SAFETY DATA SHEET

1. IDENTIFICATION

Product identifier: Children's Chewable 81mg Aspirin
Synonyms: 467

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 – treatment of pain and fever
Restrictions on use: Use only as directed.

2. HAZARD(S) IDENTIFICATION

Classification:

Physical	Health
Not hazardous	Reproductive Toxicity Category 2

Warning!

Hazard statement(s)

Suspected of damaging fertility or the unborn child.

Precautionary statement(s)

Obtain special instructions before use.
Do not handle until all safety precautions have been read and understood.
Wear protective clothing and gloves.
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
Aspirin	50-78-2	35-40%
Dextrose	50-99-7	Proprietary
Corn Starch	9005-25-8	Proprietary
Flavors	Mixture	Proprietary
FD&C Yellow #6 lake	2783-94-0	Proprietary
Saccharin Sodium	6155-57-3	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 damaged tablets, remove contaminated clothing. Wash skin with soap and water. If irritation or symptoms of exposure develop, 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 immediate medical attention.

Most important symptoms/effects, acute and delayed: May cause eye irritation. Inhalation of dust from broken tablets may cause upper respiratory tract irritation and symptoms similar to ingestion. Swallowing may cause gastrointestinal effects such as heartburn, nausea, stomach pain, diarrhea, ringing in the ears, visual disturbances, flushing, sweating and mental status changes. May cause severe stomach bleeding in some individuals.

Indication of immediate medical attention and special treatment, if necessary: Immediate medical attention is recommended for overdosage.

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: Tablets are not a fire hazard but will burn under fire conditions. Combustion will produce carbon oxides. Fine dust from crushed tablets 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 tablets 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 tablets (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 tablets 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.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure guidelines:

Aspirin	4000 ug/m3 TWA (Perrigo OEL)
Dextrose (as PNOC)	5 mg/m3 (respirable particulate) TWA OSHA PEL 15 mg/m3 (total particulate) TWA OSHA PEL
Corn Starch	5 mg/m3 (respirable particulate) TWA OSHA PEL 15 mg/m3 (total particulate) TWA OSHA PEL 10 mg/m3 TWA ACGIH TLV
Flavors	None Established
FD&C Yellow #6 lake	None Established
Saccharin Sodium	None Established

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

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

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance (physical state, color, etc.): Tablets, orange
Odor: Orange odor

Odor threshold: Not determined	**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 determined	**Solubility(ies):** Partially soluble in water
Partition coefficient: n-octanol/water: 1.19 (aspirin)	**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 tablets may cause irritation of the mucous membranes and upper respiratory tract and symptoms similar to ingestion.
Ingestion: Swallowing may cause gastrointestinal effects such as heartburn, nausea, stomach pain, diarrhea, ringing in the ears, visual disturbances, flushing, sweating and mental status changes.
Skin contact: Contact with damaged tablets may cause slight irritation. Absorption through the skin is possible with effects similar to ingestion.
Eye contact: Contact with damaged tablets may cause mild irritation with redness and tearing.
Chronic Effects: Prolonged use of aspirin may cause gastrointestinal bleeding, kidney and liver effects.
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. Aspirin was negative in the Ames test, in-vitro chromosome aberration test with human lymphocytes, an in-vivo rat micronucleus test and an in-vivo chromosome aberration test in the mouse.
Reproductive Toxicity: Aspirin given to rats at 250 mg/kg/day did not affect reproductive performance but delayed ossification and renal development in the offspring. In a study in rabbits, aspirin did not induce malformation when administered as a single dose or during the period of organogenesis, even at doses that cause material toxicity. NOAEL maternal 125 mg/kg; NOAEL malformations 350 mg/kg/day, NOAEL development 250 mg/kg/day. In another study with rats aspirin was associated with increased malformations when administered at high dose – NOAEL maternal 50 mg/kg and developmental 50 mg/kg. Aspirin is suspected to cause adverse pregnancy outcome if taken in the third trimester of pregnancy in humans. Salicylates are associated with increased prenatal and newborn mortality, anemia, prolonged pregnancy, maternal bleeding complications, and prolonged or complicated deliveries when used therapeutically in the third trimester of pregnancy. It has been suggested that maternal ingestion of salicylates may cause premature closure of the fetal ductus arteriosus and lead to pulmonary hypertension in some infants.
Carcinogenicity: None of the components are listed as carcinogens or suspected carcinogens by IARC, NTP, ACGIH or OSHA. In an 18 month study in rats with aspirin, no carcinogenic effects were observed at a dose of 200 mg/kg/day.

Acute Toxicity Values: Acute Oral Toxicity Estimate (ATE) calculated: 4348 mg/kg
Aspirin: Oral rat LD50 1725 mg/kg; Dermal rabbit LD50 >7940 mg/kg

12. ECOLOGICAL INFORMATION

Ecotoxicity values:
Aspirin: LC50 leuciscus idus (fish) >1000 mg/L/48 hr; EC50 daphnia magna 1293 mg/L/48 hr; ErC50 Desmodesmus subspicatus 106.7 mg/L/72 hr.
Persistence and degradability: Aspirin is readily biodegradable
Bioaccumulative potential: Based on a log Kow of 1.19, aspirin is not bioaccumulative.
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): 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: Convert to OSHA Hazcom 2012 format and content
Date of preparation: January 16, 2016

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).