

**Your Wellness. Our Passion.****SAFETY DATA SHEET****Section 1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION**

Identity	KOPELAX
Company Name	International Pharmaceuticals, Inc.
Company Address	Golam Drive, Pope John Paul II Avenue, Kasambagan, Cebu City, Cebu, Philippines
Telephone Number	+63 32 412-6900 / +63 32 260-6910
Intended Use	Medicated soap for the relief of common skin infections

Section 2. HAZARD(S) IDENTIFICATION

GHS Classification	Not classified as hazardous.
GHS Label Element	
Hazard Pictogram(s)	None
Signal Word(s)	None
Hazard Statement(s)	None
Precautionary Statement(s)	
Prevention	None
Response	None
Storage	None known.
Disposal	None known.
Other hazards	None known.

Section 3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Identity	Mixture
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Ingredients	CAS Number	EC Number	Concentration
Pyrantel Embonate	22204-24-6	244-837-1	7.00 – 8.00%
Non-Hazardous Ingredients*	-----	-----	92.00 – 93.00%

In accordance with the paragraph (i) of Sec. 1910.1200, the specific chemical identity and/or exact percentage (concentration) of mixture has been withheld as a trade secret.

* Unidentified ingredients are not considered hazardous under the Federal Hazard Communication Standard (28 CFR Sec. 1910.1200)

Section 4. FIRST AID MEASURES**Necessary first-aid measures**

Inhalation	If skin or hair contact occurs, remove contaminated clothing and flush skin and hair with running water for at least 15 minutes. Get medical attention if symptoms persist.
Skin Contact	If in eyes, hold eyelids apart and flush the eye continuously with running water. Get medical attention if irritation occurs.
Eye Contact	Drink 1 or 2 glasses of water. Do not induce vomiting. Get medical attention immediately if symptoms occur.



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Ingestion
Most important symptoms / effects, both acute and delayed

No information available.
Treat symptomatically.

Note(s) to physician

If skin or hair contact occurs, remove contaminated clothing and flush skin and hair with running water for at least 15 minutes. Get medical attention if symptoms persist.

Section 5. FIRE FIGHTING MEASURES

Suitable extinguishing media	Product is non-flammable.
Unsuitable extinguishing media	Product is non-flammable.
Specific hazards arising from the chemical	Not combustible, however if involved in a fire it may decompose and release toxic fumes.
Hazardous combustion products	Not flammable or combustible
Special protective actions for fire-fighters	Fire fighters should wear Self-Contained Breathing Apparatus (SCBA) operated in a positive pressure mode and full protective clothing to prevent exposure vapors and fumes.
Specific extinguishing methods	Water spray may be used too cool down heat-exposed containers.

Section 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	
Non-emergency personnel	Evacuate unnecessary personnel.
Emergency responders	Individuals involved in the cleanup must wear appropriate Personal Protective Equipment.
Environmental precautions	Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters.
Methods and materials for containment and cleaning up	After cleanup, dilute residual on surfaces with water and rinse into sanitary sewer system or soak up with absorbent material.

Section 7. HANDLING AND STORAGE

Precautions for safe handling	Handle containers carefully to prevent damage.
Conditions for safe storage	Keep in a dry and well-ventilated area, at normal temperatures. Keep out of reach of children. Store in suitable labeled containers.
Materials to avoid	Keep away from water during storage.

Section 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control parameters

If a component is disclosed in Section 3. (Composition/Information on Ingredients) but does not appear in the table below, an occupational exposure limit or recorded limit is not available for the component.

Chemical Name	Exposure Limits	
	OSHA [A]	NIOSH [B]
Pyrantel Embonate	N/A	N/A

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[A] Occupational Safety and Health Administration (OSHA)

[B] The National Institute of Occupational Safety and Health (NIOSH)

Appropriate engineering controls	Good general ventilation should be sufficient to control worker exposure to airborne contaminants.
Individual protection measures	
Eye / face protection	No special protective equipment required.
Hand protection	No special protective equipment required.
Skin / body protection	No special protective equipment required.
Respiratory protection	No personal respiratory protective equipment normally required.
Thermal hazards	No special protective equipment required.
Hygiene measures	General industrial hygiene practice.

Section 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance (physical state, color, etc.)	Orange, round, bisected on one side and logo on the side tablet
Odor	Characteristic
Odor threshold	Not determined.
pH	Not determined.
Melting point / freezing point	Not determined.
Initial boiling point and boiling range	Not determined.
Flash point	Not determined.
Evaporation rate	Not determined.
Flammability (solid, gas)	Not determined.
Upper / lower flammability or explosive limits	Not determined.
Vapor pressure	Not determined.
Vapor density	Not determined.
Specific gravity	Not determined.
Solubility(ies)	Not determined.
Partition coefficient (n-octanol / water)	Not determined.
Auto-ignition temperature	Not determined.
Decomposition temperature	Not determined.
Viscosity	Not determined.

Section 10. STABILITY AND REACTIVITY

Reactivity	None known.
Chemical stability	Stable under recommended storage conditions.
Possibility of hazardous reactions	No hazards to be specially mentioned.
Conditions to avoid	Extreme temperatures.
Incompatible materials	Strong oxidizing agents
Hazardous decomposition products	Thermal decomposition may result in release to toxic and/or irritating fumes.

Section 11. TOXICOLOGICAL INFORMATION

This product has not been tested on animals to obtain toxicological data. There are toxicology data for the components of this product, which are found in the scientific literature. These data



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have not been presented in this document.

Information of the likely routes of exposure

Inhalation, Skin Contact, Eye Contact, Ingestion

Potential health effects

Inhalation	Health injuries are not known or expected under normal use.
Skin contact	Health injuries are not known or expected under normal use.
Ingestion	Health injuries are not known or expected under normal use.
Eye contact	Health injuries are not known or expected under normal use.

Experience with human exposure

Inhalation	No symptoms known or expected.
Skin contact	No symptoms known or expected.
Ingestion	Product used as intended is not expected to cause gastrointestinal irritation. Accidental ingestion of undiluted product may cause mild gastrointestinal irritation with nausea, vomiting and diarrhea.
Eye contact	Contact may cause mild, transient irritation.

Acute toxicity

<u>Product</u>	No data available
<u>Ingredient(s)</u>	<ul style="list-style-type: none">• Pyrantel Embonate Oral Toxicity LD₅₀(rat): >24 g/kg LD₅₀(mouse): >24 g/kg

Skin corrosion / irritation

<u>Product</u>	Not classified.
<u>Ingredient(s)</u>	<ul style="list-style-type: none">• Pyrantel Embonate Irritant.

Serious eye damage / irritation

<u>Product</u>	Not classified.
<u>Ingredient(s)</u>	<ul style="list-style-type: none">• Pyrantel Embonate Irritant.

Respiratory or skin sensitization

<u>Product</u>	Not classified.
<u>Ingredient(s)</u>	<ul style="list-style-type: none">• Pyrantel Embonate Classified.

Germ cell mutagenicity

<u>Product</u>	No data available.
<u>Ingredient(s)</u>	No data available.

Carcinogenicity

<u>Product</u>	No data available.
<u>Ingredient(s)</u>	No data available.

STOT-single exposure

<u>Product</u>	No data available.
<u>Ingredient(s)</u>	No data available.

STOT-repeated exposure

<u>Product</u>	No data available.
<u>Ingredient(s)</u>	No data available.

Aspiration hazard

<u>Product</u>	No data available.
<u>Ingredient(s)</u>	No data available.



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Section 12. ECOLOGICAL INFORMATION

Ecotoxicity

Environmental effects	Harmful to aquatic life.	
Toxicity to fish		
<u>Product</u>	No data available.	
<u>Ingredient(s)</u>	• Pyrantel Embonate	No data available.
Toxicity to daphnia and other aquatic invertebrates		
<u>Product</u>	No data available.	
<u>Ingredient(s)</u>	• Pyrantel Embonate	No data available.
Toxicity to algae		
<u>Product</u>	No data available.	
<u>Ingredient(s)</u>	No data available.	

Persistence and degradability

<u>Product</u>	No data available.
<u>Ingredient(s)</u>	No data available.

Bioaccumulative potential

<u>Product</u>	No data available.
<u>Ingredient(s)</u>	No data available.

Mobility in soil

<u>Product</u>	No data available.
<u>Ingredient(s)</u>	No data available.

Other adverse effects

<u>Product</u>	No data available.
<u>Ingredient(s)</u>	No data available.

Section 13. DISPOSAL CONSIDERATIONS

Disposal Methods	This product can be disposed of after consultation with the responsible authorities according to disposal code. Where possible recycling is preferred to disposal or incineration. Dispose wastes in an approved waste disposal facility.
Disposal considerations	Dispose of as unused product. Empty containers should be taken to an approved waste handling site for recycling or disposal. Reusing of empty containers is recommended.

Section 14. TRANSPORT INFORMATION

Transport labeling: The shipper/consignor/sender is responsible to ensure that the packaging, labeling, and markings are in compliance with the selected mode of transport.

Land transport

UN Number	Not regulated as dangerous goods.
UN proper shipping name	Not regulated as dangerous goods.
Transport hazard class(es)	Not regulated as dangerous goods.
Packing group	Not regulated as dangerous goods.



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Environmental hazard	Not regulated as dangerous goods.
Sea transport	
UN Number	Not regulated as dangerous goods.
UN proper shipping name	Not regulated as dangerous goods.
Transport hazard class(es)	Not regulated as dangerous goods.
Packing group	Not regulated as dangerous goods.
Environmental hazard	Not regulated as dangerous goods.
Air transport	
UN Number	Not regulated as dangerous goods.
UN proper shipping name	Not regulated as dangerous goods.
Transport hazard class(es)	Not regulated as dangerous goods.
Packing group	Not regulated as dangerous goods.
Environmental hazard	Not regulated as dangerous goods.

Section 15. REGULATORY INFORMATION

No further information.

Section 16. OTHER INFORMATION

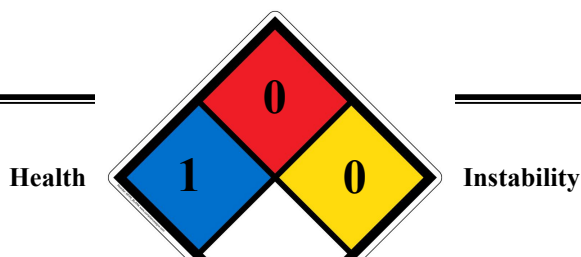
Further Information

Abbreviations:

- MSDS – Material Safety Data Sheet*
- GHS – Globally Harmonized System of Classification*
- PEG – Polyethylene Glycol*
- CAS – Chemistry Abstracts Service*
- EC – European Community Number*
- CFR – Code of Federal Regulations*
- OSHA – Occupational Safety and Health Administration*
- NIOSH – The National Institute of Occupational Safety and Health (NIOSH)*
- PEL – Permissible Exposure Limit*
- TWA - Time Weighted Average*
- PEL-TWA – Permissible Exposure Limit – 8-hour Time Weighted Average*
- CAPEL-TWA – California Permissible Exposure Limit – Time Weighted Average*
- IDLH – Immediately Dangerous to Life or Health*
- STOT – Specific Target Organ Toxicity*
- OECD – Organization for Economic Co-operation and Development*
- NTP – National Toxicology Program*
- NOEL – No Observable Effect Level*
- NOEC – No Observable Effect Concentration*
- LOEC – Lowest Observed Effects Concentration*
- LD₅₀ – median Lethal Dose*
- LC₁₀₀ – observed concentration involving 100% of mortality*
- LC₅₀ – Lethal Concentration required to kill 50% of the population*
- EC₅₀ – half maximal Effective Concentration*
- EL₅₀ – Effective Loading rate resulting in 50% effect*
- LL₅₀ – Lethal Loading rate resulting in 50% mortality*
- ErC₅₀ – 50% reduction in growth rate*
- ISO – International Organization for Standardization*
- RCRA – Resource Conservation and Recovery Act*
- UN Number – United Nations Number*
- NFPA – National Fire Protection Association*
- HMS – Health Management Information Systems*

NFPA

Flammability





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HMIS

HEALTH	1	0 = not significant
FLAMMABILITY	0	1 = slight
PHYSICAL HAZARD	0	2 = moderate
PERSONAL PROTECTION	0	3 = high
		4 = extreme
		* = chronic

Data	Publicly available information.
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The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.