



# SAFETY DATA SHEET

Revision date: 29-Aug-2015

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## 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

### Product Identifier

**Material Name:** Preparation H Suppositories

**Trade Name:** Preparation H  
**Compound Number:** WH 1470-0001  
**Chemical Family:** Not determined

### Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

**Intended Use:** Consumer healthcare product used as hemorrhoidal treatment

### Details of the Supplier of the Safety Data Sheet

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## 2. HAZARDS IDENTIFICATION

### Classification of the Substance or Mixture

**GHS - Classification** Not classified as hazardous

### Label Elements

**Hazard Statements:** Non-hazardous in accordance with international standards for workplace safety.

### Other Hazards

**Note:** No data available  
This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients 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.

## 3. COMPOSITION / INFORMATION ON INGREDIENTS

### Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Corn Starch	9005-25-8	232-679-6	Not Listed	*
Phenylephrine hydrochloride	61-76-7	200-517-3	Acute Tox. 4, H302	0.25

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Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Cocoa Butter	8002-31-1	Not Listed	Not Listed	88.4
Methylparaben	99-76-3	202-785-7	Not Listed	*
Propylparaben	94-13-3	202-307-7	Not Listed	*

**Additional Information:**

\* Proprietary  
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.  
In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

For the full text of the R phrases mentioned in this Section, see Section 16

### 4. FIRST AID MEASURES

**Description of 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.

**Most Important Symptoms and Effects, Both Acute and Delayed**

**Symptoms and Effects of Exposure:** No data available

**Medical Conditions Aggravated by Exposure:** None known

**Indication of the Immediate Medical Attention and Special Treatment Needed**

**Notes to Physician:** None

### 5. FIRE FIGHTING MEASURES

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

**Special Hazards Arising from the Substance or Mixture**

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

**Fire / Explosion Hazards:** Fine particles (such as dust and mists) may fuel fires/explosions.

**Advice for Fire-Fighters**

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

### 6. ACCIDENTAL RELEASE MEASURES

**Personal Precautions, Protective Equipment and Emergency Procedures**

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

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### Environmental Precautions

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

### Methods and Material for Containment and Cleaning Up

**Measures for Cleaning / Collecting:** Use absorbent material to wipe up spill and place in a sealed container for disposal. Clean spill area thoroughly.

**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

### Precautions for Safe Handling

Avoid contact with eyes. Avoid prolonged or repeated contact with skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

### Conditions for Safe Storage, Including any Incompatibilities

**Storage Conditions:** Store as directed by product packaging.

**Specific end use(s):** Consumer healthcare product used for skin care

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

### Control Parameters

Refer to available public information for specific member state Occupational Exposure Limits.

#### Corn Starch

ACGIH Threshold Limit Value (TWA)	10 mg/m <sup>3</sup>
Australia TWA	10 mg/m <sup>3</sup>
Belgium OEL - TWA	10 mg/m <sup>3</sup>
Bulgaria OEL - TWA	10.0 mg/m <sup>3</sup>
Czech Republic OEL - TWA	4.0 mg/m <sup>3</sup>
Greece OEL - TWA	10 mg/m <sup>3</sup>
Ireland OEL - TWAs	5 mg/m <sup>3</sup>
	10 mg/m <sup>3</sup>
	4 mg/m <sup>3</sup>
OSHA - Final PELs - TWAs:	15 mg/m <sup>3</sup>
Portugal OEL - TWA	10 mg/m <sup>3</sup>
Slovakia OEL - TWA	4 mg/m <sup>3</sup>
Spain OEL - TWA	10 mg/m <sup>3</sup>
Switzerland OEL - TWAs	3 mg/m <sup>3</sup>

#### Phenylephrine hydrochloride

Pfizer OEL TWA-8 Hr: 0.04 mg/m<sup>3</sup>, Skin

### Exposure Controls

**Engineering Controls:** Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

**Personal Protective Equipment:** Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<b>Hands:</b>	Not required for the normal use of this product. Wear protective gloves when working with large quantities.
<b>Eyes:</b>	Not required for the normal use of this product. Glasses or goggles are recommended if eye contact is possible.
<b>Skin:</b>	Not required for the normal use of this product. Wear protective clothing when working with large quantities.
<b>Respiratory protection:</b>	None required under normal conditions of use. If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

### 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Physical State:</b>	Suppository	<b>Color:</b>	Light yellow
<b>Odor:</b>	No data available.	<b>Odor Threshold:</b>	No data available.
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture

<b>Solvent Solubility:</b>	No data available
<b>Water Solubility:</b>	No data available
<b>pH:</b>	No data available.
<b>Melting/Freezing Point (°C):</b>	No data available
<b>Boiling Point (°C):</b>	No data available.

**Partition Coefficient: (Method, pH, Endpoint, Value)**

**Phenylephrine hydrochloride**

No data available

**Propylparaben**

No data available

**Methylparaben**

No data available

**Cocoa Butter**

No data available

**Corn Starch**

No data available

**Decomposition Temperature (°C):** No data available.

<b>Evaporation Rate (Gram/s):</b>	No data available
<b>Vapor Pressure (kPa):</b>	No data available
<b>Vapor Density (g/ml):</b>	No data available
<b>Relative Density:</b>	No data available
<b>Viscosity:</b>	No data available

**Flammability:**

<b>Autoignition Temperature (Solid) (°C):</b>	No data available
<b>Flammability (Solids):</b>	No data available
<b>Flash Point (Liquid) (°C):</b>	No data available
<b>Upper Explosive Limits (Liquid) (% by Vol.):</b>	No data available
<b>Lower Explosive Limits (Liquid) (% by Vol.):</b>	No data available

### 10. STABILITY AND REACTIVITY

<b>Reactivity:</b>	No data available
<b>Chemical Stability:</b>	Stable under normal conditions of use.
<b>Possibility of Hazardous Reactions</b>	
<b>Oxidizing Properties:</b>	No data available

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### 10. STABILITY AND REACTIVITY

**Conditions to Avoid:** Fine particles (such as dust and mists) may fuel fires/explosions.  
**Incompatible Materials:** As a precautionary measure, keep away from strong oxidizers  
**Hazardous Decomposition Products:** No data available

### 11. TOXICOLOGICAL INFORMATION

#### Information on Toxicological Effects

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

**Short Term:** Active ingredient may be harmful if swallowed.

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

##### Phenylephrine hydrochloride

Rat Oral LD50 350 mg/kg  
Mouse Oral LD50 120mg/kg

##### Propylparaben

Mouse Oral LD 50 6332 mg/kg  
Mouse Sub-tenon injection (eye) LD 50 200 mg/kg

**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.

#### Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

##### Phenylephrine hydrochloride

12 Week(s) Rat Oral 10,000 ppm Death

##### Propylparaben

3 Week(s) Rat Oral 27.1 g/kg LOAEL Endocrine system  
4 Week(s) Rat Oral 347.2 mg/kg LOAEL Male reproductive system

#### Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

##### Phenylephrine hydrochloride

Prenatal & Postnatal Development Rabbit Subcutaneous 15 mg/kg/day LOAEL Maternal toxicity, Fetotoxicity

#### Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

##### Phenylephrine hydrochloride

Chromosome Aberration Chinese Hamster Ovary (CHO) cells Negative  
Mammalian Cell Mutagenicity Mouse Lymphoma Equivocal  
Bacterial Mutagenicity (Ames) *Salmonella* Negative

#### Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

##### Phenylephrine hydrochloride

2 Year(s) Rat Oral 50 mg/kg/day Not carcinogenic

**Carcinogen Status:** See below No known carcinogens are present at greater than 0.1%

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### 11. TOXICOLOGICAL INFORMATION

### 12. ECOLOGICAL INFORMATION

<b>Environmental Overview:</b>	The environmental characteristics of this mixture have not been fully evaluated. Releases to the environment should be avoided.
<b>Toxicity:</b>	No data available
<b>Persistence and Degradability:</b>	No data available
<b>Bio-accumulative Potential:</b>	No data available
<b>Mobility in Soil:</b>	No data available

### 13. DISPOSAL CONSIDERATIONS

<b>Waste Treatment Methods:</b>	Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.
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### 14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

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

### 15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

#### Cocoa Butter

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present

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### 15. REGULATORY INFORMATION

EU EINECS/ELINCS List	Not Listed
<b>Corn Starch</b>	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	232-679-6
<b>Methylparaben</b>	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	202-785-7
<b>Phenylephrine hydrochloride</b>	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	200-517-3
<b>Propylparaben</b>	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	202-307-7

**Additional Information:** White petrolatum is not classified as a carcinogen. Nota N applies since the full refining history is known and it can be shown that the substances from which the petroleum jelly was produced are not a carcinogen.

### 16. OTHER INFORMATION

#### Text of CLP/GHS Classification abbreviations mentioned in Section 3

Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed

**Data Sources:** Pfizer proprietary drug development information. Publicly available toxicity information. Safety data sheets for individual ingredients.

**Reasons for Revision:** Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 16 - Other Information.

**Revision date:** 29-Aug-2015

**Prepared by:** Product Stewardship Hazard Communication  
Pfizer Global Environment, Health, and Safety Operations

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**End of Safety Data Sheet**