



MATERIAL SAFETY DATA SHEET

Revision date: 22-Jun-2012

Version: 2.0

Page 1 of 7

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

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Material Name: Tixocortol Pivalate/Chlorhexidine Gluconate Spray

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

2. 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

Australian Hazard Classification (NOHSC): Non-Hazardous Substance. Non-Dangerous Goods.

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.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Tixocortol Pivalate	55560-96-8	259-706-4	Not Listed	0.3
Chlorhexidine Gluconate	18472-51-0	242-354-0	Xn;R22	<1.0
Cetylpyridinium chloride	123-03-5	204-593-9	Not Listed	*

MATERIAL SAFETY DATA SHEET

Material Name: Tixocortol Pivalate/Chlorhexidine Gluconate
Spray
Revision date: 22-Jun-2012

Page 2 of 7

Version: 2.0

3. COMPOSITION/INFORMATION ON INGREDIENTS

Glycerin, USP	56-81-5	200-289-5	Not Listed	*
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Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Acesulfame potassium salt	55589-62-3	259-715-3	Not Listed	*
Flavor	NOT ASSIGNED	Not Listed	Not Listed	*
Water, purified	7732-18-5	231-791-2	Not Listed	*

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

For the full text of the R phrases mentioned in this Section, see Section 16

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.

Symptoms and Effects of Exposure: For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

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.

MATERIAL SAFETY DATA SHEET

Material Name: Tixocortol Pivalate/Chlorhexidine Gluconate
Spray
Revision date: 22-Jun-2012

Page 3 of 7

Version: 2.0

7. HANDLING AND STORAGE

General Handling: Use appropriate ventilation. Avoid contact with eyes, skin and clothing. Avoid breathing vapor or mist. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Storage Conditions: Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Refer to available public information for specific member state Occupational Exposure Limits.

Tixocortol Pivalate

Pfizer OEL TWA-8 Hr: 2 mg/m³

Glycerin, USP

ACGIH Threshold Limit Value (TWA)	10 mg/m ³
Australia TWA	10 mg/m ³
Belgium OEL - TWA	10 mg/m ³
Czech Republic OEL - TWA	10 mg/m ³
Estonia OEL - TWA	10 mg/m ³
Finland OEL - TWA	20 mg/m ³
France OEL - TWA	10 mg/m ³
Germany (DFG) - MAK	50 mg/m ³ inhalable fraction
Greece OEL - TWA	10 mg/m ³
Ireland OEL - TWAs	10 mg/m ³
OSHA - Final PELs - TWAs:	15 mg/m ³
Poland OEL - TWA	10 mg/m ³
Portugal OEL - TWA	10 mg/m ³
Spain OEL - TWA	10 mg/m ³

Chlorhexidine Gluconate

Pfizer Occupational Exposure Band (OEB): OEB 4 (control exposure to the range of >1ug/m³ to <10ug/m³)

Engineering Controls: Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

Environmental Exposure Controls: Refer to specific Member State legislation for requirements under Community environmental legislation.

Personal Protective Equipment: Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

Hands: Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.

Eyes: Wear safety glasses or goggles if eye contact is possible.

Skin: Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

Respiratory protection: 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.

MATERIAL SAFETY DATA SHEET

Material Name: Tixocortol Pivalate/Chlorhexidine Gluconate
Spray
Revision date: 22-Jun-2012

Page 4 of 7

Version: 2.0

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Aqueous suspension	Color:	No data available.
Molecular Formula:	Mixture	Molecular Weight:	Mixture

10. STABILITY AND REACTIVITY

Chemical Stability:	Stable under normal conditions of use.
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

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/m³

Chlorhexidine Gluconate

Rat Oral LD50 2000 mg/kg
Rat Para-periosteal 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/m³
Rat Dermal LD 50 >21.9 g/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)

Tixocortol Pivalate

Skin Sensitization - GPMT Guinea Pig Positive

Cetylpyridinium chloride

Eye Irritation Rabbit Severe
Skin Irritation Rabbit Mild

Chlorhexidine Gluconate

MATERIAL SAFETY DATA SHEET

Material Name: Tixocortol Pivalate/Chlorhexidine Gluconate
Spray
Revision date: 22-Jun-2012

Page 5 of 7

Version: 2.0

11. TOXICOLOGICAL INFORMATION

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 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.

Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

Glycerin, USP

Oncorhynchus mykiss (Rainbow Trout) LD50 96 Hours 50 mg/L

Daphnia magna (Water Flea) EC50 24 Hours >500 mg/L

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

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods:

Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

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

MATERIAL SAFETY DATA SHEET

Material Name: Tixocortol Pivalate/Chlorhexidine Gluconate
Spray
Revision date: 22-Jun-2012

Page 6 of 7

Version: 2.0

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/ELINCS List 259-706-4

Chlorhexidine Gluconate

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

Australia (AICS): Present

EU EINECS/ELINCS List 242-354-0

Cetylpyridinium chloride

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

Australia (AICS): Present

EU EINECS/ELINCS List 204-593-9

Glycerin, USP

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

Australia (AICS): Present

REACH - Annex V - Exemptions from the obligations of Register: Present if not chemically modified, except they meet the criteria for classification as dangerous according to Directive 67/548/EEC, except those only classified as flammable [R10], as a skin irritant [R38] or as an eye irritant [R36], except they are persistent, bioaccumulative, and toxic or very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII, except they were identified in accordance with Article 59[1] at least two years previously as substances giving rise to an equivalent level of concern

EU EINECS/ELINCS List 200-289-5

Acesulfame potassium salt

Australia (AICS): Present

EU EINECS/ELINCS List 259-715-3

MATERIAL SAFETY DATA SHEET

Material Name: Tixocortol Pivalate/Chlorhexidine Gluconate
Spray
Revision date: 22-Jun-2012

Page 7 of 7

Version: 2.0

15. REGULATORY INFORMATION

Water, purified

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	231-791-2

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

R22 - Harmful if swallowed.

Data Sources:

Publicly available toxicity information. Pfizer proprietary drug development information.

Reasons for Revision:

Updated Section 3 - Composition / Information on Ingredients. Updated Section 2 - Hazard Identification. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 10 - Stability and Reactivity. Updated Section 12 - Ecological Information. Updated Section 11 - Toxicology Information. Updated Section 7 - Handling and Storage.

Prepared by:

Product Stewardship Hazard Communication
Pfizer Global Environment, Health, and Safety Operations

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. If data for a hazard are not included in this document there is no known information at this time.

End of Safety Data Sheet