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

1.1. Identification of the substance or preparation

Material: panzyga®

Description: Intravenous Immunglobulin human 10% SD

1.2. Use of the substance / preparation

Panzyga® is a ready-to-use human normal immunoglobulin (IgG) solution of human antibodies stabilised with glycine, and administered via the intravenous route.
It is produced from the plasma of human donors.

Panzyga® is a treatment for people with certain immune system disorders.

1.3. Company / undertaking identification

Company Name: **Manufacturer:**

Octapharma Pharmazeutika Produktionsges.m.b.H
Oberlaaer Straße 235
A-1100 Vienna
Austria

Octapharma S.A.S
70 – 72 Rue du Maréchal Foch
F-67381 Lingolsheim
France

1.4. Emergency contact

Customer Service: uscustomerservice@octapharma.com
Toll-Free #: 866-766-4860

Drug Safety Officer: US1.DrugSafety@octapharma.com
Phone: 201-604-1105

Medical Affairs: usmedicalaffairs@octapharma.com
Toll-Free #: 888-429-4535

2. HAZARDS IDENTIFICATION

2.1. Health

CAUTION! Pharmaceutical agent

2.2. Environment

Being endogenous human constituents all the active substances listed in **"3. Composition / information on ingredients"** 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 products listed in number 3 are considered not to pose any threat to the environment.

3. COMPOSITION / INFORMATION ON INGREDIENTS

3.1. Active ingredient

Human normal immunoglobulin (IgG)

Approximate values of the distribution of the IgG subclasses:

IgG_1 65%
IgG_2 28%
IgG_3 3%
IgG_4 4%

3.2. Specifications

protein composition	≥ 95 % IgG (Immunoglobulin)
total protein	9.0 – 11.0 g/100 ml
osmolality	≥ 240 mosmol/kg
IgA content	≤ 0.3 mg/ml
IgM content	≤ 0.10 mg/ml
chloride	≤ 30 mmol/l
sodium	≤ 30 mmol/l
potassium	≤ 1.0 mmol/l
aluminium	≤ 200 µg/ml
tri(n-butyl)phosphate	≤ 1.0 ppm
octoxynol	≤ 2.0 ppm
glycine	15.0 – 19.5 mg/ml

4. FIRST AID MEASURES

Ingestion: Do not attempt to introduce 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 gentle 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 human normal immunoglobulin solution.

Medical conditions caused or aggravated by overexposure:
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

Special firefighting procedures: No special requirements needed

Hazardous combustion products: No special requirements needed

6. ACCIDENTAL RELEASE MEASURES

Spills

Personal precaution:	No personal precaution 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

7.1. Handling

For intravenous use only.

Prior to use, allow Panzyga® to reach ambient room temperature.

7.2. Storage

Storage temperature as stated on the packaging.
Keep the container in the outer carton to protect from light.
Do not freeze.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Occupational Exposure Limit:	n.a.
Environmental Exposure Limit:	n.a.
Personal protective equipment:	None required for normal handling. Wash hands and arms thoroughly after handling.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1. General information

Physical form:	liquid preparation
Colour:	The liquid preparation is colourless or not more intensely coloured than reference solution Y5 (Ph. Eur. 2.2.2).
Clarity:	The liquid preparation is clear or not more opalescent than the reference suspension II (Ph. Eur. 2.2.1).
Sterility:	sterile
Endotoxins:	< 1.0 IU7ml (Ph. Eur. 2.6.14)

9.2. Important health, safety and environmental information

pH of aqueous solution:	4.5 – 5.0
boiling point:	n.a.
flammability:	the product is not flammable
explosive properties:	the product has no explosive properties
oxidising properties:	the product has no oxidising properties
water solubility:	the product is watersoluble

10. STABILITY AND REACTIVITY

Stability: the product is stable

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 embryofetal toxicity studies are impracticable due to induction of, and interference with antibodies. Effects of the product on the immune system of 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.

12. ECOLOGICAL INFORMATION

Ecotoxicity:	n.a.
Mobility:	n.a.
Persistence:	n.a.
Bioaccumulative potential:	n.a.
Other adverse effects:	none identified

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:	Follow all local and national regulations when disposing of this material.

14. TRANSPORT INFORMATION

EU classification and labeling:	The product is not subject to transport regulations.
Additional information:	The product shall be transported at the temperature as stated on the packaging. Protect from light.

15. REGULATORY INFORMATION

Classification(s):	Pharmacotherapeutic group: immunoglobulins, normal, human, for intravascular administration ATC code: J06BA02

16. OTHER INFORMATION

Shelf-life of the product: as stated on the packaging

Date approved/Revised: October 2017