



Issue Date 11-Nov-2008

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Version 3

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

**Product identifier**

**Product Name** Pentasa® Capsules

**Other means of identification**

**Synonyms** Mesalamine, 5-Amino-2-hydroxybenzoic acid

**Recommended use of the chemical and restrictions on use**

**Recommended Use** The treatment of patients with mildly to moderately active ulcerative colitis.

**Uses advised against** Unknown

**Details of the supplier of the safety data sheet**

**Manufacturer Address**

Shire Pharmaceuticals LLC  
300 Shire Way  
Lexington, MA 02421

**Emergency telephone number**

**Company Phone Number** 617-349-0200

**24 Hour Emergency Phone Number** Chemtrec  
Within USA and Canada: 1-800-424-9300  
Outside USA and Canada: +1 703-527-3887 (collect calls accepted)

**2. HAZARDS IDENTIFICATION**

**Classification**

**Health Hazards**

Not classified.

**Physical Hazards**

Not classified.

**OSHA Regulatory Status**

Drugs when in solid final form (e.g. capsules, tablets or pills) are considered exempt under the criteria of the Federal OSHA Hazard Communication Standard 29 CFR 1910.1200. However, in an industrial setting where a component's occupational exposure limits may be surpassed, they can be considered hazardous.

**Label elements**

**Emergency Overview**

<b>Appearance</b> Green and Blue (250 mg); Blue (500 mg) Capsules	<b>Physical state</b> Solid	<b>Odor</b> Not applicable.
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**Precautionary Statements - Prevention**

Not applicable.

**Hazards not otherwise classified (HNOC)**

Unknown

**Other Information**

Unknown

**3. COMPOSITION/INFORMATION ON INGREDIENTS****Synonyms** Mesalamine, 5-Amino-2-hydroxybenzoic acid

Chemical Name	CAS No.	Weight-%
Talc	14807-96-6	5-10
Castor oil	8001-79-4	0.1-1
Stearic acid	57-11-4	0.1-1
White wax	NONE	0.1-1
Sugar spheres, 30-35 Mesh	NONE	10-30
Sugar spheres, 18-20 Mesh	NONE	20-30
Mesalamine	89-57-6	40-70
Hydroxypropyl methylcellulose USP	9004-65-3	1-5
Ethylcellulose	9004-59-5	1-5
Colloidal silicone dioxide	7631-86-9	0.1-1
Acetylated monoglyceride, distilled	NONE	0.1-1

**4. FIRST AID MEASURES****First aid measures**

<b>Eye contact</b>	In case of eye contact, immediately flush eyes with fresh water for at least 15 minutes while holding the eyelids open. Remove contact lenses if worn. Get medical attention if irritation persists.
<b>Skin Contact</b>	In case of contact, remove contaminated clothing. Immediately flush skin with copious amounts of water for at least 15 minutes. Obtain medical attention if skin reaction occurs.
<b>Inhalation</b>	In case of inhalation, remove to fresh air. If not breathing, provide artificial respiration. If breathing is difficult, administer oxygen. Seek medical attention immediately.
<b>Ingestion</b>	In case of accidental ingestion, wash out mouth with copious amounts of water. Administer charcoal as a slurry (240 mL water/30g charcoal). Usual dose: 25 to 100g in adults/adolescents, 25 to 50g in children (1 to 12 years), and 1g/kg in infants less than 1 year old. Seek medical attention immediately. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.
<b>Self-protection of the first aider</b>	Do not use mouth-to-mouth method if victim ingested or inhaled the substance; give artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device.

**Most important symptoms and effects, both acute and delayed**

<b>Symptoms</b>	Mesalamine: Tinnitus, vertigo, headache, confusion, drowsiness, sweating, hyperventilation, vomiting, and diarrhea. Severe intoxication with salicylates can lead to disruption of electrolyte balance and blood-pH, hyperthermia, and dehydration.
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**Indication of any immediate medical attention and special treatment needed**

<b>Note to physicians</b>	Treat symptomatically.
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## 5. FIRE-FIGHTING MEASURES

### Suitable extinguishing media

Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

**Unsuitable extinguishing media** Unknown

### Specific hazards arising from the chemical

Unknown

#### Explosion data

**Sensitivity to Mechanical Impact** Unknown

**Sensitivity to Static Discharge** Unknown

### Protective equipment and precautions for firefighters

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

## 6. ACCIDENTAL RELEASE MEASURES

### Personal precautions, protective equipment and emergency procedures

**Personal precautions** Ensure adequate ventilation, especially in confined areas.

### Environmental precautions

**Environmental precautions** See Section 12 for additional ecological information.

### Methods and material for containment and cleaning up

**Methods for containment** Prevent further leakage or spillage if safe to do so.

**Methods for cleaning up** Pick up and transfer to properly labeled containers.

## 7. HANDLING AND STORAGE

### Precautions for safe handling

**Advice on safe handling** Handle in accordance with good industrial hygiene and safety practice.

### Conditions for safe storage, including any incompatibilities

**Storage Conditions** Commercially available oral mesalamine delayed-release tablets should be stored at a controlled room temperature of 20-25°C, while the commercially available oral extended-release capsules should be stored at 25°C but may be exposed to temperatures ranging from 15-30°C.

**Incompatible materials** Unknown

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Control parameters

**Exposure Guidelines** This product, as supplied, does not contain any other hazardous materials with Occupational Exposure Limits (OEL) established by the region specific regulatory bodies.

Chemical Name	ACGIH TLV	OSHA PEL	NIOSH REL
Talc 14807-96-6	TWA: 2 mg/m <sup>3</sup> particulate matter containing no asbestos and <1% crystalline silica, respirable fraction	<1% Crystalline silica, containing no Asbestos TWA: 20 mppcf if 1% Quartz or more, use Quartz limit	IDLH: 1000 mg/m <sup>3</sup> TWA: 2 mg/m <sup>3</sup> containing no Asbestos and <1% Quartz respirable dust
Colloidal silicone dioxide 7631-86-9	-	<1% Crystalline silica TWA: 20 mppcf (80)/(% SiO <sub>2</sub> ) mg/m <sup>3</sup> TWA	IDLH: 3000 mg/m <sup>3</sup> TWA: 6 mg/m <sup>3</sup>

**Appropriate engineering controls**

**Engineering Controls**

The health hazard risks of handling this material are dependent on factors, such as physical form and quantity. Site-specific risk assessments should be conducted to determine the appropriate exposure control measures. Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels as low as reasonably achievable.

**Individual protection measures, such as personal protective equipment**

**Eye/face protection**

None required for consumer use. In laboratory, medical or industrial settings, safety glasses with side shields are recommended. The use of goggles or full face protection may be required depending on the industrial exposure setting. Contact a health and safety professional for specific information.

**Skin and body protection**

None required for consumer use. In laboratory, medical or industrial settings, gloves and lab coats are recommended. The use of additional personal protective equipment such as shoe coverings, gauntlets, hood or head coverings may be necessary. Contact a health and safety professional for specific information.

**Respiratory protection**

None required for consumer use. Respirators may be required for certain laboratory and manufacturing tasks if engineering controls do not maintain airborne concentrations below recommended exposure limits (where applicable) or to an acceptable level (where the exposure limits have not been established). Workplace risk assessments should be completed before specifying and implementing respirator usage. All respirators must conform to specifications for efficiency and performance. In the United States of America, if respirators are used, a program should be instituted to assure compliance with OSHA Standard 29 CFR 1910.134. Contact a health and safety professional or manufacturer for specific information.

**General Hygiene Considerations**

Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

**9. PHYSICAL AND CHEMICAL PROPERTIES**

**Information on basic physical and chemical properties**

<b>Physical state</b>	Solid	<b>Odor threshold</b>	Not applicable.
<b>Appearance</b>	Green and Blue (250 mg); Blue (500 mg) Capsules		
<b>Color</b>	Green and Blue 250mg 500mg		
<b>Property</b>	<b>Values</b>	<b>Remarks</b>	
<b>pH</b>	Not applicable.	Not applicable.	
<b>Melting point/freezing point</b>	Not applicable.	Not applicable.	
<b>Boiling point / boiling range</b>	Not applicable.	Not applicable.	
<b>Flash point</b>	Not applicable.	Not applicable.	
<b>Evaporation rate</b>	Not applicable.	Not applicable.	
<b>Flammability (solid, gas)</b>	Not applicable.	Not applicable.	
<b>Flammability Limit in Air</b>	Not applicable.	Not applicable.	

<b>Upper flammability limit:</b>	Not applicable.	
<b>Lower flammability limit:</b>	Not applicable.	
<b>Vapor pressure</b>	Not applicable.	Not applicable.
<b>Vapor density</b>	Not applicable.	
<b>Specific Gravity</b>	Not applicable.	Not applicable.
<b>Water solubility</b>	Not applicable.	Not applicable.
<b>Solubility in other solvents</b>	Not applicable.	Not applicable.
<b>Partition coefficient</b>	Not applicable.	Not applicable.
<b>Autoignition temperature</b>	Not applicable.	Not applicable.
<b>Decomposition temperature</b>	Not applicable.	Not applicable.
<b>Kinematic viscosity</b>	Not applicable.	Not applicable.
<b>Dynamic viscosity</b>	Not applicable.	Not applicable.
<b>Explosive properties</b>	Not applicable.	
<b>Oxidizing properties</b>	Not applicable.	

**Other Information**

<b>Softening point</b>	Not applicable.
<b>Molecular weight</b>	Unknown
<b>VOC Content (%)</b>	Not applicable.
<b>Density</b>	Not applicable.
<b>Bulk density</b>	Not applicable.

## 10. STABILITY AND REACTIVITY

**Reactivity**

Stable at normal conditions.

**Chemical stability**

Mesalamine is unstable in the presence of water and light.

**Possibility of Hazardous Reactions**

None under normal processing.

**Conditions to avoid**

Extremes of temperature and direct sunlight.

**Incompatible materials**

Unknown

**Hazardous Decomposition Products**

None known based on information supplied.

## 11. TOXICOLOGICAL INFORMATION

**Information on likely routes of exposure**

<b>Product Information</b>	Unknown
<b>Inhalation</b>	Unknown
<b>Eye contact</b>	Unknown
<b>Skin Contact</b>	Unknown
<b>Ingestion</b>	Unknown
<b>Acute toxicity</b>	Not available.

Acute Effects:

Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50	Intravenous LD50
Stearic acid 57-11-4	-	> 5 g/kg ( Rabbit )	-	-
Mesalamine 89-57-6	= 2800 mg/kg ( Rat )	> 5 g/kg ( Rabbit )	-	-
Colloidal silicone dioxide 7631-86-9	> 5000 mg/kg ( Rat )	> 2000 mg/kg ( Rabbit )	> 2.2 mg/L ( Rat ) 1 h	-

**Information on toxicological effects**

**Symptoms** Mesalamine: Tinnitus, vertigo, headache, confusion, drowsiness, sweating, hyperventilation, vomiting, and diarrhea. Severe intoxication with salicylates can lead to disruption of electrolyte balance and blood-pH, hyperthermia, and dehydration.

**Delayed and immediate effects as well as chronic effects from short and long-term exposure**

**Skin corrosion/irritation** Unknown  
**Serious eye damage/eye irritation** Unknown  
**Irritation** Unknown  
**Corrosivity** Unknown  
**Sensitization** Unknown  
**Germ cell mutagenicity** Unknown  
**Carcinogenicity** Unknown

Chemical Name	ACGIH	IARC	NTP	OSHA
Talc 14807-96-6	-	Group 3	-	-
Colloidal silicone dioxide 7631-86-9	-	Group 3	-	-

**Reproductive toxicity** Mesalamine: No adverse effect on male fertility in rats or fetal development in rats or rabbits.  
**Developmental Toxicity** Unknown  
**Teratogenicity** Unknown  
**STOT - single exposure** Not classified.  
**STOT - repeated exposure** Not available.  
**Chronic toxicity** Mesalamine: Dose-related renal damage (chronic nephritis) was also observed following dosing of 80-160mg/kg/day of uncoated Mesalamine by gavage to dogs over 1 year. Gastrointestinal effects (inflammation, erosion, ulceration) induced by unformulated Mesalamine in rats occurred in the stomach in 2-year studies and, additionally, at a low incidence in the small intestines of male rats in the high does group of the 2-year study.

**Subchronic toxicity** Mesalamine: The kidney is the principal target organ of toxicity. Papillary necrosis and tubular lesions were observed in rats with no observed adverse effect level of 80mg/kg/day over 26-weeks. Dose-related renal damage (chronic nephritis) was also observed following dosing of 80-160mg/kg/day of uncoated Mesalamine in rats occurred in the stomach in 13 26-week and 2-year studies and, additionally, at a low incidence in the small intestines of male rats in the high dose group of the 2-year study.

**Neurological effects** Unknown  
**Other adverse effects** Unknown  
**Aspiration hazard** Due to the physical form of the product it is not an aspiration hazard.

**Numerical measures of toxicity - Product Information**

**12. ECOLOGICAL INFORMATION**

**Ecotoxicity**

Unknown

Chemical Name	Algae/aquatic plants	Fish	Toxicity to microorganisms	Crustacea
Talc 14807-96-6	-	100: 96 h Brachydanio rerio g/L LC50 semi-static	-	
Colloidal silicone dioxide 7631-86-9	440: 72 h Pseudokirchneriella subcapitata mg/L EC50	5000: 96 h Brachydanio rerio mg/L LC50 static	-	7600: 48 h Ceriodaphnia dubia mg/L EC50

**Persistence and degradability**

Mesalamine is considered completely biodegradable under anaerobic conditions.

**Bioaccumulation**

The potential for bioconcentration in aquatic organisms is low.

**Mobility**

Mesalamine is expected to have very high mobility in soil.

**Other adverse effects**

Unknown

### 13. DISPOSAL CONSIDERATIONS

**Waste treatment methods****Disposal of wastes**

Disposal should be in accordance with applicable regional, national and local laws and regulations.

**Contaminated packaging**

Improper disposal or reuse of this container may be dangerous and illegal.

### 14. TRANSPORT INFORMATION

**DOT**

Not regulated as a hazardous material by DOT.

**ICAO (air)**

Not regulated.

**IATA**

Not regulated.

**IMDG**

Not regulated.

**RID**

Not regulated.

**ADR**

Not regulated.

### 15. REGULATORY INFORMATION

**International Inventories**

TSCA	Does not comply.
DSL/NDL	Does not comply.
EINECS/ELINCS	Does not comply.
ENCS	Does not comply.
IECSC	Does not comply.
KECL	Does not comply.
PICCS	Does not comply.
AICS	Does not comply.

**Legend:**

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

DSL/NDL - Canadian Domestic Substances List/Non-Domestic Substances List

EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

ENCS - Japan Existing and New Chemical Substances  
 IECSC - China Inventory of Existing Chemical Substances  
 KECL - Korean Existing and Evaluated Chemical Substances  
 PICCS - Philippines Inventory of Chemicals and Chemical Substances  
 AICS - Australian Inventory of Chemical Substances

### US Federal Regulations

#### SARA 313

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

#### SARA 311/312 Hazard Categories

Acute health hazard	No
Chronic Health Hazard	No
Fire hazard	No
Sudden release of pressure hazard	No
Reactive Hazard	No

#### CWA (Clean Water Act)

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

#### CERCLA

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

### US State Regulations

#### California Proposition 65

This product does not contain any Proposition 65 chemicals.

#### U.S. State Right-to-Know Regulations

Chemical Name	New Jersey	Massachusetts	Pennsylvania
Talc 14807-96-6	X	X	X
Colloidal silicone dioxide 7631-86-9	X	X	X

#### U.S. EPA Label Information

EPA Pesticide Registration Number Not applicable.

### 16. OTHER INFORMATION

Issue Date	11-Nov-2008
Revision Date	24-Mar-2015
Revision Note	Not applicable.

#### Disclaimer

Shire Pharmaceuticals LLC considers that the information contained in this Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. The information contained herein is designated only as guidance for safe handling, storage and use of the substance and is not a specification nor does it guarantee any specific properties. Only competent personnel, within a controlled environment should handle all chemicals. Shire Pharmaceuticals LLC shall not be held liable for any loss, injury or damage from contact with the product.

**End of Safety Data Sheet**