SAFETY DATA SHEET

Section 1: Identification of the Substance/Preparation and the Company/Undertaking

Product Name: **Nifedipine Extended-Release Tablets, USP.**
***Product Strengths*:** 30 mg, 60 mg, 90 mg
Trade Name: Not applicable
Synonyms: None
Chemical Family: Mixture
Intended Use: Pharmaceutical product for the treatment of high blood pressure (hypertension), angina

Manufacturer : Novast Laboratories Limited
Nantong, China 226009

Distributor: Ingenus Pharmaceuticals, LLC
Orlando, FL 32839-6408
Tel: Toll Free 877-748-1970

Section 2: Hazard(s) Identification

Appearance:

Round film coated tablets

Strength	Color	Markings
30 mg	Yellow	Novast on one side and 33 on the other side
60 mg	Pink	Novast on one side and 36 on the other side
90 mg	Brown	Novast on one side and 39 on the other side

Additional Hazard Information:
Short Term:

Dust may cause irritation. May be harmful if swallowed. Individuals sensitive to this chemical or other materials in its chemical class may develop allergic reactions. Exposure to sunlight following contact may result in skin reactions. Antihypertensive drug: has blood pressure-lowering properties.

Known Clinical Effects:

Ingestion of this material may cause effects similar to those seen in clinical use including hypotension (low blood pressure), dizziness, headache and drowsiness.

EU Indication of danger:

Not classified

Australian Hazard Classification (NOHSC):

Non-Hazardous Substance. Non-Dangerous Goods.

Note:

This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

Section 3: Composition/Information on Ingredients

Active Ingredients	**CAS #**
Nifedipine USP	21829-25-4
Inactive Ingredients	**CAS #**
Lactose Monohydrate, NF	64044-51-5
Microcrystalline Cellulose, NF	9004-34-6
Hypromellose USP	9004-65-3
Magnesium Stearate, NF	557-04-0
polyvinyl alcohol	9002-89-5
talc	14807-96-6
titanium dioxide	13463-67-7
macrogol/polyethylene glycol 3350	25322-68-3
lecithin (soy)	8002-43-5
iron oxide yellow	20344-49-4
iron oxide black	12227-89-3
iron oxide red	1332-37-2

Section 4: First-Aid Measures

Eye Contact	Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately
Skin Contact	Remove contaminated clothing and flush exposed area with large amounts of water. Wash all exposed areas of skin with plenty of soap and water. Obtain medical attention if skin reaction occurs.
Ingestion	If conscious, give water to drink and induce vomiting. Do not attempt to give any solid or liquid by mouth if the exposed subject is unconscious or semi-conscious. Wash out the mouth with water. Obtain medical attention.
Inhalation	Remove to fresh air and keep patient at rest. Seek medical attention immediately.
Symptoms and Effects of Exposure	For information on potential signs and symptoms of exposure, See Section 2 – Hazards Identification and/or Section 11 - Toxicological Information.

Section 5: Fire-Fighting Measures

Extinguishing Media	Use carbon dioxide, dry chemical, or water spray.
Hazardous Combustion Products	Emits toxic fumes of carbon monoxide, carbon dioxide, and nitrogen oxides.
Fire Fighting Procedures	During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.
Fire / Explosion Hazards	Not applicable

Section 6: Accidental Release Measures

Health and Safety Precautions:	Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.
Measures for Cleaning / Collecting:	Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.
Measures for Environmental Protections:	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.
Additional Consideration for Large Spills:	Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

Section 7: Handling and Storage

General Handling:	Minimize dust generation and accumulation. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.
Storage Conditions:	Keep this drug and all drugs out of the reach of children. The tablets should be protected from light and moisture and stored at 20°-25°C (68°-77°F); [See USP Controlled Room Temperature]. Dispense in tight, light-resistant containers.

Section 8: Exposure Controls/Personal Protection

Wear appropriate clothing to avoid skin contact. Wash hands and arms thoroughly after handling.

Section 9: Physical and Chemical Properties

Physical Form

How Supplied

Nifedipine extended-release tablets, USP are supplied as 30 mg, 60 mg, and 90 mg round film coated tablets. The different strengths can be identified as follows:

Strength	Color	Markings
30 mg	Yellow	Novast on one side and 33 on the other side
60 mg	Pink	Novast on one side and 36 on the other side
90 mg	Brown	Novast on one side and 39 on the other side

Section 10: Stability and Reactivity

Stability: Stable under normal conditions of use.

Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions.

Incompatible Materials: As a precautionary measure, keep away from strong oxidizers

Section 11: Toxicological Information

General Information: The information included in this section describes the potential hazards of the individual ingredients.

Acute Toxicity: (Species, Route, End Point, Dose)

Magnesium stearate
Rat Oral LD50 > 2000 mg/kg
Rat Inhalation LC50 > 2000 mg/m^3

Nifedipine
Mouse Oral LD50 454 mg/kg
Rat Oral LD50 1022 mg/kg
Mouse IV LD50 4.2 mg/kg
Rat IV LD50 15.5 mg/kg

Irritation / Sensitization: (Study Type, Species, Severity)

Polyethylene glycol
Eye Irritation Rabbit Mild
Skin Irritation Rabbit Mild

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Nifedipine
13 Week(s) Rat Oral 100mg/kg/day NOAEL No effects at maximum dose
13 Week(s) Dog Oral 50mg/kg/day NOAEL No effects at maximum dose
4 Week(s) Dog Oral 125mg/kg/day NOAEL No effects at maximum dose
4 Week(s) Dog Intravenous 0.6 mg/kg/day NOAEL No effects at maximum dose
1 Year(s) Dog Oral 100mg/kg/day NOAEL No effects at maximum dose
Subchronic intravenous and oral toxicity studies revealed no drug-related effects in general behavior, clinical laboratory tests, gross necropsy, or histopathology in any of the dog and rat studies. Oral doses administered demonstrated nifedipine to be without significant toxic effects at doses up to 100 - 125 mg/kg/day.

Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Nifedipine
Reproductive & Fertility Rat Oral 3 mg/kg/day NOAEL Reproductive toxicity, Embryotoxicity, Postnatal mortality, Maternal toxicity
Peri-/Postnatal Development Rat Oral 4 mg/kg/day NOAEL Reproductive toxicity, Fetotoxicity, Maternal Toxicity
Peri-/Postnatal Development Rat Oral 3 mg/kg/day NOAEL Embryotoxicity
Embryo / Fetal Development Rat Oral 10 mg/kg/day NOAEL Maternal Toxicity, Fetotoxicity, Developmental toxicity
Embryo / Fetal Development Rabbit Oral 10 mg/kg/day LOAEL Developmental toxicity

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Nifedipine
In Vivo Dominant Lethal Assay Mouse Negative
In Vivo Cytogenetics Hamster Negative
In Vivo Micronucleus Mouse Negative
Bacterial Mutagenicity (Ames) *Salmonella* Negative

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Nifedipine
2 Year(s) Rat Oral 156-210 mg/kg/day NOAEL Not carcinogenic

Section 12: Ecological Information

Environmental Overview: The environmental characteristics of this mixture have not been fully evaluated. Releases to the environment should be avoided.
Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

Nifedipine
Bacterial Mutagenicity (Ames) *Salmonella* Negative
Brachydanio rerio (Zebra fish) LC50 96 Hours > 5.77 mg/L
Aquatic Toxicity Comments: A greater than symbol (>) indicates that aquatic toxicity was not observed at the maximum dose tested.

Bacterial Inhibition: (Species, Method, End Point, Duration, Result)

Nifedipine
2 Year(s) Rat Oral 156-210 mg/kg/day NOAEL Not carcinogenic

Section 13: Disposal Considerations

Disposal Procedures: Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

Section 14: Transport Information

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

Section 15: Regulatory Information

Generic Medicine
Approved by USFDA; ANDA Number 202987

US State Regulations
Proprietary Ingredient C
Nifedipine

California Proposition 65	developmental toxicity, initial date 1/29/99 female reproductive toxicity, initial date 1/29/99 male reproductive toxicity, initial date 1/29/99

Lactose

Inventory - United States TSCA - Sect. 8(b)	

Microcrystalline Cellulose

Inventory - United States TSCA - Sect. 8(b)	Listed

Hypromellose

Inventory - United States TSCA - Sect. 8(b)	Listed

Magnesium Stearate

Inventory - United States TSCA - Sect. 8(b)	Listed

polyvinyl alcohol

Inventory - United States TSCA - Sect. 8(b)	Listed

talc

Inventory - United States TSCA - Sect. 8(b)	Listed

titanium dioxide

Inventory - United States TSCA - Sect. 8(b)	Listed

Polyethylene glycol

Inventory - United States TSCA - Sect. 8(b)	Listed

lecithin

Inventory - United States TSCA - Sect. 8(b)	Listed

iron oxide yellow

Inventory - United States TSCA - Sect. 8(b)	Listed

iron oxide black

Inventory - United States TSCA - Sect. 8(b)	Listed

iron oxide red

Inventory - United States TSCA - Sect. 8(b)	Listed

Section 16: Other Information

Revision Date: 09-Feb-2017 v.01
Other Information: This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR1910.1200

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.

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