SAFETY DATA SHEET

Nadolol Tablets, USP

1. IDENTIFICATION

Manufacturer:

InvaGen Pharmaceuticals Inc.
7, Oser Avenue
Hauppauge, NY 11788

Emergency Phone:

1-631-231-3233

Common Name: Nadolol Tablets, USP

Chemical Family: Alkylamine derivative; propanolamine.

Synonym(s): Not applicable.

Chemical Name: 2,3-Naphthalenediol, 5-[3-[(1,1-dimethylethyl)amino]-2-hydroxypropoxy]- 1,2,3,4-tetrahydro-, cis.

Trade Name(s): Nadolol Tablets, USP 20 mg, 40 mg and 80 mg.

Therapeutic Category: Nonselective beta-adrenergic receptor blocking agent.

Molecular formula: $C_{17}H_{27}NO_4$ **Molecular Weight:** 309.4 g/mol

2.HAZARDS IDENTIFICATION

Not considered hazardous when handled under normal conditions.

EMERGENCY OVERVIEW

Caution Statement:
Each Nadolol Tablet intended for oral administration contains Nadolol, USP and excipients generally considered to be non-toxic and non-hazardous in small quantities and under conditions of normal occupational exposure.

WARNING:
Exacerbation of Ischemic Heart Disease Following Abrupt Withdrawal—Hypersensitivity to catecholamines has been observed in patients withdrawn from beta-blocker therapy; exacerbation of angina and, in some cases, myocardial infarction have occurred after abrupt discontinuation of such therapy. When discontinuing chronically administered Nadolol, particularly in patients with ischemic heart disease, the dosage should be gradually reduced over a period of one to two weeks and the patient should be carefully monitored. If angina markedly worsens or acute coronary insufficiency develops, Nadolol administration should be reinstituted

promptly, at least temporarily, and other measures appropriate for the management of unstable angina should be taken. Patients should be warned against interruption or discontinuation of therapy without the physician's advice. Because coronary artery disease is common and may be unrecognized, it may be prudent not to discontinue Nadolol therapy abruptly even in patients treated only for hypertension.

Routes of Entry: Oral

Effects of Overexposure: Tablets are intended for human consumption under guidance of a physician. Intact Tablets are not considered hazardous under normal handling procedures.

Medical conditions Aggravated by Long Term Exposure: Beta-adrenergic blockers: Heart disorders, Hypotension, Peripheral vascular disease, Respiratory disorders, Psoriasis, History of allergies, Type 1 diabetes, Hyperthyroidism, Depression, Pheochromocytoma, Impaired liver or kidney function.

Carcinogenicity: Nadolol - Not listed by IARC, NTP and OSHA.

3.COMPOSITION / INFORMATION ON INGREDIENTS

Ingredient	CAS #	Concentration %		
		20 mg	40 mg	80 mg
Nadolol, USP	42200-33-9	≈16.67 %	≈16.67 %	≈16.67 %
Excipients	NA	≈83.33 %	≈83.33 %	≈83.33 %

Contains no hazardous components (one percent or greater) or carcinogens (one-tenth percent or greater) not listed above.

* All Concentrations are percent by weight.

4. FIRST AID MEASURES

Inhalation: Move in to fresh air and keep at rest. For breathing difficulties, Oxygen may be necessary. Get medical attention. If breathing stops, provide artificial respiration.

Skin Contact: Wash skin thoroughly with soap and water. Get medical attention if irritation persists after washing. Remove contaminated clothing and shoes. Wash contaminated clothing before reuse. Destroy or thoroughly clean contaminated shoes.

Eye Contact: Immediately flush with plenty of water for at least 15 minutes. If easy to do, remove contact lenses. Get medical attention.

Ingestion: Do not induce vomiting unless directed to do so by medical personnel. Never give liquid to an unconscious person. Get medical attention.

Notes to the Physician:
Nadolol is a nonselective beta-adrenergic receptor blocking agent. Clinical pharmacology studies have demonstrated beta-blocking activity by showing (1) reduction in heart rate and cardiac output at rest and on exercise, (2) reduction of systolic and diastolic blood pressure at rest and on exercise, (3) inhibition of isoproterenol-induced tachycardia, and (4) reduction of reflex orthostatic tachycardia.

Overdose Treatment:
Nadolol can be removed from the general circulation by hemodialysis.
In addition to gastric lavage, the following measures should be employed, as appropriate. In determining the duration of corrective therapy, note must be taken of the long duration of the effect of Nadolol.

Excessive Bradycardia
Administer atropine (0.25 to 1.0 mg). If there is no response to vagal blockade, administer isoproterenol cautiously.

Cardiac Failure
Administer a digitalis glycoside and diuretic. It has been reported that glucagon may also be useful in this situation.

Hypotension
Administer vasopressors, e.g., epinephrine or norepinephrine (There is evidence that epinephrine may be the drug of choice.)

Bronchospasm
Administer a beta2-stimulating agent and/or a theophylline derivative.

5.FIRE-FIGHTING MEASURES

Extinguishing Media: Water spray, CO2, dry chemical or alcohol resistant foam.

Unusual Fire & Explosion Hazards: Emits toxic fumes under fire conditions.

Special Fire Fighting Procedures: Self-Contained breathing apparatus and full protective clothing must be worn in case of fire.

Protective Measures: Prevent runoff from fire control or dilution from entering streams, sewers, or drinking water supply.

6.ACCIDENTAL RELEASE MEASURES

Personal precautions: Use personal protective equipment. Immediately contact emergency personnel. Keep unnecessary personnel away. Follow all firefighting procedures.

Environmental precautions: Do not release in to the environment.

Spill Cleanup methods: Use a vacuum cleaner. If not possible, moisten dust with water before it is collected with shovel, broom or the like. Collect in containers and seal securely. For waste disposal, see section 13 of the SDS.

7.HANDLING AND STORAGE

Handling: Do not breathe dust. Avoid contact with eyes, skin, and clothing. Wash thoroughly after handling.

Storage: Keep container tightly closed in a cool, well-ventilated place. Keep away from heat and direct sun light.

8.EXPOSURE CONTROLS / PERSONAL PROTECTION

Tablets are not considered hazardous under normal handling procedures and protective equipment is not required. The following are recommended for manufacturing or other situations where exposure to the powder may occur.

Protective Measures: Minimize open handling. Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas.

Respiratory Protection: Use a NIOSH approved respirator or an alternate approved dust mask should be used.

Hand Protection: Chemical resistant gloves.

Eye Protection: Wear safety glasses with side shields (or goggles). If the work environment or activity involves dusty conditions, mist or aerosols, wear the appropriate goggles. Wear a face shield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Skin and Body Protection: Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.

Hygiene Measures: Wash skin thoroughly with soap and water.

9.PHYSICAL AND CHEMICAL PROPERTIES

Physical Properties:

Physical State: Solid

Form: Tablets

Appearance:

20 mg Tablets	Yellow, Round, biconvex tablets de-bossed "347" on one side and "I" on the left side of bisect and "G" on the right side of bisect on other.
40 mg Tablets	Yellow, Round, biconvex tablets de-bossed "348" on one side and "I" on the left side of bisect and "G" on the right side of bisect on other.
80 mg Tablets	Yellow, Round, biconvex tablets de-bossed "349" on one side and "I" on the left side of bisect and "G" on the right side of bisect on other.

10. STABILITY AND REACTIVITY

Possibility of hazardous reactions: Stable under ordinary conditions of use and storage.

Conditions to avoid: Excessive heat & Moisture.

Incompatible materials: Strong oxidizers, Strong Bases and Strong Acids.

Hazardous Decomposition products: Thermal decomposition or combustion may liberate irritating gases or vapors.

11.TOXICOLOGICAL INFORMATION

General information: The information presented below pertains to the individual ingredients (Nadolol, USP), and not to the mixture(s) or final formulations.

Inhalation: No data available.

Ingestion: No data available.

Skin Corrosion/ irritation: May cause an allergic skin reaction.

Serious eye damage/eye irritation: Causes serious eye irritation.

Respiratory sensitizer/Skin sensitizer: No data available.

Carcinogenesis:
No evidence of carcinogenicity was observed in chronic toxicity studies in animals.

Mutagenesis:
Nadolol has been demonstrated to be devoid of mutagenic potential in the following tests: Ames test and unscheduled DNA synthesis assay in rat and human hepatocytes.

Impairment of Fertility:
Fertility and general reproductive performance studies in rats, Nadolol caused no adverse effects.

Other information:
Medically adverse effects reported with Nadolol Tablets include: Bradycardia, Dizziness, fatigue, paresthesias, sedation, Nausea, diarrhea, abdominal discomfort, constipation, vomiting, indigestion, anorexia, bloating, flatulence, rash, pruritus, headache, dry mouth, eyes, or skin, impotence or decreased libido, facial swelling, weight gain, slurred speech, cough, nasal stuffiness, sweating, tinnitus, blurred vision.

12.ECOLOGICAL INFORMATION

General information: The information presented below pertains to the individual ingredients (Nadolol, USP), and not to the mixture(s) or final formulations.

Ecotoxicity Effects:

Acute toxicity to Fish: No data available.

Acute toxicity to Aquatic Invertebrates: No data available.

Toxicity to Aquatic Plants: No data available.

Bioaccumulation: No data available.

Mobility: No data available.

13.DISPOSAL CONSIDERATIONS

Waste Disposal: Dispose of waste must be in accordance with all applicable Federal, State and local laws.

Measures for Avoidance and Recovery: Incineration is the most effective method of disposal in most instances. Do not allow runoff to sewer, waterway or ground. Operations that involve the crushing or shredding of waste materials or returned goods should take into account recommended exposure limits where they exist.

14.TRANSPORT INFORMATION

DOT: Not Regulated

IMDG: Not regulated

ICAO/IATA: Not Regulated

IMO: Not Regulated

15.REGULATORY INFORMATION

Stated regulatory information chosen primarily for possible usage of InvaGen Pharmaceutical, Inc. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your country/state.

CERLA Hazardous Substance List (40 CFR 302.4): None

TSCA : None

SARA Title III

Section 302 Extremely Hazardous Substance (40 CFR 355, Appendix A): None

Section 313 Toxic Release Inventory (40 CFR 372): None

16.OTHER INFORMATION

SDS Sections Revised:

Revision 00: New

GLOSSARY:

SDS	Safety Data Sheet
NA	Not Applicable
CAS Number	Chemical Abstract Service Registry Number
NTP	National Toxicology Program
NIOSH	National Institute for Occupational Safety and Health
DOT	Department of Transportation
IMDG	International Maritime Dangerous Goods Code
ICAO	International Civil Aviation Organization
IATA	International Air Transport Association
IMO	International Maritime Organization
TSCA	Toxic Substances Control Act
CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act
SARA	Superfund Amendments and Reauthorization Act
OSHA	Occupational Safety and Health Administration

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