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

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


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

<table>
<thead>
<tr>
<th>Hazardous Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tixocortol Pivalate</td>
<td>55560-96-8</td>
<td>259-706-4</td>
<td>Not Listed</td>
<td>0.3</td>
</tr>
<tr>
<td>Chlorhexidine Gluconate</td>
<td>18472-51-0</td>
<td>242-354-0</td>
<td>Xn;R22</td>
<td>&lt;1.0</td>
</tr>
<tr>
<td>Cetylpyridinium chloride</td>
<td>123-03-5</td>
<td>204-593-9</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>
### 3. COMPOSITION/INFORMATION ON INGREDIENTS

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

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.
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/m³
Australia TWA 10 mg/m³
Belgium OEL - TWA 10 mg/m³
Czech Republic OEL - TWA 10 mg/m³
Estonia OEL - TWA 10 mg/m³
Finland OEL - TWA 20 mg/m³
France OEL - TWA 10 mg/m³
Germany (DFG) - MAK 50 mg/m³ inhalable fraction
Greece OEL - TWA 10 mg/m³
Ireland OEL - TWAs 10 mg/m³
OSHA - Final PELS - TWAs: 15 mg/m³
Poland OEL - TWA 10 mg/m³
Portugal OEL - TWA 10 mg/m³
Spain OEL - TWA 10 mg/m³

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.
9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Physical State:</th>
<th>Aqueous suspension</th>
</tr>
</thead>
<tbody>
<tr>
<td>Molecular Formula:</td>
<td>Mixture</td>
</tr>
<tr>
<td>Color:</td>
<td>No data available.</td>
</tr>
<tr>
<td>Molecular Weight:</td>
<td>Mixture</td>
</tr>
</tbody>
</table>

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 LD\textsubscript{50} 200 mg/kg
  - Rat Inhalation LC\textsubscript{50} 4h 90 mg/m\textsuperscript{3}

- **Chlorhexidine Gluconate**
  - Rat Oral LD\textsubscript{50} 2000 mg/kg
  - Rat Para-periosteal LD\textsubscript{50} 24.2 mg/kg
  - Mouse Oral LD\textsubscript{50} 1260 mg/kg
  - Mouse Intravenous LD\textsubscript{50} 12.9 mg/kg

- **Glycerin, USP**
  - Mouse Oral LD\textsubscript{50} 4090 mg/kg
  - Rat Oral LD\textsubscript{50} 12.6 g/kg
  - Rabbit Dermal LD\textsubscript{50} > 10 g/kg
  - Rat Inhalation LC\textsubscript{50} 1hr > 570 mg/m\textsuperscript{3}
  - 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 Pivatate**
  - Skin Sensitization - GPMT Guinea Pig Positive

- **Cetylpyridinium chloride**
  - Eye Irritation Rabbit Severe
  - Skin Irritation Rabbit Mild

**Chlorhexidine Gluconate**
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
7 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
Onchorhynchus 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.
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)
   Australia (AICS): Present
   EU EINECS/ELINCS List 242-354-0

Cetylpyridinium chloride
   Inventory - United States TSCA - Sect. 8(b)
   Australia (AICS): Present
   EU EINECS/ELINCS List 204-593-9

Glycerin, USP
   Inventory - United States TSCA - Sect. 8(b)
   Australia (AICS): Present
   REACH - Annex V - Exemptions from the obligations of Register:
   EU EINECS/ELINCS List

Acesulfame potassium salt
   Australia (AICS): Present
   EU EINECS/ELINCS List 259-715-3
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