

MATERIAL SAFETY DATA SHEET

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

Material Octagam 5%

Synonyms Human Immunoglobulin G

Company Name Manufacturer:
Octapharma Pharmazeutika Produktionsges.m.b.H.
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2. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredients **Active ingredients:** Human Immunoglobulin G

1 ml of solution contains:

Protein,	50 mg
of which $\geq 96\%$ is human normal immunoglobulin G	
IgA	$\leq 0.2\text{mg}$
IgM	$\leq 0.1\text{mg}$

Distribution of IgG subclasses:

IgG ₁	app.	65%
IgG ₂	app	30%
IgG ₃	app	3%
IgG ₄	app	2%

Maltose	100 mg
Water for injections	ad 1 ml
Triton X-100	$\leq 5 \mu\text{g}$
TNBP	$\leq 1 \mu\text{g}$

3. HAZARDS IDENTIFICATION

Health Caution – Pharmaceutical agent.

Environment 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 the above product is considered not to pose any threat to the environment.

4. FIRST-AID MEASURES

Ingestion	Do not attempt to induce vomiting. Do not attempt to give any solid or liquid by mouth if the concerned subject is unconscious or semi-conscious. Wash out the mouth with water. If the exposed subject is fully conscious, give plenty of water to drink. Obtain medical attention.
Inhalation	Using appropriate personal protective equipment, move concerned subject to fresh air. If breathing is difficult or ceases, ensure and maintain ventilation. Give oxygen as appropriate. Obtain medical attention in cases with symptoms including disturbed breathing, loss of consciousness, chest pain, marked coughing or other side effects which may be delayed.
Skin Contact	Using appropriate personal protective equipment, flush exposed area with water. Obtain medical attention if skin reaction occurs which may be immediate or delayed.
Eye Contact	Wash with clean and gently flowing water. Continue for about 15 minutes. Obtain medical attention.

NOTES TO HEALTH PROFESSIONALS

Medical Treatment	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 an human immunoglobulin.
Medical Conditions Caused or Aggravated by Exposure	Refer to current prescribing information for detailed description of medical conditions caused or aggravated by overexposure of this product.
Antidotes	No specific antidotes are recommended.

5. FIRE-FIGHTING MEASURES

Fire and Explosion Hazards	This product is non-combustible, although the packaging is combustible.
Special Firefighting Procedures	No special requirements needed.
Hazardous Combustion Products	No special requirements needed.

6. ACCIDENTAL RELEASE MEASURES

Spills	Care must be taken when removing broken glass vials. For clean up water can be used
Personal Precaution	No personal precautions needed.
Environmental Precautions	n.a.
Clean-up Methods	Water can be used for clean-up.
Decontamination Procedures	There are no decontamination operations needed.

7. HANDLING AND STORAGE

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.
Storage:	OCTAGAM may be stored for 24 months at +2 °C to +8 °C (36 °F to 46 °F) or may be stored at temperatures not to exceed +25 °C (77 °F) for up to 18 months from the date of manufacture. Do not freeze. Keep container in the outer carton in order to protect from light.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

INGREDIENT	Human Immunoglobulin G
GSK Occupational Hazard Category	n.a.
GSK Occupational Exposure Limit	n.a.
ENGINEERING CONTROLS	
Exposure Controls	n.a.
Other Equipment or Procedures	None required for normal handling. Wash hands and arms thoroughly after handling.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance

Clarity	The liquid preparation is clear or not more opalescent than the reference suspension II.
Colour	The liquid preparation is colourless or not more intensely coloured than reference solution Y5.
Physical Form	Solution for infusion.
pH of Aqueous Solutions	5.1 – 6.0

10. STABILITY AND REACTIVITY

Stability:	24 months at +2 °C to +8 °C (36 °F to 46 °F) protected from light or 18 months at ≤ + 25 °C (77 °F) protected from light.
Conditions to Avoid	None for normal handling of this product.

11. TOXICOLOGICAL INFORMATION

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 embryo-

foetal 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 heterologous species, are not considered necessary.

12. ECOLOGICAL INFORMATION

Summary Immunoglobulins are normal constituents of the human body.

13. DISPOSAL CONSIDERATIONS

Disposal Recommendations Collect for recycling or recovery if possible. The disposal method for rejected products/returned goods must ensure that they cannot be re-sold or re-used.

Regulatory Requirements Observe all local and national regulations when disposing of this material.

14. REGULATORY INFORMATION

EU Classification and Labelling

Classification(s)Pharmacotherapeutic group ATC code: J06B A02 / Immunoglobulin G (Human)

15. OTHER INFORMATION

Date Approved/Revised April 2004