SAFETY DATA SHEET

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

Product Identifier

<table>
<thead>
<tr>
<th>Material Name: Tafamidis Capsules, 61 mg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trade Name: VYNDAMAX</td>
</tr>
<tr>
<td>Chemical Family: Not determined</td>
</tr>
</tbody>
</table>

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
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

Emergency telephone number:
International Chemtrec (24 hours): +1-703-527-3887

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

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS - Classification

Reproductive Toxicity: Category 1B

Label Elements

<table>
<thead>
<tr>
<th>Signal Word: Danger</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hazard Statements: H360D - May damage the unborn child</td>
</tr>
</tbody>
</table>

Precautionary Statements:

P201 - Obtain special instructions before use
P202 - Do not handle until all safety precautions have been read and understood
P281 - Use personal protective equipment as required
P308 + P313 - IF exposed or concerned: Get medical attention/advice
P405 - Store locked up
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>Ammonium hydroxide</td>
<td>1336-21-6</td>
<td>215-647-6</td>
<td>Skin Corr. 1B (H314)</td>
<td>&lt;1.0</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Aquatic Acute 1 (H400)</td>
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</tr>
<tr>
<td>Butylated hydroxytoluene</td>
<td>128-37-0</td>
<td>204-881-4</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>ETHYL ALCOHOL</td>
<td>64-17-5</td>
<td>200-578-6</td>
<td>Flam. Liq. 2 (H225)</td>
<td>*</td>
</tr>
<tr>
<td>Iron oxide</td>
<td>1309-37-1</td>
<td>215-168-2</td>
<td>Not Listed</td>
<td>*</td>
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<tr>
<td>Isopropyl alcohol</td>
<td>67-63-0</td>
<td>200-661-7</td>
<td>STOT SE 3 (H336)</td>
<td>&lt;1.0</td>
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<td></td>
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<td>Flam. Liq. 2 (H225)</td>
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<td></td>
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<td></td>
<td>Eye Irrit. 2A (H319)</td>
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<td>Polyethylene glycol 400</td>
<td>25322-68-3</td>
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<td>Tafamidis</td>
<td>594839-88-0</td>
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<td>Repr.1B (H360D)</td>
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<tr>
<td>Titanium dioxide</td>
<td>13463-67-7</td>
<td>236-675-5</td>
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<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>GHS Classification</th>
<th>%</th>
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</thead>
<tbody>
<tr>
<td>Gelatin</td>
<td>9000-70-8</td>
<td>232-554-6</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Glycerin, USP</td>
<td>56-81-5</td>
<td>200-289-5</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Polysorbate 20</td>
<td>9005-64-5</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Polyvinyl Acetate Phthalate</td>
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<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
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<tr>
<td>Povidone</td>
<td>9003-39-8</td>
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<td>Not Listed</td>
<td>*</td>
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<tr>
<td>Propylene glycol</td>
<td>57-55-6</td>
<td>200-338-0</td>
<td>Not Listed</td>
<td>*</td>
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<tr>
<td>Purified water</td>
<td>7732-18-5</td>
<td>231-791-2</td>
<td>Not Listed</td>
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<tr>
<td>Sorbitol</td>
<td>6706-59-8</td>
<td>Not Listed</td>
<td>Not Listed</td>
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</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.
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 Products: Formation of toxic gases is possible during heating or fire.

Fire / Explosion Hazards: 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: Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. 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
Minimize dust generation and accumulation. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. 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.

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.

Butylated hydroxytoluene

ACGIH Threshold Limit Value (TWA) 2 mg/m³
Australia TWA 10 mg/m³
Austria OEL - MAKs 10 mg/m³
Belgium OEL - TWA 2 mg/m³
Bulgaria OEL - TWA 10 mg/m³
Denmark OEL - TWA 10 mg/m³
Finland OEL - TWA 10 mg/m³
France OEL - TWA 10 mg/m³
Germany - TRGS 900 - TWAs 10 mg/m³
Germany (DFG) - MAK 10 mg/m³ can occur as vapor and aerosol at the same time
Greece OEL - TWA 10 mg/m³
Ireland OEL - TWAs 10 mg/m³
Portugal OEL - TWA 2 mg/m³
Slovenia OEL - TWA 10 mg/m³
Spain OEL - TWA 10 mg/m³
Switzerland OEL - TWAs 10 mg/m³

ETHYL ALCOHOL

ACGIH Threshold Limit Value (STEL) 1000 ppm
Australia TWA 1000 ppm
1880 mg/m³
Austria OEL - MAKs 1000 ppm
1900 mg/m³
Belgium OEL - TWA 1000 ppm
1907 mg/m³
Bulgaria OEL - TWA 1000 mg/m³
Czech Republic OEL - TWA 1000 mg/m³
Denmark OEL - TWA 1000 ppm
1900 mg/m³
Estonia OEL - TWA 500 ppm
1000 mg/m³
Finland OEL - TWA 1000 ppm
1900 mg/m³
France OEL - TWA 1000 ppm
1900 mg/m³
Germany - TRGS 900 - TWAs 500 ppm
960 mg/m³
Germany (DFG) - MAK 500 ppm
960 mg/m³
Greece OEL - TWA 1000 ppm
1900 mg/m³
Hungary OEL - TWA 1900 mg/m³
Latvia OEL - TWA 1000 mg/m³
Lithuania OEL - TWA 500 ppm
1000 mg/m³
Netherlands OEL - TWA 260 mg/m³
OSHA - Final PELs - TWAs: 1000 ppm
1900 mg/m³
### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<table>
<thead>
<tr>
<th>Country</th>
<th>Unit</th>
<th>Level</th>
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<tbody>
<tr>
<td>Poland OEL - TWA</td>
<td>mg/m³</td>
<td>1900</td>
</tr>
<tr>
<td>Portugal OEL - TWA</td>
<td>ppm</td>
<td>1000</td>
</tr>
<tr>
<td>Romania OEL - TWA</td>
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<tr>
<td>Russia OEL - TWA</td>
<td>mg/m³</td>
<td>1000</td>
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<tr>
<td>Slovakia OEL - TWA</td>
<td>ppm</td>
<td>500</td>
</tr>
<tr>
<td>Slovenia OEL - TWA</td>
<td>ppm</td>
<td>1900</td>
</tr>
<tr>
<td>Sweden OEL - TWA</td>
<td>ppm</td>
<td>1000</td>
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<tr>
<td>Switzerland OEL -TWA</td>
<td>ppm</td>
<td>500</td>
</tr>
<tr>
<td>Vietnam OEL - TWAs</td>
<td>mg/m³</td>
<td>1000</td>
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</table>

**Glycerin, USP**

<table>
<thead>
<tr>
<th>Country</th>
<th>Unit</th>
<th>Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia TWA</td>
<td>mg/m³</td>
<td>10</td>
</tr>
<tr>
<td>Belgium OEL - TWA</td>
<td>mg/m³</td>
<td>10</td>
</tr>
<tr>
<td>Czech Republic OEL - TWA</td>
<td>mg/m³</td>
<td>10</td>
</tr>
<tr>
<td>Estonia OEL - TWA</td>
<td>mg/m³</td>
<td>20</td>
</tr>
<tr>
<td>Finland OEL - TWA</td>
<td>mg/m³</td>
<td>10</td>
</tr>
<tr>
<td>France OEL - TWA</td>
<td>mg/m³</td>
<td>10</td>
</tr>
<tr>
<td>Germany (DFG) - MAK</td>
<td>mg/m³</td>
<td>200</td>
</tr>
<tr>
<td>Greece OEL - TWA</td>
<td>mg/m³</td>
<td>10</td>
</tr>
<tr>
<td>Ireland OEL - TWAs</td>
<td>mg/m³</td>
<td>10</td>
</tr>
<tr>
<td>OSHA - Final PELS - TWAs:</td>
<td>mg/m³</td>
<td>15</td>
</tr>
<tr>
<td>Poland OEL - TWA</td>
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<td>Portugal OEL - TWA</td>
<td>mg/m³</td>
<td>10</td>
</tr>
<tr>
<td>Spain OEL - TWA</td>
<td>mg/m³</td>
<td>10</td>
</tr>
<tr>
<td>Switzerland OEL -TWA</td>
<td>mg/m³</td>
<td>50</td>
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**Iron oxide**

<table>
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<tr>
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<tr>
<td>Australia TWA</td>
<td>mg/m³</td>
<td>5</td>
</tr>
<tr>
<td>Austria OEL - MAKs</td>
<td>mg/m³</td>
<td>5</td>
</tr>
<tr>
<td>Belgium OEL - TWA</td>
<td>mg/m³</td>
<td>5</td>
</tr>
<tr>
<td>Bulgaria OEL - TWA</td>
<td>mg/m³</td>
<td>5.0</td>
</tr>
<tr>
<td>Denmark OEL - TWA</td>
<td>mg/m³</td>
<td>3.5</td>
</tr>
<tr>
<td>Estonia OEL - TWA</td>
<td>mg/m³</td>
<td>3.5</td>
</tr>
<tr>
<td>Finland OEL - TWA</td>
<td>mg/m³</td>
<td>5</td>
</tr>
<tr>
<td>France OEL - TWA</td>
<td>mg/m³</td>
<td>5</td>
</tr>
<tr>
<td>Greece OEL - TWA</td>
<td>mg/m³</td>
<td>10</td>
</tr>
<tr>
<td>Hungary OEL - TWA</td>
<td>mg/m³</td>
<td>6</td>
</tr>
<tr>
<td>Ireland OEL - TWAs</td>
<td>mg/m³</td>
<td>5</td>
</tr>
<tr>
<td>Lithuania OEL - TWA</td>
<td>mg/m³</td>
<td>3.5</td>
</tr>
<tr>
<td>OSHA - Final PELS - TWAs:</td>
<td>mg/m³</td>
<td>10</td>
</tr>
<tr>
<td>Poland OEL - TWA</td>
<td>mg/m³</td>
<td>5</td>
</tr>
<tr>
<td>Portugal OEL - TWA</td>
<td>mg/m³</td>
<td>5</td>
</tr>
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</table>

PZ03734
### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<table>
<thead>
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<th>Value</th>
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<tbody>
<tr>
<td>Romania OEL - TWA</td>
<td>5 mg/m³</td>
</tr>
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<td>6 mg/m³</td>
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<td>Slovakia OEL - TWA</td>
<td>1.5 mg/m³</td>
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<tr>
<td>Spain OEL - TWA</td>
<td>5 mg/m³</td>
</tr>
<tr>
<td>Sweden OEL - TWAs</td>
<td>3.5 mg/m³</td>
</tr>
<tr>
<td>Switzerland OEL - TWAs</td>
<td>3 mg/m³</td>
</tr>
<tr>
<td>Vietnam OEL - TWAs</td>
<td>5 mg/m³</td>
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</table>

Isopropyl alcohol

<table>
<thead>
<tr>
<th>Description</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACGIH Threshold Limit Value (TWA)</td>
<td>200 ppm</td>
</tr>
<tr>
<td>ACGIH Threshold Limit Value (STEL)</td>
<td>400 ppm</td>
</tr>
<tr>
<td>ACGIH - Biological Exposure Limit:</td>
<td>40 mg/L</td>
</tr>
<tr>
<td>Australia STEL</td>
<td>500 ppm</td>
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<tr>
<td></td>
<td>1230 mg/m³</td>
</tr>
<tr>
<td>Australia TWA</td>
<td>400 ppm</td>
</tr>
<tr>
<td></td>
<td>983 mg/m³</td>
</tr>
<tr>
<td>Austria OEL - MAKs</td>
<td>200 ppm</td>
</tr>
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<td>500 mg/m³</td>
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<tr>
<td>Belgium OEL - TWA</td>
<td>200 ppm</td>
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<td>500 mg/m³</td>
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<tr>
<td>Bulgaria OEL - TWA</td>
<td>980.0 mg/m³</td>
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<td>Czech Republic OEL - TWA</td>
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<td>200 ppm</td>
</tr>
<tr>
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<td>490 mg/m³</td>
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<td>Estonia OEL - TWA</td>
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<td>350 mg/m³</td>
</tr>
<tr>
<td>Finland OEL - TWA</td>
<td>200 ppm</td>
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<td>500 mg/m³</td>
</tr>
<tr>
<td>Germany - TRGS 900 - TWAs</td>
<td>200 ppm</td>
</tr>
<tr>
<td></td>
<td>500 mg/m³</td>
</tr>
<tr>
<td>Germany (DFG) - MAK</td>
<td>200 ppm</td>
</tr>
<tr>
<td></td>
<td>500 mg/m³</td>
</tr>
<tr>
<td>Germany - Biological Exposure Limit:</td>
<td>25 mg/L</td>
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<tr>
<td>Greece OEL - TWA</td>
<td>400 ppm</td>
</tr>
<tr>
<td></td>
<td>980 mg/m³</td>
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<td>Ireland OEL - TWAs</td>
<td>200 ppm</td>
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<td>Japan - OELs - Ceilings</td>
<td>400 ppm</td>
</tr>
<tr>
<td></td>
<td>980 mg/m³</td>
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<tr>
<td>Latvia OEL - TWA</td>
<td>350 mg/m³</td>
</tr>
<tr>
<td>Lithuania OEL - TWA</td>
<td>150 ppm</td>
</tr>
<tr>
<td></td>
<td>350 mg/m³</td>
</tr>
<tr>
<td>OSHA - Final PELS - TWAs</td>
<td>400 ppm</td>
</tr>
<tr>
<td></td>
<td>980 mg/m³</td>
</tr>
<tr>
<td>Poland OEL - TWA</td>
<td>900 mg/m³</td>
</tr>
<tr>
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<td>81 ppm</td>
</tr>
<tr>
<td></td>
<td>200 mg/m³</td>
</tr>
<tr>
<td>Romania - Biological Exposure Limit:</td>
<td>50 mg/L</td>
</tr>
<tr>
<td>Russia OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Slovakia OEL - TWA</td>
<td>200 ppm</td>
</tr>
<tr>
<td></td>
<td>500 mg/m³</td>
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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<table>
<thead>
<tr>
<th>Material Name</th>
<th>Limit Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Slovenia OEL - TWA</td>
<td>200 ppm</td>
</tr>
<tr>
<td>Spain OEL - TWA</td>
<td>200 ppm</td>
</tr>
<tr>
<td>Spain - Biological Exposure Limit:</td>
<td>40 mg/L</td>
</tr>
<tr>
<td>Sweden OEL - TWAs</td>
<td>150 ppm</td>
</tr>
<tr>
<td>Switzerland OEL -TWAs</td>
<td>200 ppm</td>
</tr>
<tr>
<td>Polyethylene glycol 400</td>
<td></td>
</tr>
<tr>
<td>Austria OEL - MAKs</td>
<td>1000 mg/m³</td>
</tr>
<tr>
<td>Germany - TRGS 900 - TWAs</td>
<td>1000 mg/m³</td>
</tr>
<tr>
<td>Germany (DFG) - MAK</td>
<td>1000 mg/m³ average molecular weight 200-600</td>
</tr>
<tr>
<td>Slovakia OEL - TWA</td>
<td>1000 mg/m³</td>
</tr>
<tr>
<td>Slovenia OEL - TWA</td>
<td>1000 mg/m³</td>
</tr>
<tr>
<td>Switzerland OEL -TWAs</td>
<td>1000 mg/m³</td>
</tr>
<tr>
<td>Propylene glycol</td>
<td></td>
</tr>
<tr>
<td>Australia TWA</td>
<td>150 ppm</td>
</tr>
<tr>
<td></td>
<td>474 mg/m³</td>
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<tr>
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<td>10 mg/m³</td>
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<tr>
<td>Ireland OEL - TWAs</td>
<td>150 ppm</td>
</tr>
<tr>
<td></td>
<td>470 mg/m³</td>
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<tr>
<td></td>
<td>10 mg/m³</td>
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<tr>
<td>Latvia OEL - TWA</td>
<td>7 mg/m³</td>
</tr>
<tr>
<td>Lithuania OEL - TWA</td>
<td>7 mg/m³</td>
</tr>
<tr>
<td>Tafamidis</td>
<td></td>
</tr>
<tr>
<td>Pfizer OEL TWA-8 Hr:</td>
<td>20 µg/m³</td>
</tr>
<tr>
<td>Titanium dioxide</td>
<td></td>
</tr>
<tr>
<td>ACGIH Threshold Limit Value (TWA)</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Australia TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Austria OEL - MAKs</td>
<td>5 mg/m³</td>
</tr>
<tr>
<td>Belgium OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Bulgaria OEL - TWA</td>
<td>10.0 mg/m³</td>
</tr>
<tr>
<td>Denmark OEL - TWA</td>
<td>6 mg/m³</td>
</tr>
<tr>
<td>Estonia OEL - TWA</td>
<td>5 mg/m³</td>
</tr>
<tr>
<td>France OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Greece OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td></td>
<td>5 mg/m³</td>
</tr>
<tr>
<td>Ireland OEL - TWAs</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td></td>
<td>4 mg/m³</td>
</tr>
<tr>
<td>Latvia OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Lithuania OEL - TWA</td>
<td>5 mg/m³</td>
</tr>
<tr>
<td>OSHA - Final PELS - TWAs:</td>
<td>15 mg/m³</td>
</tr>
<tr>
<td>Poland OEL - TWA</td>
<td>10.0 mg/m³</td>
</tr>
<tr>
<td>Portugal OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Romania OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Russia OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Spain OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Sweden OEL - TWAs</td>
<td>5 mg/m³</td>
</tr>
</tbody>
</table>
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure Controls

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.

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 EN140, EN143, ASTM F2704-10 or international equivalent.)

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State: Soft gelatin capsule
Odor: No data available.
Molecular Formula: Mixture

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)
Tafamidis Predicted 7.4 Log D -0.644
Gelatin No data available
Polyethylene glycol 400 No data available
Polysorbate 20 No data available
Povidone No data available
Butylated hydroxytoluene No data available
Iron oxide

Vietnam OEL - TWAs
3 mg/m³
5 mg/m³

Switzerland OEL - TWAs
6 mg/m³

Odor Threshold:
Predicted 7.4 Log D -0.644
9. PHYSICAL AND CHEMICAL PROPERTIES

No data available

**Purified water**
No data available

d-glucitol, 1-deoxy-1-(methylamino)-, 2-(3,5-dichlorophenyl)-6-benzoxazolecarboxylate
No data available

**ETHYL ALCOHOL**
No data available

**Glycerin, USP**
No data available

**Polyvinyl Acetate Phthalate**
No data available

**Propylene glycol**
No data available

**Titanium dioxide**
No data available

**Sorbitol**
No data available

**Ammonium hydroxide**
No data available

**Isopropyl alcohol**
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. As a precautionary measure, keep away from heat sources and electrostatic discharge.
- **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 information included in this section describes the potential hazards of various forms of the active ingredient and the individual ingredients.
**11. TOXICOLOGICAL INFORMATION**

**Known Clinical Effects:** Adverse effects most commonly reported in clinical use include headache, sleepiness (somnolence), infection, gastrointestinal disturbances, insomnia, muscle pain.

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

**Tafamidis**

Dog  Oral  Maximally Tolerated Dose  > 600 mg/kg

**Butylated hydroxytoluene**

Rat  Oral  LD50  1700 mg/kg  
Mouse  Oral  LD50  650 mg/kg  
Rat  Oral  LD50  890 mg/kg  
Mouse  Intraperitoneal  LD 50  138 mg/kg

**ETHYL ALCOHOL**

Rat  Oral  LD 50  7060 mg/kg  
Rat  IV  LD 50  1440mg/kg  
Rat  Inhalation  LC 50  124700mg/m³

**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

**Propylene glycol**

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

**Titanium dioxide**

Rat  Oral  LD50  > 7500 mg/kg  
Rat  Subcutaneous  LD50  50 mg/kg

**Ammonium hydroxide**

Rat  Oral  LD50  350 mg/kg

**Isopropyl alcohol**

Rat  Oral  LD50  > 2000 mg/kg  
Mouse  Oral  LD50  3600 mg/kg  
Rat  Inhalation  LC50-8h  16,000 ppm  
Rabbit  Dermal  LD50  12800 mg/kg  
Rat  Inhalation  LC50  30mg/L

**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)**

**Tafamidis**
11. TOXICOLOGICAL INFORMATION

Skin Corrosivity (In vitro, RHE) Not applicable Negative
Eye Irritation (In vitro, BCOP) Not applicable Negative
Skin Sensitization - LLNA Mouse Negative
Skin Irritation Rabbit Negative
Eye Irritation Rabbit Minimal

**Polyethylene glycol 400**
Eye Irritation Rabbit Mild
Skin Irritation Rabbit Mild

**Butylated hydroxytoluene**
Eye Irritation Rabbit Moderate
Skin Irritation Rabbit Moderate

**d-glucitol, 1-deoxy-1-(methylamino)-, 2-(3,5-dichlorophenyl)-6-benzoxazolecarboxylate**
Eye Irritation (In vitro, BCOP) Not applicable Mild
Skin Corrosivity (In vitro, RHE) Not applicable Negative
Eye Irritation Rabbit Minimal
Skin Irritation Rabbit Negative
Skin Sensitization - LLNA Mouse Negative

**Glycerin, USP**
Eye Irritation Rabbit Mild

**Propylene glycol**
Skin Irritation Rabbit Mild
Eye Irritation Rabbit Mild

**Ammonium hydroxide**
Eye Irritation Rabbit Severe

**Isopropyl alcohol**
Eye Irritation Rabbit Severe
Skin Irritation Rabbit Mild

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

**Tafamidis**
- 10 Day(s) Rat Oral 100 mg/kg/day NOAEL None identified
- 7 Day(s) Dog Oral 300 mg/kg/day NOAEL None identified

**Butylated hydroxytoluene**
- 4 Week(s) Rat Oral 5185 mg/kg LOAEL Liver
- 4 Day(s) Mouse Oral 2000 mg/kg LOAEL Liver, Kidney, Ureter, Bladder

**d-glucitol, 1-deoxy-1-(methylamino)-, 2-(3,5-dichlorophenyl)-6-benzoxazolecarboxylate**
- 28 Day(s) Mouse Oral 10 mg/kg/day NOAEL Liver
- 28 Day(s) Rat Oral 30 mg/kg/day NOAEL Thymus, Gastrointestinal system
- 13 Week(s) Rat Oral 30 mg/kg/day NOAEL None identified
11. TOXICOLOGICAL INFORMATION

28 Day(s) Dog Oral 10 mg/kg/day NOAEL Gastrointestinal system, Liver
39 Week(s) Dog Oral 45 mg/kg/day NOAEL None identified
26 Week(s) Rat Oral 30 mg/kg/day NOAEL No effects at maximum dose
28 Day(s) Mouse Oral 120 mg/kg/day LOAEL Liver Lymphoid tissue

**Isopropyl alcohol**

20 Week(s) Rat Inhalation 4000 ppm NOAEL Liver, Central nervous system
104 Week(s) Rat Inhalation 5000 ppm Kidney

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

**Butylated hydroxytoluene**

Embryo / Fetal Development Rat Oral 6 g/kg LOEL Teratogenic,

d-glucitol, 1-deoxy-1-(methylamino)-, 2-(3,5-dichlorophenyl)-6-benzoxazolecarboxylate

Reproductive & Fertility Rat Oral 30 mg/kg/day NOEL Paternal toxicity, Reproductive toxicity
Reproductive & Fertility Rat Oral (F) 30 mg/kg/day LOAEL Maternal Toxicity
Embryo / Fetal Development Rat Oral 45 mg/kg/day LOAEL Maternal Toxicity
Embryo / Fetal Development Rat Oral 30 mg/kg/day LOAEL Fetal toxicity
Embryo / Fetal Development Rabbit Oral 2 mg/kg/day LOAEL Maternal Toxicity
Embryo / Fetal Development Rabbit Oral 0.5 mg/kg/day LOAEL Fetal toxicity
Prenatal & Postnatal Development Rat Oral 15 mg/kg/day LOAEL Fetal toxicity

**Isopropyl alcohol**

Prenatal & Postnatal Development Rat Inhalation 7,000 ppm LOAEL Maternal toxicity, Fetal toxicity, Embryotoxicity
2 Generation Reproductive Toxicity Rat Oral 1000 mg/kg/day LOAEL Maternal Toxicity, Fetal mortality
Prenatal & Postnatal Development Rat Oral 1200 mg/kg/day NOAEL No effects at maximum dose,

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

d-glucitol, 1-deoxy-1-(methylamino)-, 2-(3,5-dichlorophenyl)-6-benzoxazolecarboxylate

Bacterial Mutagenicity (Ames) *Salmonella* , *E. coli* Negative
Chromosome Aberration Human Lymphocytes Negative
*In Vivo* Micronucleus Rat Bone Marrow Negative

**Isopropyl alcohol**

Bacterial Mutagenicity (Ames) *Salmonella* Negative
Mammalian Cell Mutagenicity HGPRT Chinese Hamster Ovary (CHO) cells Negative
*In Vitro* Sister Chromatid Exchange Negative

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

d-glucitol, 1-deoxy-1-(methylamino)-, 2-(3,5-dichlorophenyl)-6-benzoxazolecarboxylate

26 Week(s) Mouse Oral 90 mg/kg/week NOAEL None identified

**Carcinogen Status:** See below

**Povidone**

IARC: Group 3 (Not Classifiable)
11. TOXICOLOGICAL INFORMATION

Butylated hydroxytoluene
IARC: Group 3 (Not Classifiable)

Iron oxide
IARC: Group 3 (Not Classifiable)

ETHYL ALCOHOL
IARC: Group 1 (Carcinogenic to Humans)

Titanium dioxide
IARC: Group 2B (Possibly Carcinogenic to Humans)

Isopropyl alcohol
IARC: Group 3 (Not Classifiable)

12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties of the formulation have not been investigated. Releases to the environment should be avoided. The following information is available for the individual ingredients.

Toxicity:

ETHYL ALCOHOL
Brachydanio rerio (Zebra fish) OECD NOEC 42 Hours 500 mg/L

Glycerin, USP
Oncorhynchus mykiss (Rainbow Trout) LC50 96 Hours 50 mg/L
Daphnia magna (Water Flea) EC50 24 Hours >500 mg/L

Ammonium hydroxide
Daphnia magna (Water Flea) LC50 48 Hours 0.66 mg/L
Leponis macrochirus (Bluegill Sunfish) LC50 48 Hours 0.024 mg/L
Pimephales promelas (Fathead Minnow) LC50 96 Hours 8.2 mg/L

Persistence and Degradability: No data available

Bio-accumulative Potential:
Partition Coefficient: (Method, pH, Endpoint, Value)
Tafamidis
Predicted 7.4 Log D -0.644

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.

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

15. REGULATORY INFORMATION

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

Ammonium hydroxide

CERCLA/SARA 313 Emission reporting: Not Listed
CERCLA/SARA Hazardous Substances and their Reportable Quantities: 1000 lb
California Proposition 65: Not Listed
Inventory - United States TSCA - Sect. 8(b): Present
Australia (AICS): Present
Standard for the Uniform Scheduling for Drugs and Poisons: Schedule 5
EU EINECS/ELINCS List: 215-647-6

Butylated hydroxytoluene

CERCLA/SARA 313 Emission reporting: Not Listed
California Proposition 65: Not Listed
Inventory - United States TSCA - Sect. 8(b): Present
Australia (AICS): Present
EU EINECS/ELINCS List: 204-881-4

ETHYL ALCOHOL

CERCLA/SARA 313 Emission reporting: Not Listed
carcinogen 4/29/2011 in alcoholic beverages
developmental toxicity 10/1/1987 in alcoholic beverages
California Proposition 65: Present
Inventory - United States TSCA - Sect. 8(b): Present
Australia (AICS): Present
EU EINECS/ELINCS List: 200-578-6
15. REGULATORY INFORMATION

Gelatin
  CERCLA/SARA 313 Emission reporting: Not Listed
  California Proposition 65: Not Listed
  Inventory - United States TSCA - Sect. 8(b): Present
  Australia (AICS): Present
  EU EINECS/ELINCS List: 232-554-6

Glycerin, USP
  CERCLA/SARA 313 Emission reporting: Not Listed
  California Proposition 65: Not Listed
  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, bio accumulative, and toxic or very persistent and very bio accumulative 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

Iron oxide
  CERCLA/SARA 313 Emission reporting: Not Listed
  California Proposition 65: Not Listed
  Inventory - United States TSCA - Sect. 8(b): Present
  Australia (AICS): Present
  EU EINECS/ELINCS List: 215-168-2

Isopropyl alcohol
  CERCLA/SARA 313 Emission reporting: 1.0 %
  California Proposition 65: Not Listed
  Inventory - United States TSCA - Sect. 8(b): Present
  Australia (AICS): Present
  EU EINECS/ELINCS List: 200-661-7

Polyethylene glycol 400
  CERCLA/SARA 313 Emission reporting: Not Listed
  California Proposition 65: Not Listed
  Inventory - United States TSCA - Sect. 8(b): Present
  Australia (AICS): Present
  Standard for the Uniform Scheduling for Drugs and Poisons: Schedule 2
  EU EINECS/ELINCS List: Not Listed

Polysorbate 20
  CERCLA/SARA 313 Emission reporting: Not Listed
  California Proposition 65: Not Listed
  Inventory - United States TSCA - Sect. 8(b): Present
  Australia (AICS): Present
  EU EINECS/ELINCS List: Not Listed
15. REGULATORY INFORMATION

Polyvinyl Acetate Phthalate
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- EU EINECS/ELINCS List: Not Listed

Povidone
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS): Present
- EU EINECS/ELINCS List: Not Listed

Propylene glycol
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS): Present
- EU EINECS/ELINCS List: 200-338-0

Purified water
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS): Present
- REACH - Annex IV - Exemptions from the obligations of Register:
  - EU EINECS/ELINCS List: 231-791-2

Sorbitol
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- EU EINECS/ELINCS List: Not Listed

Tafamidis
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- EU EINECS/ELINCS List: Not Listed

Titanium dioxide
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: carcinogen 9/2/2011 airborne, unbound particles of respirable size
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS): Present
- EU EINECS/ELINCS List: 236-675-5

16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3
Reproductive toxicity-Cat.1B; H360D - May damage the unborn child
Skin corrosion/irritation-Cat.1B; H314 - Causes severe skin burns and eye damage
Flammable gases-Cat.2; H225 - Highly flammable liquid and vapor
Specific target organ toxicity, single exposure; Narcotic effects-Cat.3; H336 - May cause drowsiness and dizziness
Serious eye damage/eye irritation-Cat.2A; H319 - Causes serious eye irritation
Hazardous to the aquatic environment, acute toxicity-Cat.1; H400 - Very toxic to aquatic life

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

Reasons for Revision: Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 12 - Ecological Information. Updated Section 11 - Toxicology Information. Updated Section 16 - Other Information.

Revision date: 06-May-2019
Prepared by: Product Stewardship Hazard Communication

Pfizer Inc believes that the information contained in this 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