

SAFETY DATA SHEET (SDS)

Nateglinide Tablets, USP 60 mg and 120 mg

Revision Date: 31-January-2025

Version 1.0

1. IDENTIFICATION OF THE SUBSTANCE / PREPARATION AND COMPANY UNDERTAKING

Product Name: Nateglinide Tablets, USP 60 mg and 120 mg

Product Information: Nateglinide Tablets, USP

Company Name: Cadila Pharmaceuticals Limited

Address: 1389, Dholka – 382225, District: Ahmedabad, Gujarat State, India.

Phone No.: 02714/221481

Fax No.: 02714/220315

2. HAZARD(S) IDENTIFICATION:

Statement of Hazard: Non-hazardous under OSHA Hazard Communication Standard (29 CFR 1910.1200).

Short Term: Dust may cause irritation if tablets are crushed or broken. Individuals sensitive to this chemical or other materials in its chemical class may develop allergic reactions.

Known Clinical Effects: May cause effects similar to those seen in clinical use including transient diarrhea, nausea and abdominal pain.

EU Indication of danger: Not classified as hazardous.

Australian Hazard Classification (NOHSC): Non-Hazardous Substance. Non-Dangerous Goods.

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3. COMPOSITION / INFORMATION ON INGREDIENTS

Chemical Name: D-Phenylalanine, N [[Trans-4-(1-methylethyl) cyclohexyl} carbonyl]-; or
 (-)-N-[(trans-4-Isopropylcyclohexyl) carbonyl-D-phenylalanine

Product Code: Not applicable

Hazardous Ingredients / Components: Not Applicable

CAS No.: 105816-04-4

Other Components:

Inactive Ingredients	Exposure Limit	CAS No.
Colloidal Silicon Dioxide	Not Found	7631-86-9
Croscarmellose Sodium	Not Found	74811-65-7
Mannitol	Not Found	69-65-8
Iron oxide (yellow)	Not Found	1309-33-7
Iron oxide (red)	Not Found	1309-37-1
Corn starch	Not Found	9005-25-8
Sodium Lauryl Sulphate	Not Found	151-21-3
Pregelatinized Starch	Not Found	9005-25-8
Sodium Starch Glycolate	Not Found	9063-38-01
Hypromellose	Not Found	9004-65-3
Sodium Stearyl Fumarate	Not Found	4070-80-8
Polyethylene Glycol	Not Found	25322-68-3
Povidone	Not Found	9003-39-8
Talc	Not Found	14807-96-6
Titanium Dioxide	Not Found	13463-67-7

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4. FIRST – AID MEASURES

Inhalation: Remove to fresh air. If not breathing, give artificial respiration or give oxygen by trained personnel. Get immediate medical attention.

Skin Contact: Immediately wash skin with soap and plenty of water for at least 15 minutes. Remove contaminated clothing. Get medical attention if symptoms occur. Wash clothing before reuse.

Eye Contact: Hold eyelids apart and flush eyes with plenty of water for at least 15 minutes. Have eyes examined and tested by medical personnel.

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.

5. FIRE FIGHTING MEASURES

Extinguishing media: Use alcohol-resistant foam, carbon dioxide, water, or dry chemical spray. Use water spray to cool fire-exposed containers.

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire.

Fire Fighting Protective Equipment: During all fire fighting activities, wear appropriate protective equipment, including self contained breathing apparatus.

Specific Hazards: Not Applicable

6. ACCIDENTAL RELEASE MEASURES

Personal precautions: Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Avoid raising and breathing dust, and provide adequate ventilation. As conditions warrant, wear a NIOSH approved self-contained breathing

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apparatus, or respirator, and appropriate personal protection (rubber boots, safety goggles, and heavy rubber gloves).

Environmental precautions: Take steps to avoid release into the environment, if safe to do so.

Method and Material Containment and cleaning up: Contain spill and collect, as appropriate. Transfer to a chemical waste container for disposal in accordance with local regulations.

7. HANDLING AND STORAGE

Handling: Avoid breathing dust/fume/gas/mist/vapours/spray. Avoid prolonged or repeated exposure.

Storage: Store in accordance with information listed on the product insert.

Storage incompatibilities: Store away from oxidizing agents.

8. EXPOSURE CONTROL / PERSONAL PROTECTION

Engineering measures: Use process enclosures, local exhaust ventilation, or other engineering controls to control airborne levels below recommended exposure limits.

Respiratory Protection: Not required for the normal use of this product. If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate NIOSH approved respirator, as conditions warrant.

Eye Protection: Wear safety glasses or goggles if eye contact is possible.

Personal protective equipment: Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

Skin Protection: Compatible chemical-resistant gloves are recommended if skin contact with drug product is possible and for bulk processing operations.

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9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance:

Nateglinide Tablets, USP 60 mg

Pink, round, beveled edge tablet with "C" debossed on one side and "123" on other side.

Nateglinide Tablets, USP 120 mg

Yellow ovaloid tablet with "C" debossed on one side and "125" on other side.

Odour:	Odourless
pH (Value):	Not Applicable
Boiling Point:	Not Applicable
Melting Point:	Not Applicable
Flash Point:	Not Applicable
Flammable Limits:	Not Applicable
Auto Ignition Temperature:	Not Applicable
Explosive Properties:	Not Applicable
Oxidizing Properties:	Not Applicable
Vapor Pressure (mm Hg):	Not Applicable
Density (g/ml):	Not Applicable
Solubility (Water):	Practically Insoluble
Solubility (Other):	Alcohol, ether, acetonitrile, Methanol
Partition Coefficient:	Not Applicable

Other Information: Nateglinide is white or almost white powder. Freely soluble in Methanol, Methylene Chloride and in alcohol, soluble in ether, sparingly soluble in acetonitrile and in octanol, practically, insoluble in water.

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10. STABILITY AND REACTIVITY

Hazardous Reactions: No data available.

Stable: Stable under normal ambient and anticipated storage and handling conditions.

Hazardous Decomposition Product(s): carbon dioxide, carbon monoxide, nitrogen oxides

Conditions to avoid: No data available.

Materials to avoid: strong oxidizing agents

11. TOXICOLOGY INFORMATION

Toxicological Effects: The toxicological effects of this product have not been thoroughly studied. Oral LD (rat) : >2 gm/kg; Oral TDLO (mouse): 50 mg/kg; Oral TDLO (man): 5.1 mg/kg; Oral TDLO (woman): 7.2 mg/kg;

Target organ: Eye contact, Skin contact and inhalation is not great risk as this product is tablet.

Inhalation (LC50): Not Applicable

Skin Contact (Dermal – LD50): Not Applicable

Eye Contact: Not Applicable

Ingestion (Oral – LD50): Not Applicable

12. ECOLOGICAL INFORMATION

Toxicity: Avoid release into the environment. Runoff from fire control or dilution water may cause pollution.

Persistence and Degradability: No data available.

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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

Dispose the waste in accordance with all applicable Federal, State and local laws.

14. TRANSPORT INFORMATION

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. REGULATORY INFORMATION

Generic Medicine. Approved by USFDA & the ANDA Number is 206432

Classification and labeling Danger symbol: Not Applicable

Danger Label: Not Applicable

Safety phrases: Not Applicable

16. OTHER 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. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.

Cadila Pharmaceutical Limited shall not be held liable for any damage resulting from handling or from contact with the above product.

Cadila Pharmaceutical Limited reserves the right to revise this MSDS.