



MATERIAL SAFETY DATA SHEET

Revision date: 04-Jan-2007

Version: 1.1

Page 1 of 7

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

Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
New York, New York 10017
1-212-573-2222

Pfizer Ltd
Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom
+00 44 (0)1304 616161

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300

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

Material Name: Bufexamac Cream

Trade Name: Malipuran(R); Droxyaryl(R) Cream
Chemical Family: Mixture
Intended Use: Pharmaceutical product used as anti-inflammatory

2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS List	%
Befexamac	2438-72-4	219-451-1	5
Glycerol	56-81-5	200-289-5	*
Sodium lauryl sulfate	151-21-3	205-788-1	*

Ingredient	CAS Number	EU EINECS List	%
Water	7732-18-5	231-791-2	*
Methylparaben	99-76-3	202-785-7	*
Cetyl/Stearyl alcohol	67762-27-0	267-008-6	*
Cetyl alcohol	36653-82-4	253-149-0	*

Additional Information: * Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

3. HAZARDS IDENTIFICATION

Appearance: Opaque cream
Signal Word: WARNING

Statement of Hazard: May cause allergic skin reaction.

Additional Hazard Information:

Short Term: May cause eye irritation (based on components) . May cause mild skin irritation (based on animal data). May cause allergic reaction . Accidental ingestion may cause effects similar to those seen in clinical use.

Long Term: Animal studies have shown a potential to cause adverse effects on the fetus.

Known Clinical Effects: Adverse effects most commonly reported in clinical use include skin rash and gastrointestinal disturbances.

EU Indication of danger: Irritant

MATERIAL SAFETY DATA SHEET

Material Name: Bufexamac Cream
Revision date: 04-Jan-2007

Page 2 of 7
Version: 1.1

EU Hazard Symbols:



EU Risk Phrases:

R43 - May cause sensitization by skin contact.

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. Flush eye(s) immediately with plenty of water.
- Skin Contact:** Due to the nature of this material first aid is not normally required. If irritation occurs or persists, get medical attention.
- 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:** Not an expected route of exposure. If discomfort occurs, get medical attention.

5. FIRE FIGHTING MEASURES

- Extinguishing Media:** Use carbon dioxide, dry chemical, or water spray.
- Hazardous Combustion Products:** Carbon monoxide, carbon dioxide, and oxides of nitrogen may be generated in a fire.
- Fire Fighting Procedures:** During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.
- Fire / Explosion Hazards:** Not applicable

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.
- 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

MATERIAL SAFETY DATA SHEET

Material Name: Bufenamac Cream
Revision date: 04-Jan-2007

Page 3 of 7
Version: 1.1

Storage Conditions: Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Glycerol

OSHA - Final PELs - TWAs: = 15 mg/m³ TWA total
= 5 mg/m³ TWA
ACGIH Threshold Limit Value (TWA) = 10 mg/m³ TWA
Australia TWA = 10 mg/m³ TWA

Sodium lauryl sulfate

Pfizer OEL TWA-8 Hr: 0.3 mg/m³
Pfizer STEL 0.75 mg/m³

The exposure limit(s) listed for solid components are only relevant if dust or mist may be generated.

Analytical Method: Analytical method available for Sodium lauryl sulfate. Contact Pfizer Inc for further information.

Engineering Controls: Engineering controls should be used as the primary means to control exposures.

Personal Protective Equipment:

Hands: Not required for the normal use of this product. Wear protective gloves when working with large quantities.
Eyes: Not required for the normal use of this product. 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: None required under normal conditions of use. If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

9. PHYSICAL AND CHEMICAL PROPERTIES:

Physical State:	Cream	Color:	Opaque
Molecular Formula:	Mixture	Molecular Weight:	Mixture

10. STABILITY AND REACTIVITY

Stability: Stable at normal conditions
Conditions to Avoid: Not determined
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)

MATERIAL SAFETY DATA SHEET

Material Name: **Bufexamac Cream**
Revision date: **04-Jan-2007**

Page 4 of 7
Version: 1.1

Befexamac

Rat Oral LD50 3370 mg/kg

Methylparaben

Mouse Oral LD50 > 8000 mg/kg

Rat Oral LD50 2280 mg/kg

Glycerol

Rat Oral LD50 12600 mg/kg

Sodium lauryl sulfate

Rat Oral LD50 1288 mg/kg

Cetyl alcohol

Rat Oral LD50 5000 mg/kg

Rabbit Dermal LD50 > 2,600 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)

Befexamac

Eye Irritation Rabbit No effect

Skin Irritation Rabbit Mild

Glycerol

Skin Irritation Rabbit Mild

Eye Irritation Rabbit Mild

Sodium lauryl sulfate

Eye Irritation Rabbit Severe

Skin Irritation Rabbit Severe

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Befexamac

30 Day(s) Rat Subcutaneous 400 mg/kg LOAEL Thymus

3 Month(s) Rat Oral 1400 mg/kg LOAEL Gastrointestinal system

6 Month(s) Rat Oral 180 mg/kg LOAEL Thymus, Gastrointestinal system

12 Month(s) Non-human Primate Oral 200 mg/kg LOAEL Kidney

Glycerol

28 Day(s) Rat Oral 16800 mg/kg LOAEL Endocrine system

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

Befexamac

Embryo / Fetal Development Rat Oral 600 mg/kg LOAEL Fetotoxicity

Embryo / Fetal Development Mouse Oral 600 mg/kg NOAEL Fetotoxicity, Fertility

Embryo / Fetal Development Rat Oral 500 mg/kg NOAEL Not Teratogenic

Embryo / Fetal Development Rabbit Oral 500 mg/kg NOAEL Not Teratogenic

Glycerol

Reproductive & Fertility-Males Rat Oral 100 mg/kg LOEL Fertility

MATERIAL SAFETY DATA SHEET

Material Name: Bufexamac Cream
Revision date: 04-Jan-2007

Page 5 of 7
Version: 1.1

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

Bufexamac

Bacterial Mutagenicity (Ames) *Salmonella* Negative
Mammalian Cell Mutagenicity Not specified Negative

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Bufexamac

2 Year(s) Male Rat Oral 250 mg/kg/day NOEL Not carcinogenic
2 Year(s) Female Rat Oral 300 mg/kg/day NOEL Not carcinogenic

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 thoroughly 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 Symbol: Xi
EU Indication of danger: Irritant

EU Risk Phrases:
R43 - May cause sensitization by skin contact.

EU Safety Phrases:
S22 - Do not breathe dust.
S36/37 - Wear suitable protective clothing and gloves.

OSHA Label:
WARNING

MATERIAL SAFETY DATA SHEET

Material Name: **Bufexamac Cream**
Revision date: 04-Jan-2007

Page 6 of 7
Version: 1.1

May cause allergic skin reaction.

Canada - WHMIS: Classifications

WHMIS hazard class:

Class D, Division 2, Subdivision B



Befexamac

Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4
EU EINECS List	219-451-1

Water

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	231-791-2

Methylparaben

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	202-785-7

Glycerol

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	200-289-5

Cetyl/Stearyl alcohol

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	267-008-6

Cetyl alcohol

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	253-149-0

Sodium lauryl sulfate

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	205-788-1

16. OTHER INFORMATION

Reasons for Revision:

Updated Section 3 - Hazard Identification. Updated Section 5 - Fire Fighting Measures.
Updated Section 6 - Accidental Release Measures. Updated Section 8 - Exposure Controls /
Personal Protection. Updated Section 10 - Stability and Reactivity. Updated Section 13 -
Disposal Considerations. Updated Section 15 - Regulatory Information.

MATERIAL SAFETY DATA SHEET

Material Name: **Bufexamac Cream**
Revision date: **04-Jan-2007**

Page 7 of 7
Version: 1.1

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