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

Material Name: Eletriptan Hydrobromide Film Coated Tablets

Trade Name: RELPAX
Chemical Family: Mixture
Intended Use: Pharmaceutical product for the treatment of migraine headache

2. HAZARDS IDENTIFICATION

Appearance: Round, convex orange tablet
Signal Word: DANGER

Statement of Hazard: Causes severe eye damage.

Additional Hazard Information:
- **Short Term:** Active ingredient may be harmful if swallowed. May cause respiratory tract irritation. (based on components).
- **Long Term:** Repeat-dose studies in animals have shown a potential to cause adverse effects on liver, thyroid, heart.

Known Clinical Effects:
- Adverse effects most commonly reported in clinical use include weakness, sleepiness, nausea and dizziness

EU Indication of danger:
- Irritant

EU Hazard Symbols:
- Xi

EU Risk Phrases:
- R41 - Risk of serious damage to eyes.

Australian Hazard Classification (NOHSC):
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 active substance or its intermediates 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

Hazardous

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>%</th>
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<tr>
<td>Eletriptan hydrobromide</td>
<td>177834-92-3</td>
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<td>Xi;R41</td>
<td>23.42</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Xn;R22</td>
<td></td>
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<td>Magnesium stearate</td>
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<td>209-150-3</td>
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<tr>
<td>Microcrystalline cellulose</td>
<td>9004-34-6</td>
<td>232-674-9</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>
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<tr>
<td>Croscarmellose sodium</td>
<td>74811-65-7</td>
<td>Not Listed</td>
<td>Not Listed</td>
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<tr>
<td>Lactose NF, monohydrate</td>
<td>64044-51-5</td>
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<tr>
<td>Triacetin</td>
<td>102-76-1</td>
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<tr>
<td>Hydroxypropyl methylcellulose</td>
<td>9004-65-3</td>
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<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>FD&amp;C yellow No.6 aluminum lake</td>
<td>15790-07-5</td>
<td>239-888-1</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: Fine particles (such as dust and mists) may fuel fires/explosions.

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: If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. Minimize dust generation and accumulation. 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.

Eletriptan hydrobromide
Pfizer OEL TWA-8 Hr: 0.1 mg/m³

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 4 mg/m³

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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.

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: Wear impervious gloves to prevent skin contact.
- Eyes: Wear safety goggles as minimum protection.
- Skin: Wear impervious protective clothing to prevent skin contact.
- 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: Orange
- Molecular Weight: Mixture
- Polymerization: Will not occur
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: There are no data for this formulation. The information included in this section describes the potential hazards of eletriptan in hydrobromide and/or hemisulfate salt forms. The remaining information describes the potential hazards of the individual ingredients.

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

Eletriptan hydrobromide
Rat Dermal LD50 2000 mg/kg
Rat/Mouse Oral LD50 100-1000 mg/kg (hemisulfate)
Rat/Mouse IV LDmin. 20 mg/kg (hemisulfate)

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

Hydroxypropyl methylcellulose
Rat Oral LD50 > 10,000 mg/kg

Triacetin
Rat Oral LD50 3000 mg/kg
Mouse Oral LD 50 1100 mg/kg

Titanium dioxide
Rat Oral LD50 > 7500 mg/kg
Rat Subcutaneous LD50 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)

Eletriptan hydrobromide
Eye Irritation Rabbit Very severe
Skin Irritation Rabbit Non-irritating
Antigenicity- Passive cutaneous anaphylaxis Guinea Pig Negative
Antigenicity- Active anaphylaxis Guinea Pig Negative

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

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)
11. TOXICOLOGICAL INFORMATION

Eletriptan hydrobromide
1 Month(s)  Rat  Oral  5 mg/kg/day  NOAEL  Liver, Thyroid
6 Month(s)  Rat  Oral  15 mg/kg/day  NOAEL  Liver
6 Month(s)  Dog  Oral  1.25 mg/kg/day  NOAEL  Heart
12 Month(s) Dog  Oral  0.75 mg/kg/day  NOAEL  Heart
24 Month(s) Mouse  Oral  20 mg/kg/day  NOAEL  Liver, Thyroid

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

Eletriptan hydrobromide
Reproductive & Fertility  Rat  Oral  50 mg/kg/day  NOAEL  No effects at maximum dose
Embryo / Fetal Development  Rat  Oral  10 mg/kg/day  NOAEL  Maternal Toxicity, Fetotoxicity
Embryo / Fetal Development  Rabbit  Oral  10 mg/kg/day  NOAEL  Maternal Toxicity, Not Teratogenic
Peri-/Postnatal Development  Rat  Oral  15 mg/kg/day  NOAEL  Maternal Toxicity, Neonatal toxicity

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

Eletriptan hydrobromide
Bacterial Mutagenicity (Ames)  Salmonella, E. coli  Negative
Mammalian Cell Mutagenicity  Chinese Hamster Ovary (CHO) cells  Negative
In Vitro Chromosome Aberration  Human Lymphocytes  Negative
In Vivo Micronucleus  Mouse Bone Marrow  Negative

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

Eletriptan hydrobromide
24 Month(s)  Mouse  Oral, in feed  400 mg/kg/day  NOAEL  Not carcinogenic
24 Month(s)  Rat  Oral  75 mg/kg/day  NOAEL  Not carcinogenic

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

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

12. ECOLOGICAL INFORMATION

Environmental Overview:  In the environment, the active ingredient in this formulation is expected to remain in water or migrate through the soil to groundwater. Harmful effects to aquatic organisms could occur. Releases to the environment should be avoided.

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

Eletriptan hydrobromide
Daphnia magna (Water Flea)  TAD OECD  LC50  48 Hours  29 mg/L
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

<table>
<thead>
<tr>
<th>EU Symbol:</th>
<th>Xi</th>
</tr>
</thead>
<tbody>
<tr>
<td>EU Indication of danger:</td>
<td>Irritant</td>
</tr>
<tr>
<td>EU Risk Phrases:</td>
<td>R41 - Risk of serious damage to eyes.</td>
</tr>
<tr>
<td>EU Safety Phrases:</td>
<td>S26 - In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.</td>
</tr>
</tbody>
</table>

OSHA Label:
DANGER
Causes severe eye damage.

Canada - WHMIS: Classifications
WHMIS hazard class:
Class D, Division 2, Subdivision B

Croscarmellose sodium
California Proposition 65: Not Listed
Australia (AICS): Present

Eletriptan hydrobromide
### 15. REGULATORY INFORMATION

<table>
<thead>
<tr>
<th>Material Name</th>
<th>California Proposition 65</th>
<th>Australia (AICS)</th>
<th>EU EINECS/ELINCS List</th>
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</thead>
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<tr>
<td>Lactose NF, monohydrate</td>
<td>Present</td>
<td>Not Listed</td>
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<td>Present</td>
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<td>Not Listed</td>
<td>Present</td>
<td>239-888-1</td>
</tr>
</tbody>
</table>

**Text of R phrases mentioned in Section 3**

- R22 - Harmful if swallowed.
- R41 - Risk of serious damage to eyes.
- R52/53 - Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
Data Sources: Safety data sheets for individual ingredients. Pfizer proprietary drug development information.

Reasons for Revision: Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 4 - First Aid Measures. Updated Section 5 - Fire Fighting Measures. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 10 - Stability and Reactivity. Updated Section 12 - Ecological Information. Updated Section 15 - Regulatory 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 a warranty of any kind, expressed or implied.

End of Safety Data Sheet