



MATERIAL SAFETY DATA SHEET

Revision date: 21-Aug-2013

Version: 3.0

Page 1 of 9

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

Pfizer Inc
Pfizer Pharmaceuticals Group
235 East 42nd Street
New York, New York 10017
1-212-573-2222

Emergency telephone number:
CHEMTREC (24 hours): 1-800-424-9300
Contact E-Mail: pfizer-MSDS@pfizer.com

Pfizer Ltd
Ramsgate Road
Sandwich, Kent
CT13 9NJ
United Kingdom
+00 44 (0)1304 616161
Emergency telephone number:
International CHEMTREC (24 hours): +1-703-527-3887

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.
Hazardous Substance. Non-Dangerous Goods.

Australian Hazard Classification
(NOHSC):

MATERIAL SAFETY DATA SHEET

Material Name: Eletriptan Hydrobromide Film Coated Tablets
Revision date: 21-Aug-2013

Page 2 of 9
Version: 3.0

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

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Eletriptan hydrobromide	177834-92-3	Not Listed	R52/53 Xi;R41 Xn;R22	23.42
Magnesium stearate	557-04-0	209-150-3	Not Listed	*
Microcrystalline cellulose	9004-34-6	232-674-9	Not Listed	*
Titanium dioxide	13463-67-7	236-675-5	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Croscarmellose sodium	74811-65-7	Not Listed	Not Listed	*
Lactose NF, monohydrate	64044-51-5	Not Listed	Not Listed	*
Triacetin	102-76-1	203-051-9	Not Listed	*
Hydroxypropyl methylcellulose	9004-65-3	Not Listed	Not Listed	*
FD&C yellow No.6 aluminum lake	15790-07-5	239-888-1	Not Listed	*

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.

MATERIAL SAFETY DATA SHEET

Material Name: Eletriptan Hydrobromide Film Coated Tablets
Revision date: 21-Aug-2013

Page 3 of 9
Version: 3.0

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/m ³

Magnesium stearate	
ACGIH Threshold Limit Value (TWA)	10 mg/m ³
Lithuania OEL - TWA	5 mg/m ³
Sweden OEL - TWAs	5 mg/m ³

Microcrystalline cellulose	
ACGIH Threshold Limit Value (TWA)	10 mg/m ³
Australia TWA	10 mg/m ³
Belgium OEL - TWA	10 mg/m ³
Estonia OEL - TWA	10 mg/m ³
France OEL - TWA	10 mg/m ³
Ireland OEL - TWAs	10 mg/m ³
	4 mg/m ³
Latvia OEL - TWA	2 mg/m ³

MATERIAL SAFETY DATA SHEET

Material Name: Eletriptan Hydrobromide Film Coated Tablets
Revision date: 21-Aug-2013

Page 4 of 9
Version: 3.0

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

OSHA - Final PELs - TWAs:	15 mg/m ³
Portugal OEL - TWA	10 mg/m ³
Spain OEL - TWA	10 mg/m ³

Titanium dioxide

ACGIH Threshold Limit Value (TWA)	10 mg/m ³
Australia TWA	10 mg/m ³
Austria OEL - MAKs	5 mg/m ³
Belgium OEL - TWA	10 mg/m ³
Bulgaria OEL - TWA	10.0 mg/m ³
Denmark OEL - TWA	6 mg/m ³
Estonia OEL - TWA	5 mg/m ³
France OEL - TWA	10 mg/m ³
Greece OEL - TWA	10 mg/m ³
	5 mg/m ³
Ireland OEL - TWAs	10 mg/m ³
	4 mg/m ³
Latvia OEL - TWA	10 mg/m ³
Lithuania OEL - TWA	5 mg/m ³
OSHA - Final PELs - TWAs:	15 mg/m ³
Poland OEL - TWA	10.0 mg/m ³
Portugal OEL - TWA	10 mg/m ³
Romania OEL - TWA	10 mg/m ³
Spain OEL - TWA	10 mg/m ³
Sweden OEL - TWAs	5 mg/m ³

Analytical Method:	Analytical method available for Eletriptan. Contact Pfizer Inc for further information.
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	Color:	Orange
Molecular Formula:	Mixture	Molecular Weight:	Mixture

Polymerization: Will not occur

MATERIAL SAFETY DATA SHEET

Material Name: Eletriptan Hydrobromide Film Coated Tablets
Revision date: 21-Aug-2013

Page 5 of 9
Version: 3.0

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 LD 50 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)

MATERIAL SAFETY DATA SHEET

Material Name: Eletriptan Hydrobromide Film Coated Tablets
Revision date: 21-Aug-2013

Page 6 of 9
Version: 3.0

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)	<i>Salmonella</i> , <i>E. coli</i>	Negative
Mammalian Cell Mutagenicity	Chinese Hamster Ovary (CHO) cells	Negative
<i>In Vitro</i> Chromosome Aberration	Human Lymphocytes	Negative
<i>In Vivo</i> 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

<i>Daphnia magna</i> (Water Flea)	TAD OECD	LC50	48 Hours	29 mg/L
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MATERIAL SAFETY DATA SHEET

Material Name: Eletriptan Hydrobromide Film Coated Tablets
Revision date: 21-Aug-2013

Page 7 of 9
Version: 3.0

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: Xi
EU Indication of danger: Irritant

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

EU Safety Phrases:
S26 - In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

OSHA Label:
DANGER
Causes severe eye damage.

Canada - WHMIS: Classifications

WHMIS hazard class:
Class D, Division 2, Subdivision B



Croscarmellose sodium
California Proposition 65
Australia (AICS):

Not Listed
Present

Eletriptan hydrobromide

MATERIAL SAFETY DATA SHEET

Material Name: Eletriptan Hydrobromide Film Coated Tablets
Revision date: 21-Aug-2013

Page 8 of 9
Version: 3.0

15. REGULATORY INFORMATION

California Proposition 65	Not Listed
Lactose NF, monohydrate	
California Proposition 65	Not Listed
Australia (AICS):	Present
Magnesium stearate	
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	209-150-3
Microcrystalline cellulose	
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	232-674-9
Titanium dioxide	
California Proposition 65	carcinogen initial date 9/2/11 airborne, unbound particles of respirable size
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	236-675-5
Triacetin	
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	203-051-9
Hydroxypropyl methylcellulose	
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4
FD&C yellow No.6 aluminum lake	
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 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.

MATERIAL SAFETY DATA SHEET

Material Name: Eletriptan Hydrobromide Film Coated Tablets
Revision date: 21-Aug-2013

Page 9 of 9
Version: 3.0

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

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End of Safety Data Sheet