



MATERIAL SAFETY DATA SHEET

Revision date: 07-Jun-2011

Version: 1.0

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

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Material Name: Sumatriptan Injection

Trade Name:	ALSUMA
Synonyms:	ALSUMA Autoinjector; Sumatriptan Autoinjector
Chemical Family:	Not determined
Intended Use:	Pharmaceutical product for the treatment of migraine headache

2. HAZARDS IDENTIFICATION

Appearance: Clear, colorless to pale yellow liquid
Signal Word: WARNING

Statement of Hazard: May damage the unborn child.

Known Clinical Effects: Adverse effects most commonly reported in clinical use include effects on cardiovascular system, nausea, vomiting, migraine headache increased salivation, dizziness, drowsiness, sleepiness (somnolence)

EU Indication of danger: Toxic to Reproduction: Category 2

EU Hazard Symbols:



EU Risk Phrases:

Australian Hazard Classification (NOHSC):

R61 - May cause harm to the unborn child.
Hazardous Substance. Non-Dangerous Goods.

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.

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3. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Sumatriptan Succinate	103628-48-4	Not Listed	Repr.Cat.2;R61	1.68
Hydrochloric Acid	7647-01-0	231-595-7	C;R35 T;R23	**

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Sodium chloride	7647-14-5	231-598-3	Not Listed	*
Water for injection	7732-18-5	231-791-2	Not Listed	*

Additional Information:

** to adjust pH

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 spill with absorbent material. Clean spill area thoroughly.

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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 breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. 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.

Hydrochloric Acid

ACGIH Ceiling Threshold Limit:	2 ppm
Australia PEAK	5 ppm
	7.5 mg/m ³
Austria OEL - MAKs	Listed
Belgium OEL - TWA	Listed
Bulgaria OEL - TWA	Listed
Cyprus OEL - TWA	Listed
Czech Republic OEL - TWA	Listed
Estonia OEL - TWA	Listed
Germany - TRGS 900 - TWAs	2 ppm
	3 mg/m ³
Germany (DFG) - MAK	2 ppm MAK
	3.0 mg/m ³ MAK
Greece OEL - TWA	Listed
Hungary OEL - TWA	Listed
Ireland OEL - TWAs	Listed
Italy OEL - TWA	Listed
Japan - OELs - Ceilings	5 ppm
	7.5 mg/m ³
Latvia OEL - TWA	Listed
Lithuania OEL - TWA	Listed
Luxembourg OEL - TWA	Listed
Malta OEL - TWA	Listed
Netherlands OEL - TWA	Listed
Poland OEL - TWA	Listed
Romania OEL - TWA	Listed
Slovenia OEL - TWA	Listed
Spain OEL - TWA	Listed

Sodium chloride

Latvia OEL - TWA	Listed
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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Lithuania OEL - TWA

Listed

Sumatriptan Succinate

Pfizer Occupational Exposure Band (OEB): OEB 3 (control exposure to the range of >10ug/m³ to < 100ug/m³)

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:

Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.

Eyes:

Wear safety glasses or goggles if eye contact is possible.

Skin:

Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

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:

Liquid

Color:

Clear, colorless to pale yellow

Molecular Formula:

Mixture

Molecular Weight:

Mixture

pH:

4.2-5.3

Specific Gravity:

1.002

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:

The information included in this section describes the potential hazards of the individual ingredients.

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

Sumatriptan Succinate

Rat Oral LD50 > 2939 mg/kg

Sodium chloride

Rat Oral LD50 3000 mg/kg

Mouse Oral LD50 4000 mg/kg

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11. TOXICOLOGICAL INFORMATION

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)

Sodium chloride

Eye Irritation	Rabbit	Moderate
Skin Irritation	Rabbit	Mild

Hydrochloric Acid

Skin Irritation	Severe
Eye Irritation	Severe

Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Sumatriptan Succinate

Reproductive & Fertility	Rat	Subcutaneous	60 mg/kg/day	NOAEL	No effects at maximum dose
Reproductive & Fertility	Rat	Oral	5 mg/kg/day	NOAEL	Fertility, Reproductive toxicity
Embryo / Fetal Development	Rabbit	Oral	50 mg/kg/day	NOAEL	Embryotoxicity
Embryo / Fetal Development	Rat	Oral	50 mg/kg/day	NOAEL	Embryotoxicity, Fetotoxicity
Embryo / Fetal Development	Rabbit	Oral	15 mg/kg/day	NOAEL	Teratogenic

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

Sumatriptan Succinate

<i>In Vitro</i> Bacterial Mutagenicity (Ames)	Not specified	Negative
<i>In Vitro</i> Mammalian Cell Mutagenicity	Hamster	Negative
<i>In Vitro</i> Cytogenetics	Human Lymphocytes	Negative
<i>In Vivo</i> Cytogenetics	Rat	Negative

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

Sumatriptan Succinate

104 Week(s)	Rat	Oral	160 mg/kg/day	NOAEL	Not carcinogenic
78 Week(s)	Mouse	Oral	160 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.

Hydrochloric Acid

IARC: Group 3

12. ECOLOGICAL INFORMATION

Environmental Overview: The active ingredient in this formulation may be harmful to aquatic organisms. Releases to the environment should be avoided. See aquatic toxicity data for individual components below:

Mobility, Persistence and Degradability: Hydrolysis (half life 365 days @ pH 7) (Sumatriptan succinate)

Persistence and Degradability: Inherently biodegradable; Not readily biodegradable.

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

Sumatriptan Succinate

<i>Scenedesmus subspicatus</i> (Green Alga)	IC-50	72 Hours	36 mg/L
<i>Oncorhynchus mykiss</i> (Rainbow Trout)	EC50	96 Hours	> 100 mg/L

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12. ECOLOGICAL INFORMATION

Activated sludge IC50 3 Hours > 750 mg/L
Ceriodaphnia dubia (Daphnids) NOEC 8 Days 32 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

EU Indication of danger: Toxic to Reproduction: Category 2

EU Risk Phrases: R61 - May cause harm to the unborn child.

OSHA Label:
WARNING
May damage the unborn child.

Canada - WHMIS: Classifications

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



Hydrochloric Acid
CERCLA/SARA 313 Emission reporting

1.0% de minimis concentration acid aerosols including mists, vapors, gas, fog, and other airborne forms of any particle size

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15. REGULATORY INFORMATION

CERCLA/SARA Hazardous Substances and their Reportable Quantities:	2270 kg final RQ 5000 lb final RQ
CERCLA/SARA - Section 302 Extremely Hazardous TPQs	500 lb TPQ gas only
CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs	5000 lb
Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 5 Schedule 6
EU EINECS/ELINCS List	231-595-7

Sodium chloride

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
EU EINECS/ELINCS List	231-598-3

Water for injection

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	231-791-2

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

R61 - May cause harm to the unborn child.

R23 - Toxic by inhalation.

R35 - Causes severe burns.

Data Sources:

Publicly available toxicity information. Safety data sheets for individual ingredients. The data contained in this MSDS may have been gathered from confidential internal sources, raw material suppliers, or from the published literature.

Prepared by:

Product Stewardship Hazard Communications
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 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