SAFETY DATA SHEET

1. IDENTIFICATION

Product identifier: Acetaminophen Suppositories 120mg, 650mg
Synonyms: 579, 363

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 – 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	5-30%
Vegetable Oil	68990-82-9	70-95%

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 suppositories, 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 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.

Most important symptoms/effects, acute and delayed: May cause eye irritation. Inhalation of mists or dust from broken suppositories may cause upper respiratory tract irritation and symptoms similar to ingestion. Swallowing 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 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: Suppositories are not a fire hazard but may burn under fire conditions.

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 suppositories are damaged, respiratory protection may be required. Avoid generating airborne mists or dust during cleanup.

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 suppositories (scoop up carefully) and place in appropriate container for disposal. Clean area thoroughly.

7. HANDLING AND STORAGE

Precautions for safe handling: Avoid the generation of dust or mists in handling. If suppositories are damaged, avoid contact with eyes, skin and clothing. 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)
Vegetable Oil (as mist)	5 mg/m3 (respirable dust) TWA OSHA PEL 15 mg/m3 (total dust) TWA OSHA PEL

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 suppositories.
Eye protection: Chemical safety goggles recommended for handling damaged suppositories.
Other: None known.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance (physical state, color, etc.): White suppositories
Odor: None

Odor threshold: Not applicable	**pH:** Not applicable
Melting point/freezing point: Not applicable	**Boiling Point:** Not determined
Flash point: Not determined	**Evaporation rate:** Not determined
Flammability (solid, gas): Not flammable	**VOC:** Not determined
Flammable limits: LEL: Not applicable	**UEL:** Not applicable
Vapor pressure: Not determined	**Vapor density:** Not determined
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 or mists from damaged suppositories may cause irritation of the mucous membranes and upper respiratory tract.
Ingestion: Swallowing may cause gastrointestinal effects, nervousness, dizziness and sleeplessness.
Skin contact: Contact with damaged suppositories may cause slight irritation.
Eye contact: Contact with damaged suppositories 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: 6667 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: New SDS
Date of preparation: April 11, 2015

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).