



MATERIAL SAFETY DATA SHEET

Revision date: 15-Dec-2006

Version: 1.1

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1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

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Material Name: Quinfamide Tablets

Trade Name: Amefin; Finalam
Chemical Family: Mixture
Intended Use: Pharmaceutical product used for intestinal amoebiasis; antiprotozoal agent.

2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS List	%
Quinfamide	62265-68-3	263-478-1	62
Microcrystalline cellulose	9004-34-6	232-674-9	*
Magnesium stearate	557-04-0	209-150-3	*

Ingredient	CAS Number	EU EINECS List	%
Crospovidone	9003-39-8	Not listed	*
Lactose hydrous	64044-51-5	Not listed	*
Povidone	9003-39-8	Not listed	*
Purified water	7732-18-5	231-791-2	*

Additional Information: * Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

3. HAZARDS IDENTIFICATION

Appearance: White, round tablet

Statement of Hazard: Non-hazardous in accordance with international standards for workplace safety.

Additional Hazard Information:

Short Term: Not acutely toxic : Not a skin irritant : Not an eye irritant (based on components) .
Known Clinical Effects: Adverse effects associated with the therapeutic use include headache, nausea, abdominal pain.
EU Indication of danger: Not classified

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Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

4. FIRST AID MEASURES

Eye Contact: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

Skin Contact: Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

Ingestion: Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

5. FIRE FIGHTING MEASURES

Extinguishing Media: Use carbon dioxide, dry chemical, or water spray.

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire.

Fire Fighting Procedures: During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

Fire / Explosion Hazards: Not applicable

6. ACCIDENTAL RELEASE MEASURES

Health and Safety Precautions: Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.

Measures for Environmental Protections: Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

General Handling: If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes. Avoid generating airborne dust.

Storage Conditions: Keep in a dry, cool place. Keep away from heat, sparks, flame, and other sources of ignition.

Storage Temperature: < 30 °C

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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Microcrystalline cellulose

OSHA - Final PELs - TWAs: = 15 mg/m³ TWA total
= 5 mg/m³ TWA
ACGIH Threshold Limit Value (TWA) = 10 mg/m³ TWA
Australia TWA = 10 mg/m³ TWA

Magnesium stearate

ACGIH Threshold Limit Value (TWA) = 10 mg/m³ TWA except stearates of toxic metals
Australia TWA = 10 mg/m³ TWA

The exposure limit(s) listed for solid components are only relevant if dust may be generated.

The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

Quinfamide

Pfizer Occupational Exposure Band (OEB): OEB2 (control exposure to the range of >100ug/m³ to < 1000ug/m³)

Analytical Method: Not available

Engineering Controls: Engineering controls should be used as the primary means to control exposures. Use process containment, local exhaust ventilation, or other engineering controls to maintain airborne levels within the OEB range.

Personal Protective Equipment:

Hands: Not required for the normal use of this product. Wear protective gloves when working with large quantities.
Eyes: Not required under normal conditions of use. Wear safety glasses or goggles if eye contact is possible.
Skin: Not required for the normal use of this product. Wear protective clothing when working with large quantities.
Respiratory protection: Not required for the normal use of this product. If airborne exposures are within or exceed the Occupational Exposure Band (OEB) range, wear an appropriate respirator with a protection factor sufficient to control exposures to the bottom of the OEB range.

9. PHYSICAL AND CHEMICAL PROPERTIES:

Physical State:	Round tablet	Color:	White
Molecular Formula:	Mixture	Molecular Weight:	Mixture

10. STABILITY AND REACTIVITY

Stability: Stable under normal conditions of use.
Conditions to Avoid: None known
Incompatible Materials: As a precautionary measure, keep away from strong oxidizers.

11. TOXICOLOGICAL INFORMATION

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General Information: The information included in this section describes the potential hazards of the individual ingredients.

Acute Toxicity: (Species, Route, End Point, Dose)

Microcrystalline cellulose

Rat Oral LD50 > 5000 mg/kg
Rabbit Dermal LD50 > 2000 mg/kg

Quinfamide

Rat Oral LD 50 >10,000 mg/kg

Magnesium stearate

Rat Oral LD50 > 2000 mg/kg
Rat Inhalation LC50 > 2000 mg/m³

Acute Toxicity Comments: A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

Irritation / Sensitization: (Study Type, Species, Severity)

Microcrystalline cellulose

Skin Irritation Rabbit Non-irritating
Eye Irritation Rabbit Non-irritating

Carcinogen Status: None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

Povidone

IARC: Group 3

Crospovidone

IARC: Group 3

12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been thoroughly investigated. Releases to the environment should be avoided.

13. DISPOSAL CONSIDERATIONS

Disposal Procedures: Dispose of waste in accordance with all applicable laws and regulations.

14. TRANSPORT INFORMATION

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

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15. REGULATORY INFORMATION

EU Indication of danger: Not classified

OSHA Label:

Non-hazardous in accordance with international standards for workplace safety.

Canada - WHMIS: Classifications

WHMIS hazard class:

None required

This product has been classified in accordance with the hazard criteria of the CPR and the MSDS contains all of the information required by the CPR.

Quinfamide

EU EINECS List 263-478-1

Microcrystalline cellulose

Inventory - United States TSCA - Sect. 8(b) XU
Australia (AICS): Present
EU EINECS List 232-674-9

Crospovidone

Inventory - United States TSCA - Sect. 8(b) XU
Australia (AICS): Present

Lactose hydrous

Australia (AICS): Present

Magnesium stearate

Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
EU EINECS List 209-150-3

Povidone

Inventory - United States TSCA - Sect. 8(b) XU
Australia (AICS): Present

Purified water

Inventory - United States TSCA - Sect. 8(b) Present
Australia (AICS): Present
EU EINECS List 231-791-2

16. OTHER INFORMATION

Reasons for Revision:

Updated Section 2 - Composition / Information on Ingredients. Updated Section 3 - Hazard Identification. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 9 - Physical and Chemical Properties. Updated Section 15 - Regulatory Information.

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Prepared by:

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End of Safety Data Sheet