



MATERIAL SAFETY DATA SHEET

Revision date: 15-Dec-2006

Version: 1.1

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1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

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CHEMTREC (24 hours): 1-800-424-9300

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ChemSafe (24 hours): +44 (0)208 762 8322

Material Name: Diflorasone Diacetate Cream

Trade Name: FLORONE®
Chemical Family: Mixture
Intended Use: Pharmaceutical product used as anti-inflammatory

2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS List	%
Diflorasone Diacetate	33564-31-7	251-575-1	<0.1
Sorbic acid	110-44-1	203-768-7	*
Sorbitan monostearate	1338-41-6	215-664-9	*
Stearic acid	57-11-4	200-313-4	*
Citric acid	77-92-9	201-069-1	*
Propylene glycol	57-55-6	200-338-0	*

Ingredient	CAS Number	EU EINECS List	%
Water	7732-18-5	231-791-2	*
Sorbitan oleate	1338-43-8	215-665-4	*
Polysorbate 60	9005-67-8	Not listed	*

Additional Information: * Proprietary

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

3. HAZARDS IDENTIFICATION

Appearance: White to off-white cream

Statement of Hazard: Non-hazardous in accordance with international standards for workplace safety.

Additional Hazard Information:

Short Term: Not expected to cause skin irritation (based on animal data) . May cause allergic reactions in susceptible individuals.

Long Term: Repeated or prolonged exposure may cause effects similar to those seen in clinical use. Due to its pharmacological action, exposure to this compound may produce adverse effects on fetal development.

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Known Clinical Effects: Ingestion of this material may cause effects similar to those seen in clinical use including nausea, vomiting, muscle cramps, weakness, nervousness, restlessness and trouble sleeping. Clinical use has resulted in changes in electrolytes and/or blood chemistry changes. Drugs of this class may cause Cushing's syndrome, manifested by moon face, obesity, headache, acne, thirst, increased urination, impotence, menstrual irregularities, facial hair growth, and mental changes. Clinical use may cause an increase in blood pressure (hypertension).

EU Indication of danger: Not classified

Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates 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.

4. FIRST AID MEASURES

Eye Contact: If irritation occurs or persists, get medical attention.

Skin Contact: Due to the nature of this material first aid is not normally required. Wash skin with soap and water.

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: Due to the nature of this material first aid is not normally required.

5. FIRE FIGHTING MEASURES

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

Hazardous Combustion Products: Combustion may produce hydrogen fluoride, other fluorinated products, oxides of carbon, and other irritating or toxic gases.

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

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

6. ACCIDENTAL RELEASE MEASURES

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

Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

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

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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

General Handling: Avoid contact with eyes. Avoid prolonged or repeated contact with skin and clothing.

Storage Conditions: Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Sorbitan monostearate

ACGIH Threshold Limit Value (TWA) = 10 mg/m³ TWA except stearates of toxic metals
Australia TWA = 10 mg/m³ TWA

Propylene glycol

Australia TWA = 10 mg/m³ TWA
= 150 ppm TWA
= 474 mg/m³ TWA

The purpose of the Occupational Exposure Band (OEB) classification system is to separate substances into different Hazard categories when the available data are sufficient to do so, but inadequate to establish an Occupational Exposure Limit (OEL). The OEB given is based upon an analysis of all currently available data; as such, this value may be subject to revision when new information becomes available.

Diflorasone Diacetate

Pfizer Occupational Exposure Band (OEB): OEB 3 - Skin (control exposure to the range of >10ug/m³ to < 100ug/m³, provide additional precautions to protect from skin contact)

Engineering Controls: Engineering controls should be used as the primary means to control exposures. Use process containment, local exhaust ventilation, or other engineering controls to maintain airborne levels within the OEB range.

Personal Protective Equipment:

Hands: Not required for the normal use of this product. Wear protective gloves when working with large quantities.
Eyes: Not required under normal conditions of use. Wear safety glasses or goggles if eye contact is possible.
Skin: Not required for the normal use of this product. Wear protective clothing when working with large quantities.
Respiratory protection: Not required for the normal use of this product. If airborne exposures are within or exceed the Occupational Exposure Band (OEB) range, wear an appropriate respirator with a protection factor sufficient to control exposures to the bottom of the OEB range.

9. PHYSICAL AND CHEMICAL PROPERTIES:

Physical State: Cream
Molecular Formula: Mixture
Color: White to off-white
Molecular Weight: Mixture

10. STABILITY AND REACTIVITY

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Stability: Stable at normal conditions
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.
Polymerization: Will not occur

11. TOXICOLOGICAL INFORMATION

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

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

Diflorasone Diacetate

Rat Oral LD50 > 2000 mg/kg

Citric acid

Rat Oral LD50 3000 mg/kg

Propylene glycol

Mouse Oral LD50 22,000 mg/kg

Rat Oral LD50 20,000 mg/kg

Rabbit Dermal LD50 20,800 mg/kg

Stearic acid

Rat Oral LD50 > 4640 mg/kg

Rabbit Dermal LD50 > 5000 mg/kg

Polysorbate 60

Rat Oral LD50 64,000 mg/kg

Sorbic acid

Rat Oral LD50 7360 mg/kg

Mouse Oral LD50 3200 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.

Irritation / Sensitization: (Study Type, Species, Severity)

Diflorasone Diacetate

Eye Irritation Rabbit Moderate

Skin Irritation Rabbit Non-irritating

Citric acid

Eye Irritation Rabbit Severe

Skin Irritation Rabbit Mild

Propylene glycol

Skin Irritation Rabbit Mild

Eye Irritation Rabbit Mild

Stearic acid

Skin Irritation Rabbit Mild

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

Diflorasone Diacetate

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Bacterial Mutagenicity (Ames) Negative
In Vitro Micronucleus Negative

Carcinogen Status: None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been investigated. Releases to the environment should be avoided.

13. DISPOSAL CONSIDERATIONS

Disposal Procedures: Dispose of waste in accordance with all applicable laws and regulations.

14. TRANSPORT INFORMATION

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

15. REGULATORY INFORMATION

EU Indication of danger: Not classified

OSHA Label:
Non-hazardous in accordance with international standards for workplace safety.

Canada - WHMIS: Classifications

WHMIS hazard class:
None required
This product has been classified in accordance with the hazard criteria of the CPR and the MSDS contains all of the information required by the CPR.

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EU EINECS List	251-575-1
Sorbic acid	
Inventory - United States TSCA - Sect. 8(b)	T
Australia (AICS):	Present
EU EINECS List	203-768-7
Sorbitan monostearate	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	215-664-9
Stearic acid	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	200-313-4
Water	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	231-791-2
Sorbitan oleate	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	215-665-4
Polysorbate 60	
Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present
Citric acid	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	201-069-1
Propylene glycol	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	200-338-0

16. OTHER INFORMATION

Reasons for Revision: Updated Section 2 - Composition / Information on Ingredients. Updated Section 3 - Hazard Identification. Updated Section 6 - Accidental Release Measures. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 13 - Disposal Considerations.

Prepared by: Corporate Occupational Toxicology & Hazard Assessment

Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied.

End of Safety Data Sheet