

# Environmental Product Declaration

in accordance with ISO 14025 for

**Ig Vena 50g/l** 100ml, 50ml and 200ml

**KEDRION**  
B I O P H A R M A

Programme/  
The International  
EPD® System  
[www.environdec.com](http://www.environdec.com)

Programme operator/  
EPD International AB

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Geographical scope/  
Global



EPD should provide current information, and may be updated if conditions change. The stated validity is therefore subject to the continued registration and publication at [www.environdec.com](http://www.environdec.com)

## General information

### Information about the organization

#### Owner of the EPD:

Kedrion S.p.A.  
Loc. ai Conti  
IT 55051 Castelvechio Pascoli Barga (LU)  
[www.kedrion.com](http://www.kedrion.com)

#### Description of the organisation:

Kedrion Biopharma is a biopharmaceutical company that collects and fractionates blood plasma to produce and distribute plasma-derived therapies for use in treating patients suffering from Hemophilia, Immunodeficiencies and other serious illnesses.

Kedrion puts people at its heart, placing a high value on the welfare of those who benefit from its products, as well as on the people and the communities it serves.

Kedrion acts as a bridge between donors and the people who need treatments, and works on a global scale to expand the patients' access to available treatments.

Headquartered in Italy, Kedrion Biopharma has a market presence in over 100 countries. In the field of plasma derivatives, it is the world's 5th most important player and Italy's 1st. The company employs more than 2,600 people, over 1100 of whom are in Italy: over 37% of staff is under the age of 35 and women account for more than 50% of the workforce.

In Italy, Kedrion is a partner of the National Health System, which it concretely supports in the pursuit of self-sufficiency in the supply of plasma-derived products. At the same time, the company offers its expertise and its efforts to communities and health systems all over the world to achieve the same goal, in the attempt to help improve the quality of life of people with rare diseases.

The company manages the entire plasma transformation cycle (supply, production and distribution), on a vertical integration business model.

Our production plants are in Italy (Bolognana and Castelvechio Pascoli - which is nearing completion - near Lucca, and Sant'Antimo, near Naples), Hungary (in Gödöllő, near Budapest) and the United States (in Melville, New York).

Kedrion owns fully-operational plasma collection centers in the United States and Europe. In particular, a collection centre in Buffalo, State of New York, specializes in plasma with a high Anti-D antibody content, used to manufacture an Anti-D Immuno-globulin-based medicinal product which for half a century has been effective in the prevention of Haemolytic Disease of the Fetus and the Newborn (HDFN).

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## About the company

In Kedrion's philosophy, care for the environment at large starts from the environment in which we operate. Reducing the environmental impact of our production plants - for example by decreasing waste production and the use of resources as much as possible - expands this care to include local communities. Aware of human responsibility in climate change, Kedrion commits to respecting an internal policy aimed at mitigating the environmental implications of its manufacturing processes. We pay great attention to our environmental performances, cooperate in monitoring the effects of our activities on the environment, and are always on the lookout of ways to improve our performances.

Kedrion has undertaken to put into effect, maintain and communicate information on its processes and activities, in compliance with the highest standard qualities including:

UNI EN ISO 14001 and EMAS regulations (Environmental Management System)

UNI EN ISO 9001

BS OHSAS 18001 (Occupational Health and Safety System).

The present EPD refers to the production of IG VENA in Kedrion's Bolognana plant.

## Product information

### Product name:

IG VENA

### Product identification and description:

IG VENA is a solution for infusion containing Human normal immunoglobulin (IVIg). It is a human plasma derived product for intravenous administration.

IG VENA is used for:

Replacement therapy in adults, and children and adolescents (0-18 years) in:

- Primary immunodeficiency syndromes with impaired antibody production (see section 4.4);
- Hypogammaglobulinaemia and recurrent bacterial infections in patients with chronic lymphocytic leukaemia, in whom prophylactic antibiotics have failed;
- Hypogammaglobulinaemia and recurrent bacterial infections in plateau phase multiple myeloma patients who have failed to respond to pneumococcal immunisation;
- Hypogammaglobulinaemia in patients after allogeneic haematopoietic stem cell transplantation (HSCT);
- Congenital AIDS with recurrent bacterial infections.

Immunomodulation in adults, and children and adolescents (0-18 years) in:

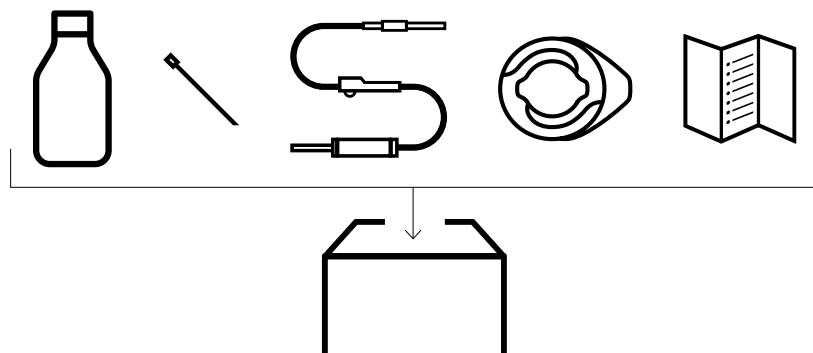
- Primary immune thrombocytopenia (ITP), in patients at high risk of bleeding or prior to surgery to correct the platelet count;
- Guillain Barré syndrome;
- Chronic Inflammatory Demyelinating Poliradiculoneuropathy (CIDP);
- Kawasaki disease.

IG VENA 50 g/l Solution for infusion, included in this EPD, are provided in 3 different sizes:

- Vial of 50 ml contains: 2.5 g of human normal immunoglobulin;
- Vial of 100 ml contains: 5 g of human normal immunoglobulin;
- Vial of 200 ml contains: 10 g of human normal immunoglobulin.

A single dose kit (Fig.1) includes:

100ml, 50ml or 200ml vial containing 50g/L IG VENA; stopper; blister; pipe; needle; leaflet; cardboard box





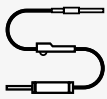



UN CPC code:

CPC code Ver.2: 35270 - Other pharmaceutical products

Geographical scope:

Global

fig. 1  
Components of a single dose kit

Components	Materials	Units	Quantity per		
			50 ml	100 ml	200 ml
 vial	bottle/ glass	g	57	92	170
	stopper/ bromobutyl rubber	g	8	8	8
	aluminium overseal/ aluminium	g	1	1	1
	plastic flip-off top cap/ polypropylene	g	1	1	1
 needle	steel + pvc	g	2	2	2
 pipe	pvc	g	22	22	22
 blister	pvc	g	4	6	6
 leaflet	paper	g	7	3	3
 paper box	paper	g	20	21	26



## Content declaration

Components in IG VENA are:

- Human normal immunoglobulin
- maltose
- Water for injections

Human normal immunoglobulin should be infused intravenously at an initial rate of 0.46 – 0.92 ml/kg/hr (10 - 20 drops per minute) for 20 - 30 minutes. If well tolerated, the rate of administration may be gradually increased to a maximum of 1.85 ml/kg/hr (40 drops/minute).

tab. 1  
Content of IG VENA single dose

Materials / chemical substances	
	[Unit] %
Human normal immunoglobulin	4.5-5.5 %
Maltose	9-11%
Water for injections	83-86 %

Globally Harmonized System of Classification and Labeling of Chemicals (GHS). No hazards are expected from using this product. This product is not regulated under the United Nations Globally Harmonized System for the Classification and Labeling of Hazardous Chemicals (GHS).

### Packaging

#### Distribution packaging:

cardboard box is used to transport single dose kits (the number of kits may vary depending on the product size) (ISO 21067-1:2016, Par. 2.2.6)

#### Consumer packaging:

a single dose kit for the final user is packaged in cardboard box (ISO 21067-1:2016, Par. 2.2.7).

## LCA information

Time representativeness	data refer to the year 2017
Database used	EcoInvent Database v.3.4
LCA software used	SimaPro 8.5.2.0

The scope of the present Environmental Product Declaration is to assess potential environmental impact values for the IG VENA production, based on the Life Cycle Assessment methodology, and make them explicit. A description follows with details on functional/declared unit, system boundaries, key assumptions and a flow chart describing the lifecycle stages of the product. A comprehensive quantitative evaluation of environmental performances in the IG VENA production chain has been provided based on Life Cycle Assessment (LCA). The considered lifecycle includes all the main processes from the withdrawing of raw materials, to the fractioning, purification, bottling and packaging of IG VENA, until its use and end-use treatment.

### Functional Unit

The Functional Unit (FU) is a single dose kit of IG VENA including: 100mL, 50mL or 200mL vial containing 50g/L IG VENA; stopper; blister; pipe; needle; leaflet; cardboard box, produced by Kedrion S.p.A. in the Bolognana site (Lucca – IT)

### Description of system boundaries

Based on a “from cradle to grave” approach, the IG VENA lifecycle system boundaries concern:



#### UPSTREAM PROCESS

it consists in the “from cradle to gate” set of processes that includes:

- production and transport of raw materials used (e.g. plastic and chemical products);
- production and transport of materials for packaging (e.g. PVC, cardboard boxes)
- production and transport of materials for the final product packaging (e.g. glass, cardboard boxes)

The production of plasma from human blood in transfusion centres and its transport to reception centres are not included in the analysis, according to reference PCR (PCR 2016:07 UN CPC 35270 -39931, 2019-01-30, v. 1.1).



#### CORE PROCESS

it consists in processes within the production plant (from gate to gate) that include the following sub-sections:

- 0 Transport of plasma to the gate:** transport of plastic bags of frozen human plasma from the reception centres to the gate of the production plant (Bolognana).
- 1 Gate and check-in:** reception, check-in (control and registration) and warehousing of plastic bags of frozen human plasma in refrigerating rooms.

**2 Pool Plasma:** opening process of plastic bags, plasma defrosting and centrifuging for the extraction of cryopaste and supernatant. The supernatant is almost 97% of the plasma and it is used to produce a wide range of products (e.g. Albumin, PTC, ATIII), including the IG VENA. The cryopaste is used for the production of Factor VIII.

Material use in sections 0, 1 and 2 is allocated to the mass of plasma specifically addressed to the production of IG VENA to which was added the reattribution of waste jointly produced along the whole process of Bolognana (i.e. 31.04%). See Neri and Pulselli 2018 for detailed description of allocation procedures.

**3 Fractioning:** specific sequence of processes, including multiple filtering, centrifugations, extractions and separations, for the production of Fraction II.

**4 Purification and Inactivation of Fraction II:** specific sequence of processes, including dilutions, filtering, pH variations, viral inactivation and dialysis to obtain a bulk of IG VENA.

From this sub-section to the packaging, collected data on material use were directly referred to the production of IG VENA (any allocation avoided).

**5 Bottling:** filtering in sterile room and hermetic closing of glass vial containing 100mL, 50 mL or 200mL of IG VENA. Afterwards, capped vials are sent to the packaging.

**6 Packaging:** semi-manual assembling and packaging of the IG VENA single dose kit: 100mL, 50mL or 200mL vial containing 50g/L IG VENA; blister; pipe; needle; leaflet; cardboard box, produced by Kedrion S.p.A. in the Bolognana site (Lucca - IT) (external commitment).

Waste from the production process that include contaminated materials (all the materials kept in touch with organic substances), were addressed to incineration. Non contaminated paper and cardboard were considered 100% recycled. A little quantity of plastic materials (5%) was addressed to recycling (7.5%), incineration (23.9%) and landfill (68.5%) coherently to the current state of waste treatment in the Tuscan Region (ARRR, 2008). Transport of waste to the waste plant was also considered (50km average distance). Transport of materials and products (e.g. empty vials of IG VENA from the production plant to the packaging plant) were also considered.



## DOWNSTREAM PROCESS

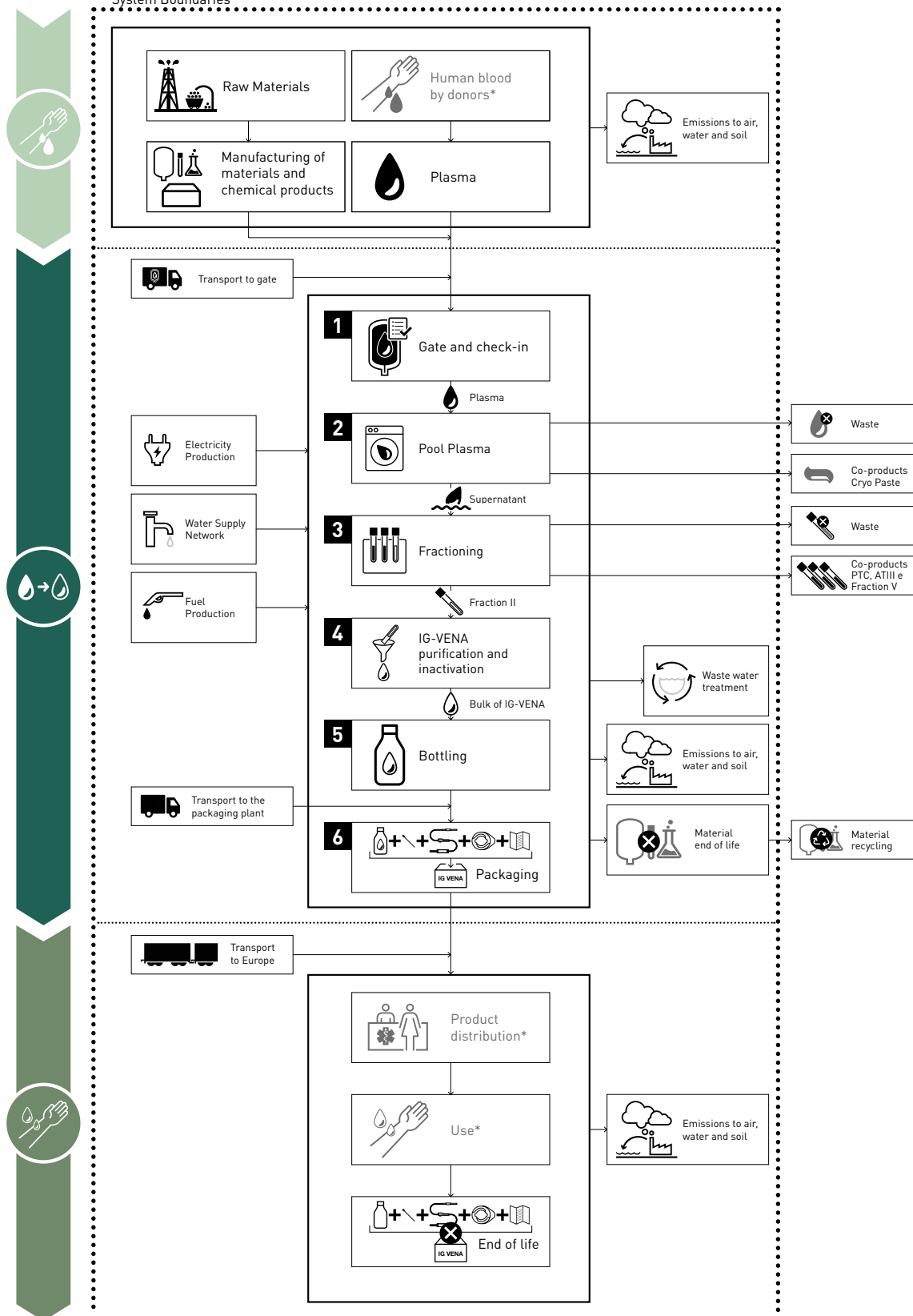
it consists in the "from gate to grave" set of processes that includes:

- Distribution (transport) of the final product to points of sale (pharmacy or hospital) considering an average transport to Europe by railway; two other different distribution scenarios are accounted: to Italy (roadway); to USA (airway).
- End of life treatment of materials used and packaging. Waste that include contaminated materials (all the materials kept in touch with organic substances) and mono-dose vials were addressed to incineration. Non contaminated paper and cardboard were considered 100% recycled. This estimate could cause little (negligible) variation according to the regional policy for waste management. Transport of waste to the waste plant was also considered (50 km average distance).

The Downstream process does not include transport to the end user (in case of distribution in pharmacy) and the use of the product.

fig. 2  
Flow chart and system boundaries of the IG VENA production, divided into Upstream, Core and Downstream

\* not included



**Excluded lifecycle stages:** Based on the definition of system boundaries and cut-off criteria, a number of processes were considered not relevant or not directly referred to the IG VENA lifecycle. Excluded processes are the following:

- construction of buildings and machineries in the Bolognana site;
- production and maintenance of machineries with more than 3 years estimated lifetime;
- technical materials reused in an indefinite number of production cycles;
- activity and travels of employers;
- blood withdrawing and plasma production in transfusion centres and transport to reception centres;
- transport to the end user (in case of distribution in pharmacy)
- the use of the product.

Not significant data were neglected, such as energy use for the final packaging, because this plants is not specifically dedicated to the production of IG VENA and not relevant. Moreover, the final packaging is a semi-manual process. Transport of final products from points of sale (pharmacy) to the final user is not included.

The considered cut-off is under the threshold of relevance (1% of total inputs), in accordance with the maximum percentage for exclusion recommended by the reference PCR 2016:07 UN CPC 35270 -39931, 2019-01-30, v. 1.1 and GPI 2017-12-11 v.3.0.

#### **More information:**

The LCA has been performed in compliance with ISO 14040:2006, ISO 14025:2006 (Environmental labels and declarations - Type III) and the GPI (General Programme Instructions for the International EPD System), 2017-12 11 v.3.0.

The LCA refers to the PCR UN CPC 35270 and 39931 (2016:07, version 1.0) dealing with "Blood and blood derived products for therapeutic or prophylactic uses".

Primary data have been collected in the Kedrion plant of Bolognana (Lucca - IT) based on direct interviews with the employers involved in production processes during specific field-visits in different plant sections or derive from certified company reports (i.e. EMAS, 2018). All quantities derive from primary data, except for coverall washing and transport of the final product to the points of sale i.e. contribution <1% to total impacts), as recommended by data quality requirements of reference PCR..

Environmental impacts due to the production and use of energy (electricity, natural gas and gasoline), water and other products (ethyl alcohol, glycol, caustic soda, re-frigerant gases, tensioactive agents), besides wastewater, sludge treatment and other solid waste (except for directly collected data on materials for packaging) were based on data reported in the EMAS 2018 certified report. EMAS data, directly related to mass processed (e.g. water, caustic soda, tensioactive agents, filtering waste), were allocated to the mass of plasma specifically addressed to the production of IG VENA to which was added the reattribution of waste jointly produced along the whole process of Bolognana (i.e. 31.03%). Whilst, EMAS data related to energy sector or temperature control (e.g. electricity, methane, glycol, refrigerant gases) were allocated according to company estimations and energy consumption recognition along the production chain (i.e. 21.46%). In fact, energy consumption is linked to the characteristics of several processes that can be more or less energy intensive, rather than the quantity of mass processed.

Secondary data refer to the Ecoinvent database v.3.4. The LCA has been performed based on the SimaPro 8.5.2.0 software, selected method CML-IA, characterisation factors IPCC 2013 for the impact category GWP100. The characterisation factors for the Acidification Potential (AP) refer to the non-baseline version, the POFP impacts are calculated using the method ReCiPe 2008 Midpoint, the Water Scarcity Footprint (AWARE method) was multiplied with the local water consumption factor for Italy (selecting non-agricultural), as recommended by the general rule of the EPD International Program. All primary and secondary data, selected database and accounting models are compliant with the PCR data quality requirements (par. 4.7).

The LCA study was performed by Elena Neri and Riccardo Pulselli, INDACO2 (Siena – Italy)

## Environmental performance

### Potential environmental impact

The assessed potential environmental impacts are reported in table 2, detailed into upstream, core and downstream processes. Values refer to the functional unit (IG VENA 100mL single dose kit).

tab. 2a  
Environmental Impact  
Potentials referred to the IG  
VENA 100mL production system  
per FU (2017)



UPSTREAM



CORE



DOWNSTREAM



Downstream scenario:  
distribution to Europe (railway)

Reference to characterisation  
factors used:  
GWP: IPCC 2013;  
AP: Hauschild & Wenzel (1998);  
EP: Heijungs et al. (1992);  
POP: Van Zelm et al 2008;  
ADP: Oers, et al (2002);  
Water Scarcity Potential:  
AWARE v.1 Boulay et al., 2017

#### Environmental Impact Potentials/ IG VENA 100mL

		Unit				
					EU	Total
Global warming potential (GWP)	Fossil	kg CO <sub>2</sub> eq	2.54E+00	1.17E+01	2.69E-02	1.43E+01
	Biogenic	kg CO <sub>2</sub> eq	1.06E-01	1.31E-01	6.56E-04	2.38E-01
	Land use and land transformation	kg CO <sub>2</sub> eq	2.22E-02	5.74E-04	1.56E-05	2.27E-02
	total	kg CO <sub>2</sub> eq	2.67E+00	1.19E+01	2.76E-02	1.46E+01
Depletion potential of the stratospheric ozone layer (ODP)		kg CFC 11 eq	9.31E-07	1.31E-06	3.37E-09	2.24E-06
Acidification potential (AP)		kg SO <sub>2</sub> eq	1.27E-02	1.36E-02	1.51E-04	2.64E-02
Eutrophication potential (EP)		kg PO <sub>4</sub> <sup>3-</sup> eq	5.62E-03	3.88E-03	4.48E-05	9.55E-03
Formation potential of tropospheric ozone (POFP)		kg NMVOCeq	7.79E-03	4.09E-02	1.89E-04	4.89E-02
Abiotic depletion potential - Elements		kg Sb eq	2.72E-05	1.80E-06	2.89E-08	2.91E-05
Abiotic depletion potential - Fossil resources		MJ net calorific value	4.10E+01	1.12E+02	2.95E-01	1.53E+02
Water scarcity potential		m <sup>3</sup> eq	2.77E+00	3.42E+00	9.61E-03	6.21E+00

**Global Warming Potential:** core processes generate the highest impact (82.0%), mainly due to the use of natural gas for thermoelectricity production (35.7%) and vapour production (6.7%), besides direct emission of refrigerant gases (24.0%) and grid electricity absorption (3.2%). The upstream phase generates 18.3% of the total impact due to the production of chemical products (mainly ethanol, 4.7%) The downstream phase contributes with 0.2%, due to the end-life treatment of wasted materials for packaging.

**Acidification Potential:** the upstream processes generate highest impacts (48%) of the total impact, due to the use of chemical products (mainly sodium phosphate and ethanol, 27% and 9% respectively). Core phase generates 51% of impacts, mainly due to the use of natural gas for thermoelectricity production (20%), grid electricity absorption (10%), transport of plasma from USA (8%) and hazardous waste treatment (5%). The downstream phase contributes to 1%, due to the end-life treatment of wasted materials.

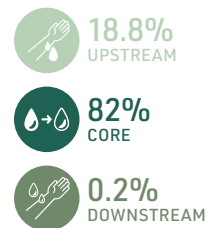
**Eutrophication Potential:** upstream processes generate the highest impact (59%) due to the production of chemical products (mainly sodium phosphate and ethanol, 37% and 10% respectively). The core phase generates 40% of the total impact, mainly due to processes or wastewater treatment (10%), the use of natural gas (8%), hazardous waste treatment (8%), grid electricity absorption (6%). The downstream phase contributes to 1%, due to the end-life treatment of wasted materials.

**Photochemical Formation Oxidation Potential:** core processes generate the most of the impact (84%), mainly due to the use of chemical products (mainly direct emission from ethanol, 58%). The upstream phase generates 16% of the total impact due to the use of chemical products (mainly chemical products, 6%, and ethanol, 5%).

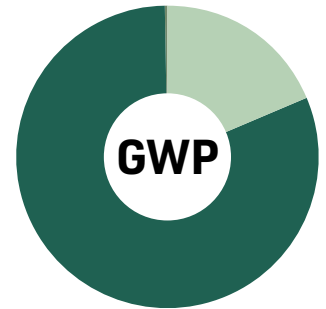
Results are shown in Figure 3.

fig. 3  
LCA based estimated values  
of environmental impacts of IG  
VENA 100mL

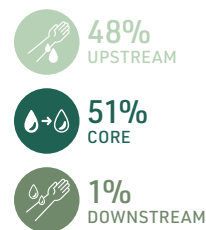
### Global Warming Potential



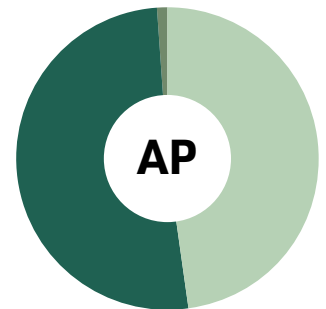
14.60 kg CO<sub>2</sub> eq



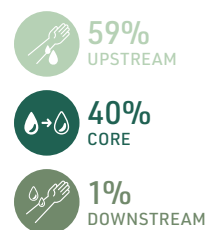
### Acidification Potential



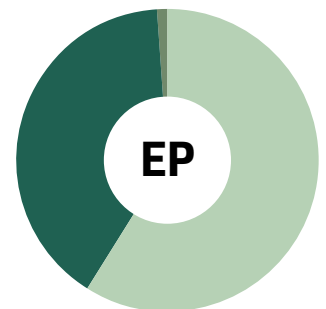
2.64\*10<sup>-2</sup> kg SO<sub>2</sub> eq



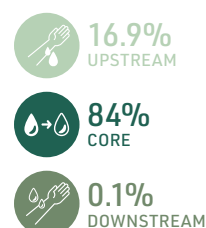
### Eutrophication Potential



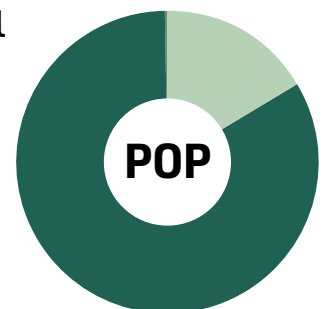
9.55\*10<sup>-3</sup> kg PO<sub>4</sub><sup>3-</sup> eq



### Photochemical Formation Oxidation Potential



4.89\*10<sup>-2</sup> kg NMVOC eq



In general, energy use is the most relevant aspect in terms of environmental impact management, particularly referring to GWP assessed values.

Considering that IG VENA is a medical product, the production of waste - often due to the mandatory single use of materials and their classification into hazardous waste - and the use of chemical products determine relevant effects. Nevertheless, these cannot be easily managed and mitigated to not compromise quality and safety of the final product.

The following tables show Environmental Impact Results for different sizes.

tab. 2b  
Environmental Impact  
Potentials referred to the IG  
VENA 50mL production system  
per FU (2017)



UPSTREAM



CORE






DOWNSTREAM



Downstream scenario:  
distribution to Europe (railway)

#### Environmental Impact Potentials/ IG VENA 50mL

		Unit	  			Total
Global warming potential (GWP)	Fossil	kg CO <sub>2</sub> eq	1.38E+00	5.87E+00	9.40E-02	7.34E+00
	Biogenic	kg CO <sub>2</sub> eq	6.61E-02	6.58E-02	7.53E-04	1.33E-01
	Land use and land transformation	kg CO <sub>2</sub> eq	1.15E-02	2.93E-04	1.62E-05	1.18E-02
	total	kg CO <sub>2</sub> eq	1.45E+00	5.94E+00	9.47E-02	7.49E+00
Depletion potential of the stratospheric ozone layer (ODP)		kg CFC 11 eq	4.82E-07	6.58E-07	4.68E-09	1.14E-06
Acidification potential (AP)		kg SO <sub>2</sub> eq	6.84E-03	6.85E-03	1.69E-04	1.39E-02
Eutrophication potential (EP)		kg PO <sub>4</sub> <sup>3-</sup> eq	2.98E-03	1.96E-03	5.11E-05	4.98E-03
Formation potential of tropospheric ozone (POFP)		kg NMVOCeq	4.28E-03	2.06E-02	1.96E-04	2.51E-02
Abiotic depletion potential - Elements		kg Sb eq	1.39E-05	9.41E-07	4.20E-08	1.49E-05
Abiotic depletion potential - Fossil resources		MJ net calorific value	2.21E+01	5.64E+01	3.41E-01	7.88E+01
Water scarcity potential		m <sup>3</sup> eq	1.56E+00	1.67E+00	9.71E-02	3.33E+00

tab. 2c  
Environmental Impact  
Potentials referred to the IG  
VENA 200mL production system  
per FU (2017)



UPSTREAM



CORE






DOWNSTREAM



Downstream scenario:  
distribution to Europe (railway)

#### Environmental Impact Potentials/ IG VENA 200mL

		Unit	  			Total
Global warming potential (GWP)	Fossil	kg CO <sub>2</sub> eq	4.90E+00	2.32E+01	1.15E-01	2.82E+01
	Biogenic	kg CO <sub>2</sub> eq	1.99E-01	2.61E-01	1.12E-03	4.61E-01
	Land use and land transformation	kg CO <sub>2</sub> eq	4.39E-02	1.12E-03	2.49E-05	4.51E-02
	total	kg CO <sub>2</sub> eq	5.14E+00	2.35E+01	1.17E-01	2.87E+01
Depletion potential of the stratospheric ozone layer (ODP)		kg CFC 11 eq	1.84E-06	2.60E-06	7.42E-09	4.44E-06
Acidification potential (AP)		kg SO <sub>2</sub> eq	2.47E-02	2.68E-02	2.75E-04	5.18E-02
Eutrophication potential (EP)		kg PO <sub>4</sub> <sup>3-</sup> eq	1.10E-02	7.67E-03	7.91E-05	1.88E-02
Formation potential of tropospheric ozone (POFP)		kg NMVOCeq	1.49E-02	8.13E-02	3.37E-04	9.66E-02
Abiotic depletion potential - Elements		kg Sb eq	5.40E-05	3.47E-06	6.33E-08	5.75E-05
Abiotic depletion potential - Fossil resources		MJ net calorific value	7.90E+01	2.22E+02	5.75E-01	3.02E+02
Water scarcity potential		m <sup>3</sup> eq	5.18E+00	6.65E+00	1.07E-01	1.19E+01

## Use of resources

tab. 3a  
Total renewable and non-renewable resources used in the IG VENA 100mL production system (2017)



UPSTREAM



CORE



DOWNSTREAM

### Renewable and non-renewable resources/ IG VENA 100mL

Resources		Unit				Total
Primary energy resources - RENEWABLE	Used as ENERGY carrier	MJ, net calorific value	3.09E+00	2.14E+00	1.97E-02	5.25E+00
	Used as RAW MATERIALS	MJ, net calorific value	2.34E+00	5.60E-01	7.64E-03	2.91E+00
	total	MJ, net calorific value	5.43E+00	2.70E+00	2.73E-02	8.16E+00
Primary energy resources - NON RENEWABLE	Used as ENERGY carrier	MJ, net calorific value	4.65E+01	1.25E+02	3.73E-01	1.72E+02
	Used as RAW MATERIALS	MJ, net calorific value	7.10E-01	0.00E+00	0.00E+00	7.10E-01
	total	MJ, net calorific value	4.72E+01	1.25E+02	3.73E-01	1.73E+02
Secondary Material	kg		0	0	0	0
Renewable secondary fuels	kg		0	0	0	0
Non-Renewable secondary fuels	MJ		0	0	0	0
Net use of fresh water	m <sup>3</sup>		2.00E-02	1.43E-01	2.48E-04	1.63E-01

tab. 3b  
Total renewable and non-renewable resources used in the IG VENA 50mL production system (2017)



UPSTREAM



CORE



DOWNSTREAM

### Renewable and non-renewable resources/ IG VENA 50mL

Resources		Unit				Total
Primary energy resources - RENEWABLE	Used as ENERGY carrier	MJ, net calorific value	1.94E+00	1.08E+00	2.15E-02	3.04E+00
	Used as RAW MATERIALS	MJ, net calorific value	1.64E+00	2.81E-01	9.57E-03	1.93E+00
	total	MJ, net calorific value	3.58E+00	1.36E+00	3.11E-02	4.97E+00
Primary energy resources - NON RENEWABLE	Used as ENERGY carrier	MJ, net calorific value	2.51E+01	6.32E+01	4.12E-01	8.87E+01
	Used as RAW MATERIALS	MJ, net calorific value	6.69E-01	0.00E+00	0.00E+00	6.69E-01
	total	MJ, net calorific value	2.58E+01	6.32E+01	4.12E-01	8.93E+01
Secondary Material	kg		0	0	0	0
Renewable secondary fuels	kg		0	0	0	0
Non-Renewable secondary fuels	MJ		0	0	0	0
Net use of fresh water	m <sup>3</sup>		1.09E-02	7.06E-02	2.41E-03	8.40E-02

tab. 3c  
Total renewable and non-renewable resources used in the IG VENA 200mL production system (2017)



UPSTREAM






CORE



DOWNSTREAM

Renewable and non-renewable resources/ IG VENA 200mL

Resources		Unit	  			Total
Primary energy resources - RENEWABLE	Used as ENERGY carrier	MJ, net calorific value	5.82E+00	4.24E+00	2.92E-02	1.01E+01
	Used as RAW MATERIALS	MJ, net calorific value	4.34E+00	1.11E+00	1.49E-02	5.46E+00
	total	MJ, net calorific value	1.02E+01	5.35E+00	4.42E-02	1.56E+01
Primary energy resources - NON RENEWABLE	Used as ENERGY carrier	MJ, net calorific value	9.00E+01	2.49E+02	6.91E-01	3.40E+02
	Used as RAW MATERIALS	MJ, net calorific value	7.10E-01	0.00E+00	0.00E+00	7.10E-01
	total	MJ, net calorific value	9.07E+01	2.49E+02	6.91E-01	3.41E+02
Secondary Material	kg		0	0	0	0
Renewable secondary fuels	kg		0	0	0	0
Non-Renewable secondary fuels	MJ		0	0	0	0
Net use of fresh water	m <sup>3</sup>		3.88E-02	2.80E-01	2.83E-03	3.22E-01

## Waste production

tab. 4a  
Total waste generation for the  
IG VENA 100mL production  
system (2017)

Waste/ IG VENA 100mL					
Parameter	Unit				Total
Hazardous waste disposed	kg	4.73E-05	2.38E-01	1.28E-01	3.66E-01
Non-hazardous waste disposed	kg	4.54E-01	3.33E-01	1.86E-1	9.72E-1
Radioactive waste disposed	kg	6.15E-05	1.24E-04	3.61E-06	1.89E-04

tab. 4b  
Total waste generation for the  
IG VENA 50mL production  
system (2017)

Waste/ IG VENA 50mL					
Parameter	Unit				Total
Hazardous waste disposed	kg	3.16E-05	1.19E-01	9.10E-02	2.10E-01
Non-hazardous waste disposed	kg	2.40E-01	2.53E-01	6.1E-2	5.54E-01
Radioactive waste disposed	kg	3.51E-05	6.43E-05	1.67E-06	1.01E-04

tab. 4c  
Total waste generation for the  
IG VENA 200mL production  
system (2017)

Waste/ IG VENA 200mL					
Parameter	Unit				Total
Hazardous waste disposed	kg	9.07E-05	4.74E-01	2.06E-01	6.80E-01
Non-hazardous waste disposed	kg	8.88E-01	8.64E-01	1.07E-1	1.86E0
Radioactive waste disposed	kg	1.19E-04	2.45E-04	4.44E-06	3.68E-04

## Output flows

tab. 5a  
Total output flows for the IG  
VENA 100mL production system  
(2017)




Output flows/ IG VENA 100mL					
Parameter	Unit				Total
Components for reuse	kg	0	0	0	0
Material for recycling	kg	0	2.96E-02	3.33E-2	6.29E-2
Materials for energy recovery	kg	0	0	0	0
Exported energy, electricity	MJ	0	0	0	0
Exported energy, thermal	MJ	0	0	0	0

tab. 5b  
Total output flows for the IG  
VENA 50mL production system  
(2017)

Output flows/ IG VENA 50mL					
Parameter	Unit				Total
Components for reuse	kg	0	0	0	0
Material for recycling	kg	0	1.49E-02	4.1 E-2	5.62E-2
Materials for energy recovery	kg	0	0	0	0
Exported energy, electricity	MJ	0	0	0	0
Exported energy, thermal	MJ	0	0	0	0

tab. 5c  
Total output flows for the IG VENA 200mL production system (2017)

#### Output flows/ IG VENA 200mL
























Parameter	Unit	  			Total
Components for reuse	kg	0	0	0	0
Material for recycling	kg	0	5.89E-02	5.2 E-2	1.11E-1
Materials for energy recovery	kg	0	0	0	0
Exported energy, electricity	MJ	0	0	0	0
Exported energy, thermal	MJ	0	0	0	0

#### Other environmental indicators

Downstream scenarios were provided considering different destinations and ways (tab.6): to Italy (roadway), Europe (railway) and USA (airway). Values refer to the impact category GWP100, AP, EP and POFP.

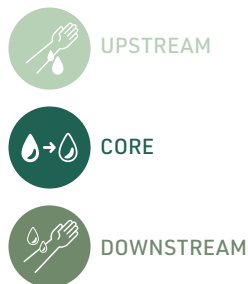
tab. 6  
Environmental Impact Potentials referred to the IG VENA 100mL, 50 mL and 200 mL production system (2017). Compared downstream scenarios: distribution to Italy (roadway) and USA (airway)


#### Environmental Impact Potentials/ IG VENA 100,50 and 200mL (only downstream)


						
Parameter		Unit		100mL	50mL	200mL
Global warming potential (GWP)	Fossil	kg CO <sub>2</sub> eq	 IT	1.44E+01	7.38E+00	2.83E+01
			 USA	1.61E+01	8.63E+00	3.04E+01
	Biogenic	kg CO <sub>2</sub> eq	 IT	2.38E-01	1.33E-01	4.61E-01
			 USA	2.40E-01	1.34E-01	4.63E-01
	Land use and land transformation	kg CO <sub>2</sub> eq	 IT	2.28E-02	1.18E-02	4.51E-02
			 USA	2.29E-02	1.19E-02	4.52E-02
	total	kg CO <sub>2</sub> eq	 IT	1.46E+01	7.53E+00	2.88E+01
			 USA	1.64E+01	8.77E+00	9.40E-02
Depletion potential of the stratospheric ozone layer (ODP)		kg CFC 11 eq	 IT	2.25E-06	1.15E-06	4.46E-06
			 USA	2.58E-06	1.38E-06	4.84E-06
Acidification potential (AP)		kg SO <sub>2</sub> eq	 IT	2.66E-02	1.40E-02	5.19E-02
			 USA	3.44E-02	1.94E-02	6.10E-02
Eutrophication potential (EP)		kg PO <sub>4</sub> <sup>3-</sup> eq	 IT	9.57E-03	5.00E-03	1.88E-02
			 USA	1.08E-02	5.86E-03	2.02E-02
Formation potential of tropospheric ozone (POFP)		kg NMVOCeq	 IT	4.91E-02	2.52E-02	9.68E-02
			 USA	5.80E-02	3.14E-02	1.07E-01
Abiotic depletion potential – Elements		kg Sb eq	 IT	2.94E-05	1.51E-05	5.80E-05
			 USA	2.92E-05	1.51E-05	5.77E-05
Abiotic depletion potential – Fossil resources		MJ net calorific value	 IT	1.54E+02	7.94E+01	3.03E+02
			 USA	1.80E+02	9.72E+01	3.33E+02
Water scarcity potential		m <sup>3</sup> eq	 IT	6.21E+00	3.33E+00	1.19E+01
			 USA	6.32E+00	3.41E+00	1.21E+01

Other impact categories were considered in the analysis such as:

- Human, Fresh-water and Marine Toxicity Potential (HTP, FAETP and MAETP inf., respectively) assessed based on the CML2001;
- Energy content (HHV) of the product (Ecoinvent v. 3.4)




 Downstream scenario: distribution to ITA (roadway)

 Downstream scenario: distribution to USA (airway)

tab. 7a

Environmental Impact Potentials referred to the IG VENA 100mL production system per FU (2017). Other assessed impact categories




Other assessed impact categories/ IG VENA 100mL

Parameter	Unit	  			Total
Human Toxicity Potential	kg DCB e	1.34E+00	9.83E-01	1.26E-02	2.34E+00
Fresh-water Toxicity Potential	kg DCB e	1.34E+00	7.39E-01	4.83E-02	2.13E+00
Marine Toxicity Potential	kg DCB e	3.56E+03	1.50E+03	3.42E+01	5.10E+03

tab. 7b

Environmental Impact Potentials referred to the IG VENA 50mL production system per FU (2017). Other assessed impact categories




Other assessed impact categories/ IG VENA 50mL

Parameter	Unit	  			Total
Human Toxicity Potential	kg DCB e	7.16E-01	4.81E-01	4.41E-02	1.24E+00
Fresh-water Toxicity Potential	kg DCB e	7.10E-01	3.45E-01	1.02E-01	1.16E+00
Marine Toxicity Potential	kg DCB e	1.94E+03	7.30E+02	9.48E+01	2.76E+03

tab. 7c

Environmental Impact Potentials referred to the IG VENA 50mL production system per FU (2017). Other assessed impact categories

Other assessed impact categories/ IG VENA 1200mL

Parameter	Unit	  			Total
Human Toxicity Potential	kg DCB e	2.61E+00	1.88E+00	5.24E-02	4.54E+00
Fresh-water Toxicity Potential	kg DCB e	2.62E+00	1.37E+00	9.22E-02	4.09E+00
Marine Toxicity Potential	kg DCB e	6.88E+03	2.85E+03	1.05E+02	9.83E+03

tab. 8a

Energy content of IG VENA 100mL, considering the gross calorific value (HHV) of materials which energy is suitable for an eventual energy recovery at the end of life (MJ/FU)

Energy content/ IG VENA 100mL

Paperboard	MJ/FU	0.59
Plastics	MJ/FU	1.16

tab. 8b

Energy content of IG VENA 50mL, considering the gross calorific value (HHV) of materials which energy is suitable for an eventual energy recovery at the end of life (MJ/FU)

Energy content/ IG VENA 50mL

Paperboard	MJ/FU	0.73
Plastics	MJ/FU	1.08

tab. 8b

Energy content of IG VENA 200mL, considering the gross calorific value (HHV) of materials which energy is suitable for an eventual energy recovery at the end of life (MJ/FU)

Energy content / IG VENA 200mL

Paperboard	MJ/FU	0.91
Plastics	MJ/FU	1.16

## Programme-related information and verification

The EPD owner has the sole ownership, liability, and responsibility for the EPD. EPDs within the same product category but from different programmes may not be comparable.

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### Programme/ The International EPD® System

EPD International AB  
Box 210 60  
SE-100 31 Stockholm  
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[www.environdec.com](http://www.environdec.com)

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**EPD registration number/** S-P-01596

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**Published/** 2019-06-05

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**Valid until/** 2024-03-10

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**Product Category Rules/** PCR 2016:07, Blood and blood derived products for therapeutic or prophylactic uses, v.1.1, 2019-01-30

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**Product group classification/** UN CPC 35270

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**Reference year for data/** 2017

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**Geographical scope/** Global

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### Product category rules (PCR)/

Blood and blood derived products for therapeutic or prophylactic uses, 2016:07, v.1.1, 2019-01-30

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### PCR review was conducted by/

The Technical Committee of the The International® EPD System.  
Chair: Lars-Gunnar Lindfors

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### Independent verification of the declaration and data, according to ISO 14025:2006/

☐ EPD Process Certification (internal) ☒ EPD Verification (external)

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### Third party verifier/ SGS Italia S.p.A

via Caldera, 21  
20153 - Milano  
Tel. +39 02.73931 - Fax +39 02.70124630

[www.sgsgroup.it](http://www.sgsgroup.it)

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### Accredited by/

ACCREDIA - Registration n.006H

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### Procedure for follow-up of data during EPD validity involves third party verifier/

☒ yes ☐ no

## Company

PCR 2016:07. *Blood and blood derived products for therapeutic or prophylactic uses*. V.1.1. CPC 35270, 39931, publication date:30-01-2019, available at: [www.environdec.com](http://www.environdec.com)

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**KEDRION**  
B I O P H A R M A

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INDicatori Ambientali e CO<sub>2</sub>

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