1. PRODUCT & COMPANY IDENTIFICATION

Product Name: Hydrocortisone Butyrate Ointment, 0.1%
Manufacturer: Ferndale Laboratories, Inc.
780 West Eight Mile Road
Ferndale, Michigan 48220-2498

Emergency Telephone: For emergency involving spill, leak, fire exposure or accident, call CHEMTREC (800) 424-9300, day or night

Product Technical and Medical Information: (800) 621-6003

2. COMPOSITION/HAZARDOUS INGREDIENTS (OSHA-regulated, present at ≥ 1%)

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>CAS Number</th>
<th>Percent (by weight)</th>
<th>Exposure Limits (Mineral Oil)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Plastibase 50W</td>
<td>8042-47-5</td>
<td>&lt;100%</td>
<td>ACGIH: 10 mg/m³ (STEL) and 5 mg/m³ (TWA)</td>
</tr>
<tr>
<td>Mineral Oil</td>
<td>9002-88-4</td>
<td></td>
<td>OSHA: 5 mg/m³ (TWA)</td>
</tr>
<tr>
<td>Polyethylene</td>
<td></td>
<td></td>
<td>NIOSH: 10 mg/m³ (STEL) and 5 mg/m³ (TWA)</td>
</tr>
</tbody>
</table>

Listed Carcinogens: The following components, present at concentrations of ≥0.1% are listed as carcinogens or potential carcinogens by either the National Toxicology Program (NTP), the International Agency for Research on Cancer (IARC), OSHA or ACGIH: None.

3. HAZARDS IDENTIFICATION

National Fire Protection Association (NFPA) (estimated) 1 1 0

This product is HAZARDOUS by OSHA Hazard Communication definition. Target organs are lungs and the gastrointestinal tract.

Emergency Overview

Appearance: Colorless and semitransparent ointment
Odor: Characteristic

Potential Health Effects

Eye Contact: May cause irritation.
Skin Contact: Mildly and/or transiently irritating to skin.
Ingestion: May cause irritation. However, if material is aspirated into the lungs, it may cause lung damage.

4. FIRST AID MEASURES

Eyes: Immediately flush eyes with plenty of water for at least 15 minutes. Keep eye wide open while rinsing. Get medical attention immediately if irritation continues.
Skin: Wash skin thoroughly with soap and water. Get medical attention if symptoms persist or irritation develops after washing.

Ingestion: If swallowed, seek medical advice immediately. Do NOT induce vomiting unless directed to do so by medical personnel. If large quantities of material are swallowed, obtain medical attention.

Note to Physician: This product can cause: gastrointestinal discomfort, diarrhea, soft stools, shortness of breath, cough, and noisy respiration. Organs affected may include: lungs and gastrointestinal tract.

5. FIRE FIGHTING

Flammable Properties: Keep away from heat and sources of ignition.
Flash Point: Not available.
Extinguishing Media: Suitable extinguishing media: Dry chemical, water spray or foam.
Unsuitable extinguishing media: Do NOT use water jet.
Special Fire Fighting Procedures: Self-contained breathing apparatus and full protective clothing should be worn when fighting chemical fires.

6. ACCIDENTAL RELEASE MEASURES

Personal Protection: Use personal protection recommended in Section 8 of the MSDS.
Spill Cleanup Methods: Cover with inert, absorbent material (e.g. sand, earth, diatomaceous earth, or vermiculite) and place in container for disposal according to local, state, and federal regulations recommended in Section 13 of the MSDS.

7. HANDLING AND STORAGE

Handling: Store at controlled room temperature between 36-86°F (2-30°C). Protect against light.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Engineering Controls: Not applicable.
Respiratory Protection: Inhalation of vapor or mist may caused lipoid pneumonia.
Eye Protection: None required during normal administration or use of Hydrocortisone Butyrate Ointment, 0.1% although care should be taken to avoid the eyes. When handling large quantities, use approved eye protection to safeguard against potential eye contact.
Protective Clothing: Prolonged skin contact may require protective gloves.
Hygienic Work Practices: Wash hands thoroughly after handling product. If working with large quantities of the ointment (such as spill clean-up), use chemical resistant gloves and appropriate eye protection. No eating, drinking or smoking in area.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: Colorless and semitransparent ointment
10. STABILITY AND REACTIVITY

Stability: Stable under normal ambient and anticipated storage and handling conditions of temperature and pressure.

Conditions to avoid: Avoid high temperatures and all sources of ignition.

Materials to avoid: Avoid contact with oxidizing agents, chlorine, nitric acid, and oxygen.

Hazardous Decomposition Products: Combustion can yield carbon oxides and nitrogen oxides.

Hazardous Polymerization: Will not occur.

11. TOXICOLOGICAL INFORMATION

Mineral Oil:
- Acute Oral LD50: > 5,000 mg/kg (rat)
- Inhalation of mist may cause irritation of respiratory system (only at high concentrations)
- Not a dermal sensitizer

Polyethylene:
- Acute Oral LD50: > 3,000 mg/kg (rat)
- Acute Oral LD10: 5,000 mg/kg (mouse)
- Acute Inhalation Toxicity LC50: 12 g/m³/30 min (mouse)

The topical safety of Hydrocortisone Butyrate Ointment 0.1% has been demonstrated in the following studies. The product showed no mutagenic activity in gene mutation test with and without extrinsic metabolic activation. A primary dermal irritation study in the rabbit showed the product to be a minimal irritant consistent with corticosteroid effect. Several repeat dose toxicity studies showed mineral oil (a component of plastibase) may cause chronic effects after prolonged exposure.

Teratogenicity: Hydrocortisone butyrate was not teratogenic in rats at doses up to and including 5.4 mg/kg/day. Hydrocortisone butyrate was similarly evaluated for teratogenicity in rabbits at doses up to and including 0.3 mg/kg/day. At the two high doses of 0.2 and 0.3 mg/kg/day, post-implantation loss that resulted in a reduction in litter size was observed, and the incidence of fetal malformations was increased. Thus, hydrocortisone butyrate produced developmental toxicity, including some teratogenic effects, in these offspring. Plastibase did not show teratogenic effects in animal experiments. No adverse maternal effects were observed.

Reproductive Effects: Hydrocortisone butyrate did not produce effects on fertility in male and female rats at doses up to and including 1.8 mg/kg/day. In a similar study, hydrocortisone butyrate was evaluated for effects on lactation and development of newborn rat offspring, no effect of these offspring were seen following evaluation of survival, behavioral and developmental parameters and subsequent reproductive performance at doses up to 1.8 mg/kg/day. Plastibase showed no effects on mating or fertility in rat studies.

Mutagenicity: In a series of genetic toxicology studies, hydrocortisone butyrate was found to be devoid of mutagenic potential in the Ames test, the mouse lymphoma assay and the in vivo micronucleus assay in the mouse. This indicates that this material lacks the ability to produce gene mutations and is not clastogenic.
12. ECOLOGICAL INFORMATION

Experimental data indicates low potential for acute harm to aquatic organisms. Prevent spilled material from entering sewers, storm drains, other unauthorized drainage systems, and natural waterways.

13. DISPOSAL RECOMMENDATIONS

This product is not hazardous waste when disposed of. For small quantities, disposal by incineration is recommended. For large quantities, any disposal practice must be in compliance with local, state, and federal laws and regulations (contact local or state environmental agency for specific rules). Do not dispose of via sinks, drains, or into immediate environment.

14. TRANSPORT INFORMATION

This product is not a hazardous material for DOT, IATA, IMO or TDG shipment.

15. REGULATORY INFORMATION

TSCA: Exempt
CERCLA: This product contains no components subject to reporting or notification requirements.
SARA Title III: Exempt

16. OTHER INFORMATION

Date Issued: September 3, 2008
Supersedes Date: New
MSDS: 0271, Hydrocortisone Butyrate Ointment, 0.1%

Notice: The preceding information is based on available data compiled by the manufacturer from its own studies and the work of others and is believed to be correct. However, no warranty is expressed or implied as to the accuracy, completeness or adequacy of this information, the results to be obtained from the use thereof or the hazards connected with the use of the material. Since the information contained herein may be applied under conditions beyond our control and with which we may be unfamiliar, Ferndale Laboratories, Inc. does not assume any responsibility for the results of its use. The information is furnished upon the condition that the persons receiving it shall make their own determination as to the suitability of the product for their particular use.