

1. IDENTIFICATION

Product identifier: NAPROXEN SODIUM 220mg CAPLET

Synonyms: 140, 368

Manufacturer Name: Perrigo Company
Address: 515 Eastern Avenue
 Allegan, MI 49010 USA

Telephone number: 269-673-8451

Emergency phone number: 888-464-2986 (U.S. calls)
 +1 760-476-3962 Code 333304 (International calls)

Email Address: SDSRequest@perrigo.com

Recommended use: Human drug – Analgesic (NSAID)

Restrictions on use: Use only as directed.

2. HAZARD(S) IDENTIFICATION

Classification:

Physical	Health
Not hazardous	Acute Oral Toxicity Category 4 Reproductive Toxicity Category 2

Label Elements:

Warning!



Hazard statement(s)

Harmful if swallowed.
 Suspected of damaging the unborn child.

Precautionary statement(s)

Obtain special instructions before use.
 Do not handle until all safety precautions have been read and understood.
 Wash hands thoroughly after handling.
 Do not eat, drink or smoke when using this product.
 If swallowed: Call a poison center or physician if you feel unwell. Rinse mouth.
 Wear protective gloves for handling damaged caplets.
 IF exposed or concerned: Get medical attention.
 Store locked up.
 Dispose in accordance with local and national regulations.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Chemical name	CAS No.	Concentration
Naproxen Sodium	26159-34-2	55-75%

Microcrystalline Cellulose	9004-34-6	Proprietary
Hypromellose	9004-65-3	Proprietary
Povidone	9003-39-8	Proprietary
Magnesium Stearate	557-04-0	Proprietary
Talc	14807-96-6	Proprietary
Titanium Dioxide (bound in caplet)	13463-67-7	Proprietary
Polyethylene Glycol	25322-68-3	Proprietary
FD&C Blue #2 Aluminum Lake	16521-38-3	Proprietary

The exact percentage (concentration) of composition has been withheld as a trade secret.

4. FIRST-AID MEASURES

Inhalation: Remove victim to fresh air. If irritation occurs or symptoms develop, get medical attention.

Skin contact: In the case of contact with crushed or broken caplets, remove contaminated clothing. Wash skin with soap and water. If irritation develops, get medical attention. Launder clothing before reuse.

Eye contact: Immediately flush eyes with water while lifting the upper and lower lids. Get medical attention if irritation persists.

Ingestion: In the case of unintended ingestion, rinse mouth with water. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to a person who is unconscious or convulsing. Get prompt medical attention.

Most important symptoms/effects, acute and delayed: Dust may cause eye irritation. Inhalation of dust from broken caplets may cause upper respiratory tract irritation and symptoms similar to ingestion. Ingestion of amounts above the recommended dose may cause gastrointestinal upset. This product contains a NSAID, which may cause severe stomach bleeding. Other nonsteroidal anti-inflammatory drugs (NSAIDs) are known to impact delivery, late fetal development, and lactation.

Indication of immediate medical attention and special treatment, if necessary: Immediate medical attention is required for unintended ingestion of large amounts.

5. FIRE-FIGHTING MEASURES

Extinguishing media: Use water spray, carbon dioxide, dry chemical or foam to extinguish a fire.

Specific hazards arising from the chemical: Caplets are not a fire hazard but may burn under fire conditions. Fine dust from crushed caplets will present a dust explosion hazard.

Special protective equipment and precautions for fire-fighters: Firefighters should wear positive pressure self-contained breathing apparatus and full protective clothing for all fires involving chemicals.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment, and emergency procedures: Wear appropriate protective clothing and equipment as described in Section 8. If caplets are damaged, respiratory protection may be required. Avoid generating airborne dust during cleanup. If dust is present, eliminate all sources of ignition.

Environmental Precautions: Prevent spill from entering sewers and water courses. Report releases as required by local and national authorities.

Methods and materials for containment and cleaning up: Collect using methods that avoid the generation of dust and damage to caplets (scoop up carefully) and place in appropriate container for disposal. Clean area thoroughly. If dust is present, do not use vacuum unless explosion-proof.

7. HANDLING AND STORAGE

Precautions for safe handling: Avoid the generation of dust. If caplets are damaged, avoid contact with eyes, skin and clothing and avoid breathing dust. Wash thoroughly with soap and water after handling.

Conditions for safe storage, including any incompatibilities: Store as indicated on product packaging in a secure location.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure guidelines:

Naproxen Sodium	500 ug/m3 TWA Perrigo OEB2
Microcrystalline Cellulose	10 mg/m3 TWA ACGIH TLV 5 mg/m3 (respirable dust) TWA OSHA PEL 15 mg/m3 (total dust) TWA OSHA PEL
Hypromellose	None Established
Povidone	None Established
Magnesium Stearate	10 mg/m3 TWA total dust ACGIH TLV
Talc	10 mppcf TWA OSHA PEL 2 mg/m3 (respirable dust) TWA ACGIH TLV
Titanium Dioxide (bound in caplet)	10 mg/m3 TWA ACGIH TLV 15 mg/m3 (total dust) TWA OSHA PEL
Polyethylene Glycol	None Established
FD&C Blue #2 Aluminum Lake	None Established

Appropriate engineering controls: Use with adequate general or local exhaust ventilation to keep exposures below occupational exposure limits.

Individual protection measures:

Respiratory protection: None needed under normal use conditions. If exposure limits are exceeded, a NIOSH approved particulate respirator is recommended. Selection of respiratory protection depends on the contaminant type, form and concentration. Select in accordance with OSHA 1910.134 and good Industrial Hygiene practice.

Skin protection: Impervious gloves recommended for handling damaged caplets.

Eye protection: Chemical safety goggles recommended for handling damaged caplets.

Other: None known.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance (physical state, color, etc.): Blue Caplet

Odor: None

Odor threshold: Not applicable	pH: Not applicable
Melting point/freezing point: Not applicable	Boiling Point: Not applicable
Flash point: Not applicable	Evaporation rate: Not applicable
Flammability (solid, gas): Not flammable	VOC: Not applicable
Flammable limits: LEL: Not applicable	UEL: Not applicable
Vapor pressure: Not applicable	Vapor density: Not applicable

Relative density: Not available	Solubility(ies): Not available
Partition coefficient: n-octanol/water: Not available	Auto-ignition temperature: Not available
Decomposition temperature: Not available	Viscosity: Not applicable

10. STABILITY AND REACTIVITY

Reactivity: Not reactive under normal conditions of use.

Chemical stability: Stable.

Possibility of hazardous reactions: None known.

Conditions to avoid: None known.

Incompatible materials: Avoid oxidizing agents.

Hazardous decomposition products: Thermal decomposition may yield carbon and nitrogen oxides.

11. TOXICOLOGICAL INFORMATION

Acute effects of exposure:

Inhalation: Inhalation of dust from damaged caplets may cause irritation of the mucous membranes and upper respiratory tract.

Ingestion: Ingestion of amounts above the recommended dose may cause gastrointestinal upset. This product contains an NSAID, which may cause severe stomach bleeding.

Skin contact: Contact with damaged caplets may cause slight irritation.

Eye contact: Contact with damaged caplets may cause slight irritation with redness and tearing.

Chronic Effects: None known.

Sensitization: Components are not known to be sensitizers. Allergic reactions are possible in aspirin sensitive individuals.

Germ Cell Mutagenicity: No adverse effects are expected. Components are not germ cell mutagens.

Reproductive Toxicity: Naproxen sodium did not cause effects on development or fertility in rats or rabbits at a dose of 20 mg/kg/day. Other nonsteroidal anti-inflammatory drugs (NSAIDs) are known to impact delivery, late fetal development, and lactation.

Carcinogenicity: Titanium dioxide is classified by IARC as a suspected carcinogen (Group 2B). Titanium dioxide causes cancer only by inhalation of respirable particles. The titanium dioxide is bound in the caplet matrix and no inhalation exposure will occur during the handling of these caplets. None of the other components are listed as carcinogens by IARC, NTP or OSHA. Naproxen sodium was not carcinogenic when tested in laboratory animals, including a 2 year study in rats.

Acute Toxicity Values: Acute Oral Toxicity Estimate (ATE) calculated: 714 mg/kg
Naproxen Sodium: LD50 oral rat 534 mg/kg.

12. ECOLOGICAL INFORMATION

Ecotoxicity values: No data is available

Persistence and degradability: No data is available

Bioaccumulative potential: No data is available

Mobility in soil: No data is available.

Other adverse effects: None known.

13. DISPOSAL CONSIDERATIONS

Dispose in accordance with all local, state and federal regulations. No specific disposal method is recommended.

14. TRANSPORT INFORMATION

	UN Number	Proper shipping name	Hazard Class	Packing Group	Environmental Hazard
DOT		Not Regulated			
TDG		Not Regulated			
IMDG		Not Regulated			
IATA		Not Regulated			

Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code): Not applicable – product is transported only in packaged form.

Special precautions: None known.

15. REGULATORY INFORMATION

Safety, health, and environmental regulations specific for the product in question.

CERCLA: This product is not subject to CERCLA release reporting. Many states have more stringent release reporting requirements. Report spills as required under federal, state and local regulations.

SARA Hazard Category (311/312): Acute Health, Chronic Health

EPA SARA 313: This product contains the following chemicals regulated under SARA Title III, section 313:
None

EPA TSCA Inventory: This product is a drug and not subject to TSCA.

CANADA:

Canadian CEPA: This product is a drug and not subject to CEPA regulations.

16. OTHER INFORMATION

NFPA Rating: Health = 1 Flammability = 1 Instability = 0
HMIS Rating: Health = 1* Flammability = 1 Physical Hazard = 0

SDS Revision History: Updated CAS No. in Section 3.

Date of preparation: April 24, 2023

Disclaimer: This SDS has been prepared for occupational exposure. Consumers: Refer to the package insert or product label for appropriate consumer-specific information about this product when used according to manufacturer’s directions. Although reasonable care has been taken in the preparation of this document, we extend no warranties and make no representations as to the accuracy of the information contained therein, and assume no responsibility regarding the suitability of this information for the user’s intended purposes or for the consequence of its use. Each individual should make a determination as to the suitability of the information for their particular purpose(s).