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

Material Name: TOTELLE Cycle (Estradiol) Tablets

Trade Name: TOTELLE
Chemical Family: Mixture
Intended Use: Pharmaceutical product used as oral contraceptive

2. HAZARDS IDENTIFICATION

Appearance: Tablets
Signal Word: DANGER

Statement of Hazard:
May cause cancer.
May damage fertility or the unborn child.

Additional Hazard Information:

Short Term: Dust may be absorbed through the skin and cause systemic effects. May be harmful if swallowed. (based on components) Accidental ingestion may cause effects similar to those seen in clinical use.

Long Term: Occupational exposure to components of this mixture has resulted in menstrual irregularities in women and breast changes (enlargement, mammary secretions), loss of libido, and changes in sex hormone levels in men.

Known Clinical Effects: The use of oral contraceptives is associated with increased risks of myocardial infarction, thromboembolism, stroke, hepatic neoplasia, and gallbladder disease. The most common adverse effects seen during clinical use of oral contraceptives are menstrual irregularities.

EU Indication of danger: Carcinogenic: Category 1
Toxic to reproduction: Category 1

EU Hazard Symbols: T

EU Risk Phrases:
R45 - May cause cancer.
R60 - May impair fertility.
R61 - May cause harm to the unborn child.
R52/53 - Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
2. HAZARDS IDENTIFICATION


Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the product or its ingredients 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>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calcium sulfate</td>
<td>7778-18-9</td>
<td>231-900-3</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Estradiol</td>
<td>50-28-2</td>
<td>200-023-8</td>
<td>Carc.Cat.1;R45</td>
<td>0.3</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Repr.Cat.1;R60</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Repr.Cat.1;R61</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>N;R50/53</td>
<td></td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>209-150-3</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Microcrystalline cellulose</td>
<td>9004-34-6</td>
<td>232-674-9</td>
<td>Not Listed</td>
<td>*</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>Starch</td>
<td>9005-25-8</td>
<td>232-679-6</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Sucrose</td>
<td>57-50-1</td>
<td>200-334-9</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Talc (non-asbestiform)</td>
<td>14807-96-6</td>
<td>238-877-9</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Titanium dioxide</td>
<td>13463-67-7</td>
<td>236-675-5</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>

<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>Carnauba wax</td>
<td>8015-86-9</td>
<td>232-399-4</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Glyceril oleate</td>
<td>25496-72-4</td>
<td>247-038-6</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Lactose NF, monohydrate</td>
<td>64044-51-5</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
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<tr>
<td>Pharmaceutical glaze</td>
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<tr>
<td>Povidone</td>
<td>9003-39-8</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Red iron oxide</td>
<td>Not assigned</td>
<td>Not Listed</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 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.

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: Minimize dust generation and accumulation. If tablets or capsules are crushed and/or broken, Restrict access to work area. 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. Refer to Section 12 - Ecological Information, for information on potential effects on the environment. 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.

Calcium sulfate

<table>
<thead>
<tr>
<th>Source</th>
<th>Threshold Limit Value (TWA)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACGIH</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>France OEL - TWA</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Germany - TRGS 900 - TWAs</td>
<td>6 mg/m³</td>
</tr>
</tbody>
</table>
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<table>
<thead>
<tr>
<th>Material</th>
<th>Exposure Control</th>
<th>Limit Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Germany (DFG) - MAK</td>
<td></td>
<td>1.5 mg/m³ respirable fraction</td>
</tr>
<tr>
<td></td>
<td></td>
<td>4 mg/m³ inhalable fraction</td>
</tr>
<tr>
<td>Hungary OEL - TWA</td>
<td></td>
<td>6 mg/m³</td>
</tr>
<tr>
<td>Ireland OEL - TWAs</td>
<td></td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>OSHA - Final PELS - TWAs:</td>
<td></td>
<td>15 mg/m³</td>
</tr>
<tr>
<td>Poland OEL - TWA</td>
<td></td>
<td>10.0 mg/m³</td>
</tr>
<tr>
<td>Portugal OEL - TWA</td>
<td></td>
<td>10 mg/m³</td>
</tr>
<tr>
<td>Slovakia OEL - TWA</td>
<td></td>
<td>6 mg/m³</td>
</tr>
<tr>
<td>Slovenia OEL - TWA</td>
<td></td>
<td>6 mg/m³</td>
</tr>
<tr>
<td>Spain OEL - TWA</td>
<td></td>
<td>10 mg/m³</td>
</tr>
</tbody>
</table>

Estradiol

Pfizer OEL TWA-8 Hr: 0.2 µg/m³, Skin

Magnesium stearate

ACGIH Threshold Limit Value (TWA) 10 mg/m³
Lithuania OEL - TWA 5 mg/m³
Sweden OEL - TWAs 5 mg/m³

Microcrystalline cellulose

ACGIH Threshold Limit Value (TWA) 10 mg/m³
Australia TWA 10 mg/m³
Belgium OEL - TWA 10 mg/m³
Estonia OEL - TWA 10 mg/m³
France OEL - TWA 10 mg/m³
Ireland OEL - TWAs 10 mg/m³
Latvia OEL - TWA 2 mg/m³
OSHA - Final PELS - TWAs: 15 mg/m³
Portugal OEL - TWA 10 mg/m³
Romania OEL - TWA 10 mg/m³
Spain OEL - TWA 10 mg/m³

Propylene glycol

Australia TWA 150 ppm
474 mg/m³
10 mg/m³

Ireland OEL - TWAs 150 ppm
470 mg/m³
10 mg/m³

Latvia OEL - TWA 7 mg/m³
Lithuania OEL - TWA 7 mg/m³

Starch

ACGIH Threshold Limit Value (TWA) 10 mg/m³
Australia TWA 10 mg/m³
Belgium OEL - TWA 10 mg/m³
Bulgaria OEL - TWA 10.0 mg/m³
Czech Republic OEL - TWA 4.0 mg/m³
Greece OEL - TWA 10 mg/m³
5 mg/m³

Ireland OEL - TWAs 10 mg/m³
4 mg/m³
### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<table>
<thead>
<tr>
<th>Material Name: TOTELLE Cycle (Estradiol) Tablets</th>
</tr>
</thead>
<tbody>
<tr>
<td>OSHA - Final PELs - TWAs: 15 mg/m³</td>
</tr>
<tr>
<td>Portugal OEL - TWA 10 mg/m³</td>
</tr>
<tr>
<td>Slovakia OEL - TWA 4 mg/m³</td>
</tr>
<tr>
<td>Spain OEL - TWA 10 mg/m³</td>
</tr>
</tbody>
</table>

**Sucrose**

- ACGIH Threshold Limit Value (TWA) 10 mg/m³
- Australia TWA 10 mg/m³
- Belgium OEL - TWA 10 mg/m³
- Bulgaria OEL - TWA 10.0 mg/m³
- Estonia OEL - TWA 10 mg/m³
- France OEL - TWA 10 mg/m³
- Ireland OEL - TWAs 10 mg/m³
- Latvia OEL - TWA 5 mg/m³
- Lithuania OEL - TWA 10 mg/m³
- OSHA - Final PELs - TWAs: 15 mg/m³
- Portugal OEL - TWA 10 mg/m³
- Slovakia OEL - TWA 6 mg/m³
- Spain OEL - TWA 10 mg/m³

**Talc (non-asbestiform)**

- ACGIH Threshold Limit Value (TWA) 2 mg/m³
- Australia TWA 2.5 mg/m³
- Austria OEL - MAKs 2 mg/m³
- Belgium OEL - TWA 2 mg/m³
- Bulgaria OEL - TWA 1.0 fiber/cm³
- Czech Republic OEL - TWA 2.0 mg/m³
- Denmark OEL - TWA 0.3 fiber/cm³
- Finland OEL - TWA 0.5 fiber/cm³
- Greece OEL - TWA 10 mg/m³
- Hungary OEL - TWA 2 mg/m³
- Ireland OEL - TWAs 10 mg/m³
- Lithuania OEL - TWA 2 mg/m³
- Netherlands OEL - TWA 0.25 mg/m³
- OSHA - Final PELs - Table Z-3 Mineral D: 20 mppcf
- Poland OEL - TWA 4.0 mg/m³
- Portugal OEL - TWA 2 mg/m³
- Romania OEL - TWA 2 mg/m³
- Slovakia OEL - TWA 2 mg/m³
- Slovenia OEL - TWA 10 mg/m³
- Spain OEL - TWA 2 mg/m³
- Sweden OEL - TWAs 2 mg/m³
- Spain OEL - TWA 1 mg/m³
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Titanium dioxide

ACGIH Threshold Limit Value (TWA) 10 mg/m³
Australia TWA 10 mg/m³
Austria OEL - MAKs 5 mg/m³
Belgium OEL - TWA 10 mg/m³
Bulgaria OEL - TWA 10.0 mg/m³
Denmark OEL - TWA 6 mg/m³
Estonia OEL - TWA 5 mg/m³
France OEL - TWA 10 mg/m³
Greece OEL - TWA 10 mg/m³ 5 mg/m³
Ireland OEL - TWAs 10 mg/m³ 4 mg/m³
Latvia OEL - TWA 10 mg/m³
Lithuania OEL - TWA 5 mg/m³
OSHA - Final PELS - TWAs: 15 mg/m³
Poland OEL - TWA 10.0 mg/m³
Portugal OEL - TWA 10 mg/m³
Romania OEL - TWA 10 mg/m³
Spain OEL - TWA 10 mg/m³
Sweden OEL - TWAs 5 mg/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, disposable gloves (double suggested) 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 disposable 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

Physical State: Tablet
Molecular Formula: Mixture
Color: Various
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, except where noted.

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

**Magnesium stearate**
- Rat Oral LD50 > 2000 mg/kg
- Rat Inhalation LC50 > 2000 mg/m³

**Microcrystalline cellulose**
- Rat Oral LD50 > 5000 mg/kg
- Rabbit Dermal LD50 > 2000 mg/kg

**Povidone**
- Rat Oral LD50 100 g/kg

**Sucrose**
- Rat Oral LD50 29.7 g/kg

**Talc (non-asbestiform)**
- Rat Oral LD50 > 1600 mg/kg

**Propylene glycol**
- Mouse Oral LD50 22,000 mg/kg
- Rat Oral LD50 20,000 mg/kg
- Rabbit Dermal LD50 20,800 mg/kg

**Titanium dioxide**
- Rat Oral LD50 > 7500 mg/kg
- Rat Subcutaneous LD 50 50 mg/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)

**Microcrystalline cellulose**
- Skin Irritation Rabbit Non-irritating
- Eye Irritation Rabbit Non-irritating

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

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

**Estradiol**
- 90 Day(s) Rat Oral 0.003 mg/kg/day NOAEL Blood, Female reproductive system, Male reproductive system, Endocrine system, Liver

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))
11. TOXICOLOGICAL INFORMATION

Estradiol
Reproductive & Fertility-Females  Rat  Oral  0.003 mg/kg/day  LOAEL  Reproductive toxicity
Embryo / Fetal Development  Rat  Intramuscular  30 mg/kg/day  LOAEL  Fetotoxicity

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

Estradiol
Sister Chromatid Exchange  Human Lymphocytes  Positive
Micronucleus  Human  Positive
Chromosome Aberration  Human  Negative
In Vivo  Direct DNA Damage  Hamster  Positive
In Vivo  Micronucleus  Rodent Bone Marrow  Negative

Sucrose
Bacterial Mutagenicity (Ames)  Salmonella  Negative

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

Estradiol
2 Year(s)  Female Mouse  Oral  0.1 mg/kg  LOEL  Tumors, Mammary gland, Female reproductive system

Carcinogen Status:  See below

Estradiol
IARC:  Group 1 (Carcinogenic to Humans)
NTP:  Listed
OSHA:  Listed

Povidone
IARC:  Group 3 (Not Classifiable)

Talc (non-asbestiform)
IARC:  Group 3 (Not Classifiable)

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

12. ECOLOGICAL INFORMATION

Environmental Overview:  The environmental characteristics of this mixture have not been fully evaluated. Releases to the environment should be avoided. See Aquatic toxicity data of the active ingredient, below:

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

Estradiol
Fish  LC50  96 Hours  2 mg/L

Aquatic Toxicity Comments:  A greater than (>) symbol indicates that acute ecotoxicity was not observed at the maximum solubility. Since the substance is insoluble in aqueous solutions above this concentration, an acute ecotoxicity value (i.e. LC/EC50) is not achievable.
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 Symbol: T
EU Indication of danger: Carcinogenic: Category 1
Toxic to reproduction: Category 1

EU Risk Phrases:
R45 - May cause cancer.
R60 - May impair fertility.
R61 - May cause harm to the unborn child.
R52/53 - Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

EU Safety Phrases:
S36/37 - Wear suitable protective clothing and gloves.
S22 - Do not breathe dust.
S53 - Avoid exposure - obtain special instructions before use.
S57 - Use appropriate containment to avoid environmental contamination.

OSHA Label:
DANGER
May cause cancer.
May damage fertility or the unborn child.

Canada - WHMIS: Classifications
WHMIS hazard class:
Class D, Division 2, Subdivision A
### 15. REGULATORY INFORMATION

**Calcium sulfate**
- **Inventory - United States TSCA - Sect. 8(b):** Present
- **Australia (AICS):** Present
- **EU EINECS/ELINCS List:** 231-900-3

**Carnauba wax**
- **Inventory - United States TSCA - Sect. 8(b):** Present
- **Australia (AICS):** Present
- **EU EINECS/ELINCS List:** 232-399-4

**Estradiol**
- **California Proposition 65:** carcinogen initial date 1/1/88
- **Australia (AICS):** Present
- **Standard for the Uniform Scheduling for Drugs and Poisons:** Schedule 4
- **EU EINECS/ELINCS List:** 200-023-8

**Glyceryl oleate**
- **Inventory - United States TSCA - Sect. 8(b):** Present
- **Australia (AICS):** Present
- **EU EINECS/ELINCS List:** 247-038-6

**Lactose NF, monohydrate**
- **Australia (AICS):** Present

**Magnesium stearate**
- **Inventory - United States TSCA - Sect. 8(b):** Present
- **Australia (AICS):** Present
- **EU EINECS/ELINCS List:** 209-150-3

**Microcrystalline cellulose**
- **Inventory - United States TSCA - Sect. 8(b):** Present
- **Australia (AICS):** Present
- **EU EINECS/ELINCS List:** 232-674-9

**Povidone**
- **Inventory - United States TSCA - Sect. 8(b):** Present
- **Australia (AICS):** Present

**Propylene glycol**
- **Inventory - United States TSCA - Sect. 8(b):** Present
- **Australia (AICS):** Present
- **EU EINECS/ELINCS List:** 200-338-0

**Starch**
- **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:** 232-679-6
15. REGULATORY INFORMATION

Sucrose
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS): Present
- REACH - Annex IV - Exemptions from the obligations of Register:
  - EU EINECS/ELINCS List: 200-334-9

Talc (non-asbestiform)
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS): Present
- EU EINECS/ELINCS List: 238-877-9

Titanium dioxide
- Inventory - United States TSCA - Sect. 8(b): Present
- Australia (AICS): Present
- EU EINECS/ELINCS List: 236-675-5

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3
R45 - May cause cancer.
R60 - May impair fertility.
R61 - May cause harm to the unborn child.
R50/53 - Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Data Sources:
- Pfizer proprietary drug development information. Publicly available toxicity information.

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