

SAFETY DATA SHEET

Section 1: Identification	
Material	Nimodipine Oral Solution, 60 mg/20 mL
Recommended use	Pharmaceutical Use
Manufacturer	Annora Pharma Private Limited, Survey No. 261, Annaram Village, Gummadidala Mandal, Sangareddy, Telangana 502313, India.
Distributor	Camber Pharmaceuticals, Inc. , Piscataway, NJ 08854
Section 2: Hazard(s) Identification	
Hazard Statements	May cause damage to organs through prolonged or repeated exposure
Precautionary Statements	
Prevention	Do not breathe dust/fume/gas/mist/vapors/spray
Response	Get medical attention/advice if you feel unwell
Disposal	Dispose of contents/container to an approved waste disposal plant
Section 3: Composition/Information on Ingredients	
Ingredients	CAS
Nimodipine	66085-59-4
Dibasic sodium phosphate anhydrous	7558-79-4
Ethanol	64-17-5
Glycerin	56-81-5
Methylparaben	99-76-3
Monobasic sodium phosphate monohydrate	10049-21-5
Polyethylene glycol	25322-68-3
Purified water	7732-18-5
Section 4: First-Aid Measures	
General Advice	If symptoms persist, call a physician.
Eye Contact	Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Get medical attention
Skin Contact	Wash off immediately with plenty of water for at least 15 minutes. Get medical attention
Inhalation	Remove to fresh air. Get medical attention. If not breathing, give artificial respiration
Ingestion	Clean mouth with water and drink afterwards plenty of water. Get medical attention if symptoms occur
Most important symptoms and effects	None reasonably foreseeable
Notes to Physician	Treat symptomatically

Section 5: Fire-Fighting Measures	
Suitable Extinguishing Media	Water spray, carbon dioxide (CO ₂), dry chemical, alcohol-resistant foam
Unsuitable Extinguishing Media	No information available
Flash Point	No information available
Method -	No information available
Autoignition Temperature	No information available
Explosion Limits Upper No data available Lower No data available Sensitivity to Mechanical Impact No information available Sensitivity to Static Discharge No information available	
Specific Hazards Arising from the Chemical Keep product and empty container away from heat and sources of ignition.	
Hazardous Combustion Products Carbon monoxide (CO). Carbon dioxide (CO ₂). Nitrogen oxides (NO _x).	
Protective Equipment and Precautions for Firefighters As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear	
<u>NEPA</u>	
Health 2*	Flammability 1
Instability 0	Physical Hazards N/A
Section 6: Accidental Release Measures	
Personal Precautions	Ensure adequate ventilation. Use personal protective equipment as required. Avoid dust formation.
Environmental Precautions	Should not be released into the environment. See Section 12 for additional Ecological Information.
Methods for Containment and Clean Up	Sweep up and shovel into suitable containers for disposal. Keep in suitable, closed containers for disposal.
Section 7: Handling and Storage	
Handling	Wear personal protective equipment/face protection. Ensure adequate ventilation. Do not get in eyes, on skin, or on clothing. Avoid ingestion and inhalation. Avoid dust formation.
Storage	Keep containers tightly closed in a dry, cool and well-ventilated place. Incompatible Materials. Strong oxidizing agents.

Section 8: Exposure Controls/Personal Protection	
Exposure Guidelines	This product does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.
Engineering Measures	Ensure adequate ventilation, especially in confined areas
Personal Protective Equipment	
Eye/face Protection	Wear appropriate protective eyeglasses or chemical safety goggles as described by OSHA's eye and face protection regulations in 29 CFR 1910.133 or European Standard EN166.
Skin and body protection	Wear appropriate protective gloves and clothing to prevent skin exposure
Respiratory Protection	Follow the OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149. Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced
Hygiene Measures	Handle in accordance with good industrial hygiene and safety practice
Section 9: Physical and Chemical Properties	
Physical Form	Solution
Colour	Pale yellow
Appearance	<p>Nimodipine Oral Solution 3 mg/mL is a pale yellow solution and is supplied as follows:</p> <p>NDC 31722-039-47: 16 oz. bottle (473 mL) 60 mg/20 mL (3 mg/mL).</p> <p>Store between 20° C to 25° C (68° F to 77° F); excursions permitted to 15° C to 30° C (59° F to 86° F). [see USP Controlled Room Temperature].</p> <p>Protect from light. Do not refrigerate.</p>
Section 10: Stability and Reactivity	
Reactive Hazard	None known, based on information available
Stability	Stable under normal conditions.
Conditions to Avoid	Incompatible products. Excess heat. Avoid dust formation
Incompatible Materials	Strong oxidizing agents
Hazardous Decomposition Products	Carbon monoxide (CO), Carbon dioxide (CO ₂), Nitrogen oxides (NO _x)
Hazardous Polymerization	Hazardous polymerization does not occur
Hazardous Reactions	None under normal processing.

Section 11: Toxicological Information

Acute Toxicity

Product Information

Component Information

Component	LD50 Oral	LD50 Dermal	LC50 Inhalation
Nimodipine	2738 mg/kg (Rat) 940 mg/kg (Mouse)	Not listed	Not listed

Toxicologically Synergistic No information available

Products

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Irritation No information available

Sensitization No information available

Carcinogenicity The table below indicates whether each agency has listed any ingredient as a carcinogen.

Component	CAS No	IARC	NTP	ACGIH	OSHA	Mexico
Nimodipine	66085-59-4	Not listed	Not listed	Not listed	Not listed	Not listed

Mutagenic Effects No information available

Reproductive Effects No information available

Developmental Effects No information available

Teratogenicity No information available.

STOT - single exposure None known

STOT - repeated exposure None known

Aspiration hazard No information available

Symptoms / effects, both acute and delayed No information available

Endocrine Disruptor Information No information available

Other Adverse Effects The toxicological properties have not been fully investigated

Section 12: Ecological Information

Ecotoxicity

Persistence and Degradability Insoluble in water

Bioaccumulation/ Accumulation No information available.

Mobility Is not likely mobile in the environment due its low water solubility.

Section 13: Disposal Considerations

Waste Disposal Methods

Chemical waste generators must determine whether a discarded chemical is classified as a hazardous waste. Chemical waste generators must also consult local, regional, and national hazardous waste regulations to ensure complete and accurate classification.

Section 14: Transport Information

DOT	Not regulated
TDG	Not regulated
IATA	Not regulated
IMDG/IMO	Not regulated

Section 15: Regulatory Information

United States of America Inventory

Component	CAS No	TSCA	TSCA Inventory notification -Active- Inactive	TSCA - EPA Regulatory Flags
Nimodipine	66085-59-4	-	-	-

Legend:

TSCA US EPA (TSCA) - Toxic Substances Control Act, (40 CFR Part 710)

X - Listed

'-' - Not Listed

TSCA 12(b) - Notices of Export Not applicable

International Inventories

Canada (DSL/NDSL), Europe (EINECS/ELINCS/NLP), Philippines (PICCS), Japan (ENCS), Japan (ISHL), Australia (AICS), China (IECSC), Korea (KECL).

Component	CAS No	DSL	NDSL	EINECS	PICCS	ENCS	ISHL	AICS	IECSC	KECL
Nimodipine	66085-59-4	--	--	266-127-0	--	--	--	--	--	--

KECL - NIER number or KE number (<http://ncis.nier.go.kr/en/main.do>)

U.S. Federal Regulations

SARA 313 Not applicable

SARA 311/312 Hazard Categories See section 2 for more information

CWA (Clean Water Act) Not applicable

Clean Air Act Not applicable

OSHA - Occupational Safety and Health Administration Not applicable

CERCLA Not applicable

California Proposition 65 This product contains the following Proposition 65 chemicals.

Component	CAS No	California Prop. 65	Prop 65 NSRL	Category
Nimodipine	66085-59-4	Developmental	--	Developmental

U.S. State Right-to-Know Regulations Not applicable

U.S. Department of Transportation

Reportable Quantity (RQ): N

DOT Marine Pollutant N

DOT Severe Marine Pollutant N

U.S. Department of Homeland

Security This product does not contain any DHS chemicals

Section 16: Other Information

Issue Date : 15-11-2024

Version : 00

Further information

Revision date: NA

Revision note: NA.

The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. 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.

Annora Pharma Private Limited shall not be held liable for any damage resulting from handling or from contact with the above product. Annora Pharma Private Limited reserves the right to revise this SDS.