

1. PRODUCT IDENTIFICATION

Product Name(s):
Psorcon E Cream

Dermik Laboratories, Inc.
500 Arcola Road
Collegeville, PA 19426-0107
24-Hour Emergency Phone: (610) 454-8000

2. COMPOSITION / INFORMATION ON INGREDIENTS

| Common Name | CAS No. | Exposure Limits |
|-----------------------|------------|---|
| Diflorasone Diacetate | 33564-31-7 | |
| Propylene Glycol | 57-55-6 | AIHA WEEL: Vapor + aerosol = 50 ppm aerosol =10 mg/m3 |
| Stearyl Alcohol | 112-92-5 | |
| Cetyl Alcohol | 124-29-8 | |
| Sorbitan Monostearate | 1338-41-6 | 8 hr TWA 10 mg/m3 total dust TLV |
| Polysorbate 60 | 9005-67-8 | |
| Mineral Oil | 8012-95-1 | 8 hr TWA 5 mg/m3 PEL and TLV (as sampled by a method that does not collect vapor) |
| Purified Water | 7732-18-5 | |

3. HAZARDS IDENTIFICATION

Potential Health Effects

Emergency Overview:

R36 Irritating to the eyes. May be irritating to the skin.

Eye

R36 Irritating to the eyes. Exposure to the eye may cause dilated pupils and long-term eye exposure could result in glaucoma.

Inhalation

As a gel, not an expected route of exposure.

Skin Contact

Certain individuals may be hypersensitive to some ingredients. Potentially irritating to skin. Absorption of active ingredient may occur.

Ingestion

If ingested long term in significant quantities this product could result in allergic reactions, nausea, vomiting, digestive disorders, headache, emotional disturbances, glaucoma, menstrual disorders, heart damage and/or convulsions (see section 11). R 64 May cause harm to breastfed babies.

Chronic Effects/Carcinogenicity

See section 11 for chronic health effects. The active ingredient is not listed as a carcinogen by OSHA, NTP or IARC.

4. FIRST AID MEASURES

Eyes

S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

Skin

If not being used therapeutically, after contact with skin, wash immediately with plenty of soap and water. Seek medical attention if symptoms appear.

Ingestion

S46 If inadvertently swallowed (in significant quantity), seek medical advice immediately and show this MSDS.

Inhalation

Not an expected route of exposure.

Note to Physician

Additional details are available on the package insert or in the Physicians' Desk Reference.

5. FIRE FIGHTING MEASURES

FLAMMABLE LIMITS

Flash Pt: Unspecified

Flammable Limits in Air-Lower: Unspecified

Flammable Limits in Air-Upper: Unspecified

Auto-Ignition Temperature: Unspecified

General Hazards

CO, CO₂, HF and oxides of nitrogen and fluorine may be generated in a fire.

Fire Fighting Extinguishing Media

Water spray or fog, carbon dioxide, or dry chemical.

Fire Fighting Instructions

S43 In case of fire, use full firefighting turnout gear and self-contained breathing apparatus (SCBA). Keep personnel upwind and away from fire.

Hazardous Combustion Products

CO, CO₂, HF and oxides of nitrogen and fluorine may be generated in a fire.

6. ACCIDENTAL RELEASE MEASURES

Large Spill

Absorb on suitable medium and deposit in suitable container for disposal. Mop area with detergent and water.

Small Spill

Wipe up with disposable towels and deposit in suitable container for disposal. Wipe down area with detergent and water.

7. HANDLING AND STORAGE

Special Handling

Protect package from physical damage.

Special Storage

Store at controlled room temperature. Do not freeze.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Eye Protection

For manufacturing and packaging operations, S25 avoid contact with eyes. S39 Wear eye/face protection.

Skin Protection

For manufacturing and packaging operations, S24 avoid contact with skin. S36 Wear suitable protective clothing.

Respiratory Protection

As packaged, none required. Manufacturing and packaging operations may require respiratory protection based upon potential exposures to individual ingredients.

Engineering Controls

Maintain employee exposures below exposure limits. Manufacturing and packaging operations should be designed so as to offer no significant exposure to this material.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical Form: Gel

Odor: Distinct fragrance

Boiling Point: Unspecified

Melting Point: Unspecified

Freezing Point: Unspecified

pH: Unspecified

Solubility in Water: Slight

Specific Gravity: Unspecified

Decomposition Temperature:

430-433(F (221-223(C) (for active ingredient)

Evaporation Rate: Unspecified

Vapor Pressure: Unspecified

Vapor Density: Unspecified

Molecular Weight: 494.58 (for active ingredient)

10. STABILITY AND REACTIVITY

Stability

Stable.

Incompatibility

Light. Strong oxidizers. Alkalis.

Hazardous Decomposition Products

No data.

Hazardous Polymerization

Will not occur.

General Information

No additional information.

11. TOXICOLOGICAL INFORMATION

DIFLORASONE DIACETATE:

ANIMAL TOXICITY DATA:

The oral, intraperitoneal and subcutaneous-LD50 in both mice and rats is reported in the literature to be >3 g/kg. The lowest published toxic dose (TDLo) by continuous dermal application in rats is 3.5 mg/kg/5 week(s) and produced changes in thymus weight and leukocyte counts. A 7-day dermal

application of 1 and 4 mg/kg b.i.d. to the abraded skin of rats caused decreased body weight gain, decreased food consumption, decreased organ weights of adrenals, thymus and spleen, and atrophy of the adrenal cortex and thymus. A 28-day dermal application of 1, 2 and 4 mg/kg b.i.d. to the shaved skin of rats caused decreased body weight gain, decreased food consumption, decreased leukocytes and increased erythrocyte parameters, decreased organ weights of adrenals, thymus and spleen, atrophy of the adrenal cortex, thymus and lymphoid tissue and reduced hematopoiesis. A 13-week dermal application of 0.1, 0.3 and 1.0 mg/kg/day to the skin of monkeys caused a slight decrease in body weight, decreased lymphocyte and eosinophil counts, increased heterophil counts, decreased thymus weight, atrophy of the adrenal cortex, thymus and lymphoid tissue and reduced hematopoiesis. Single oral doses of glucocorticoids ranging from 0.5 to 8.0 gm/kg suppressed the immune response in mice to the extent that high mortality occurred as a result of intercurrent infections over 1 to 3 weeks.

There have been no long-term studies to evaluate the carcinogenic potential of diflorasone diacetate. Diflorasone diacetate was not found to be mutagenic in a micronucleus test in rats at doses of 2400 mg/kg.

ANIMAL REPRODUCTIVE DATA:

Studies in the rat following topical administration at doses up to 0.5 mg/kg revealed no effects on fertility.

Subcutaneous administration of diflorasone diacetate produced both maternal and fetal effects in the rat. In one study, a TDLo of 495 and 4950 (g/kg by subcutaneous administration during gestation days 7-17 produced effects of extra embryonic structures and fetotoxicity, respectively. In another study, a TDLo of 225 and 4500 (g/kg by subcutaneous administration during gestation days 17-21 produced effects on parturition and newborn viability index, respectively. Diflorasone diacetate has been shown to cause cleft palate in rats when applied dermally at a dose of approximately 0.001 mg/kg/day to the shave thorax of pregnant animals. When pregnant rats were treated topically with approximately 0.5 mg/kg/day, uterine deaths were higher in the treated animals than in the control animals.

In addition, subcutaneous administration of diflorasone diacetate produced fetal effects in the rabbit. A TDLo of 208 and 3250 (g/kg by dermal application during gestation days 6-18 produced effects of fetotoxicity/cardiovascular developmental abnormalities and musculoskeletal developmental abnormalities, respectively. Also, dermal application as low as 20 mg/kg/day of diflorasone diacetate produced cleft palate, depression of fetal weight and smaller litter sizes.

ADDITIONAL DATA: Interactions with other drugs may occur. May be excreted in breast milk. May cross the placenta.

MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE: Bone, joint or tooth disorders, convulsive disorders, diabetes, eye disorders, gastrointestinal disorders, heart or cardiovascular disorders, hormonal disorders, kidney disorders, liver disorders, personality disorders, skin disorders and allergies

SKIN CONTACT: Allergic contact dermatitis may develop in previously exposed persons. Repeated topical application may cause irritation, itching, burning erythema, dryness, folliculitis, and epidermal and dermal atrophy manifested by thinning of the skin, telangiectasia, purpura, striae and possibly pustulation, perioral dermatitis, impeded healing, local hypertrichosis and masking or spread of preexisting infections. Repeated application, especially to inflamed or damaged skin, or

application to large areas may cause systemic poisoning as described in chronic ingestion. Absorption is greatly enhanced by occlusive covering. Sensitization may develop in susceptible individuals.

INGESTION: A large single dose of corticosteroid is reported to be virtually without harmful effects. Anaphylactoid or hypersensitivity reactions to corticosteroids have been reported in previously exposed individuals. Repeated ingestion of corticosteroids may cause sodium and fluid retention, edema, hypovolemia, hypokalemic alkalosis, hypocalcemia, hypotension or shock-like reactions. Other effects of corticosteroids are listed below. **Endocrine System:** Effects on metabolism and the endocrine system may include redistribution of fat may result in moonface, buffalo hump, supraclavicular fat pad enlargement and central obesity, secondary adrenocortical and pituitary suppression and unresponsiveness, increased sweating, decreased carbohydrate tolerance, increased gluconeogenesis, hyperglycemia, glycosuria, manifestations of latent diabetes mellitus, steroid diabetes, and negative nitrogen balance. Life-threatening acute adrenal insufficiency and other symptoms of withdrawal may occur after cessation of long-term administration of corticosteroids. **Blood and the Immune System:** Effects on blood include relative neutrophilia, a decrease in circulating eosinophils and transient lymphocytopenia may occur. Effects on the immune system may include activation, aggravation, masking or increased susceptibility to infections. **Cardiovascular System:** Cardiovascular effects may include embolism, thrombophlebitis, necrotizing angitis, cardiac arrhythmias or ECG changes, syncope, arterial hypertension and congestive heart failure. **Musculoskeletal System:** Effects on the musculoskeletal system may include muscle weakness, myopathy with loss of muscle mass, arthropathy, Achilles tendon rupture, osteoporosis, aseptic bone necrosis and spontaneous fractures. **Nervous System and Behavioral Effects:** Effects on the nervous system may include malaise, decrease in pain sensation, vertigo, headache, insomnia, neuritis or paresthesias, convulsions. Effects on behavior and mental status may include nervousness, depression or euphoria, aggravation of preexisting psychiatric conditions, psychoses, delusions, hallucinations and catatonia. Suicidal tendencies are not uncommon. **Reproductive System and Teratological Effects:** Corticosteroids may also cause amenorrhea, postmenopausal bleeding, and other menstrual irregularities. Steroids may increase or decrease motility and number of spermatozoa. Corticosteroids are excreted in breast milk and may suppress growth or interfere with endogenous corticosteroid production in the nursing infant. Chronic maternal ingestion during the first trimester has shown a 1% incidence of cleft palate in humans. **Gastrointestinal System:** Gastrointestinal effects may include ulcerative esophagitis, gastric irritation, abdominal distension, nausea, vomiting, increased appetite, peptic ulcer with perforation and hemorrhage and possibly perforation of the bowel and pancreatitis may occur. **Cutaneous Effects:** Effects on the skin may include impaired wound healing, thin fragile skin, petechiae and ecchymoses, erythema, lupus erythematosus-like lesions, suppression of skin test reactions, subcutaneous fat atrophy, purpura, striae, hyperpigmentation, hirsutism in women, acne, allergic dermatitis, urticaria, angioneurotic edema and perineal irritation may occur. **Effects on the Eye:** Ocular effects may include exophthalmos, posterior subcapsular cataracts, increased intraocular pressure and glaucoma, possibly resulting in blindness.

12. ECOLOGICAL INFORMATION

No information for determination of unusual environmental fate or toxicity (in addition to toxicity data presented in section 11) is available at this time.

13. DISPOSAL CONSIDERATIONS

Disposal Information

Waste must be disposed of in accordance with federal, state and local environmental regulations. Waste may be placed in a leakproof, puncture resistant container which is then placed in a disposable wire-tie or sealable 4 mil-thick polyethylene or 2 mil-thick propylene bags.

Waste Disposal Methods

Dissolve or mix the material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber. Observe all federal, state and local environmental regulations.

14. TRANSPORT INFORMATION

Proper Shipping Name:

Not Regulated

Transportation of Hazardous Material Description

Not a regulated material. Ship according to DOT and/or IATA regulations.

15. REGULATORY INFORMATION

TSCA

This material is a pharmaceutical agent and as such is regulated by the United States Food and Drug Administration (FDA).

CERCLA NA

SARA 302 NA

SARA 313 NA

16. OTHER INFORMATION

Prepared By: David Eherts CIH

Approved By: ITAC

Approved Date: 12/18/98

Supersedes Date: Original Version

Other Information

The information contained herein is based upon data considered true and accurate. Rhone-Poulenc Rorer makes no warranties, express or implied, as to the adequacy of the information contained herein. This information is offered solely for the user's consideration, investigation and verification. Report to the manufacturer any allegations of health effects resulting from handling or accidental contact with this material.

Revision Summary

Original version.

Material Safety Data Sheet

Effective Date: 12/15/98

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