



HETERO LABS LIMITED

"Hetero Corporate", 7-2-A2, Industrial Estates, Sanath Nagar, Hyderabad - 500 018. A.P., INDIA.
Tel : 91-40-23704923/24/25, Fax : 91-40-23704926, 23714250
e-mail : contact@heterodrugs.com URL : http://www.heterodrugs.com

SAFETY DATA SHEET

Section 1: Identification	
Material	Naproxen Oral Suspension USP 125mg/5mL
Recommended use	Pharmaceutical product
Manufacturer	Hetero Labs Limited Unit III 22-110, Part-II, IDA, Jeedimetla, Hyderabad-500 055, Telangana, India.
Distributor	Camber Pharmaceuticals, Inc. , Piscataway, NJ 08854
Section 2: Hazard(s) Identification	
Hazard statement(s):	Causes skin irritation. Causes serious eye irritation. Suspected of causing genetic defects. May damage fertility or the unborn child. Toxic to aquatic life.
Precautionary statement(s) Prevention	Obtain special instructions before use. Use personal protective equipment as required. Avoid release to the environment. Wear protective gloves/protective clothing/eye protection/face protection.
Section 3: Composition/Information on Ingredients	
Ingredients	Naproxen
CAS	22204-53-1
Section 4: First-Aid Measures	
Ingestion:	Immediately give a glass of water. First aid is not generally required. If in doubt, contact a Poisons Information Centre or a doctor.
Inhalation	If fumes, aerosols or combustion products are inhaled remove from contaminated area. Other measures are usually unnecessary.
Skin Contact	Skin contact occurs: Immediately remove all contaminated clothing, including footwear. Flush skin and hair with running water (and soap if available). Seek medical attention in event of irritation.
Eye Contact	If this product comes in contact with the eyes: Wash out immediately with fresh running water.



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	<p>Ensure complete irrigation of the eye by keeping eyelids apart and away from eye and moving the eyelids by occasionally lifting the upper and lower lids.</p> <p>Seek medical attention without delay; if pain persists or recurs seek medical attention.</p> <p>Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.</p>
Section 5: Fire-Fighting Measures	
Suitable Extinguishing Media:	<p>The product contains a substantial proportion of water, therefore there are no restrictions on the type of extinguishing media which may be used. Choice of extinguishing media should take into account surrounding areas.</p> <p>Though the material is non-combustible, evaporation of water from the mixture, caused by the heat of nearby fire, may produce floating layers of combustible substances.</p> <p>In such an event consider:</p> <p>Foam.</p> <p>Dry chemical powder.</p> <p>Carbon dioxide.</p>
Section 6: Accidental Release Measures	
Clean-up Methods	<p>Clean up all spills immediately.</p> <p>Avoid breathing vapours and contact with skin and eyes.</p> <p>Control personal contact with the substance, by using protective equipment.</p> <p>Contain and absorb spill with sand, earth, inert material or vermiculite.</p> <p>Wipe up.</p> <p>Place in a suitable, labelled container for waste disposal.</p>
i) Minor Spills	
ii) Major Spills	<p>Moderate hazard.</p> <p>Clear area of personnel and move upwind.</p> <p>Alert Fire Brigade and tell them location and nature of hazard.</p> <p>Wear breathing apparatus plus protective gloves.</p> <p>Prevent, by any means available, spillage from entering drains or water course.</p> <p>Stop leak if safe to do so.</p> <p>Contain spill with sand, earth or vermiculite.</p> <p>Collect recoverable product into labelled containers for recycling.</p>
Section 7: Handling and Storage	
Handling:	<p>Avoid all personal contact, including inhalation.</p> <p>Wear protective clothing when risk of exposure occurs.</p> <p>Use in a well-ventilated area.</p>



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	<p>Prevent concentration in hollows and sumps. Avoid contact with incompatible materials. When handling, DO NOT eat, drink or smoke. DO NOT allow clothing wet with material to stay in contact with skin</p>
Section 8: Exposure Controls/Personal Protection	
Engineering Controls:	<p>Enclosed local exhaust ventilation is required at points of dust, fume or vapour generation. HEPA terminated local exhaust ventilation should be considered at point of generation of dust, fumes or vapours. Barrier protection or laminar flow cabinets should be considered for laboratory scale handling. A fume hood or vented balance enclosure is recommended for weighing/ transferring quantities exceeding 500 mg. When handling quantities up to 500 gram in either a standard laboratory with general dilution ventilation (e.g. 6-12 air changes per hour) is preferred. Quantities up to 1 kilogram may require a designated laboratory using fume hood, biological safety cabinet, or approved vented enclosures. Quantities exceeding 1 kilogram should be handled in a designated laboratory or containment laboratory using appropriate barrier/ containment technology. Manufacturing and pilot plant operations require barrier/ containment and direct coupling technologies.</p>
Eye and face protection	<p>When handling very small quantities of the material eye protection may not be required. For laboratory, larger scale or bulk handling or where regular exposure in an occupational setting occurs: Chemical goggles. Face shield. Full face shield may be required for supplementary but never for primary protection of eyes. Contact lenses may pose a special hazard; soft contact lenses may absorb and concentrate irritants. A written policy document, describing the wearing of lenses or restrictions on use, should be created for each workplace or task. This should include a review of lens absorption and adsorption for the class of chemicals in use and an account of injury experience. Medical and first-aid personnel should be trained in their removal and suitable equipment should be readily available.</p>
Section: 9 Physical and Chemical Properties	
Physical Form	Suspension
Colour	Light orange



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Description	<p>Naproxen oral suspension, USP: 125 mg/5 mL (contains 39 mg sodium) is available as a light orange-colored oral suspension in 1 pint (500 mL) light-resistant bottles. It is supplied as follows:</p> <p>500 mL bottle NDC 31722-682-05</p>
Section 10: Stability and Reactivity	
Chemical stability	<p>Unstable in the presence of incompatible materials. Product is considered stable. Hazardous polymerization will not occur.</p>
Section 11: Toxicological Information	
Toxicology	<p>No significant acute toxicological data identified in literature search.</p>
Section 12: Ecological Information	
<p>Environmental Fate: Naproxen and naproxen sodium, a drug widely used for treating pain and swelling, were found to be sensitive to sunlight resulting to the formation of several photoproducts. Study shows that naproxen can be rapidly mineralized in soil depending on the temperature and moisture content of the soil. Further, the study demonstrates that naproxen can be removed primarily by microbial degradation. In the absence of preferential flow or runoff, the chemical pose little risk in contaminating adjacent water or crops.</p>	
Section 13: Disposal Considerations	
Product / Packaging disposal	<p>Legislation addressing waste disposal requirements may differ by country, state and/ or territory. Each user must refer to laws operating in their area. In some areas, certain wastes must be tracked.</p> <p>A Hierarchy of Controls seems to be common - the user should investigate: Reduction Reuse Recycling Disposal (if all else fails)</p> <p>This material may be recycled if unused, or if it has not been contaminated so as to make it unsuitable for its intended use. If it has been contaminated, it may be possible to reclaim the product by filtration, distillation or some other means. Shelf life considerations should also be applied in making decisions of this type. Note that properties of a material may change in use, and recycling or reuse may not always be appropriate.</p> <p>DO NOT allow wash water from cleaning or process equipment to enter drains.</p> <p>It may be necessary to collect all wash water for treatment before disposal. In all cases disposal to sewer may be subject to local laws and regulations and these should be considered first.</p> <p>Where in doubt contact the responsible authority.</p>



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Recycle wherever possible.
Consult manufacturer for recycling options or consult local or regional waste management authority for disposal if no suitable treatment or disposal facility can be identified.
Dispose of by: burial in a land-fill specifically licensed to accept chemical and / or pharmaceutical wastes or incineration in a licensed apparatus (after admixture with suitable combustible material).
Decontaminate empty containers. Observe all label safeguards until containers are cleaned and destroyed.

Section 14: Transport Information

Land transport (ADG): Not regulated for Transport of dangerous goods.
Air transport (ICAO-IATA / DGR): Not regulated for Transport of dangerous goods.
Sea transport (IMDG-Code / GGVSee): Not regulated for Transport of dangerous goods.
Transport in bulk according to Annex II of MARPOL and the IBC code

Not Applicable

Section 15: Regulatory Information

Safety, health and environmental regulations / legislation specific for the substance or mixture

USA – TSCA N (Naproxen)

N = Not determined or one or more ingredients are not on the inventory and are not exempt from listing(see specific ingredients in brackets)

Section 16: Other Information

Issue Date: 02-07-2022

Version: 00

Further information

Revision date: New issue

Revision note: New issue

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.

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