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

Material Name: Ketazolam Capsules

Trade Name: Marcen

Chemical Family: Mixture

Intended Use: Pharmaceutical product used as antianxiety agent.

2. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Hazardous</th>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS List</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ketazolam</td>
<td><em>(27223-35-4) (248-346-3)</em>**</td>
<td>15mg;30mg;45mg***</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS List</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hydrogenated vegetable oil</td>
<td>68334-00-9</td>
<td>269-804-9</td>
<td>*</td>
</tr>
<tr>
<td>Carboxy methylcellulose calcium</td>
<td>9050-04-8</td>
<td>Not listed</td>
<td>*</td>
</tr>
</tbody>
</table>

Additional Information:
* Proprietary
*** per tablet/capsule/lozenge/suppository
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

3. HAZARDS IDENTIFICATION

Appearance: White capsules

Signal Word: WARNING

Statement of Hazard: Anti-anxiety drug: causes central nervous system effects

Additional Hazard Information:

- Short Term: Not acutely toxic: Not expected to cause skin irritation, eye irritation (based on components).
- Long Term: Repeat-dose studies in animals have shown a potential to cause adverse effects on liver, spleen, kidneys and bone marrow

Known Clinical Effects: Adverse effects most commonly reported in clinical use include drowsiness, lightheadedness and headache. The following effects are based on a chemically-related material: symptoms of dependence/withdrawal. May cause adverse effects on the developing fetus.

EU Indication of danger: Not classified
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.

5. FIRE FIGHTING MEASURES

Extinguishing Media: Use carbon dioxide, dry chemical, or water spray.

Hazardous Combustion Products: May emit toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, hydrogen chloride, and other chlorine-containing compounds.

Fire Fighting Procedures: During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

Fire / Explosion Hazards: Not determined

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: Avoid generating airborne dust. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes.

Storage Conditions: Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Ketazolam

Pfizer OEL TWA-8 Hr: 15ug/m³

The exposure limit(s) listed for solid components are only relevant if dust may be generated.


Engineering Controls: Engineering controls should be used as the primary means to control exposures.

Personal Protective Equipment:

Hands: Not required for the normal use of this product. Wear protective gloves when working with large quantities.

Eyes: Not required under normal conditions of use. Wear safety glasses or goggles if eye contact is possible.

Skin: Not required for the normal use of this product. Wear protective clothing when working with large quantities.

Respiratory protection: Not required for the normal use of this product. 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: Capsule
Molecular Formula: Mixture
Color: White
Molecular Weight: Mixture

10. STABILITY AND REACTIVITY

Stability: Stable under normal conditions of use.
Conditions to Avoid: None for the normal use of this material
Incompatible Materials: No reactions identified

11. TOXICOLOGICAL INFORMATION

General Information: The information included in this section describes the potential hazards of the active ingredient.

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

Ketazolam

<table>
<thead>
<tr>
<th>Species</th>
<th>Route</th>
<th>End Point</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>Oral</td>
<td>LD 50</td>
<td>5 g/kg</td>
</tr>
<tr>
<td>Mouse</td>
<td>Oral</td>
<td>LD 50</td>
<td>2 g/kg</td>
</tr>
<tr>
<td>Rat</td>
<td>Intraperitoneal</td>
<td>LD 50</td>
<td>3.9 g/kg</td>
</tr>
<tr>
<td>Mouse</td>
<td>Intraperitoneal</td>
<td>LD 50</td>
<td>2.6 g/kg</td>
</tr>
</tbody>
</table>

Irritation / Sensitization: (Study Type, Species, Severity)
Ketazolam
Eye Irritation  Rabbit  Minimal
Skin Irritation  Rabbit  No effect

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

Ketazolam
92 Day(s)  Mouse  Oral  30 mg/kg/day  NOAEL  Liver
95 Day(s)  Rat  Oral  10 mg/kg/day  NOAEL  Adrenal gland, Kidney, Liver
1 Year(s)  Rat  Oral  10 mg/kg/day  NOAEL  Central Nervous System, Kidney, Liver, Bone Marrow, Spleen
28 Week(s)  Dog  Oral  6 mg/kg/day  NOAEL  Central Nervous System
1 Year(s)  Dog  Oral  1 mg/kg/day  NOAEL  Kidney

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

Ketazolam
Reproductive & Fertility  Rat  Oral  20 mg/kg/day  NOAEL  No effects at maximum dose
Peri-/Postnatal Development  Rat  Oral  10 mg/kg/day  NOAEL  Fetotoxicity
Embryo / Fetal Development  Mouse  Oral  100 mg/kg/day  NOAEL  Not Teratogenic
Embryo / Fetal Development  Rat  Oral  10 mg/kg/day  NOAEL  Not Teratogenic
Embryo / Fetal Development  Rabbit  Oral  100 mg/kg/day  NOAEL  Not Teratogenic

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

Ketazolam
In Vivo Micronucleus  Rat  Negative
Bacterial Mutagenicity (Ames)  Salmonella  Negative

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

Ketazolam
2 Year(s)  Mouse  Oral  50 NOAEL  Not carcinogenic
22 Month(s)  Rat  Oral  100 NOAEL  Not carcinogenic

Carcinogen Status:  None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

12. ECOLOGICAL INFORMATION

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

13. DISPOSAL CONSIDERATIONS

Disposal Procedures:  Dispose of waste in accordance with all applicable laws and regulations.

14. TRANSPORT INFORMATION

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

EU Indication of danger: Not classified

OSHA Label:
WARNING
Anti-anxiety drug: causes central nervous system effects

Canada - WHMIS: Classifications

WHMIS hazard class:
D2b toxic materials

Ketazolam
California Proposition 65: developmental toxicity, initial date 10/1/92
Drug Enforcement Administration: Schedule IV
Standard for the Uniform Scheduling for Drugs and Poisons: Schedule 4
EU EINECS List 248-346-3

Hydrogenated vegetable oil
Inventory - United States TSCA - Sect. 8(b): Present
Australia (AICS): Present
EU EINECS List 269-804-9

Carboxy methylcellulose calcium
Inventory - United States TSCA - Sect. 8(b): XU
Australia (AICS): Present

Additional Information: US DEA Schedule IV substance

16. OTHER INFORMATION

Reasons for Revision: Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 13 - Disposal Considerations. Updated Section 15 - Regulatory Information.

Prepared by: Corporate Occupational Toxicology & Hazard Assessment

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End of Safety Data Sheet