



# MATERIAL SAFETY DATA SHEET

Revision date: 06-Jan-2006

Version: 1.1

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

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

**Material Name: Tixocortol Pivalate/Chlorhexidine Gluconate Spray**

**Trade Name:** THIOVALONE  
**Chemical Family:** Mixture  
**Intended Use:** Pharmaceutical product used as anti-inflammatory, antiseptic

## 2. COMPOSITION/INFORMATION ON INGREDIENTS

### Hazardous

Ingredient	CAS Number	EU EINECS List	%
Tixocortol Pivalate	55560-96-8	259-706-4	0.3
Chlorhexidine Gluconate	18472-51-0	242-354-0	<1.0
Cetylpyridinium chloride	123-03-5	204-593-9	*
Glycerin, USP	56-81-5	200-289-5	*

Ingredient	CAS Number	EU EINECS List	%
Acesulfame potassium salt	55589-62-3	259-715-3	*
Flavor	NOT ASSIGNED	Not listed	*
Water, purified	7732-18-5	231-791-2	*

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

## 3. HAZARDS IDENTIFICATION

**Appearance:** aqueous suspension

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

**Additional Hazard Information:**  
**Short Term:** May cause allergic skin reaction (based on animal data) . May cause irritation (based on components) .

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

**EU Indication of danger:** Not classified

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**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:** Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

**Skin Contact:** Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek 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:** Remove to fresh air and keep patient at rest. Seek medical attention immediately.

### 5. FIRE FIGHTING MEASURES

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

**Hazardous Combustion Products:** Formation of toxic gases is possible during heating or 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:** Use appropriate ventilation. Avoid contact with eyes, skin and clothing. Avoid breathing vapor or mist.

**Storage Conditions:** No special storage conditions required.

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Tixocortol Pivalate  
Pfizer OEL TWA-8 Hr:

2 mg/m<sup>3</sup>

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## Glycerin, USP

OSHA - Final PELs - TWAs:	= 15 mg/m <sup>3</sup> TWA	total
	= 5 mg/m <sup>3</sup> TWA	
ACGIH Threshold Limit Value (TWA)	= 10 mg/m <sup>3</sup> TWA	
Australia TWA	= 10 mg/m <sup>3</sup> TWA	

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

## Personal Protective Equipment:

<b>Hands:</b>	Wear impervious gloves if skin contact is possible.
<b>Eyes:</b>	Wear safety glasses or goggles if eye contact is possible.
<b>Skin:</b>	Wear protective clothing when working with large quantities.
<b>Respiratory protection:</b>	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:

<b>Physical State:</b>	Aqueous suspension	<b>Color:</b>	No data available.
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture

## 10. STABILITY AND REACTIVITY

<b>Stability:</b>	Stable under normal conditions of use.
<b>Conditions to Avoid:</b>	None known
<b>Incompatible Materials:</b>	As a precautionary measure, keep away from strong oxidizers.

## 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)

#### Cetylpyridinium chloride

Rat	Oral	LD50	200 mg/kg
Rat	Inhalation	LC50/4h	90 mg/m <sup>3</sup>

#### Chlorhexidine Gluconate

Rat	Oral	LD50	2000 mg/kg
Rat	Intravenous	LD50	24.2 mg/kg
Mouse	Oral	LD50	1260 mg/kg
Mouse	Intravenous	LD50	12.9 mg/kg

#### Glycerin, USP

Mouse	Oral	LD50	4090 mg/kg
Rat	Oral	LD50	12.6 g/kg
Rabbit	Dermal	LD50	> 10 g/kg
Rat	Inhalation	LC50 1hr	> 570 mg/m <sup>3</sup>
Rat	Dermal	LD 50	>21.9 g/kg

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**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)

#### **Tixocortol Pivalate**

Skin Sensitization - GPMT Guinea Pig Positive

#### **Cetylpyridinium chloride**

Eye Irritation Rabbit Severe

Skin Irritation Rabbit Mild

#### **Chlorhexidine Gluconate**

Eye Irritation Rabbit Moderate

#### **Glycerin, USP**

Eye Irritation Rabbit Mild

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

#### **Tixocortol Pivalate**

6 Day(s) Rat Oral 1620 mg/kg/day LOAEL Endocrine system

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

#### **Chlorhexidine Gluconate**

Embryo / Fetal Development Rat Oral 68 mg/kg/day NOAEL Not teratogenic

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

#### **Chlorhexidine Gluconate**

*In Vivo* Cytogenetics Hamster Negative

*In Vivo* Dominant Lethal Assay Mouse Negative

**Carcinogen Status:** None of the other components of this mixture 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.

#### **Glycerin, USP**

*Oncorhynchus mykiss* (Rainbow Trout) LC-50 96 Hours 50 mg/L

*Daphnia Magna* (Water Flea) EC-50 24 Hours >500 mg/L

**Aquatic Toxicity Comments:** A greater than symbol (>) indicates that aquatic toxicity was not observed at the maximum dose tested.

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## 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.

#### Tixocortol Pivalate

EU EINECS List 259-706-4

#### Chlorhexidine Gluconate

Inventory - United States TSCA - Sect. 8(b) Present

Australia (AICS): Present

EU EINECS List 242-354-0

#### Cetylpyridinium chloride

Inventory - United States TSCA - Sect. 8(b) Present

Australia (AICS): Present

EU EINECS List 204-593-9

#### Glycerin, USP

Inventory - United States TSCA - Sect. 8(b) Present

Australia (AICS): Present

EU EINECS List 200-289-5

#### Acesulfame potassium salt

Australia (AICS): Present

EU EINECS List 259-715-3

Water, purified

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

### 16. OTHER INFORMATION

**Reasons for Revision:** Updated Section 2 - Composition / Information on Ingredients. 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 11 - Toxicology Information. Updated Section 12 - Ecological Information.

**Prepared by:** Toxicology and Hazard Communication  
Pfizer Global Environment, Health, and Safety

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**End of Safety Data Sheet**