



SAFETY DATA SHEET

1. IDENTIFICATION

Product identifier: DIPHEDRYL ALLERGY 25mg TABLETS

Synonyms: 479, KZ3

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 – Antihistamine

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
Diphenhydramine hydrochloride	147-24-0	5-11%
Microcrystalline Cellulose	9004-53-9	Proprietary
Dibasic Calcium Phosphate Dihydrate	7789-77-7	Proprietary
Pregelatinized Starch	9005-25-8	Proprietary
Hypromellose	9004-65-3	Proprietary
Polyethylene Glycol	25322-68-3	Proprietary
Crospovidone	25249-54-1	Proprietary
Carnauba Wax	8015-86-9	Proprietary
D&C Red #27 Aluminum Lake	13473-26-2	Proprietary
Magnesium Stearate	557-04-0	Proprietary
Stearic Acid	57-11-4	Proprietary
Polysorbate 80	9005-65-6	Proprietary
Titanium Dioxide (bound in tablet)	13463-67-7	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 tablets, 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 overdosage.

Most important symptoms/effects, acute and delayed: Dust may cause eye irritation. Inhalation of dust from damaged tablets may cause upper respiratory tract irritation and symptoms similar to ingestion. Swallowing amounts above the recommended dosage may cause drowsiness, and gastrointestinal disturbances.

Indication of immediate medical attention and special treatment, if necessary: Immediate medical attention is generally not required.

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 may burn under fire conditions. 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 in a secure location.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure guidelines:

Diphenhydramine hydrochloride	125 ug/m ³ TWA (Perrigo OEL)
Microcrystalline Cellulose	15 mg/m ³ (total dust) TWA OSHA PEL 5 mg/m ³ (respirable dust) TWA OSHA PEL 10 mg/m ³ TWA ACGIH TLV
Dibasic Calcium Phosphate Dihydrate	None Established
Pregelatinized Starch	15 mg/m ³ (total dust) TWA OSHA PEL 5 mg/m ³ (respirable dust) TWA OSHA PEL 10 mg/m ³ TWA ACGIH TLV
Hypromellose	None Established
Polyethylene Glycol (as PNOG)	15 mg/m ³ (total dust) TWA OSHA PEL 5 mg/m ³ (respirable dust) TWA OSHA PEL
Crospovidone	None Established
Carnauba Wax	5 mg/m ³ (respirable), 15 mg/m ³ (total dust) TWA OSHA PEL (as mist)
D&C Red #27 Aluminum Lake	None Established
Magnesium Stearate	10 mg/m ³ TWA ACGIH TLV
Stearic Acid	None Established
Polysorbate 80	None Established
Titanium Dioxide (bound in tablet)	15 mg/m ³ (total dust) TWA OSHA PEL 10 mg/m ³ TWA ACGIH TLV

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
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Appearance (physical state, color, etc.): Bright pink tablets

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): Partially soluble in water
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 or mists from damaged tablets may cause irritation of the mucous membranes and upper respiratory tract and effects similar to ingestion.

Ingestion: Swallowing amounts above the recommended dosage may cause drowsiness and gastrointestinal disturbances. Higher doses may cause central nervous system stimulation or depression and impairment of motor and cognitive skills.

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

Eye contact: Contact with damaged tablets 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 sensitive individuals.

Germ Cell Mutagenicity: None of the components have been shown to cause germ cell mutagenicity. Diphenhydramine hydrochloride was not genotoxic in the Ames test, the in-vitro mammalian cell mutagenicity mouse lymphoma test, the in-vitro unscheduled DNA synthesis rat hepatocyte test and the in-vitro Chinese hamster ovary cell sister chromatid exchange test. It was positive without activation and negative with activation in the Chinese hamster ovary cell in-vitro chromosome aberration assay.

Reproductive Toxicity: Components are not reproductive toxins. Diphenhydramine hydrochloride was not teratogenic in studies in rats and mice but was toxic to the fetus at maternally toxic doses.

Carcinogenicity: Titanium dioxide is classified by IARC as a suspected carcinogen (Group 2B). The titanium dioxide is bound in the capsule matrix and no inhalation exposure will occur during the handling of these tablets. None of the other components are listed as carcinogens or suspected carcinogens by IARC, NTP, ACGIH or OSHA. Diphenhydramine hydrochloride was not carcinogenic in rats receiving a dose of 15 mg/kg/day for 2 years.

Acute Toxicity Values: Acute Oral Toxicity Estimate (ATE) calculated: 4545 mg/kg

Diphenhydramine hydrochloride: Oral rat LD50 500 mg/kg

Polyethylene Glycol: Oral rat LD50 >10,000 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): 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.

16. OTHER INFORMATION

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

SDS Revision History: Updated synonym in Section 1

Date of preparation: March 20, 2017

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).