SAFETY DATA SHEETS

This SDS packet was issued with item:

078906703

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078555988 078695178 078695186 078906702 078917127

SECTION 1: Identification of the substance/mixture and of the company

1.1 Product identifier

- Product Name: **Pyrantel Pamoate Suspension**
- Product Part Number(s): **09072, 09073**
- Brands: Columbia Laboratories™

1.2 Relevant identified uses of the substance or mixture and uses advised against

- Use of the substance/preparation: Oral suspension for the treatment of pinworms in humans.
- Uses advised against: Keep out of reach of children. Do not use if pregnant or have liver disease.

1.3 Details of the supplier of the safety data sheet

- Name of Manufacturer: Diversified Manufacturing Corporation for Columbia Laboratories
- Address of Manufacturer: 944 Nandino Blvd.
  Lexington, Kentucky 40511
  USA
- Telephone: 859/254-1221 • 800/525-2022
- Email: Inform@neogen.com

1.4 Emergency telephone number

- Emergency Telephone: Chemtrec: 1 (800) 424-9300
  Outside USA and Canada: +1 (703) 527-3887

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (29 CFR 1910.1200)

- Not classified as hazardous for supply

Classification (WHMIS 2015 HPR)

- Not classified as hazardous for supply

Additional information: For full text of Hazard statements: see Section 16.

2.2 Label elements

- Signal Word: None
- Symbols: None
- Hazard phrases
  None
- Precautionary Phrases
  Keep container tightly closed.
  Avoid prolonged contact with eyes, skin, or clothing.

2.3 Other hazards

- Keep out of reach of children.

SECTION 3: Composition/information on ingredients

3.1 Substances

3.2 Mixtures

This product is a mixture of the substances listed below with the addition of non-hazardous materials

Chemical	Concentration	CAS No.	H-Statements	Symbols
Water	>35.00%	7732-18-5	None	None
Sucrose	<45.00%	57-50-1	None	None
Pyrantel pamoate	<15.00%	22204-24-6	None	None
Potassium sorbate	<0.50%	590-00-1	H315, H319	GHS03
Sodium benzoate	<0.50	532-32-1	None	None
BHT	<0.1%	128-37-0	H302, H410	GHS07, GHS09
Xanthan gum	<0.2%	11138-66-2	None	None
Citric acid	<0.02%	77-92-9	H319	GHS07
Vanilla flavor	<0.5%	n/a	None	None

Ingredients not precisely identified are proprietary or non-hazardous. Values are not product specifications.

SECTION 4 First aid measures

4.1 Description of first aid measures

- General
  In case of doubt, or when symptoms persist, seek medical attention.
  In general, this product is not hazardous to humans or animals, but like any other chemical, it should be treated with care, respect, and common sense.
  Follow label directions carefully.
- Contact with skin
  Remove contaminated clothing.
  Wash affected area with plenty of soap and water.
  If skin irritation or rash occurs: Get medical advice/attention.
  Contaminated clothing should be laundered before reuse.
- Contact with eyes
  If substance has gotten into eyes, rinse with plenty of water for at least 15 minutes.
  Irrigate eyes thoroughly while lifting eyelids.
  Seek medical advice if necessary.
- Ingestion
  In case of accidental overdose, contact a poison center or doctor immediately.
  Never make an unconscious person vomit or drink fluids.
  If medical advice is needed, have product container or label at hand.
- Inhalation
  If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing.
  Call a poison center or doctor if you feel unwell.

4.2 Most important symptoms and effects, both acute and delayed

- The most important known symptoms are described in the labeling (see Section 2.2) and/or in Section 11.
- When using this product, abdominal cramps, nausea, vomiting, diarrhea, headache, or dizziness may occur.

4.3 Indication of any immediate medical attention and special treatment needed

- Treat symptomatically.

SECTION 5: Fire-fighting measures

5.1 Extinguishing media

- In case of fire: use water spray, foam, carbon dioxide or dry agent for extinction.

5.2 Special hazards arising from the substance or mixture

- Smoke from fires is toxic. Take precautions to protect personnel from exposure.
- See Section 10.

5.3 Advice for firefighters

- Keep container(s) exposed to fire cool, by spraying with water.
- Wear chemical protection suit and positive-pressure breathing apparatus, if necessary.
- Wear protective clothing as per Section 8.

5.4 Hazardous Combustion Products

- None known

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

- Remove contaminated clothing.
- Wear protective clothing as per Section 8.
- Wash thoroughly after dealing with spillage.

6.2 Environmental Precautions

- Do not allow to enter public sewers and watercourses.
- Avoid releasing to the environment.

944 Nandino Blvd • Lexington, KY 40511 • 800/525-2022 (USA/Canada) • 859/254-1221
inform@neogen.com • www.neogen.com

Obtained by Global Safety Management, www.globalsafetynet.com, (877) 683-7460

SECTION 6: Accidental release measures (continued)

6.3 Methods and material for containment and cleaning up

- Absorb spillage in inert material and shovel up.
- Place in sealable container.
- Seal containers and label them.
- Ventilate the area and wash spill site after material pick-up is complete.
- Dispose of contaminated materials and wastes in accordance with local/national/international regulations.

6.4 Reference to other sections

- See Section 7 for storage. For disposal, see Section 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

- Avoid contact with eyes.
- Do not eat, drink or smoke when using this product.
- Wash hands thoroughly after using this substance.

7.2 Conditions for safe storage, including any incompatibilities

- Store in a cool place.
- Keep lid tightly closed when not in use.
- Keep out of reach of children.

7.3 Specific end use(s)

- Oral suspension for the treatment of pinworms in humans.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

- There are no recommended or established controls for this product.

8.2 Exposure controls

- Eyewash bottles should be available.
- Engineering controls should be provided to prevent the need for ventilation.
- No respiratory protection is needed if ventilation/extraction is adequate.
- Wear protective gloves to prevent prolonged or repeated skin contact.
- Wear safety glasses approved to standard for ANSI Z87, according to the concentration and amount of dangerous substance at the specific workplace.
- Wear suitable protective clothing in accordance with good industrial hygiene and safety practices in the event of prolonged exposure to bulk quantities.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

- Appearance: Opaque yellow viscous liquid
- Odor: Vanilla
- pH: 5.3 ± 0.2
- Melting point/Range: Not determined
- Boiling Point/Range: Not determined
- Flashpoint: Not determined
- Evaporation Rate: Not determined
- Flammability: No information available
- Vapor Pressure: Not determined
- Vapor Density: Not determined
- Specific Gravity: 1.19 ± 0.01 (H_2O = 1)
- Solubility in water: Relatively soluble
- Partition Coefficient (n-Octanol/Water): No information available
- Autoignition Temperature: Product is not self-igniting
- Viscosity: No information available
- Explosive Properties: Product does not present an explosion hazard
- Oxidizing Properties: Product is not classified as an oxidizer

9.2 Other information

- No information available

944 Nandino Blvd • Lexington, KY 40511 • 800/525-2022 (USA/Canada) • 859/254-1221
inform@neogen.com • www.neogen.com

Obtained by Global Safety Management, www.globalsafetynet.com, (877) 683-7460

SECTION 10: Stability and reactivity

10.1 Reactivity
- No information available

10.2 Chemical stability
- Considered stable under normal conditions

10.3 Possibility of hazardous reactions
- No hazardous reactions known if used for its intended purpose

10.4 Conditions to avoid
- None known

10.5 Incompatible materials
- None known

10.6 Hazardous Decomposition Products
- None known

SECTION 11: Toxicological information

11.1 Information on toxicological effects
- No experimental test data available for mixture
- ATEmix = 42,017 mg/kg (oral)
- Contact with skin
  May cause redness and irritation in sensitive individuals.
- Contact with eyes
  May cause redness and irritation in sensitive individuals.
- Ingestion
  Product is not toxic, but may cause abdominal cramps, nausea. Vomiting, diarrhea, headache, or dizziness.
- Inhalation
  May cause irritation in sensitive individuals.
- Carcinogenicity
  Not listed in the National Toxicology Program (NTP) 13th Report on Carcinogens.
  Listed as Group 3, Not classifiable as to its carcinogenicity to humans, in the International Agency for Research on Cancer (IARC) Monographs, Volumes 1-112: BHT (CAS No. 128-37-0)
  Not listed in OSHA standard 1910.1003 Carcinogens.
- Mutagenicity
  No evidence of mutagenic effects.
- Teratogenicity
  No evidence of teratogenic effects.

SECTION 12: Ecological information

12.1 Toxicity
- This product is not classified as hazardous to the environment under U.S. regulations.

12.2 Persistence and degradability
- No information available

12.3 Bioaccumulation Potential
- No information available

12.4 Mobility in soil
- No information available

12.5 Other Adverse Effects
- To the best of our knowledge, the properties of this material have not been fully evaluated.
- On available data, substance is not harmful to the environment.

944 Nandino Blvd • Lexington, KY 40511 • 800/525-2022 (USA/Canada) • 859/254-1221
inform@neogen.com • www.neogen.com
Obtained by Global Safety Management, www.globalsafetynet.com, (877) 683-7460

SECTION 13: Disposal considerations

Waste treatment methods

- Disposal should be in accordance with local, state, national, or international regulations.
- Do not discharge into drains or the environment, dispose to an approved waste disposal facility.
- Do not reuse empty containers.

SECTION 14: Transport information

14.1 UN Number

- Not classified as hazardous for transport

14.2 UN Proper Shipping Name

- Not applicable

14.3 Transport hazard class(es)

- Not applicable

14.4 Packing group

- Not applicable

14.5 Environmental hazards

- Not Classified

14.6 Special precautions for user

- Not Classified

14.7 Domestic Surface Transport (US DOT)

- Proper Shipping Name: Not applicable
- DOT UN No.: Not applicable
- DOT Hazard Class: Not applicable
- DOT Packing Group: Not applicable

14.8 International Road/Rail (ADR/RID)

- Proper Shipping Name: Not applicable
- ADR UN No.: Not applicable
- ADR Hazard Class: Not applicable
- ADR Packing Group: Not applicable
- Tunnel Code: Not applicable

14.9 Ocean/Sea (IMO/IMDG)

- Proper Shipping Name: Not applicable
- IMDG UN No.: Not applicable
- IMDG Hazard Class: Not applicable
- IMDG Packing Group: Not applicable

14.10 Air (ICAO/IATA)

- Proper Shipping Name: Not applicable
- ICAO UN No.: Not applicable
- ICAO Hazard Class: Not applicable
- ICAO Packing Group: Not applicable

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

- The labeling requirements of the Federal Food, Drug, and Cosmetic Act differ from the classification criteria and hazard information required for safety data sheets and for workplace labels under the OSHA Hazard Communication Standard 29 CFR 1910.1200. Following is the hazard information as required on the drug label:
  Keep out of reach of children
  Warning: In case of accidental overdose, seek professional assistance or contact a Poison Control Center immediately.
  Warning: If pregnant or if you have liver disease, do not take this product unless directed by a physician.
- Approved by FDA under Monograph 21 CFR 357
- NDC: 62337-415-16, 62337-415-32

944 Nandino Blvd • Lexington, KY 40511 • 800/525-2022 (USA/Canada) • 859/254-1221
inform@neogen.com • www.neogen.com

Obtained by Global Safety Management, www.globalsafetynet.com, (877) 683-7460

SECTION 15: Regulatory information (continued)

15.2 United States Regulatory Information

SARA 302 Components
No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

SARA 313 Components
The material does not contain any chemical components with known CAS numbers that exceed the threshold (de minimis) reporting levels established by SARA Title III, Section 313.

SARA 311/312
No SARA Hazards

Toxic Substance Control Act (TSCA)
All components of this material are either listed or exempt from listing on the TSCA Inventory.

15.3 Canadian Regulatory Information

- This product has been classified in accordance with the hazard criteria of the Hazardous Products Regulations (HPR). The labelling may differ subject to the requirements of the Food and Drugs Act (FDA).
- WHMIS Classification: Exempt
- Inventory Status

Domestic Substances List (DSL)	Listed
Non-Domestic Substances List (NDSL)	Not listed

SECTION 16: Other information

Document Number: SDS-9006, Pyrantel Pamoate Suspension
Date of Preparation: March 11, 2016
Revision: Rev. 1
Replaces: November 18, 2015

Text not given with phrase codes where they are used elsewhere in this safety data sheet: H302: Harmful if swallowed. H315: Causes skin irritation. H319: Causes serious eye irritation. H410: Very toxic to aquatic life with long-lasting effects.

This document is believed to be correct, but does not purport to be all inclusive and shall be used only as a guide. Neogen Corporation shall not be held liable for any damage resulting from handling or from contact with the above product. These suggestions should not be confused with state, municipal or insurance requirements, and constitute NO WARRANTY.

944 Nandino Blvd • Lexington, KY 40511 • 800/525-2022 (USA/Canada) • 859/254-1221
inform@neogen.com • www.neogen.com
Obtained by Global Safety Management, www.globalsafetynet.com, (877) 683-7460