



FIRST® - Pantoprazole 4 mg/mL in FIRST®-Mint Flavored Suspension Compounding Kit

Safety Data Sheet

According To Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules And Regulations

Version: 3.0

SECTION 1: IDENTIFICATION

1.1. Product Identifier

Product Form: Mixture

Product Name: FIRST® - Pantoprazole 4 mg/mL in FIRST®-Mint Flavored Suspension Compounding Kit

Synonyms: 65628-024-10

1.2. Intended Use of the Product

Use of the Substance/Mixture: Pharmaceutical Compounding

1.3. Name, Address, and Telephone of the Responsible Party

Azurity Pharmaceuticals

8 Cabot Road, Ste. 2000

Woburn, MA 01801

781-935-8141

www.azurity.com

1.4. Emergency Telephone Number

Emergency Number

: ChemTel LLC

(800)255-3924 (North America)

+1 (813)248-0585 (International)

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the Substance or Mixture

GHS-US Classification

Not classified

2.2. Label Elements

GHS-US Labeling

No labeling applicable according to 29 CFR 1910.1200.

2.3. Other Hazards

Exposure may aggravate pre-existing eye, skin, or respiratory conditions.

2.4. Unknown Acute Toxicity (GHS-US)

No data available

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substance

Not applicable

3.2. Mixture

Name	Synonyms	Product Identifier	%	GHS US classification
1H-Benzimidazole, 6-(difluoromethoxy)-2-[[[(3,4-dimethoxy-2-pyridinyl)methyl]sulfinyl]-, sodium salt, hydrate (2:2:3)	Pantoprazole sodium sesquihydrate / Pantoprazole sodium	(CAS-No.) 164579-32-2	0.47	Acute Tox. 4 (Oral), H302
Carbonic acid, calcium salt (1:1)	C.I. Pigment White 18 / Calcium carbonate / Pigment White 18 / C.I. 77220 / Carbonic acid, calcium salt / CALCIUM CARBONATE / CI 77220 / calcium carbonate	(CAS-No.) 471-34-1	*	Not classified
Cellulose	Microcrystalline cellulose / CELLULOSE / Cellulose, microcrystalline / MICROCRYSTALLINE CELLULOSE	(CAS-No.) 9004-34-6	*	Comb. Dust

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Benzyl alcohol	Benzenecarbinol / Benzenemethanol / Methanol, phenyl- / Phenylmethanol / Phenylmethyl alcohol / BENZYL ALCOHOL / .alpha.-Hydroxytoluene / Benzylalcohol	(CAS-No.) 100-51-6	*	Flam. Liq. 4, H227 Acute Tox. 4 (Oral), H302 Acute Tox. 4 (Inhalation:dust,mist), H332 Eye Irrit. 2A, H319 Aquatic Acute 2, H401
Cyclohexanone, 5-methyl-2-(1-methylethylidene)-, (R)-	p-Menth-4(8)-en-3-one / p-Menth-4(8)-en-3-one, (R)-(+)- / Pulegone / Cyclohexanone, 5-methyl-2-(1-methylethylidene)-, (5R)- / d-Pulegone / (R)-(+)-Pulegone / (5R)-5-Methyl-2-(1-methylethylidene)cyclohexanone / D-PULEGONE / pulegone	(CAS-No.) 89-82-7	*	Acute Tox. 4 (Oral), H302 Carc. 2, H351

*Proprietary

Full text of H-phrases: see section 16

SECTION 4: FIRST AID MEASURES**4.1. Description of First-aid Measures**

First-aid Measures General: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).

First-aid Measures After Inhalation: When symptoms occur: go into open air and ventilate suspected area. Obtain medical attention if breathing difficulty persists.

First-aid Measures After Skin Contact: Remove contaminated clothing. Drench affected area with water for at least 5 minutes. Obtain medical attention if irritation develops or persists.

First-aid Measures After Eye Contact: Rinse cautiously with water for at least 5 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention if irritation develops or persists.

First-aid Measures After Ingestion: Product is a pharmaceutical preparation intended for oral usage. In cases of overdose, rinse mouth if person is conscious and alert to surroundings and place them on their side. Contact a Poison Control Center or physician immediately. DO NOT INDUCE VOMITING!

4.2. Most Important Symptoms and Effects Both Acute and Delayed

Symptoms/Injuries: Not expected to present a significant hazard under anticipated conditions of normal use.

Symptoms/Injuries After Inhalation: Prolonged exposure may cause irritation.

Symptoms/Injuries After Skin Contact: Prolonged exposure may cause skin irritation.

Symptoms/Injuries After Eye Contact: May cause slight irritation to eyes.

Symptoms/Injuries After Ingestion: Ingestion may cause adverse effects.

Chronic Symptoms: None expected under normal conditions of use.

4.3. Indication of Any Immediate Medical Attention and Special Treatment Needed

If exposed or concerned, get medical advice and attention. If medical advice is needed, have product container or label at hand.

SECTION 5: FIRE-FIGHTING MEASURES**5.1. Extinguishing Media**

Suitable Extinguishing Media: Use extinguishing media suitable for surrounding type of fire.

Unsuitable Extinguishing Media: None known.

5.2. Special Hazards Arising From the Substance or Mixture

Fire Hazard: Not considered flammable but may burn at high temperatures.

Explosion Hazard: Product is not explosive.

Reactivity: Hazardous reactions will not occur under normal conditions.

5.3. Advice for Firefighters

Precautionary Measures Fire: Exercise caution when fighting any chemical fire.

Firefighting Instructions: Use water spray or fog for cooling exposed containers.

Protection During Firefighting: Do not enter fire area without proper protective equipment, including respiratory protection.

Hazardous Combustion Products: None expected under normal conditions of use.

SECTION 6: ACCIDENTAL RELEASE MEASURES**6.1. Personal Precautions, Protective Equipment and Emergency Procedures**

General Measures: Avoid prolonged contact with eyes, skin and clothing. Avoid breathing (vapor, mist, spray).

6.1.1. For Non-Emergency Personnel

Protective Equipment: Use appropriate personal protective equipment (PPE).

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Emergency Procedures: Evacuate unnecessary personnel.**6.1.2. For Emergency Personnel****Protective Equipment:** Equip cleanup crew with proper protection.**Emergency Procedures:** Upon arrival at the scene, a first responder is expected to recognize the presence of dangerous goods, protect oneself and the public, secure the area, and call for the assistance of trained personnel as soon as conditions permit. Ventilate area.**6.2. Environmental Precautions**

Prevent entry to sewers and public waters.

6.3. Methods and Materials for Containment and Cleaning Up**For Containment:** Contain any spills with dikes or absorbents to prevent migration and entry into sewers or streams.**Methods for Cleaning Up:** Clean up spills immediately and dispose of waste safely. Transfer spilled material to a suitable container for disposal. Contact competent authorities after a spill.**6.4. Reference to Other Sections**

See Section 8 for exposure controls and personal protection and Section 13 for disposal considerations.

SECTION 7: HANDLING AND STORAGE**7.1. Precautions for Safe Handling****Precautions for Safe Handling:** Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Avoid prolonged contact with eyes, skin and clothing. Avoid breathing vapors, mist, spray.**Hygiene Measures:** Handle in accordance with good industrial hygiene and safety procedures.**7.2. Conditions for Safe Storage, Including Any Incompatibilities****Technical Measures:** Comply with applicable regulations.**Storage Conditions:** Keep container closed when not in use. Prior to compounding, store FIRST® Pantoprazole Compounding Kit at 20°C - 25°C (68°F - 77°F), excursions permitted between 15°C - 30°C (59°F - 86°F) [see USP Controlled Room Temperature].

Store the final compounded formulation at refrigerated temperature 2°C - 8°C (36°F - 46°F). Keep/Store away from direct sunlight, extremely high or low temperatures and incompatible materials.

Incompatible Materials: Strong acids, strong bases, strong oxidizers.**7.3. Specific End Use(s)**

Pharmaceutical

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION**8.1. Control Parameters**

For substances listed in section 3 that are not listed here, there are no established exposure limits from the manufacturer, supplier, importer, or the appropriate advisory agency including: ACGIH (TLV), AIHA (WEEL), NIOSH (REL), or OSHA (PEL).

Benzyl alcohol (100-51-6)		
USA AIHA	WEEL TWA [ppm]	10 ppm
Carbonic acid, calcium salt (1:1) (471-34-1)		
USA NIOSH	NIOSH REL (TWA)	10 mg/m ³ (total dust) 5 mg/m ³ (respirable dust)
Cellulose (9004-34-6)		
USA ACGIH	ACGIH OEL TWA	10 mg/m ³
USA NIOSH	NIOSH REL (TWA)	10 mg/m ³ (total dust) 5 mg/m ³ (respirable dust)
USA OSHA	OSHA PEL (TWA) [1]	15 mg/m ³ (total dust) 5 mg/m ³ (respirable fraction)

8.2. Exposure Controls**Appropriate Engineering Controls**

: Suitable eye/body wash equipment should be available in the vicinity of any potential exposure. Ensure adequate ventilation, especially in confined areas. Ensure all national/local regulations are observed.

Personal Protective Equipment

: Gloves. Protective clothing. Protective goggles.

**Materials for Protective Clothing**

: Chemically resistant materials and fabrics.

Hand Protection

: Wear protective gloves.

Eye and Face Protection

: Chemical safety goggles.

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Skin and Body Protection	: Wear suitable protective clothing.
Respiratory Protection	: If exposure limits are exceeded or irritation is experienced, approved respiratory protection should be worn. In case of inadequate ventilation, oxygen deficient atmosphere, or where exposure levels are not known wear approved respiratory protection.
Other Information	: When using, do not eat, drink or smoke.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES**9.1. Information on Basic Physical and Chemical Properties**

Physical State	: Liquid
Appearance	: No data available
Odor	: Peppermint
Odor Threshold	: No data available
pH	: No data available
Evaporation Rate	: No data available
Melting Point	: No data available
Freezing Point	: No data available
Boiling Point	: No data available
Flash Point	: No data available
Auto-ignition Temperature	: No data available
Decomposition Temperature	: No data available
Flammability (solid, gas)	: Not applicable
Vapor Pressure	: No data available
Relative Vapor Density at 20°C	: No data available
Relative Density	: No data available
Solubility	: No data available
Partition Coefficient: N-Octanol/Water	: No data available
Viscosity	: No data available

9.2. Other Information

No additional information available

SECTION 10: STABILITY AND REACTIVITY**10.1. Reactivity**

Hazardous reactions will not occur under normal conditions.

10.2. Chemical Stability

Stable under recommended handling and storage conditions (see section 7).

10.3. Possibility of Hazardous Reactions

Hazardous polymerization will not occur.

10.4. Conditions to Avoid

Direct sunlight, extremely high or low temperatures, and incompatible materials.

10.5. Incompatible Materials

Strong acids, strong bases, strong oxidizers.

10.6. Hazardous Decomposition Products

None expected under normal conditions of use.

SECTION 11: TOXICOLOGICAL INFORMATION**11.1. Information on Toxicological Effects****Acute Toxicity (Oral):** Not classified**Acute Toxicity (Dermal):** Not classified**Acute Toxicity (Inhalation):** Not classified

BenzyI alcohol (100-51-6)	
LD50 Oral Rat	1230 mg/kg
LD50 Dermal Rabbit	> 2000 mg/kg
LC50 Inhalation Rat	> 4.178 mg/l/4h
ATE (Dust/Mist)	1.50 mg/l/4h
Carbonic acid, calcium salt (1:1) (471-34-1)	
LD50 Oral Rat	6450 mg/kg
LD50 Dermal Rat	> 2000 mg/kg

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Cellulose (9004-34-6)	
LD50 Oral Rat	> 5000 mg/kg
LD50 Dermal Rabbit	> 2000 mg/kg
LC50 Inhalation Rat	> 5800 mg/m ³ (Exposure time: 4 h)
1H-Benzimidazole, 6-(difluoromethoxy)-2-[[[(3,4-dimethoxy-2-pyridinyl)methyl]sulfinyl]-, sodium salt, hydrate (2:2:3) (164579-32-2)	
LD50 Oral Rat	747 – 900 mg/kg
ATE (Oral)	500.00 mg/kg body weight
Cyclohexanone, 5-methyl-2-(1-methylethylidene)-, (R)- (89-82-7)	
ATE (Oral)	500.00 mg/kg body weight

Skin Corrosion/Irritation: Not classified

Serious Eye Damage/Irritation: Not classified

Respiratory or Skin Sensitization: Not classified

Germ Cell Mutagenicity: Not classified

Carcinogenicity: Not classified

Cyclohexanone, 5-methyl-2-(1-methylethylidene)-, (R)- (89-82-7)	
IARC group	2B
OSHA Hazard Communication Carcinogen List	In OSHA Hazard Communication Carcinogen list.

Reproductive Toxicity: Not classified

Specific Target Organ Toxicity (Single Exposure): Not classified

Specific Target Organ Toxicity (Repeated Exposure): Not classified

Aspiration Hazard: Not classified

Symptoms/Injuries After Inhalation: Prolonged exposure may cause irritation.

Symptoms/Injuries After Skin Contact: Prolonged exposure may cause skin irritation.

Symptoms/Injuries After Eye Contact: May cause slight irritation to eyes.

Symptoms/Injuries After Ingestion: Ingestion may cause adverse effects.

Chronic Symptoms: None expected under normal conditions of use.

SECTION 12: ECOLOGICAL INFORMATION**12.1. Toxicity**

Ecology - General : Not classified.

Benzyl alcohol (100-51-6)	
LC50 Fish 1	460 mg/l (Exposure time: 96 h - Species: Pimephales promelas [static])
LC50 Fish 2	10 mg/l (Exposure time: 96 h - Species: Lepomis macrochirus [static])
NOEC Chronic Crustacea	51 mg/l

12.2. Persistence and Degradability

FIRST® - Pantoprazole 4 mg/mL	
Persistence and Degradability	Not established.

12.3. Bioaccumulative Potential

FIRST® - Pantoprazole 4 mg/mL	
Bioaccumulative Potential	Not established.
Benzyl alcohol (100-51-6)	
Partition coefficient n-octanol/water (Log Pow)	1.1
Carbonic acid, calcium salt (1:1) (471-34-1)	
BCF Fish 1	(no bioaccumulation)

12.4. Mobility in Soil

No additional information available

12.5. Other Adverse Effects

Other Information : Avoid release to the environment.

SECTION 13: DISPOSAL CONSIDERATIONS**13.1. Waste Treatment Methods**

Waste Disposal Recommendations: Dispose of contents/container in accordance with local, regional, national, and international regulations.

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Ecology - Waste Materials: Avoid release to the environment.**SECTION 14: TRANSPORT INFORMATION**

The shipping description(s) stated herein were prepared in accordance with certain assumptions at the time the SDS was authored, and can vary based on a number of variables that may or may not have been known at the time the SDS was issued.

14.1. In Accordance with DOT

Not regulated for transport

14.2. In Accordance with IMDG

Not regulated for transport

14.3. In Accordance with IATA

Not regulated for transport

SECTION 15: REGULATORY INFORMATION**15.1. US Federal Regulations****Benzyl alcohol (100-51-6)**

Listed on the United States TSCA (Toxic Substances Control Act) inventory - Status: Active

Carbonic acid, calcium salt (1:1) (471-34-1)

Listed on the United States TSCA (Toxic Substances Control Act) inventory - Status: Active

Cellulose (9004-34-6)

Listed on the United States TSCA (Toxic Substances Control Act) inventory - Status: Active

EPA TSCA Regulatory Flag

XU - XU - indicates a substance exempt from reporting under the Chemical Data Reporting Rule, (40 CFR 711).

Cyclohexanone, 5-methyl-2-(1-methylethylidene)-, (R)- (89-82-7)

Listed on the United States TSCA (Toxic Substances Control Act) inventory - Status: Active

Water (7732-18-5)

Listed on the United States TSCA (Toxic Substances Control Act) inventory - Status: Active

15.2. US State Regulations**Benzyl alcohol (100-51-6)**

U.S. - Pennsylvania - RTK (Right to Know) List

U.S. - Massachusetts - Right To Know List

Cellulose (9004-34-6)

U.S. - New Jersey - Right to Know Hazardous Substance List

U.S. - Pennsylvania - RTK (Right to Know) List

U.S. - Massachusetts - Right To Know List

California Proposition 65

WARNING: This product can expose you to Cyclohexanone, 5-methyl-2-(1-methylethylidene)-, (R)-, which is known to the State of California to cause cancer. For more information go to www.P65Warnings.ca.gov.

Chemical Name (CAS No.)	Carcinogenicity	Developmental Toxicity	Female Reproductive Toxicity	Male Reproductive Toxicity
Cyclohexanone, 5-methyl-2-(1-methylethylidene)-, (R)- (89-82-7)	X			

SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION**Date of Preparation or Latest Revision**

: 09/7/2023

Other Information

: This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200

GHS Full Text Phrases:

Acute Tox. 4 (Inhalation:dust,mist)	Acute toxicity (inhalation:dust,mist) Category 4
Acute Tox. 4 (Oral)	Acute toxicity (oral) Category 4
Aquatic Acute 2	Hazardous to the aquatic environment - Acute Hazard Category 2
Aquatic Acute 3	Hazardous to the aquatic environment - Acute Hazard Category 3
Aquatic Chronic 3	Hazardous to the aquatic environment - Chronic Hazard Category 3
Carc. 2	Carcinogenicity Category 2
Comb. Dust	Combustible Dust

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Eye Irrit. 2A	Serious eye damage/eye irritation Category 2A
Flam. Liq. 3	Flammable liquids Category 3
Flam. Liq. 4	Flammable liquids Category 4
Skin Irrit. 2	Skin corrosion/irritation Category 2
Skin Sens. 1B	Skin sensitization, category 1B
STOT SE 3	Specific target organ toxicity — Single exposure, Category 3, Respiratory tract irritation
H226	Flammable liquid and vapor
H227	Combustible liquid
H302	Harmful if swallowed
H315	Causes skin irritation
H317	May cause an allergic skin reaction
H319	Causes serious eye irritation
H332	Harmful if inhaled
H335	May cause respiratory irritation
H351	Suspected of causing cancer
H401	Toxic to aquatic life
H402	Harmful to aquatic life
H412	Harmful to aquatic life with long lasting effects

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

SDS US (GHS HazCom)