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

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

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

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: R61 - May cause harm to the unborn child.


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>
</tr>
</thead>
<tbody>
<tr>
<td>Hydrochloric Acid</td>
<td>7647-01-0</td>
<td>231-595-7</td>
<td>C;R35</td>
<td>**</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>T;R23</td>
<td></td>
</tr>
<tr>
<td>Sumatriptan Succinate</td>
<td>103628-48-4</td>
<td>Not Listed</td>
<td>Repr.Cat.2;R61</td>
<td>1.68</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>EU Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium chloride</td>
<td>7647-14-5</td>
<td>231-598-3</td>
<td>Not Listed</td>
<td>*</td>
</tr>
<tr>
<td>Water for injection</td>
<td>7732-18-5</td>
<td>231-791-2</td>
<td>Not Listed</td>
<td>*</td>
</tr>
</tbody>
</table>

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.
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

<table>
<thead>
<tr>
<th>ACGIH Ceiling Threshold Limit:</th>
<th>2 ppm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia PEAK</td>
<td>5 ppm</td>
</tr>
<tr>
<td></td>
<td>7.5 mg/m³</td>
</tr>
<tr>
<td>Austria OEL - MAKs</td>
<td>5 ppm</td>
</tr>
<tr>
<td></td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Belgium OEL - TWA</td>
<td>5 ppm</td>
</tr>
<tr>
<td></td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Bulgaria OEL - TWA</td>
<td>8.0 mg/m³</td>
</tr>
<tr>
<td></td>
<td>5 ppm</td>
</tr>
<tr>
<td>Cyprus OEL - TWA</td>
<td>5 ppm</td>
</tr>
<tr>
<td></td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Czech Republic OEL - TWA</td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Estonia OEL - TWA</td>
<td>5 ppm</td>
</tr>
<tr>
<td></td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Germany - TRGS 900 - TWAs</td>
<td>2 ppm</td>
</tr>
<tr>
<td></td>
<td>3 mg/m³</td>
</tr>
<tr>
<td>Germany (DFG) - MAK</td>
<td>2 ppm</td>
</tr>
<tr>
<td></td>
<td>3.0 mg/m³</td>
</tr>
<tr>
<td>Greece OEL - TWA</td>
<td>5 ppm</td>
</tr>
<tr>
<td></td>
<td>7 mg/m³</td>
</tr>
<tr>
<td>Hungary OEL - TWA</td>
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</tr>
<tr>
<td>Ireland OEL - TWAs</td>
<td>5 ppm</td>
</tr>
<tr>
<td></td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Italy OEL - TWA</td>
<td>5 ppm</td>
</tr>
<tr>
<td></td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Japan - OELs - Ceilings</td>
<td>5 ppm</td>
</tr>
<tr>
<td></td>
<td>7.5 mg/m³</td>
</tr>
<tr>
<td>Latvia OEL - TWA</td>
<td>5 ppm</td>
</tr>
<tr>
<td></td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Lithuania OEL - TWA</td>
<td>5 ppm</td>
</tr>
<tr>
<td></td>
<td>8 mg/m³</td>
</tr>
</tbody>
</table>
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:
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.
10. STABILITY AND REACTIVITY

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

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

Reproductive & 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, Fetoxicity
Embryo / Fetal Development  Rabbit  Oral  15 mg/kg/day  NOAEL  Teratogenic

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

Sumatriptan Succinate
In Vitro Bacterial Mutagenicity (Ames)  Not specified  Negative
In Vitro Mammalian Cell Mutagenicity  Hamster  Negative
In Vitro Cytogenetics  Human Lymphocytes  Negative
In Vivo 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.
11. TOXICOLOGICAL INFORMATION

Hydrochloric Acid
IARC: Group 3 (Not Classifiable)

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)

Inherently biodegradable; Not readily biodegradable.

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

- **Sumatriptan Succinate**
  - *Scenedesmus subspicatus* (Green Alga) IC50 72 Hours 36 mg/L
  - *Oncorhynchus mykiss* (Rainbow Trout) EC50 96 Hours > 100 mg/L
  - 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
15. REGULATORY INFORMATION

May damage the unborn child.

Canada - WHMIS: Classifications

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

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.

Reasons for Revision: Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking.

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