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

Product Identifier

Material Name: Tavaborole Topical Solution
Trade Name: KERYDIN
Chemical Family: Not determined

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Intended Use: Pharmaceutical product

Details of the Supplier of the Safety Data Sheet

Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
New York, New York 10017
1-800-879-3477

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
Contact E-Mail: pfizer-MSDS@pfizer.com

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification
Serious Eye Damage/Eye Irritation: Category 1
Flammable liquids- Category 2

Label Elements

Signal Word: Danger
Hazard Statements: H318 - Causes serious eye damage
H225 - Highly flammable liquid and vapor

Precautionary Statements:
P210 - Keep away from heat/sparks/open flames/hot surfaces. - No smoking
P233 - Keep container tightly closed
P264 - Wash hands thoroughly after handling
P280 - Wear protective gloves/protective clothing/eye protection/face protection
P303 + P361 + P353 - IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water шуаер
P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P337 + P313 - If eye irritation persists: Get medical advice/attention
P403 + P235 - Store in a well-ventilated place. Keep cool
P501 - Dispose of contents/container in accordance with all local and national regulations
Other Hazards

An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

Note:

This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning 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>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tavaborole</td>
<td>174671-46-6</td>
<td>Not Listed</td>
<td>Eye Irrit. 1 (H318)</td>
<td>5</td>
</tr>
<tr>
<td>Ethyl alcohol (ethanol)</td>
<td>64-17-5</td>
<td>200-578-6</td>
<td>Flam. Liq. 2 (H225)</td>
<td>72</td>
</tr>
<tr>
<td>Propylene glycol</td>
<td>57-55-6</td>
<td>200-338-0</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Edetate calcium disodium</td>
<td>62-33-9</td>
<td>200-529-9</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. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

For the full text of the CLP/GHS abbreviations mentioned in this Section, see Section 16

4. FIRST AID MEASURES

Description of 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.

Most Important Symptoms and Effects, Both Acute and Delayed

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.
SAFETY DATA SHEET

Material Name: Tavaborole Topical Solution
Revision date: 22-Jun-2018
Version: 2.0

Medical Conditions

Aggravated by Exposure: None known

Indication of the Immediate Medical Attention and Special Treatment Needed

Notes to Physician: None

5. FIRE FIGHTING MEASURES

Extinguishing Media: Extinguish fires with CO2, extinguishing powder, foam, or water.

Special Hazards Arising from the Substance or Mixture

Hazardous Combustion: Formation of toxic gases is possible during heating or fire.

Products:

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

Advice for Fire-Fighters

During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures

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

Environmental Precautions

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

Methods and Material for Containment and Cleaning Up

Measures for Cleaning / Collecting: Remove all sources of ignition. Contain the source of the spill if it is safe to do so. Absorb spills with non-combustible absorbent material and transfer into a labeled container for disposal. Clean spill area thoroughly.

Additional Consideration for Large Spills:

Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Cleanup operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

Precautions for Safe Handling

Flammable liquid and vapor - keep away from ignition sources and clean up spills promptly. Eliminate possible ignition sources (e.g., heat, sparks, flame, impact, friction, electricity), and follow appropriate grounding and bonding procedures. Avoid contact with eyes, skin, and clothing. Use appropriate personal protective equipment. Wash thoroughly after handling. Avoid inhalation and contact with skin, eye, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. 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.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions: Store as directed by product packaging.

Specific end use(s): Pharmaceutical drug product

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters

Refer to available public information for specific member state Occupational Exposure Limits.
### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

#### Tavaborole

<table>
<thead>
<tr>
<th>Source</th>
<th>Value 1</th>
<th>Value 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pfizer OEL TWA-8 Hr</td>
<td>1000 ppm</td>
<td>3000 µg/m³</td>
</tr>
</tbody>
</table>

#### Ethyl alcohol (ethanol)

<table>
<thead>
<tr>
<th>Source</th>
<th>Value 1</th>
<th>Value 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACGIH Threshold Limit Value (STEL)</td>
<td>1000 ppm</td>
<td></td>
</tr>
<tr>
<td>Australia TWA</td>
<td>1000 ppm</td>
<td>1880 mg/m³</td>
</tr>
<tr>
<td>Austria OEL - MAKs</td>
<td>1000 ppm</td>
<td>1900 mg/m³</td>
</tr>
<tr>
<td>Belgium OEL - TWA</td>
<td>1000 ppm</td>
<td>1907 mg/m³</td>
</tr>
<tr>
<td>Bulgaria OEL - TWA</td>
<td>1000 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Czech Republic OEL - TWA</td>
<td>1000 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Denmark OEL - TWA</td>
<td>1000 ppm</td>
<td>1900 mg/m³</td>
</tr>
<tr>
<td>Estonia OEL - TWA</td>
<td>500 ppm</td>
<td>1000 mg/m³</td>
</tr>
<tr>
<td>Finland OEL - TWA</td>
<td>1000 ppm</td>
<td>1900 mg/m³</td>
</tr>
<tr>
<td>France OEL - TWA</td>
<td>1000 ppm</td>
<td>1900 mg/m³</td>
</tr>
<tr>
<td>Germany - TRGS 900 - TWAs</td>
<td>500 ppm</td>
<td>960 mg/m³</td>
</tr>
<tr>
<td>Germany (DFG) - MAK</td>
<td>500 ppm</td>
<td>960 mg/m³</td>
</tr>
<tr>
<td>Greece OEL - TWA</td>
<td>1000 ppm</td>
<td>1900 mg/m³</td>
</tr>
<tr>
<td>Hungary OEL - TWA</td>
<td>1900 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Latvia OEL - TWA</td>
<td>1000 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Lithuania OEL - TWA</td>
<td>500 ppm</td>
<td>1000 mg/m³</td>
</tr>
</tbody>
</table>

#### Netherlands OEL - TWA

<table>
<thead>
<tr>
<th>Value 1</th>
<th>Value 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>260 mg/m³</td>
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</tr>
</tbody>
</table>

#### OSHA - Final PELS - TWAs:

<table>
<thead>
<tr>
<th>Value 1</th>
<th>Value 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>1000 ppm</td>
<td>1900 mg/m³</td>
</tr>
</tbody>
</table>

#### Poland OEL - TWA

<table>
<thead>
<tr>
<th>Value 1</th>
<th>Value 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>1900 mg/m³</td>
<td></td>
</tr>
</tbody>
</table>

#### Portugal OEL - TWA

<table>
<thead>
<tr>
<th>Value 1</th>
<th>Value 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>1000 ppm</td>
<td></td>
</tr>
</tbody>
</table>

#### Romania OEL - TWA

<table>
<thead>
<tr>
<th>Value 1</th>
<th>Value 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>1000 ppm</td>
<td>1900 mg/m³</td>
</tr>
</tbody>
</table>

#### Russia OEL - TWA

<table>
<thead>
<tr>
<th>Value 1</th>
<th>Value 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>1000 mg/m³</td>
<td></td>
</tr>
</tbody>
</table>

#### Slovakia OEL - TWA

<table>
<thead>
<tr>
<th>Value 1</th>
<th>Value 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>500 ppm</td>
<td>960 mg/m³</td>
</tr>
</tbody>
</table>

#### Slovenia OEL - TWA

<table>
<thead>
<tr>
<th>Value 1</th>
<th>Value 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>1000 ppm</td>
<td>1900 mg/m³</td>
</tr>
</tbody>
</table>

#### Sweden OEL - TWAs

<table>
<thead>
<tr>
<th>Value 1</th>
<th>Value 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>500 ppm</td>
<td>1000 mg/m³</td>
</tr>
</tbody>
</table>

#### Switzerland OEL - TWAs

<table>
<thead>
<tr>
<th>Value 1</th>
<th>Value 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>500 ppm</td>
<td>960 mg/m³</td>
</tr>
</tbody>
</table>

#### Vietnam OEL - TWAs

<table>
<thead>
<tr>
<th>Value 1</th>
<th>Value 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>1000 mg/m³</td>
<td></td>
</tr>
</tbody>
</table>

#### Propylene glycol
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**Exposure Controls**

**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 below recommended exposure limits.

**Personal Protective Equipment:** Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.

**Hands:** Impervious gloves (e.g. Nitrile, etc.) are recommended if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.)

**Eyes:** Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)

**Skin:** Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)

**Respiratory protection:** 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 (e.g. particulate respirator with a half mask, P3 filter). (Respirators must meet the standards in accordance with EN149, EN143, ASTM F2704-10 or international equivalent.)

9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Physical State:</th>
<th>Liquid</th>
</tr>
</thead>
<tbody>
<tr>
<td>Odor:</td>
<td>No data available</td>
</tr>
<tr>
<td>Molecular Formula:</td>
<td>Mixture</td>
</tr>
<tr>
<td>Color:</td>
<td>No data available</td>
</tr>
<tr>
<td>Odor Threshold:</td>
<td>No data available</td>
</tr>
<tr>
<td>Molecular Weight:</td>
<td>Mixture</td>
</tr>
</tbody>
</table>

**Solvent Solubility:** No data available

**Water Solubility:** No data available

**pH:** No data available

**Melting/Freezing Point (°C):** No data available

**Boiling Point (°C):** No data available

**Partition Coefficient: (Method, pH, Endpoint, Value)**

- **Tavaborole:** No data available
- **Propylene glycol:** No data available
- **Edetate calcium disodium:** No data available
- **Ethyl alcohol (ethanol):** No data available

**Decomposition Temperature (°C):** No data available
Evaporation Rate (Gram/s): No data available
Vapor Pressure (kPa): No data available
Vapor Density (g/ml): No data available
Relative Density: No data available
Viscosity: No data available

Flammability:
  - Autoignition Temperature (Solid) (°C): No data available
  - Flammability (Solids): No data available
  - Flash Point (Liquid) (°C): No data available
  - Upper Explosive Limits (Liquid) (% by Vol.): No data available
  - Lower Explosive Limits (Liquid) (% by Vol.): No data available

10. STABILITY AND REACTIVITY

Reactivity: No data available
Chemical Stability: Stable under normal conditions of use.
Possibility of Hazardous Reactions
  - Oxidizing Properties: No data available
  - 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
  - Hazardous Decomposition Products: No data available

11. TOXICOLOGICAL INFORMATION

Information on Toxicological Effects
General Information: The following information is available for the individual ingredients.
Known Clinical Effects: Adverse effects associated with therapeutic use include abnormal redness of skin (erythema), red, itchy, scaly skin (exfoliative dermatitis)

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

Propylene glycol
  - Rat Oral LD 50 22,000 mg/kg
  - Mouse Oral LD 50 24,900mg/kg
  - Rabbit Dermal LD 50 20,800mg/kg

Ethyl alcohol (ethanol)
  - Mouse Oral LD50 3450 mg/kg
  - Rat Oral LD50 7060mg/kg
  - Rat Inhalation LC50 10h 20,000ppm

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

Tavaborole
  - Skin Irritation Rabbit Negative
  - Eye Irritation Rabbit Positive
  - Skin Sensitization - M & K Guinea Pig Negative

Propylene glycol
  - Skin Irritation Rabbit Mild
### 11. ToxicoLOGICAL INFORMATION

**Eye Irritation**
- **Rabbit**
  - **Mild**

**Ethyl alcohol (ethanol)**
- **Eye Irritation**
  - **Rabbit**
    - **Severe**
- **Skin Irritation**
  - **Rabbit**
    - **Mild**

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

<table>
<thead>
<tr>
<th>Tavaborole</th>
<th>6 Month(s)</th>
<th>Rat</th>
<th>Oral 30 mg/kg/day</th>
<th>NOAEL</th>
<th>Gastrointestinal System</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>6 Month(s)</td>
<td>Rat</td>
<td>Dermal 8.9 mg/kg/day</td>
<td>NOAEL</td>
<td>No effects at maximum dose</td>
</tr>
<tr>
<td></td>
<td>6 Month(s)</td>
<td>Rat</td>
<td>Dermal 0.9 mg/kg/day</td>
<td>NOAEL</td>
<td>Skin</td>
</tr>
</tbody>
</table>

#### Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))

<table>
<thead>
<tr>
<th>Tavaborole</th>
<th>Embryo / Fetal Development</th>
<th>Rat</th>
<th>Oral 100 mg/kg/day</th>
<th>NOAEL</th>
<th>Fetotoxicity</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Embryo / Fetal Development</td>
<td>Rabbit</td>
<td>Oral 50 mg/kg/day</td>
<td>NOAEL</td>
<td>Fetotoxicity</td>
</tr>
</tbody>
</table>

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

**Tavaborole**
- **In Vitro** Bacterial Mutagenicity (Ames)  _Salmonella_, _E. coli_  Negative
- **In Vitro** Chromosome Aberration  Human Lymphocytes  Negative
- **In Vivo** Micronucleus  Rat  Negative

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

<table>
<thead>
<tr>
<th>Tavaborole</th>
<th>2 Year(s)</th>
<th>Rat</th>
<th>Oral 50 mg/kg/day</th>
<th>NOAEL</th>
<th>Not carcinogenic</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2 Year(s)</td>
<td>Mouse</td>
<td>Dermal 15 %</td>
<td>NOAEL</td>
<td>Not carcinogenic</td>
</tr>
</tbody>
</table>

**Carcinogen Status:**
Carcinogenicity of the mixture has not been determined. Alcohol is listed as a carcinogen by IARC. The IARC monograph examining the carcinogenic potential of ethanol examined only alcoholic beverages. No other components are listed as carcinogens by IARC, US OSHA or NTP.

**Ethyl alcohol (ethanol)**
- **IARC:**
  - Group 1 (Carcinogenic to Humans)

### 12. ECOLOGICAL INFORMATION

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

**Toxicity:**

**Aquatic Toxicity: (Species, Method, End Point, Duration, Result)**
Ethyl alcohol (ethanol)
Onchorhynchus mykiss (Rainbow Trout)  LC50/96h  12,900-15,300 mg/L

Persistence and Degradability:  No data available
Ethyl alcohol (ethanol)  Not Ready

Bio-accumulative Potential:  No data available
Mobility in Soil:  No data available

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.

This material is regulated for transportation as a hazardous material/dangerous good.

UN number:  UN 1170
UN proper shipping name:  Ethanol solution
Transport hazard class(es):  3
Packing group:  II

15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Tavaborole
CERCLA/SARA 313 Emission reporting  Not Listed
California Proposition 65  Not Listed
EU EINECS/ELINCS List  Not Listed

Edetate calcium disodium
CERCLA/SARA 313 Emission reporting  Not Listed

PZ03672
15. REGULATORY INFORMATION

California Proposition 65
Inventory - United States TSCA - Sect. 8(b)
Australia (AICS):
EU EINECS/ELINCS List
Ethyl alcohol (ethanol)
CERCLA/SARA 313 Emission reporting
California Proposition 65
Inventory - United States TSCA - Sect. 8(b)
Australia (AICS):
EU EINECS/ELINCS List
Propylene glycol
CERCLA/SARA 313 Emission reporting
California Proposition 65
Inventory - United States TSCA - Sect. 8(b)
Australia (AICS):
EU EINECS/ELINCS List

16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3
Serious eye damage/eye irritation-Cat.2A; H319 - Causes serious eye irritation
Flammable liquids-Cat.2; H225 - Highly flammable liquid and vapor

Data Sources: Pfizer proprietary drug development information. Safety data sheets for individual ingredients. Publicly available toxicity information.

Reasons for Revision: Updated Section 14 - Transport Information.

Revision date: 22-Jun-2018

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