1. PRODUCT AND COMPANY IDENTIFICATION

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Preparation H Products</th>
</tr>
</thead>
<tbody>
<tr>
<td>Common Name</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Chemical Name</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Synonyms</td>
<td>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</td>
</tr>
<tr>
<td>Product Use</td>
<td>Pharmaceutical product</td>
</tr>
<tr>
<td>Classification</td>
<td>Anti-Inflammatory</td>
</tr>
</tbody>
</table>

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

| Potential Physical Hazards | Medicated wipes contain a combustible liquid. |
| __________________________|____________________________________________|
| Potential Health Effects   |                                                |
| Eyes                       | May cause irritation.                         |
|                           | The most common effects may include allergic reactions, swelling, pain, irritation, and redness. |
| Skin                      | 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

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

4. FIRST AID MEASURES

**Eye Contact**
In case of contact with eyes, rinse immediately with plenty of water for 15 minutes 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**

<table>
<thead>
<tr>
<th>Suitable Extinguishing Media</th>
<th>Unsuitable Extinguishing Media</th>
</tr>
</thead>
<tbody>
<tr>
<td>Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide</td>
<td>Do not use a solid water stream as it may scatter and spread fire</td>
</tr>
</tbody>
</table>

**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
6. ACCIDENTAL RELEASE MEASURES

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/m³
Phenylephrine HCl  40 mcg/m³
Pramoxine HCl  300 mcg/m³
Glycerine  10 mcg/m³ (ACGIH)
Propylparaben  Particulates not otherwise specified (ACGIH)
   3 mg/m³ respirable
   10 mg/m³ 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 | None
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 | 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 | 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
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/m³) induced lung inflammatory reactions and lipoid granuloma formulation in mice and rats.

**Preparation H Products**

**Glycerine**

**No Toxicologic Effect**

**Dose/Species/Study Length:**

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.

**Primary Eye Irritation**

No data available

**Sensitization**

No data available

**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.

**Mineral Oil**

**No Toxicologic Effect**

**Dose/Species/Study Length:**

Oral administration of high doses in rats did not induce hepatotoxic effects.

**Acute Dermal Irritation**

No data available

**Sensitization**

No data available

**LD50 Oral**

5 gm/kg mice

**Acute Dermal Irritation**

Not available

**Primary Eye Irritation**

Not available

**Sensitization**

Not available

**Carcinogenicity**

No data available

**Genetic Toxicity**

Genotoxic in *in vitro* micronucleus assay.

**Reproductive Toxicity**

No data available

**Developmental Toxicity**

No data available

**Mineral Oil**

**Acute Dermal Irritation**

No data available

**Sensitization**

No data available

**LD50 Oral**

Rat 3gm/kg

**Acute Dermal Irritation**

No data available

**Primary Eye Irritation**

No data available

**Sensitization**

No data available

**Primary Eye Irritation**

Not available

**Sensitization**

No data available

**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

**Witch Hazel**

**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**

**Primary Eye Irritation**

No data available

**Sensitization**

No data available

**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.
12. ECOLOGICAL INFORMATION

The following effects are based on the Active Pharmaceutical Ingredient.

<table>
<thead>
<tr>
<th>Carcinogenicity</th>
<th>Long-term studies in rats and mice revealed no evidence of carcinogenicity.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Genetic Toxicity</td>
<td>Non-mutagenic in bacterial assays.</td>
</tr>
<tr>
<td>Reproductive Toxicity</td>
<td>No data available</td>
</tr>
<tr>
<td>Developmental Toxicity</td>
<td>No data available</td>
</tr>
</tbody>
</table>

**Glycerine**

<table>
<thead>
<tr>
<th>Carcinogenicity</th>
<th>No data available</th>
</tr>
</thead>
<tbody>
<tr>
<td>Genetic Toxicity</td>
<td>Non-mutagenic in Ames test; non-clastogenic in chromosomal aberrations assay.</td>
</tr>
<tr>
<td>Reproductive Toxicity</td>
<td>Studies in rats were found to have no effect on fertility.</td>
</tr>
<tr>
<td>Developmental Toxicity</td>
<td>No teratogenic effects were observed in mice, rats and rabbits given large oral doses of &gt;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.</td>
</tr>
</tbody>
</table>

**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                                                       |

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13. DISPOSAL CONSIDERATIONS

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

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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
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.

<table>
<thead>
<tr>
<th>SARA 311/312 Hazardous Categorization</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute Health Hazard</td>
<td>No</td>
</tr>
<tr>
<td>Chronic Health Hazard</td>
<td>No</td>
</tr>
<tr>
<td>Fire Hazard</td>
<td>No</td>
</tr>
<tr>
<td>Sudden Release of Pressure Hazard</td>
<td>No</td>
</tr>
<tr>
<td>Reactive Hazard</td>
<td>No</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Prepared By</th>
<th>Wyeth Department of Environment, Health &amp; Safety</th>
</tr>
</thead>
<tbody>
<tr>
<td>Format</td>
<td>This MSDS was prepared in accordance with ANSI Z400.1-2004.</td>
</tr>
<tr>
<td>List of References</td>
<td>See Patient Package Insert for more information.</td>
</tr>
<tr>
<td>Revision Summary</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>

**Disclaimer:**

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End of MSDS