SAFETY DATA SHEET

SECTION 1: Identification

Product identifier

Trade name
Octagam 10%

Other means of identification
Human Immunoglobulin G

Relevant identified uses of the substance or mixture and uses advised against

Relevant identified uses of the substance or mixture
Pharmaceutical Use

Uses advised against
-

Chemical manufacturer

Company and address
Octapharma Pharmazeutika Produktionsges.m.b.H.
Oberlaaer Strasse 235
A-1100 Vienna, Austria

And

Octapharma AB
Lars Forssells gata 23
SE-112 75 Stockholm, Sweden

Phone: +43 1 610 32 – 0
Fax: +43 1 610 32 – 9300

SDS date
09/21/2015

SDS Version
1.0

Emergency telephone number
866-766-4860
See section 4 “First aid measures”

SECTION 2: Hazards identification

Classification of the chemical in accordance with paragraph (d) of §1910.1200
This product is not classified as hazardous.

Signal word, hazard statement(s), symbol(s) and precautionary statement(s) in accordance with paragraph (f) of §1910.1200

Hazard pictogram(s)
-

Signal word
-

Hazard statement(s)
-

Safety statement(s)	General	-
	Prevention	-
	Response	-
	Storage	-

Disposal -

Identity of the substances primarily responsible for the major health hazards

-

Other hazards

Additional warnings

-

VOC

-

SECTION 3: Composition/information on ingredients

Mixtures

Active ingredints: Human Immunoglobulin G

NAME: Human Immunoglobulin G

1 ml of solution contains:

NAME:	Protein, of which >= 96% is human normal immunoglobulin G
IDENTIFICATION CAS.:	-
CONTENT:	100 mg
CLASSIFICATION:	-
NAME:	IgA
IDENTIFICATION CAS.:	-
CONTENT:	<=0.4 mg
CLASSIFICATION:	-
NAME:	IgM
IDENTIFICATION CAS.:	-
CONTENT:	<=0.3 mg
CLASSIFICATION:	-
NAME:	IgG
IDENTIFICATION CAS.:	-
CONTENT:	IgG subclasses: IgG1 app. 65% IgG2 app. 30% IgG3 app. 3% IgG4 app. 2%
CLASSIFICATION:	-
NAME:	Maltose
IDENTIFICATION CAS.:	6363-53-7
CONTENT:	90 mg
CLASSIFICATION:	-
NAME:	Water for injections
IDENTIFICATION CAS.:	-
CONTENT:	ad. 1 ml
CLASSIFICATION:	-
NAME:	Triton X-100
IDENTIFICATION CAS.:	9002-93-1
CONTENT:	<= 5 µg
CLASSIFICATION:	Acute Tox. 4; Eye Irrit. 2A; Aquatic Acute 2; Aquatic Chronic 2, H302, H319, H401, H411
NAME:	TNBP
IDENTIFICATION CAS.:	126-73-8
CONTENT:	<= 1 µg
CLASSIFICATION:	Acute Tox.4; Skin Irrit.2; Carc.2; Aquatic Acute3; Aquatic Chronic3; H302, H315, H351, H402, H412

(*) See full text of H-phrases in chapter 16. Occupational exposure limits are listed in section 8, if these are available.

Other informations

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SECTION 4: First aid measures

Description of first aid measures

General information
In the case of accident: Contact a doctor or casualty department – bring this safety data sheet or the product label. Contact a doctor, if in doubt about the injured person's condition or if the symptoms continue. Never give water to an unconscious person.

Inhalation
Move the person into fresh air and stay with them.

Skin contact
Remove contaminated clothing and shoe. Skin in contact with the material must be washed thoroughly with water and soap. Skin cleanser can be used. DO NOT use solvents or thinners.

Eye contact
Remove any contact lenses. Flush eyes immediately with plenty of water (68-86 °F (20-30°C)) and continue until irritation stops. Make sure you flush under the upper and lower eyelids. If irritation continues, contact a doctor.

Ingestion
Give the person plenty of water to drink and stay with the person. If the person feels unwell, contact a doctor immediately and bring this safety data sheet or the product label with you. Do not induce vomiting unless recommended by the doctor. Hold head facing down so that no vomit runs back into the mouth and throat

Most important symptoms and effects, both acute and delayed
No special

Indication of any immediate medical attention and special treatment needed
No special

Information to medics
Treat according to local standard protocols. For additional guidance, refer to the current prescribing information or the local poison control information centre. Medical treatment in cases of overexposure should be treated as an overdose of human immunoglobulin.

Bring this safety data sheet in order to inform medical staff.

SECTION 5: Firefighting measures

Extinguishing media
Recommended: alcohol-resistant foam, carbonic acid, powder, water mist. Water jets should not be used, since they can spread the fire.

Special hazards arising from the substance or mixture
No special

Advice for firefighters
Wear self-contained breathing apparatus and protective clothing to prevent contact.

SECTION 6: Accidental release measures

Personal precautions, protective equipment and emergency procedures
No specific requirements.

Methods and material for containment and cleaning up
Wipe up with a cloth. Place in container for disposal, according to local regulations. Cleaning should be done as far as possible using normal cleaning agents. Solvents should be avoided.
Care must be taken when removing broken glass vials.

SECTION 7: Handling and storage

Precautions for safe handling
The product should be brought to room or body temperature before use.
Do not use non-homogenous solutions, or those which have a deposit.
Any remaining fraction should be discarded.

Conditions for safe storage, including any incompatibilities
OCTAGAM may be stored for 24 months from the date of manufacture.
Do not freeze. Keep container in the outer carton in order to protect from light.

Storage temperature

24 months at 36 °F to 46 °F (2 °C to 8°C). Within the first 12 months of this shelf-life the product may be stored up to 6 months at < 77°F (< 25°C). After storage at < 77°F (< 25°C) the product must be used or discarded.

SECTION 8: Exposure controls/personal protection

OSHA permissible exposure limit (PEL), American Conference of Governmental Industrial Hygienists (ACGIH) Threshold Limit Value (TLV), and any other exposure limit used or recommended by the chemical manufacturer, importer, or employer preparing the safety data sheet, where available.

OEL

TNBP, Tributyl phosphate, CAS 126-73-8:
OSHA PEL: 5 mg/m³,
Cal/OSHA PEL: 8 hour TWA: 0.2 ppm,
NIOSH REL: Up to 10-hour TWA: 0.2 ppm
ACGIH 2015 TLV: 8 hour TWA: 5 mg/m³ (IFV)

DNEL / PNEC

No data available.

Appropriate engineering controls

Compliance with the stated exposure limits values should be checked on a regular basis.

General recommendations

Observe general occupational hygiene.

Exposure limits

See maximum exposure limits for the substances contained in this product above.

Appropriate technical measures

Take ordinary precautions when using the product. Avoid inhalation of gas or dust.

Hygiene measures

Whenever you take a break in using this product and when you have finished using it, all exposed areas of the body must be washed. Always wash hands, forearms and face.

Measures to avoid environmental exposure

No specific requirements.

Individual protection measures, such as personal protective equipment

Respiratory Equipment

No specific requirements.

Skin protection

No specific requirements.

Hand protection

No specific requirements.

Eye protection

No specific requirements.

SECTION 9: Physical and chemical properties

Information on basic physical and chemical properties

Form	Colour	Odour	pH (of Aqueous Solution)	Viscosity	Density (g/cm3)
Liquid	Colourless or not more intensely coloured than reference solution Y5	-	5.1-6.0	-	-

Phase changes

Melting point (°C)	Boiling point (°C)	Vapour pressure (mm Hg)
-	-	-

Data on fire and explosion hazards

Flashpoint (°C)	Ignition (°C)	Self ignition (°C)
-	-	-

Explosion limits (Vol %)

Oxidizing properties

-	-

Solubility

Solubility in water	n-octanol/water coefficient
Soluble	-

Other information

Solubility in fat	Additional information
-	Solution for infusion. The liquid preparation is clear or not more opalescent than the reference suspension II.

SECTION 10: Stability and reactivity

Reactivity

No data available

Chemical stability

24 months at 36 °F to 46°F (2°C to 25°C) protected from light. Within the first 12 months of this shelf-life the product may be stored up to 6 months at 77°F (≤ 25°C). After storage at 77°F (≤ 25°C) the product must be used or discarded. The product is stable under the conditions, noted in the section on “Handling and storage”.

Possibility of hazardous reactions

No special

Conditions to avoid

None for normal handling of this product.

Incompatible materials

Strong acids, strong bases, strong oxidizing agents, and strong reductants agents.

Hazardous decomposition products

The product is not degraded when handled as specified in section 7.

SECTION 11: Toxicological information

Information on toxicological effects

Immunoglobulins are normal constituents of the human body. In animals, single dose toxicity testing is of no relevance and higher doses result in overloading. Repeated dose toxicity testing and embryofetal toxicity studies are impracticable due to induction of, and interference with antibodies. Effects of the product on the immune system of the newborn have not been studied.
Since clinical experience provides no hint for tumorigenic or mutagenic effects of immunoglobulins, experimental studies, particularly in heterogolous species, are not considered necessary.

Information on the likely routes of exposure

No data available.

Symptoms related to the physical, chemical and toxicological characteristics

No data available.

Delayed and immediate effects and also chronic effects from short- and long-term exposure

No data available.

Numerical measures of toxicity

No data available.

Acute toxicity

Substance

No data available.

Hazardous chemical is listed in NTP, IARC, OSHA

No classification data on carcinogen properties of this material is avaible from NTP, IARC or OSHA.

SECTION 12: Ecological information

Ecotoxicity

Immunoglobulins are normal constituents of the human body.
Being endogenous human constituents all the above active substances will be taken up and enter the natural endogenous pathways for activity and metabolism, and their excretion products are not supposed to be any other than those naturally excreted from the human.
Based on the above considerations all the above products are considered not to pose any threat to the environment.

Substance
No data available.

Persistence and degradability
Substance
No data available.

Bioaccumulative potential
Substance
No data available.

Mobility in soil
No data available

Other adverse effects
No special

SECTION 13: Disposal considerations

Waste treatment methods
Observe all local and national regulations when disposing of this material.

Specific labelling
None

Contaminated packing
No specific requirements.

SECTION 14: Transport information

Not listed as dangerous goods under DOT, IMDG or IATA. The product shall not be transported above 77 °F (25 °C). Protect from light. Do not freeze.

DOT
Not Applicable

IMDG
Not Applicable

IATA/ICAO
Not Applicable

Environmental hazards
No data available.

Special precautions for user
No data available.

Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code
No data available

SECTION 15: Regulatory information

Safety, health and environmental regulations/legislation specific for the product in question
TSCA listed: All substances are listed
SARA Title III: No SARA Hazards
California Prop. 65 Components: This product does not contain any Proposition 65 chemicals

SECTION 16: Other information, including date of preparation or last revision

Full text of H-phrases as mentioned in section 3

H302 - Harmful if swallowed
H315 - Causes skin irritation
H319 - Causes serious eye irritation
H351 - Suspected of causing cancer
H401 - Toxic to aquatic life
H402 - Harmful to aquatic life
H411 - Toxic to aquatic life with long lasting effects
H412 - Harmful to aquatic life with long lasting effects

Other

It is recommended to hand over this safety data sheet to the actual user of the product. Information in this safety data sheet cannot be used as a product specification.
The information in this safety data sheet applies only to this specific product (mentioned in section 1) and is not necessarily correct for use with other chemicals/products.
A change (in proportion to the last essential change (first cipher in SDS version)) is marked with a blue triangle.

Date of preparation
09/21/2015

Date of last essential change
(First cipher in SDS version)

-

Date of last minor change
(Last cipher in SDS version)

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