wear disposable coverall of low permeability and disposable shoe covers.
For manufacturing operations, air-supplied full body suits may be required for the provision of advanced respiratory protection.
Eye wash unit.
Ensure there is ready access to an emergency shower.
For Emergencies: Vinyl suit

9. PHYSICAL AND CHEMICAL PROPERTIES

Tablet Strength (Doxycycline capsules USP)	Tablet Colour/Shape	Tablet Markings	Package Size	NDC Code
75 mg	Opaque brown cap/opaque white body hard gelatin capsules	1. Size “2” having imprinting “A” on cap with black ink. 2. Size “241” on body with black ink filled with yellow to brown granular powder.	bottle of 30	62332-249-30
			bottle of 100	62332-249-31
100 mg	Opaque brown cap/opaque yellow body hard gelatin capsules	1. Size “1” having imprinting “A” on cap with white ink. 2. Size “242” on body with brown ink filled with yellow to brown granular powder.	Bottle of 30	62332-250-30
			Bottle of 50	62332-250-50
			Bottle of 60	62332-250-60
			Bottle of 250	62332-250-61

10. STABILITY AND REACTIVITY

Stable under recommended storage conditions. Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature]. Dispense in a tight light-resistant container as defined in the USP/NF.

11. TOXICOLOGICAL INFORMATION

Carcinogenesis Mutagenesis, Impairment of Fertility

Carcinogenesis

Long-term studies in animals to evaluate the carcinogenic potential of doxycycline have not been conducted. However, there has been evidence of oncogenic activity in rats in studies with related antibacterial, oxytetracycline (adrenal and pituitary tumors) and minocycline (thyroid tumors). Likewise, although mutagenicity studies of doxycycline have not been conducted, positive results in in vitro mammalian cell assays have been reported for related antibacterial (tetracycline, oxytetracycline). Doxycycline administered orally at dosage levels as high as 250 mg/kg/day had no apparent effect on the fertility of female rats. Effect on male fertility has not been studied.

12. ECOLOGICAL INFORMATION

Toxicity – Do not discharge into sewer or waterways.
Persistence and degradability - No data available
Bioaccumulative potential - No data available
Mobility in soil - No data available
Results of PBT and vPvB assessment - No data available
Other adverse effects - No data available

13. DISPOSAL CONSIDERATIONS

Product

As specific country, federal, state and local environmental regulations are varied and change frequently, we recommend that you contact your local department for Health Services for information on the correct disposal of this product.

Contaminated packaging

Empty container will retain product residue. Observe all hazard precautions.

14. TRANSPORT INFORMATION

IATA/ICAO - Not Regulated

IATA Proper shipping Name : N/A
IATA UN/ID No : N/A
IATA Hazard Class : N/A
IATA Packaging Group : N/A
IATA Label : N/A

IMDG - Not Regulated

IMDG Proper shipping Name : N/A
IMDG UN/ID No : N/A
IMDG Hazard Class : N/A
IMDG Flash Point : N/A
IMDG Label : N/A

DOT - Not Regulated

DOT Proper shipping Name : N/A
DOT UN/ID No : N/A
DOT Hazard Class : N/A
DOT Flash Point : N/A
DOT Packing Group : N/A
DOT Label : N/A

15. REGULATORY INFORMATION

This Section Contains Information relevant to compliance with other Federal and/or state laws.
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

Chemical Safety Assessment

No data available

16. OTHER INFORMATION

Further information

The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide for technically qualified personnel. 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. Alembic Pharmaceuticals Ltd. extends no warranties, makes no representations and assumes no responsibility as to the accuracy, completeness or suitability of this data for any third party use & shall not be held liable for any damage resulting from handling or from contact with the above product. See reverse side of invoice or packing slip for additional terms and conditions of sale.