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

Product Identifier

Material Name: Piroxicam Gel
Trade Name: FELDENE; FELDEN; DOLONOX; GELDENE
Chemical Family: Mixture

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

Intended Use: Pharmaceutical product used as non-steroidal, anti-inflammatory drug (nsaid)

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
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 1A

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

EU Risk Phrases:
R61 - May cause harm to the unborn child.

Label Elements

Signal Word: Danger
Hazard Statements: H360D - May damage the unborn child

Precautionary Statements:
P201 - Obtain special instructions before use
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
SAFETY DATA SHEET

Material Name: Piroxicam Gel
Revision date: 05-Nov-2014

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Version: 2.0

Other Hazards
Australian Hazard Classification (NOHSC):

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>Hazardous</th>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Piroxicam</td>
<td>36322-90-4</td>
<td>252-974-3</td>
<td>Repr.Cat.1;R61</td>
<td>Acute Tox.3 (H301)</td>
<td>0.5</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Xn;R22</td>
<td>Repr.1A (H360D)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>T;R48/25</td>
<td>STOT RE.1 (H372)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Ethanol</td>
<td>64-17-5</td>
<td>200-578-6</td>
<td>F; R11</td>
<td>Flam. Liq. 2 (H225)</td>
<td>20 - 30</td>
</tr>
<tr>
<td></td>
<td>Hydroxyethyl cellulose</td>
<td>9004-62-0</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Benzyl Alcohol</td>
<td>100-51-6</td>
<td>202-859-9</td>
<td>Xn; R20/22</td>
<td>Acute Tox.4 (H302)</td>
<td>1-5</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Acute Tox.4 (H332)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Propylene glycol</td>
<td>57-55-6</td>
<td>200-338-0</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td></td>
<td>Diisopropanolamine</td>
<td>110-97-4</td>
<td>203-820-9</td>
<td>Xi; R36</td>
<td>Eye Irrit. 2 (H319)</td>
<td>&lt;5</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 R phrases and 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: Use carbon dioxide, dry chemical, or water spray.

Special Hazards Arising from the Substance or Mixture
Hazardous Combustion Products: Emits toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, sulfur oxides and other sulfur-containing compounds.

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

Advice for Fire-Fighters
Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear. Evacuate area and fight fire from a safe distance.

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 spill with absorbent material. Clean spill area thoroughly.

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

Precautions for Safe Handling
Avoid breathing vapor or mist. Avoid contact with eyes, skin 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.

### Piroxicam

<table>
<thead>
<tr>
<th>Country</th>
<th>OEL - TWA</th>
<th>STEL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pfizer OEL TWA-8 Hr:</td>
<td>100 µg/m³</td>
<td></td>
</tr>
</tbody>
</table>

### Carbomer

<table>
<thead>
<tr>
<th>Country</th>
<th>OEL - TWA</th>
<th>STEL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Switzerland OEL - TWAs</td>
<td>0.05 mg/m³</td>
<td></td>
</tr>
</tbody>
</table>

### Ethanol

<table>
<thead>
<tr>
<th>Reference</th>
<th>OEL - TWA</th>
<th>STEL</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>1000.0 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>1900 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>
<tr>
<td>Netherlands OEL - TWA</td>
<td>260 mg/m³</td>
<td></td>
</tr>
<tr>
<td>OSHA - Final PELS - TWAs:</td>
<td>1000 ppm</td>
<td>1900 mg/m³</td>
</tr>
<tr>
<td>Poland OEL - TWA</td>
<td>1900 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Portugal OEL - TWA</td>
<td>1000 ppm</td>
<td></td>
</tr>
<tr>
<td>Romania OEL - TWA</td>
<td>1000 ppm</td>
<td>1900 mg/m³</td>
</tr>
<tr>
<td>Russia OEL - TWA</td>
<td>1000 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Slovakia OEL - TWA</td>
<td>500 ppm</td>
<td>960 mg/m³</td>
</tr>
<tr>
<td>Slovenia OEL - TWA</td>
<td>1000 ppm</td>
<td>1900 mg/m³</td>
</tr>
<tr>
<td>Spain OEL - TWA</td>
<td>1000 ppm</td>
<td>1910 mg/m³</td>
</tr>
<tr>
<td>Sweden OEL - TWAs</td>
<td>500 ppm</td>
<td>1000 mg/m³</td>
</tr>
</tbody>
</table>
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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).

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

Physical State: Gel
Odor: Ethanolic odor
Color: Pale yellow
Odor Threshold: No data available.
Molecular Formula: Mixture
Molecular Weight: Mixture

Solvent Solubility: No data available
Water Solubility: No data available
pH: 7.2 - 8.2
Melting/Freezing Point (°C): No data available
Boiling Point (°C): No data available.
Partition Coefficient: (Method, pH, Endpoint, Value)
Carbomer No data available
9. PHYSICAL AND CHEMICAL PROPERTIES

Hydroxyethyl cellulose
No data available

Piroxicam
No data available

Propylene glycol
No data available

Purified water
No data available

Ethanol
No data available

Diisopropanolamine
No data available

Benzy1 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

Polymerization: Will not occur

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 information included in this section describes the potential hazards of the individual ingredients.

Short Term: May cause eye irritation (based on components). Active ingredient may be harmful if swallowed. May cause allergic reactions in susceptible individuals. Exposure to high concentrations may cause irritation, headache, drowsiness, and symptoms of alcohol intoxication.

Long Term: Chronic ingestion of ethanol has been associated with an increased incidence of cancer, liver cirrhosis, and congenital malformations.
11. TOXICOLOGICAL INFORMATION

Known Clinical Effects: Topical application of this material may cause effects similar to those seen in clinical use including mild or moderate local irritation, erythema, rash, pityroid desquamation, pruritus, and related local reactions at the application site. Common adverse effects associated with oral administration of piroxicam include serious gastrointestinal toxicity such as bleeding, ulceration, and perforation and kidney toxicity. Other piroxicam treatment-related effects include headache, dizziness, blurred vision, ringing in the ears, skin rashes and itching, swelling, and liver effects. Individuals sensitive to this material or other materials in its chemical class may develop allergic reactions.

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

Piroxicam
Mouse Oral LD50 360 mg/kg
Rat Oral LD50 270mg/kg
Mouse IP LD50 360mg/kg
Rat IP LD50 220mg/kg
Dog Oral LD50 > 700mg/kg

Propylene glycol
Rat Oral LD50 22,000 mg/kg
Mouse Oral LD50 24,900mg/kg
Rabbit Dermal LD50 20,800mg/kg

Ethanol
Mouse Oral LD50 3,450 g/m³
Rat Oral LD50 7,060mg/kg
Mouse Inhalation LC50 4h 39g/m³
Rat Inhalation LC50 10h 20,000ppm

Benzyal Alcohol
Rat Oral LD50 1230 mg/kg
Rat Para-periosteal LD50 53mg/kg
Rat Inhalation LC50 >4.178mg/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)

Piroxicam
Eye Irritation Rabbit Non-irritating
Skin Irritation Rabbit Non-irritating

Propylene glycol
Skin Irritation Rabbit Mild
Eye Irritation Rabbit Mild

Ethanol
Eye Irritation Rabbit Severe

Benzyal Alcohol
Eye Irritation Rabbit Severe
Skin Irritation Rabbit Minimal
Skin Irritation Guinea Pig Moderate
11. TOXICOLOGICAL INFORMATION

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

Piroxicam
- 3 Month(s)  Rat  Oral  5 mg/kg/day  NOAEL  Gastrointestinal System
- 3 Month(s)  Monkey  Oral  2.5 mg/kg/day  Gastrointestinal system
- 18 Month(s)  Rat  Oral  1 mg/kg/day  NOAEL  Gastrointestinal system, Kidney

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

Piroxicam
- Reproductive & Fertility  Rat  Oral  10 mg/kg/day  NOAEL  No effects at maximum dose
- Peri-/Postnatal Development  Rat  Oral  2 mg/kg/day  LOAEL  Developmental toxicity
- Fertility and Embryonic Development  Rat  Oral  10 mg/kg/day  NOAEL  No effects at maximum dose, Not Teratogenic
- Fertility and Embryonic Development  Rabbit  Oral  10 mg/kg/day  NOAEL  No effects at maximum dose, Not Teratogenic

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

Piroxicam
- In Vitro Bacterial Mutagenicity (Ames)  Salmonella, E. coli  Negative
- In Vitro Cytogenetics  Human Lymphocytes  Negative

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

Piroxicam
- 2 Year(s)  Rat  Oral  1 mg/kg/day  NOAEL  Not carcinogenic

Carcinogen Status:  See below

Carbomer
- IARC:  Group 3 (Not Classifiable)

Ethanol
- IARC:  Group 1 (Carcinogenic to Humans)

12. ECOLOGICAL INFORMATION

Environmental Overview:  The environmental characteristics of this mixture have not been fully evaluated. Releases to the environment should be avoided.

Toxicity:

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

Ethanol
- Fingerling Trout  NPDES  LC50  24 Hours  11,200 mg/L
- *Oncorhynchus mykiss* (Rainbow Trout)  NPDES  LC50  96 Hours  12,900 mg/L
- *Pimephales promelas* (Fathead Minnow)  NPDES  LC50  96 Hours  14,200 mg/L

Benzyl Alcohol
Chronic Aquatic Toxicity: (Species, Method, Duration, Endpoint, Result, Adverse Endpoint)

Benzyl Alcohol

Persistence and Degradability:

Biodegradation: (Method, Inoculum, Biodeg Study, Result, Endpoint, Duration, Classification)

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.

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

Aqueous products containing alcohol at 24 percent or less are not subject to the requirements of the EU ADR, IATA, or IMDG. They are similarly exempt from US DOT requirements provided that they contain no less than 50 percent water.

15. REGULATORY INFORMATION

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

Canada - WHMIS: Classifications

WHMIS hazard class:

Class D, Division 2, Subdivision A
15. REGULATORY INFORMATION

Piroxicam
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- Australia (AICS): Present
- Standard for the Uniform Scheduling for Drugs and Poisons: Schedule 4
- EU EINECS/ELINCS List: 252-974-3

Carbomer
- 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

Ethanol
- CERCLA/SARA 313 Emission reporting: Not Listed
carcinogen initial date 4/29/11 in alcoholic beverages
developmental toxicity initial date 10/1/87 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

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: Present
- EU EINECS/ELINCS List: 231-791-2

Hydroxyethyl cellulose
- 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

Benzyl Alcohol
- 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: 202-859-9

Propylene glycol
15. REGULATORY INFORMATION

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

Diisopropanolamine
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: 203-820-9

16. OTHER INFORMATION

Text of R phrases and GHS Classification abbreviations mentioned in Section 3

Acute toxicity, oral-Cat.3; H301 - Toxic if swallowed
Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed
Acute toxicity, inhalation-Cat.4; H332 - Harmful if inhaled
Reproductive toxicity-Cat.1A; H360D - May damage the unborn child
Specific target organ toxicity, repeated exposure-Cat.1; H372 - Causes damage to organs through prolonged or repeated exposure
Serious eye damage/eye irritation-Cat.2A; H319 - Causes serious eye irritation
Flammable liquids-Cat.2; H225 - Highly flammable liquid and vapor

Toxic to reproduction: Category 1
Xn - Harmful
T - Toxic
Xi - Irritant
F - Highly flammable

R11 - Highly flammable.
R22 - Harmful if swallowed.
R36 - Irritating to eyes.
R61 - May cause harm to the unborn child.
R20/22 - Harmful by inhalation and if swallowed.
R48/25 - Toxic: danger of serious damage to health by prolonged exposure if swallowed.

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 11 - Toxicology Information. Updated Section 12 - Ecological Information. Updated Section 14 - Transport Information. Updated Section 15 - Regulatory Information.

Revision date: 05-Nov-2014
Prepared by: Product Stewardship Hazard Communication

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