



GLENMARK PHARMACEUTICALS LIMITED

SAFETY DATA SHEET

PRODUCT: NAPROXEN TABLETS

SDS NO. : SDSGHS.034.00

EFFECTIVE DATE :08/12/2015

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Section 1. Identification

1.1 Substance Name: Naproxen Tablets

1.2 Chemical Name: Not Known

1.3 Relevant identified uses of the substance or mixture and uses advised against:
For relief from period pain.

1.4 Company Identification: Glenmark Pharmaceuticals Inc., USA
750 Corporate Drive
Mahwah, NJ 07430

1.6 Emergency Contact details: (201) 684-8000

Section 2. Hazard Identification

2.1 Classification of the substance or mixture

Classification according to Regulation GHS

Chemwatch Hazard Ratings

		MinMax
Flammability	0	
Toxicity	2	■
Body Contact	2	■
Reactivity	1	■
Chronic	3	■

0 = Minimum

1 = Low

2 = Moderate

3 = High

4 = Extreme

Relevant risk statements are found in section 2

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2.2 Risk Phrase:

R36/37/38	Irritating to eyes, respiratory system and skin.
R50	Very toxic to aquatic organisms.
R61(2)	May cause harm to the unborn child.
R68(3)	Possible risk of irreversible effects.

2.3 Label elements:



Relevant risk statements are found in section 2

Indication(s) of danger	T, Xn, N
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2.4 Safety Advice:

S01	Keep locked up.
S13	Keep away from food, drink and animal feeding stuffs.
S20	When using do not eat or drink.
S22	Do not breathe dust.
S25	Avoid contact with eyes.
S26	In case of contact with eyes, rinse with plenty of water and contact Doctor or Poisons Information Centre.
S28	After contact with skin, wash immediately with plenty of water
S29	Do not empty into drains.
S35	This material and its container must be disposed of in a safe way.
S36	Wear suitable protective clothing.
S37	Wear suitable gloves.
S38	In case of insufficient ventilation, wear suitable respiratory equipment.



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S39	Wear eye/face protection.
S40	To clean the floor and all objects contaminated by this material, use water and detergent.
S45	In case of accident or if you feel unwell IMMEDIATELY contact Doctor or Poisons Information Centre (show label if possible).
S46	If swallowed, seek medical advice immediately and show this container or label.
S53	Avoid exposure - obtain special instructions before use.
S56	Dispose of this material and its container at hazardous or special waste collection point.
S57	Use appropriate container to avoid environmental contamination.
S61	Avoid release to the environment. Refer to special instructions/Safety data sheets.
S64	If swallowed, rinse mouth with water (only if the person is conscious).

2.5 Other hazards: Cumulative effects may result following exposure*.

Section 3- Composition/Information on Ingredients

3.1 Substances

CHEMICAL NAME	CAS #	% w/w
Naproxen Sodium	26159-34-2	92.59
ingredients determined not to be hazardous [Mfr]	-	Proprietary



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Section 4. First aid Measures

4.1 Inhalation:

- If fumes or combustion products are inhaled remove from contaminated area.
- Lay patient down. Keep warm and rested.
- Prostheses such as false teeth, which may block airway, should be removed, where possible, prior to initiating first aid procedures.
- Apply artificial respiration if not breathing, preferably with a demand valve resuscitator, bag-valve mask device, or pocket mask as trained. Perform CPR if necessary.
- Transport to hospital, or doctor, without delay.

4.2 Skin: If 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.

4.3 Eyes:

If this product comes in contact with the eyes:

- Wash out immediately with fresh running water.
- 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.
- Seek medical attention without delay; if pain persists or recurs seek medical attention.
- Removal of contact lenses after an eye injury should only be undertaken by skilled personnel.

4.4 Ingestion:

- If swallowed do NOT induce vomiting.
- If vomiting occurs, lean patient forward or place on left side (head-down position, if possible) to maintain open airway and prevent aspiration.
- Observe the patient carefully.
- Never give liquid to a person showing signs of being sleepy or with reduced awareness; i.e. becoming unconscious.
- Give water to rinse out mouth, then provide liquid slowly and as much as casualty can comfortably drink.



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- Seek medical advice.

4.5 Most important symptoms and effects, both acute and delayed

Treat symptomatically.

Section 5. Fire-fighting Measures

5.1 General Information:

- Alert Fire Brigade and tell them location and nature of hazard.
- Wear breathing apparatus plus protective gloves in the event of a fire.
- Prevent, by any means available, spillage from entering drains or water courses.
- Use firefighting procedures suitable for surrounding area.

5.2 Extinguishing Media:

- There is no restriction on the type of extinguisher which may be used.
- Use extinguishing media suitable for surrounding area.

5.3 Fire/Explosion Hazard:

- Non-combustible.
- Not considered a significant fire risk, however containers may burn.
- Decomposition may produce toxic fumes of: carbon monoxide (CO), carbon dioxide (CO₂), metal oxides, other pyrolysis products typical of burning organic material. May emit poisonous fumes.

5.4 Fire Incompatibility:

- Avoid contamination with oxidizing agents i.e. nitrates, oxidizing acids, chlorine bleaches, pool chlorine etc. as ignition may result

5.5 NFPA Rating: Not Known



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Section 6. Accidental Release Measures

6.1 General Information: Personal Protective Equipment advice is contained in Section 8 of the SDS.

6.2 Minor Spills:

- Clean up all spills immediately.
- Avoid breathing vapours/ aerosols/ or dusts and avoid contact with skin and eyes.
- Control personal contact with the substance, by using protective equipment.
- Contain and absorb spill with sand, earth, inert material or vermiculite.

6.3 Major Spills:

- Clear area of personnel and move upwind.
- Alert Fire Brigade and tell them location and nature of hazard.
- Wear breathing apparatus plus protective gloves.
- Prevent, by any means available, spillage from entering drains or water course.

Section 7. Handling and Storage

7.1 Handling:

- Avoid all personal contact, including inhalation.
- Wear protective clothing when risk of exposure occurs.
- Use in a well-ventilated area.
- Prevent concentration in hollows and sumps.

7.2 Storage:

- Store in original containers.
- Keep containers securely sealed.
- Store in a cool, dry, well-ventilated area.



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- Store away from incompatible materials and foodstuff containers.

7.3 Suitable Container:

- Packaging as recommended by manufacturer.
- Check that containers are clearly labeled.
- Tamper-proof containers.
- Polyethylene or polypropylene containers.

7.4 Storage incompatibility: Not Known

Section 8. Exposure Controls/Personal Protection

8.1 Occupational Exposure Limits (OEL):

Emergency Limits

Ingredient	Material name	TEEL-1	TEEL-2	TEEL-3
Naproxen Tablets	Naproxen Tablets	Not Available	Not Available	Not Available

Ingredient	Original IDLH	Revised IDLH
Naproxen Tablets	Not Available	Not Available
Ingredients determined not to be hazardous [Mfr]	Not Available	Not Available






Material Data

8.2 Exposure controls:

Appropriate engineering controls	General exhaust is adequate under normal operating conditions.
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Personal protection	    
Eye and face protection	<p>For laboratory, larger scale or bulk handling or where regular exposure in an occupational setting occurs:</p> <ul style="list-style-type: none"> • 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 lens 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.
Skin	See Hand protection below



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protection	
Hands/feet protection	<ul style="list-style-type: none"> • Rubber gloves (nitrile or low-protein, powder-free latex, latex/ nitrile). Employees allergic to latex gloves should use nitrile gloves in preference. • Double gloving should be considered. • PVC gloves.
Body protection	See Other protection below
Other protection	<ul style="list-style-type: none"> • For quantities up to 500 grams a laboratory coat may be suitable. • For quantities up to 1 kilogram a disposable laboratory coat or coverall of low permeability is recommended. Coveralls should be buttoned at collar and cuffs. • For quantities over 1 kilogram and manufacturing operations, wear disposable coverall of low permeability and disposable shoe covers.
Thermal hazards	Not Available

Recommended material(s)

Glove Selection Index

Glove selection is based on a modified presentation of the:

"Forsberg Clothing Performance Index".

The effect(s) of the following substance(s) are taken into account in the *computer-generated* selection:

Guardian Naproxen Tablets

Material	CPI
NATURAL RUBBER	A
NATURAL+NEOPRENE	A
NITRILE	A



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* CPI - Chemwatch Performance Index

A: Best Selection

B: Satisfactory; may degrade after 4 hours continuous immersion

C: Poor to Dangerous Choice for other than short term immersion

Note: As a series of factors will influence the actual performance of the glove, a final selection must be based on detailed observation. -

* Where the glove is to be used on a short term, casual or infrequent basis, factors such as "feel" or convenience (e.g. disposability), may dictate a choice of gloves which might otherwise be unsuitable following long-term or frequent use. A qualified practitioner should be consulted.

Respiratory protection

Not Available

Required Minimum Protection Factor	Half-Face Respirator	Full-Face Respirator	Powered Air Respirator
up to 10 x ES	P1 Air-line*	-	PAPR-P1 -
up to 50 x ES	Air-line**	P2	PAPR-P2
up to 100 x ES	-	P3 Air-line*	-
100+ x ES	-	Air-line**	PAPR-P3

* - Negative pressure demand ** - Continuous flow

A(All classes) = Organic vapours, B AUS or B1 = Acid gasses, B2 = Acid gas or hydrogen cyanide(HCN), B3 = Acid gas or hydrogen cyanide(HCN), E = Sulfur dioxide(SO2), G = Agricultural chemicals, K = Ammonia(NH3), Hg = Mercury, NO = Oxides of nitrogen, MB = Methyl bromide, AX = Low boiling point organic compounds(below 65 degC)



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Section 9. Physical and Chemical Properties

9.1 Information on basic physical and chemical properties

Physical State	:	Solid
Appearance	:	Blue film-coated round biconvex tablets.
Colour	:	Blue
pH Value	:	Not Known
Vapor Pressure	:	Not Known
Vapor Density	:	Not Known
Evaporation Rate	:	Not Known
Other information		
Flash point	:	Not Known
Molecular Weight	:	Not Known
Melting point/range	:	Not Known
Boiling point/boiling range	:	Not Known
Density	:	Not Known
Viscosity	:	Not Known
Water solubility	:	Not Known
Solubility in other solvents	:	Not Known
Minimum ignition energy (MIE)	:	Not Known
Minimum ignition temperature (MIT)	:	Not Known
Layer ignition temperature (LIT)	:	Not Known
Flammability/explosivity	:	Not Known
Reactivity/exotherms	:	Not Known



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Electrostatic nature	:	Not Known
Highly dusty material	:	Not Known
Any other properties which cause handling or processing difficulties	:	Not Known
Average PSD (particle size distribution (micron))	:	Not Known

9.2 Other Information: Not Known

Section 10. Stability and Reactivity

10.1 Reactivity: Product is considered stable

10.2 Chemical stability: Product is considered stable.

10.3 Conditions to Avoid: oxidizing agents i.e. nitrates, oxidizing acids, chlorine bleaches, pool chlorine etc. as ignition may result

10.4 Incompatibilities with Other Materials:

oxidizing agents i.e. nitrates, oxidizing acids, chlorine bleaches, pool chlorine etc. as ignition may result

10.5 Hazardous Decomposition Products: Decomposition may produce toxic fumes of: carbon monoxide (CO), carbon dioxide (CO₂), metal oxides, other pyrolysis products typical of burning organic material. May emit poisonous fumes.

10.6 Hazardous Polymerization: Will not occur



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Section 11. Toxicological Information

11.1 Information on toxicological effects

Inhaled	The material is not thought to produce respiratory irritation (as classified by EC Directives using animal models). Nevertheless inhalation, of the material, especially for prolonged periods, may produce respiratory discomfort and occasionally, distress.
Ingestion	Accidental ingestion of the material may be damaging to the health of the individual.
Skin Contact	The material is not thought to be a skin irritant (i.e. is unlikely to produce irritant dermatitis as described in EC Directives using animal models). Temporary discomfort, however, may result from prolonged dermal exposures. Good hygiene practice requires that exposure be kept to a minimum and that suitable gloves be used in an occupational setting. Open cuts, abraded or irritated skin should not be exposed to this material Entry into the blood-stream through, for example, cuts, abrasions, puncture wounds or lesions, may produce systemic injury with harmful effects. Examine the skin prior to the use of the material and ensure that any external damage is suitably protected.
Eye	Although the material is not thought to be an irritant (as classified by EC Directives), direct contact with the eye may produce transient discomfort characterised by tearing or conjunctival redness (as with windburn).
Chronic	Limited evidence suggests that repeated or long-term occupational exposure may produce cumulative health effects involving organs or biochemical systems. There is some evidence that human exposure to the material may result in developmental toxicity. This evidence is based on animal studies where effects have been observed in the absence of marked maternal toxicity, or at around the same dose levels as other toxic effects but which are not secondary non-specific consequences of the other toxic effects. Exposure to the material for prolonged periods may cause physical defects in the developing embryo (teratogenesis). NSAIDs may cause an increased risk of serious cardiovascular thrombotic events, myocardial infarction, and stroke, which can be fatal. NSAIDs cause an increased risk of serious gastrointestinal adverse events including bleeding, ulceration, and perforation of the stomach or intestines, which can be fatal. These events can occur at any time during use and without warning symptoms.



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Prolonged treatment with non-steroidal anti-inflammatory drugs (NSAIDs) has been associated with gastrointestinal irritation, erosion, ulceration, perforation, frank or occult bleeding, diarrhoea, constipation, and blood in the vomit or stool.

Naproxen Tablets	TOXICITY	IRRITATION
	Oral (rat) LD50: 248 mg/kgd ^[2]	Not Available

Legend:
 1. Value obtained from Europe ECHA Registered Substances - Acute toxicity
 2.* Value obtained from manufacturer's SDS. Unless otherwise specified data extracted from RTECS - Register of Toxic Effect of chemical Substances

Section 12. Ecological Information

12.1 Toxicity:

Not Available

Ingredient	Endpoint	Test Duration	Species	Value	Source
Naproxen	EC50	384	Crustacea	45.527mg/L	3
Naproxen	EC50	96	Algae or other aquatic plants	473.118mg/L	3
Naproxen	LC50	96	Fish	187.962mg/L	3

DO NOT discharge into sewer or waterways.

12.2 Persistence and degradability:

Ingredient	Persistence: Water/Soil	Persistence: Air
Naproxen	High	High



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12.3 Bioaccumulative potential:

Ingredient	Bioaccumulation
Naproxen	Low (LogKOW = 2.4187)

12.4 Mobility in soil:

Ingredient	Mobility
Naproxen	Low (KOC = 349.3)

12.5 Other: Not Known

Section 13. Disposal Considerations

13.1 Waste treatment methods


Product / Packaging disposal	<ul style="list-style-type: none">• Recycle wherever possible or consult manufacturer for recycling options.• Consult State Land Waste Management Authority for disposal.• Bury residue in an authorized landfill.• Recycle containers if possible, or dispose of in an authorized landfill.
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Section 14. Transport Information

14.1 Special precautions for user:

Labels Required

Marine Pollutant	
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Land transport (UN): 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 73 / 78 and the IBC code

Source	Ingredient	Pollution Category
IMO MARPOL 73/78 (Annex II) - List of Noxious Liquid Substances Carried in Bulk	Naproxen	X
IMO MARPOL 73/78 (Annex II) - List of Noxious Liquid Substances Carried in Bulk	titanium dioxide	Z

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Not Applicable

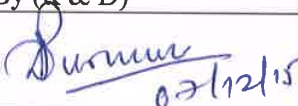
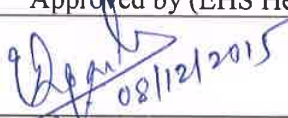
National Inventory	Status
Australia - AICS	Y
Canada - DSL	Y
Canada - NDSL	N (Naproxen, sodium chloride)
China - IECSC	N (Naproxen)
Europe - EINEC / ELINCS / NLP	Y
Japan - ENCS	N (Naproxen)
Korea - KECI	Y
New Zealand - NZIoC	Y
Philippines - PICCS	N (Naproxen)
USA - TSCA	N (Naproxen, sodium salt)
Legend:	<i>Y = All ingredients are on the inventory N = Not determined or one or more ingredients are not on the inventory and are not exempt from listing(see specific ingredients in brackets)</i>

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Section 16. Additional Information

Disclaimer:

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

Compiled By (R & D)	Approved by (EHS Head)
 02/12/15	 08/12/2015
Signature /Date	Signature /Date