



MATERIAL SAFETY DATA SHEET

Revision date: 16-Apr-2002

Version: 1.1

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

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Material Name: Eletriptan Hydrobromide Film Coated Tablets

Trade Name: RELPAXÔ , Film Coated Tablets
Synonyms: UK-116,044-04 (hydrobromide salt)
Chemical Family: 5-HT agonist
Intended Use: Treatment of migraine headache

2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS List	%
Opadry orange	NOT ASSIGNED	Not listed	*
Croscarmellose sodium	74811-65-7	Not listed	*
Microcrystalline cellulose	9004-34-6	232-674-9	*
Magnesium stearate	557-04-0	209-150-3	*
Eletriptan hydrobromide	177834-92-3	Not listed	23.42

Ingredient	CAS Number	EU EINECS List	%
Lactose NF, monohydrate	64044-51-5	Not listed	*
Opadry clear	NOT ASSIGNED	Not listed	*

Additional Information: * Proprietary

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

3. HAZARDS IDENTIFICATION

Appearance: Round, convex orange tablet
Signal Word: CAUTION

Statement of Hazard: May be harmful if swallowed.
May cause cardiovascular and central nervous system effects
Dangerous for the environment

Eye Contact: Dust may cause irritation.
Skin Contact: Dust may cause irritation to cut or abraded skin.
Inhalation: Dust may cause irritation. An Occupational Exposure Limit has been established for one or more of the ingredients (see Section 8).

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Ingestion: See 'Statements of hazard', 'Known clinical effects', and/or 'Other potential health effects' in this section.

Known Clinical Effects: weakness, sleepiness, nausea and dizziness

Potential Health Effects: Based on its pharmacologic properties and findings in animal studies, this compound may cause increased blood pressure and heart rate.

EU Indication of danger: Dangerous for the Environment

EU Hazard Symbols:

R51 - Toxic to aquatic organisms.

Additional Information: For a more detailed discussion of potential health hazards and toxicity see Section 11.

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.

4. FIRST AID MEASURES

Eye Contact: Immediately flush eyes with water for at least 15 minutes. Get medical attention.

Skin Contact: Wash skin with soap and water. Remove contaminated clothing and shoes. This material may not be completely removed by conventional laundering. Consult professional laundry service. Do not home launder. If irritation occurs or persists, get medical attention.

Ingestion: Get medical attention immediately. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person.

Inhalation: Remove to fresh air. If not breathing, give artificial respiration. Get medical attention immediately.

5. FIRE FIGHTING MEASURES

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

Hazardous Combustion Products: Emits toxic fumes of carbon monoxide, carbon dioxide, oxides of nitrogen, sulfur oxides, and other sulfur- and bromine-containing compounds

Fire Fighting Procedures: Wear approved positive pressure, self-contained breathing apparatus and full protective turn out gear.

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: Wipe up with a damp cloth and place in container for disposal. Avoid generating airborne dust. Clean spill area thoroughly. Prevent discharge to drains.

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: Vacuum or sweep material into appropriate container for disposal. Avoid generating airborne dust. Close container and move it to a secure holding area. Prevent discharge to drains.

Additional Information: Review Sections 3, 8 and 12 before proceeding with clean up.

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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. Use adequate ventilation. Minimize dust generation and accumulation.

Storage Conditions: Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Microcrystalline cellulose

OSHA - Final PELs - TWAs

15 mg/m³ total dust

5 mg/m³ respirable fraction

ACGIH Threshold Limit Value (TWA)

10 mg/m³ TWA

Eletriptan hydrobromide

Pfizer OEL TWA-8 Hr: 0.1 mg/m³

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

Analytical Method: Eletriptan: CAM-KAS-99-16; STP-E 67.8 (contact Pfizer for additional details)

Engineering Controls: General room ventilation is adequate unless the process generates dust, mist or fumes.

Personal Protective Equipment:

Hands: Rubber gloves

Eyes: Safety glasses or goggles

Skin: Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas.

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

10. STABILITY AND REACTIVITY

Stability: Stable

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: None expected under normal conditions.

Polymerization: Will not occur

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.

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Carcinogenicity: None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.
Acute Toxicity: (Species, Route, End Point, Dose)

Eletriptan hydrobromide

Rabbit Ocular Irritation Very severe
Rabbit Dermal Irritation Non-irritating
Rat Dermal LD50 > 2000mg/kg
Rat/Mouse Oral LDmin. < 1000 (hemisulfate)mg/kg
Rat/Mouse IV LDmin. 20 (hemisulfate)mg/kg

Microcrystalline cellulose

Rat Oral LD50 > 5000 mg/kg
Rabbit Dermal LD50 > 2000 mg/kg

Magnesium stearate

Rat Oral LD50 > 2000 mg/kg
Rat Inhalation LC50 > 2000 mg/m³

Inhalation Acute Toxicity High doses of eletriptan hemisulfate given by intranasal installation to rats and dogs caused reversible irritation.

Ingestion Acute Toxicity At 1000 mg/kg, death occurred in mice and rats and was preceded by signs of central nervous system effects, including convulsions, dyspnea, prostration, salivation, mydriasis, and tremors.

Microcrystalline cellulose

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

Eye Irritation / Sensitization

Eletriptan may be irritating to eyes based on intranasal and subcutaneous studies described below.

Skin Irritation / Sensitization

Moderate irritation was seen in a subcutaneous injection study in rabbits. Not a skin sensitizer based on animal data

Subchronic Effects

Eletriptan hydrobromide produced mild, adaptive changes in the liver and thyroid in rats after oral doses of 100 mg/kg/day for 1 month and 50 mg/kg/day for 6 months. In a 1-month oral dog study, significant increases in blood pressure and heart rate were observed at the highest dose of 5 mg/kg/day. In 6- and 12-month oral studies in dogs, gradual decreases in blood pressure were noted and were considered an adaptive response. Signs of CNS effects, including increased barking and restlessness, were noted in the 1-month oral study in dogs but did not appear in 6- and 12-month studies. In a 1-month intravenous study in dogs, all dose levels (0.25-1.5 mg/kg/day) were associated with increased heart rate while only the high dose raised blood pressure. Testicular atrophy occurred in all high-dose dogs and is believed to be the result of arterial vasoconstriction.

Chronic Effects/Carcinogenicity

In two-year dietary studies of eletriptan hydrobromide in mice and rats, there was no evidence of carcinogenicity. In both studies effects on liver weight and histology were observed and were attributed to adaptive metabolic changes.

Reproductive Effects

Eletriptan had no effect on the fertility of male or female rats and is not teratogenic in rats or rabbits.

Mutagenicity

No evidence of mutagenic activity in bacterial or mammalian cells in vitro, or clastogenic activity in vitro or in vivo.

Carcinogen Status:

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

At increase risk from exposure:

Individuals with severe liver or kidney impairment

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 sensitive species of aquatic organisms could occur. Releases to the environment should be avoided.

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Mobility, Persistence and Degradability:

The active ingredient in this formulation is water soluble and is expected to remain primarily in water

Bioaccumulation and Toxicity:

High acute toxicity to sensitive algal species is expected. The active ingredient in this formulation has low potential to bioaccumulate and long-term adverse effects to higher aquatic organisms are not expected. No toxicity to wastewater treatment microorganisms is expected. See the aquatic toxicity data for the active ingredient in the table, below.

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

Eletriptan hydrobromide

Polytox IC50/24 hr > 50

Polytox MIC/24h > 50

Daphnia magna LC50/48h (NPDES) 8.69

Daphnia magna EC50/1hr 28.6

Daphnia magna LC50/48h (TAD/OECD) 29

13. DISPOSAL CONSIDERATIONS

Disposal Procedures:

Incineration is the recommended method of disposal for this material. Observe all local and national regulations when disposing of this material.

14. TRANSPORT INFORMATION

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

15. REGULATORY INFORMATION

EU Labeling:

N

EU Indication of danger:

Dangerous for the Environment

EU Risk Phrases:

R51 - Toxic to aquatic organisms.

EU Safety Phrases:

S57 - Use appropriate containment to avoid environmental contamination.

OSHA Label:

CAUTION

May be harmful if swallowed.

May cause cardiovascular and central nervous system effects

Dangerous for the environment

Canada - WHMIS: Classifications

WHMIS hazard class:

None required

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Microcrystalline cellulose

EU EINECS List	232-674-9
Inventory - United States TSCA - Sect. 8(b)	Listed

Magnesium stearate

EU EINECS List	209-150-3
Inventory - United States TSCA - Sect. 8(b)	Listed

16. OTHER INFORMATION

Prepared by: Corporate Occupational Toxicology & Hazard Assessment

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