Material Safety Data Sheet
ANSI Format

Preparation H Products

Preparation Date 26-Jan-2007 **Revision Date** 15-Dec-2008 **Revision Number** 1

1. PRODUCT AND COMPANY IDENTIFICATION

Product Name	Preparation H Products
Common Name	Not applicable
Chemical Name	Not applicable
Synonyms	Preparation H Cream, Preparation H Ointment, Preparation H Hydrocortizone Cream, Preparation H Cooling Gel, Preparation H Suppositories, Preparation H Medicated Wipes, Preparation H Clear Gel International Formula, Preparation H Ointment International Formula
Product Use	Pharmaceutical product
Classification	Anti-Inflammatory
Supplier	Wyeth P.O. Box 8299 Philadelphia, PA 19101 USA. Telephone: 1-610-688-4400
Emergency Telephone Number	Chemtrec USA, Puerto Rico, Canada 1-800-424-9300 Chemtrec International 1-703-527-3887

2. HAZARDS IDENTIFICATION

Emergency Overview

This is a research material that may affect body functions

Appearance Pharmaceutical cream, ointment, suppository, wipe , Gel

Physical State Solid

Odor May have slight solvent odor

Potential Physical Hazards

Medicated wipes contain a combustible liquid.

Potential Health Effects

Eyes
May cause irritation.

Skin
The most common effects may include allergic reactions, swelling, pain, Irritation, and redness.

May cause harm to the unborn child. May be excreted in breast milk.

Please see package Insert for further information.

Inhalation
May cause mucous membrane and upper respiratory tract irritation.

Ingestion
No data available

Therapeutic Target Organ(s)
Skin.

Not listed by OSHA, NTP or IARC.

Potential Environmental Effects

There is no known ecological information for this product.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Common Name	CAS-No	Composition
Hydrocortisone	50-23-7	0 - 1%
Witch Hazel	68916-39-2	0 - 50%
Argobase L2	N/A	0 - 3%
SRF Crude Concentrate	N/A	0 - 1%
Thyme Oil Red	N/A	0 - 1%
Phenylephrine HCl	61-76-7	0 - 0.25%
Cocoa butter	8002-31-1	0 - 85.5%
Pramoxine HCl	637-58-1	0 - 1%
Mineral Oil	8042-47-5	0 - 15%
Glycerine	56-81-5	0 - 14%
Shark Liver Oil	Not assigned	0 - 3%
Petrolatum	8009-03-08	0 - 72%
Lanolin	8006-54-0	0-3%
Methylparaben	99-76-3	0 - 1%
Propylparaben	94-13-3	0 - 2%
Sodium Citrate Dihydrate	6132-04-3	0 - 1%
Citric Acid (Anhydrous)	77-92-9	0 - 1%
Edetate Disodium	000139-33-3	0 - 1%
Propylene Glycol USP	57-55-6	0 - 15%
Hydroxyethlycellulose	9004-62-0	0 - 2%

4. FIRST AID MEASURES

Eye Contact In case of contact with eyes, rinse immediately with plenty of water for 15 mintues and seek medical advice

Skin Contact Wash off immediately with soap and plenty of water

Inhalation Artificial respiration and/or oxygen may be necessary

Ingestion Immediate medical attention is not required

5. FIRE-FIGHTING MEASURES

Flammable Properties Medicated wipes contain a combustible liquid..

Extinguishing Media

Suitable Extinguishing Media Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide

Unsuitable Extinguishing Media Do not use a solid water stream as it may scatter and spread fire

Fire Fighting Evacuate area and fight fire from a safe distance

Hazardous Combustion Products Hazardous Combustion Products

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

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Personal Precautions	Safety glasses or goggles when splash potential exists
Environmental Precautions	Local authorities should be advised if a significant spill cannot be contained
Methods for Containment	Not available
Methods for Cleaning up	Take up mechanically and collect in suitable container for disposal

7. HANDLING AND STORAGE

Handling	Handle in accordance with good industrial hygiene and safety practice
Storage	Keep container tightly closed

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Common Name	**Exposure Guideline**
Hydrocortisone	8 mcg/m^3
Phenylephrine HCl	40 mcg/m^3
Pramoxine HCl	300 mcg/m^3
Glycerine	10 mcg/m^3 (ACGIH)
Propylparaben	Particulates not otherwise specified (ACGIH) 3 mg/m^3 respirable 10 mg/m^3 inhalable

Engineering Controls	Apply technical measures to comply with the occupational exposure guideline

Personal Protective Equipment

Eye/face Protection	Provide eye protection based on risk assessment.
Skin Protection	For prolonged or repeated exposure use protective gloves
Respiratory Protection	Base respirator selection on a risk assessment.
General Hygiene Considerations	When using, do not eat, drink or smoke
Other	Limit access to only personnel trained in the safe handling of this material

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	Pharmaceutical cream, ointment, suppository, wipe , Gel	**Physical State**	Solid
Color	White / yellow	**Odor**	May have slight solvent odor
Odor Threshold	Not available		
pH	Not available		
Specific Gravity	Not applicable	**Water Solubility**	Not available
Solubility	Not applicable	**Evaporation Rate**	Not applicable
Partition Coefficient (n-octanol/water)	Not available	**Vapor Pressure**	Not applicable

Boiling Point	Not available	**Autoignition Temperature**	Not available
Flash Point	Not available	**Method**	None
Melting Point	Not available		
Flammability Limits in Air	**Upper** Not applicable	**Lower** Not applicable	
Explosion Limits	**Upper** Not applicable	**Lower** Not applicable	

10. STABILITY AND REACTIVITY

Chemical Stability Stable at room temperature.

Conditions to Avoid Keep medicated wipes away from ignition sources.

Materials to Avoid No materials to be especially mentioned

Hazardous Decomposition Products None under normal use.

Possibility of Hazardous Reactions None under normal use.

11. TOXICOLOGICAL INFORMATION

The following effects are based on the Active Pharmaceutical Ingredient.

Acute Toxicity

Hydrocortisone

LD50 Oral	5000 mg/kg rats IP 2250 mg/kg mice
Acute Dermal Irritation	45 mg/kg mice
Primary Eye Irritation	Not available
Sensitization	Not available

Pramoxine HCl

LD50 Oral	1050 mg/kg mice IP 300 mg/kg mice
Acute Dermal Irritation	750 mg/kg mice
Primary Eye Irritation	Not available
Sensitization	Not available

Glycerine

LD50 Oral	12.6 gm/kg rats, 4090 mg/kg mice
Acute Dermal Irritation	Mild irritation effect in rabbits.
Primary Eye Irritation	Irritating to rabbit eyes.
Sensitization	Not available

Petrolatum

LD50 Oral	5 - 15 g/kg rats
Acute Dermal Irritation	Repeated skin contact induced changes at the cellular level in rabbits.
Primary Eye Irritation	Not available
Sensitization	Not a dermal sensitizer in guinea pigs.

Shark Liver Oil

LD50 Oral	5 gm/kg mice
Acute Dermal Irritation	Not available
Primary Eye Irritation	Not available
Sensitization	Not available

Citric Acid (Anhydrous)

LD50 Oral	Rat 3gm/kg
Acute Dermal Irritation	No data available
Primary Eye Irritation	No data available
Sensitization	No data available

Multiple Dose Toxicity

Hydrocortisone

No Toxicologic Effect	Not applicable
Dose/Species/Study Length:	

Shark Liver Oil

No Toxicologic Effect	No data available
Dose/Species/Study Length:	

Witch Hazel

No Toxicologic Effect	Oral administration of high doses in rats did not induce hepatotoxic effects.
Dose/Species/Study Length:	

Mineral Oil

No Toxicologic Effect	In a 90-day study in rats, no adverse effects were observed. Repeated prolonged inhalation exposures to highly refined mineral oils for a year at very high levels (≥ 100 mg/m^3) induced lung inflammatory reactions and lipoid granuloma formulation in mice and rats.
Dose/Species/Study Length:	

Glycerine

No Toxicologic Effect	In a 180-day study in rats, 5% in drinking water caused calcification in the renal tubules. A further drinking water study in rats resulted in increased urinary levels of oxalic acid.
Dose/Species/Study Length:	

Maximum Tolerated Dose (MTD), Oral

Hydrocortisone

Carcinogenicity	No data available
Genetic Toxicity	Non-mutagenic in *in vivo* studies.
Reproductive Toxicity	Reproduction studies in rats at a dose of 0.4 mg/kg/day between gestational days 6 and 21 resulted in an increase in fetal mortality.
Developmental Toxicity	Animal studies have shown teratogenic effects, various with species.

Shark Liver Oil

Carcinogenicity	No data available
Genetic Toxicity	Genotoxic in *in vitro* micronucleus assay.
Reproductive Toxicity	No data available
Developmental Toxicity	No data available

Witch Hazel

Carcinogenicity	No data available
Genetic Toxicity	No evidence of mutagenicity was observed in a battery of *in vitro* and *in vivo* assays.
Reproductive Toxicity	No data available
Developmental Toxicity	No data available

Mineral Oil

Carcinogenicity	Long-term studies in rats and mice revealed no evidence of carcinogenicity.
Genetic Toxicity	Non-mutagenic in bacterial assays.
Reproductive Toxicity	No data available
Developmental Toxicity	No data available

Glycerine

Carcinogenicity	No data available
Genetic Toxicity	Non-mutagenic in Ames test; non-clastogenic in chromosomal aberrations assay.
Reproductive Toxicity	Studies in rats were found to have no effect on fertility.
Developmental Toxicity	No teratogenic effects were observed in mice, rats and rabbits given large oral doses of >1 g/kg/day during pregnancy. In a further study, increased rates of embryonic and fetal death were seen when rats were dosed IV at 4 mg/kg; this was not seen in rabbit or mice studies.

Hydrocortisone

Target Organ(s) of Toxicity No data available

Shark Liver Oil

Target Organ(s) of Toxicity No data available

Witch Hazel

Target Organ(s) of Toxicity No data available

Mineral Oil

Target Organ(s) of Toxicity No data available

Glycerine

Target Organ(s) of Toxicity No data available

12. ECOLOGICAL INFORMATION

The following effects are based on the Active Pharmaceutical Ingredient.

Chemical Fate Information Not available

Ecotoxicity Not available

13. DISPOSAL CONSIDERATIONS

Waste Disposal Method Dispose of in accordance with local and national regulations.

14. TRANSPORT INFORMATION

Transport Information This material is not classified as hazardous for transport.

U.S. Department of Transport (DOT)	Not regulated
Canadian Transport of Dangerous Goods (TDG)	Not regulated
International Civil Aviation Organization (ICAO)	Not regulated
International Air Transport Association (IATA)	Not regulated
International Maritime Dangerous Goods (IMDG)/International Maritime Organization (IMO)	Not regulated
Transport of Dangerous Goods by Rail (RID)	Not regulated

Transport of Dangerous Goods by Road (ADR)	Not regulated
Transportation of Dangerous Goods via Inland Waterways (ADN)	Not regulated

15. REGULATORY INFORMATION

USA

Federal Regulations

OSHA Regulatory Status
This material is not considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200)

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 40n of the Code of Federal Regulations, Part 372.

SARA 311/312 Hazardous Categorization

Acute Health Hazard	No
Chronic Health Hazard	No
Fire Hazard	No
Sudden Release of Pressure Hazard	No
Reactive Hazard	No

This product does not contain any HAPs.

State Regulations

California Proposition 65
This product does not contain any Proposition 65 chemicals.

Canada
Not classified

WHMIS Hazard Class
Non-controlled

European Union
In accordance with EC directives or respective national laws, the product does not need to be classified nor labeled.

16. OTHER INFORMATION

Prepared By	Wyeth Department of Environment, Health & Safety
Format	This MSDS was prepared in accordance with ANSI Z400.1-2004.
List of References	See Patient Package Insert for more information.
Revision Summary	Not applicable

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