Quality Affordable Healthcare Products™

SAFETY DATA SHEET

1. IDENTIFICATION

Product identifier: APAP PAIN RELIEVER 500 mg CAPLET
Synonyms: 24K, 4U4, 484, 917, 975

Manufacturer Name:	Perrigo Company
Address:	515 Eastern Avenue Allegan, MI 49010 USA
Telephone number:	269-673-8451
Emergency phone number:	888-464-2986

Recommended use: Human drug – pain reliever/fever reducer
Restrictions on use: Use only as directed.

2. HAZARD(S) IDENTIFICATION

Classification:

Physical	Health
Not hazardous	Not Hazardous

Label Elements

Not hazardous in accordance with the GHS and OSHA Hazcom 2012.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Chemical name	CAS No.	Concentration
Acetaminophen	103-90-2	60-100%
Pregelatinized Starch	9005-25-8	Proprietary
Corn Starch	9005-25-8	Proprietary
Povidone	9003-39-8	Proprietary
Stearic Acid	57-11-4	Proprietary
Sodium Starch Glycolate	9063-38-1	Proprietary
Hypromellose	9004-65-3	Proprietary
Polyethylene Glycol	25322-68-3	Proprietary
Carnauba Wax	8015-86-9	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 medical attention if any adverse effects occur or for overdoasage.

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. Swallowing amounts above the recommended dosage may cause gastrointestinal effects, nervousness, dizziness and sleeplessness. Large ingestions or prolonged use may damage the liver and kidneys.

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

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. Cool fire exposed containers with water.

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:

Acetaminophen	4000 ug/m3 TWA (Perrigo OEL)
Pregelatinized Starch	10 mg/m3 TWA ACGIH TLV 5 mg/m3 (respirable dust) TWA OSHA PEL 15 mg/m3 (total dust) TWA OSHA PEL
Corn Starch	10 mg/m3 TWA ACGIH TLV 5 mg/m3 (respirable dust) TWA OSHA PEL 15 mg/m3 (total dust) TWA OSHA PEL
Povidone	None Established
Stearic Acid	None Established
Sodium Starch Glycolate	None Established
Hypromellose	None Established
Polyethylene Glycol	None Established
Carnauba Wax	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.): White caplets
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 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: Swallowing amounts above the recommended dosage may cause gastrointestinal effects, nervousness, dizziness and sleeplessness.
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: Large ingestions or prolonged use may damage the liver and kidney.
Sensitization: Components are not known to be sensitizers. Allergic reactions are possible in sensitive individuals.
Germ Cell Mutagenicity: None of the components have been shown to cause germ cell mutagenicity. Acetaminophen was not mutagenic in in-vitro bacterial reverse mutation assays and the drosophila SLRL test but indices sister chromatid exchange and chromosomal aberration in in-vitro and in-vivo tests with human cells. It was negative in an in-vivo mouse micronucleus assay.
Reproductive Toxicity: Acetaminophen did not cause effects on reproductive performance or development in studies with rats but cause some developmental toxicity in mice. The significance of this finding to humans is not known.
Carcinogenicity: None of the components are listed as carcinogens or suspected carcinogens by IARC, NTP, ACGIH or OSHA. Acetaminophen was tested for carcinogenicity in rats and mice with no evidence of carcinogenic effect.

Acute Toxicity Values: Acute Oral Toxicity Estimate (ATE) calculated: 2170 mg/kg
Acetaminophen: Oral rat LD50 1944 mg/kg

12. ECOLOGICAL INFORMATION

May be harmful to aquatic organisms.
Ecotoxicity values: Acetaminophen: EC50 daphnia magna 6.1-14 mg/L/48 hr.; LC50 fathead minnow 814 mg/L/96 hr.
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): Not Hazardous
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.
Canadian WHMIS Classification: Drugs are exempt from WHMIS
This product has been classified under the CPR and this SDS discloses information elements required by the CPR.

16. OTHER INFORMATION

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

SDS Revision History: Updated Section 3, CAS No.
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).