



**NATCO PHARMA LIMITED – PHARMA DIVISION; KOTHUR
MATERIAL SAFETY DATA SHEET**

1. IDENTIFICATION OF THE PRODUCT AND OF THE COMPANY

PRODUCT NAME : LANTHANUM CARBONATE CHEWABLE TABLETS
500 mg, 750 mg and 1000 mg.

MANUFACTURER : NATCO PHARMA LIMITED

Address of the Manufacturer : NATCO PHARMA LIMITED,
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2. HAZARDS IDENTIFICATION

Pictogram :



Signal word : Warning

Hazard statements:

H320 : Causes eye irritation
H335 : May cause respiratory irritation
H315 : Causes skin irritation

Precautionary statements:

P261 : Avoid breathing dust/fumes/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.



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3. COMPOSITION/INFORMATION ON INGREDIENTS

CHEMICAL NAME : Lanthanum carbonate dihydrate
MOLECULAR FORMULA : $\text{La}_2(\text{CO}_3)_3 \cdot 2\text{H}_2\text{O}$
MOLECULAR WEIGHT : 493.87
THERAPEUTIC USE : In treatment of Hyperphosphatemia
CAS NUMBER : [929207-29-4]

4. FIRST AID MEASURES

General advice : Show this safety data sheet to the doctor in attendance.
Eyes contact : Immediately flush eyes with copious amounts of water for at least 15 minutes. Assure flushing under eyelids. Consult physician.
Skin contact : Wash affected area with plenty of water. Remove contaminated clothes if necessary. If irritation persists, seek medical attention.
Inhalation : Remove to fresh air. If not breathing give artificial respiration. Seek medical attention.
Ingestion : Seek medical assistance immediately. Keep the victim calm. Wash out mouth with water, Induce vomiting only if directed by medical personnel.

5. FIRE FIGHTING MEASURES

Extinguishing media : Use water spray, Alcohol-resistant foam, Dry chemical or Carbon dioxide.
Special hazards arising from the substance or mixture : Carbon oxide, Lanthanum oxides
Unusual fire and explosion hazards : Emits Carbon monoxide under fire conditions.
Special fire fighting procedures : Wear self contained, approved breathing apparatus and full protective clothing, including eye protection and boots.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions : Wear all appropriate equipment when using this material. Ensure adequate ventilation. Avoid the formation of dust. Avoid breathing vapors, mist, gas or dust.
Environmental precautions : Prevent spillage from entering drains or allowing to be released into the environment.
Methods and materials for containment and cleaning up : Pickup and arrange disposal without creating dust. Sweep up and shovel. Keep in suitable, closed containers for disposal.



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7. HANDLING AND STORAGE

- Precautions for safe handling : Wear appropriate personal protective equipment. Avoid contact with skin and eyes. Use with adequate ventilation. Avoid formation of dusts and aerosols.
- Conditions for safe storage : Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F). [See USP controlled room temperature].

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

- Exposure controls : Contains no substance with occupational exposure limit values.
- Eye protection : Wear chemical safety goggles and face shield.
- Skin protection : Wear nitrile or rubber gloves, and a complete suit protecting against chemicals.
- Ventilation : Provide local exhaust, preferably mechanical.
- Respirator : Use an approved respirator.
- Appropriate engineering controls : Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.
- Additional protection : Provide eyewash station, quick-drench showers and washing facilities accessible to areas of use and handling.

9. PHYSICAL AND CHEMICALS PROPERTIES

- Appearance : **500 mg tablets:** White to off white Round shaped tablets debossed with "NAT" on one side and "500" on the other side.
750 mg: White to off white Round shaped tablets, debossed with "NAT" on one side and "750" on the other side.
1000 mg: White to off white Round shaped tablets debossed with "NAT" on one side and "1000" on the other side.
- Solubility : Soluble in dilute hydrochloric acid.

10. STABILITY AND REACTIVITY

- Stability : Stable under recommended conditions of use.
- Hazardous polymerization : Will not occur
- Conditions to avoid : Strong acids, Water/moisture
- Decomposition products : Carbon oxides and lanthanum oxides.

11. TOXICOLOGICAL INFORMATION

- Acute toxicity : No data available
- Carcinogenic effect : No components of this product present at levels greater than or equal to 0.1% is identified a carcinogen.
- Mutagenic effects : No data available



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LD₅₀ (oral-rat) : ≥ 8500 (La) mg/kg

LD₅₀ (oral-rabbit) : = 2450 (La) mg/kg

12. ECOLOGICAL INFORMATION

No data available

13. DISPOSAL CONSIDERATIONS

Dispose in according to local, state and federal regulations.

14. TRANSPORT INFORMATION

This product is not dangerous as per IATA DGR Manual and also not restricted.

15. REGULATORY INFORMATION

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

16. OTHER INFORMATION

The above information is based on data available to us and is believed to be correct. Since the information may be applied under conditions beyond our control and with which we may be unfamiliar, we do not assume any responsibility for the results of its use and all persons receiving it must make their own determination of the effects, properties and protections which pertain to their particular conditions. No representation, warranty, or guarantee, express or implied (including a warranty of fitness or merchantability for a particular purpose), is made with respect to the materials, the accuracy of this information, the results to be obtained from the use thereof, or the hazards connected with the use of the material. Caution should be used in the handling and use of the material because it is a pharmaceutical product. The above information is offered in good faith and with the belief that it is accurate. As of the date of issuance, we are providing all information relevant to the foreseeable handling of the material. However, in the event of an adverse incident associated with this product, this Safety Data Sheet is not, and is not intended to be, a substitute for consultation with appropriately trained personnel.