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

Product Identifier

Material Name: Eletriptan Hydrobromide Film Coated Tablets
Trade Name: RELPAX; RELERT; ELETRIPTAN-PFIZER
Chemical Family: Mixture

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against
Intended Use: Pharmaceutical product for the treatment of migraine headache

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

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture
GHS - Classification
Acute Oral Toxicity: Category 4
Serious Eye Damage/Eye Irritation: Category 1

Label Elements
Signal Word: Danger
Hazard Statements:
H302 - Harmful if swallowed
H318 - Causes serious eye damage

Precautionary Statements:
P264 - Wash hands thoroughly after handling
P270 - Do not eat, drink or smoke when using this product
P280 - Wear protective gloves/protective clothing/eye protection/face protection
P301+ P312 - IF SWALLOWED: Call a POISON CENTRE or doctor/physician if you feel unwell
P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P310 - Immediately call a POISON CENTRE or doctor/physician
P330 - Rinse mouth
P501 - Dispose of contents/container in accordance with all local and national regulations
SAFETY DATA SHEET

Material Name: Eletriptan Hydrobromide Film Coated Tablets

Revision date: 02-Jun-2016

Page 2 of 10

Other Hazards

Note: No data available

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 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>GHS Classification</th>
<th>%</th>
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<tbody>
<tr>
<td>Eletriptan hydrobromide</td>
<td>177834-92-3</td>
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<td>Acute Tox.4 (H302) Eye Dam. 1 (H318)</td>
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<td></td>
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<td>Aquatic Acute 3 (H402)</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Aquatic Chronic 3 (H412)</td>
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<td>Titanium dioxide</td>
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<td>Microcrystalline cellulose</td>
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<td>Magnesium stearate</td>
<td>557-04-0</td>
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<td>Croscarmellose sodium</td>
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<td>Triacetin</td>
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<td>Hydroxypropyl methylcellulose</td>
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<td>15790-07-5</td>
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</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 fire fighting 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. Clean up operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

Precautions for Safe 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.

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.

**Eletriptan hydrobromide**

<table>
<thead>
<tr>
<th>Country</th>
<th>TWA</th>
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</thead>
<tbody>
<tr>
<td>Pfizer OEL TWAS</td>
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**Titanium dioxide**

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<td>ACGIH OELs - Notice of Intended Changes</td>
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<tr>
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<tr>
<td>Austria OEL - MAKs</td>
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<tr>
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**Microcrystalline cellulose**

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<tr>
<td>Vietnam OEL - TWAs</td>
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Material Name:  Eletriptan Hydrobromide Film Coated Tablets

Revision date: 02-Jun-2016

Version: 4.1
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: 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
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)
Eletriptan hydrobromide Measured Log P 3.45
Magnesium stearate
No data available
Crocarmellose sodium
No data available
Lactose NF, monohydrate
No data available
Microcrystalline cellulose
No data available
Hydroxypropyl methylcellulose
No data available
Triacetin
No data available
Titanium dioxide
No data available
FD&C yellow No.6 aluminum lake
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: 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.

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

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

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

Triacetin
Rat  Oral  LD 50  3000 mg/kg
Mouse  Oral  LD 50  1100mg/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)**

**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

**Reproductive & 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**
11. TOXICOLOGICAL INFORMATION

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)

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.

Toxicity:

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

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

Persistence and Degradability: No data available

Bio-accumulative Potential:

Partition Coefficient: (Method, pH, Endpoint, Value)

Eletriptan hydrobromide
Measured Log P 3.45

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

<table>
<thead>
<tr>
<th>Material Name: Eletriptan Hydrobromide Film Coated Tablets</th>
<th>EU EINECS/ELINCS List</th>
</tr>
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#### Eletriptan hydrobromide

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<tr>
<td>California Proposition 65</td>
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#### Croscarmellose sodium

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<tr>
<td>Australia (AICS):</td>
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</tr>
<tr>
<td>EU EINECS/ELINCS List</td>
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#### Triacetin

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#### Titanium dioxide

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#### Microcrystalline cellulose

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<td>Inventory - United States TSCA - Sect. 8(b)</td>
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<td>REACH - Annex XVII - Restrictions on Certain Dangerous Substances:</td>
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#### Hydroxypropyl methylcellulose

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<td>Standard for the Uniform Scheduling for Drugs and Poisons:</td>
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</table>
15. REGULATORY INFORMATION

Lactose NF, monohydrate
- CERCLA/SARA 313 Emission reporting: Not Listed
- California Proposition 65: Not Listed
- Australia (AICS): Present
- REACH - Annex IV - Exemptions from the obligations of Register: Present
- EU EINECS/ELINCS List: Not Listed

Magnesium stearate
- 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: 209-150-3

FD&C yellow No.6 aluminum lake
- 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: 239-888-1

16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3
- Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed
- Serious eye damage/eye irritation-Cat.1; H318 - Causes serious eye damage
- Hazardous to the aquatic environment, acute toxicity-Cat.3; H402 - Harmful to aquatic life
- Hazardous to the aquatic environment, chronic toxicity-Cat.3; H412 - Harmful to aquatic life with long lasting effects

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 16 - Other Information.

Revision date: 02-Jun-2016
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