



MATERIAL SAFETY DATA SHEET

Revision date: 02-Jan-2007

Version: 1.4

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

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Material Name: Macugen (Pegaptanib sodium)

Trade Name: Macugen
Synonyms: Anti-VEGF (Vascular Endothelial Growth Factor) aptamer
Chemical Family: Mixture
Intended Use: Pharmaceutical product for the treatment of age-related macular degeneration

2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS List	%
Pegaptanib sodium	222716-86-1	Not listed	0.3 to 3.0 mg/100 µL
Sodium chloride	7647-14-5	231-598-3	*
Hydrogen chloride	7647-01-0	231-595-7	**
Sodium hydroxide	1310-73-2	215-185-5	**

Ingredient	CAS Number	EU EINECS List	%
Sodium phosphate, dibasic	7558-79-4	231-448-7	*
Sodium phosphate, monobasic	7558-80-7	231-449-2	*
Water, purified	7732-18-5	231-791-2	*

Additional Information: * Proprietary
** to adjust pH
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

3. HAZARDS IDENTIFICATION

Appearance: Clear to light yellow solution in pre-filled syringes

Statement of Hazard: Non-hazardous in accordance with international standards for workplace safety.

Additional Hazard Information:

Short Term: Not a skin sensitizer (based on animal data) . Not expected to cause skin irritation .
Known Clinical Effects: Serious allergic reactions, including anaphylaxis, have been reported.
EU Indication of danger: Not classified

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Note: This document has been prepared in accordance with standards for workplace safety, which require 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.

4. FIRST AID MEASURES

Eye Contact: Immediately flush eyes with water for at least 15 minutes. If irritation occurs or persists, get medical attention.

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

Ingestion: Get medical attention. 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.

5. FIRE FIGHTING MEASURES

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

Hazardous Combustion Products: No data available

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

Fire / Explosion Hazards: Not applicable

Additional Information: Slight fire hazard when exposed to flames.

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: Use appropriate ventilation. Avoid breathing dust. Avoid contact with eyes, skin and clothing.

Storage Conditions: Keep container tightly closed when not in use. Store out of direct sunlight in a well ventilated area at room temperature. Do not freeze.

Storage Temperature: 2-8°C (36-46°F)

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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Pegaptanib sodium

Pfizer OEL TWA-8 Hr:

0.1 mg/m³

Hydrogen chloride

ACGIH Ceiling Threshold Limit:

= 2 ppm Ceiling

Australia PEAK

= 5 ppm Peak

= 7.5 mg/m³ Peak

Sodium hydroxide

OSHA - Final PELs - TWAs:

2 mg/m³

ACGIH Ceiling Threshold Limit:

= 2 mg/m³ Ceiling

Australia PEAK

= 2 mg/m³ Peak

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

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.

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:

Solution

Color:

Colorless to light yellow

Molecular Formula:

Mixture

Molecular Weight:

Mixture

pH:

6.0 - 6.6

10. STABILITY AND REACTIVITY

Stability:

Stable under recommended storage conditions

Conditions to Avoid:

Moisture and heat

Incompatible Materials:

No data available

Hazardous Decomposition Products: None known

Polymerization:

No data available

11. TOXICOLOGICAL INFORMATION

General Information:

The information included in this section describes the potential hazards of the active ingredient.

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

Hydrogen chloride

Rat Inhalation LC50 1H 3,124 ppm

Mouse Inhalation LC50 1H 1,108 ppm

Mouse Oral LD50 900 mg/kg

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Sodium hydroxide

Mouse IP LD50 40 mg/kg

Sodium chloride

Rat Oral LD50 3000 mg/kg

Mouse Oral LD 50 4000 mg/kg

Pegaptanib sodium

Rat IV LD50 > 450 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 hydroxide

Eye Irritation Rabbit Severe

Skin Irritation Rabbit Severe

Sodium chloride

Eye Irritation Rabbit Moderate

Skin Irritation Rabbit Mild

Sodium phosphate, dibasic

Eye Irritation Rabbit Mild

Skin Irritation Rabbit Mild

Eye Irritation / Sensitization

No data available. However, the lack of irritant and inflammatory activity following chronic intravenous and chronic intravitreal administration suggests that pegaptanib sodium will have little or no dermal or mucous membrane irritant effects.

Skin Irritation / Sensitization

No data available. Pegaptanib sodium was not antigenic in a number of test systems and is expected to have little or no risk of causing allergic reactions. However, the lack of irritant and inflammatory activity following chronic intravenous and chronic intravitreal administration suggests that pegaptanib sodium will have little or no dermal or mucous membrane irritant effects.

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Sodium chloride

10 Day(s) Rat Oral 12500 mg/kg LOAEL Kidney, Ureter, Bladder

Subchronic Effects

Intravitreal administration to rabbits and dogs of 2 mg/eye and 3 mg/eye for periods of 6 and 9 months, respectively were without effect. The No Observed Adverse Effect Level (NOAEL) in rats given daily intravenous administrations for three months was 1 mg/kg/day.

Chronic Effects/Carcinogenicity

Pegaptanib demonstrated antitumor activity in a nude mouse human tumor xenograft model. No other carcinogenicity data and no chronic toxicity data were available for review.

Reproductive Effects

Teratogenicity

No data available

No embryo/fetal toxic or teratogenic effects were observed following intravenous daily dosing (gestation days 6-15) in mice treated with 40 mg/kg/day.

Mutagenicity

No evidence of mutagenic or clastogenic activity in in vitro or in vivo tests.

Carcinogen Status:

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

Hydrogen chloride

IARC:

Group 3

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12. ECOLOGICAL INFORMATION

Environmental Overview: The environmental characteristics of this material have not been fully evaluated. Releases to the environment should be avoided.

13. DISPOSAL CONSIDERATIONS

Disposal Procedures: Dispose of waste in accordance with all applicable laws and regulations.

14. TRANSPORT INFORMATION

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

15. REGULATORY INFORMATION

EU Indication of danger: Not classified

OSHA Label:

Non-hazardous in accordance with international standards for workplace safety.

Canada - WHMIS: Classifications

WHMIS hazard class:

None required

This product has been classified in accordance with the hazard criteria of the CPR and the MSDS contains all of the information required by the CPR.

Sodium phosphate, dibasic

CERCLA/SARA Hazardous Substances

and their Reportable Quantities:

Inventory - United States TSCA - Sect. 8(b)

Australia (AICS):

EU EINECS List

= 2270 kg final RQ

= 5000 lb final RQ

Present

Present

231-448-7

Sodium phosphate, monobasic

Inventory - United States TSCA - Sect. 8(b)

Australia (AICS):

EU EINECS List

Present

Present

231-449-2

Sodium chloride

Inventory - United States TSCA - Sect. 8(b)

Present

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Australia (AICS):	Present
EU EINECS List	231-598-3
Hydrogen chloride	
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
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	= 2270 kg final RQ
CERCLA/SARA - Section 302 Extremely Hazardous TPQs	= 5000 lb final RQ
CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs	= 500 lb TPQ gas only
Inventory - United States TSCA - Sect. 8(b)	= 5000 lb EPCRA RQ gas only
Australia (AICS):	T
Standard for the Uniform Scheduling for Drugs and Poisons:	Present
EU EINECS List	Schedule 5
	Schedule 6
	231-595-7
Sodium hydroxide	
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	= 1000 lb final RQ
Inventory - United States TSCA - Sect. 8(b)	= 454 kg final RQ
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Present
EU EINECS List	Schedule 5
	Schedule 6
	215-185-5
Water, purified	
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	231-791-2

16. OTHER INFORMATION

Reasons for Revision: Updated Section 2 - Composition / Information on Ingredients. Updated Section 3 - Hazard Identification. Updated Section 5 - Fire Fighting Measures. Updated Section 6 - Accidental Release Measures. Updated Section 7 - Handling and Storage. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 11 - Toxicology Information. Updated Section 13 - Disposal Considerations. Updated Section 15 - Regulatory Information.

Prepared by: Toxicology and Hazard Communication
Pfizer Global Environment, Health, and Safety

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End of Safety Data Sheet