EPD®

Environmental Product Declaration

in accordance with ISO 14025 for

Albumin 20% 50mL, **25%** 50mL, **20%** 100mL, **5%** 250mL

KEDRION BIOPHARMA

Programme/
The International EPD® System
www.environdec.com

Programme operator/
EPD International AB

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2024-03-10

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

General information

Information about the organization

Owner of the EPD:

Kedrion S.p.A.
Loc. ai Conti
IT 55051 Castelvecchio Pascoli Barga (LU)
www.kedrion.com

Description about the organization:

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 Castelvecchio 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 Immunoglobulin-based medicinal product which for half a century has been effective in the prevention of Haemolytic Disease of the Fetus and the Newborn (HDFN).

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 Albuminin in Kedrion's Bolognana plant.

Product information

Product name:

Albumin

Product identification and description:

UMAN ALBUMIN/ALBITAL/UMAN SERUM is a solution for infusion containing human albumin. It is a human plasma derived product for intravenous administration. UMAN ALBUMIN is used in: restoration and maintenance of circulating blood volume where volume deficiency has been demonstrated, and use of a colloid is appropriate. The choice of albumin rather than artificial colloid will depend on the clinical situation of the individual patient, based on official recommendations.

UMAN ALBUMIN, included in this EPD, is provided in 4 different sizes:

- 200 g/l / 50 or 100 ml vial containing human albumin equal to 10g or 20g
- 250 g/l /50 ml vial containing human albumin equal to 12.5g
- 50g/l 250 ml vial containing human albumin equal to 12.5g

A single dose kit (Fig.1) includes:

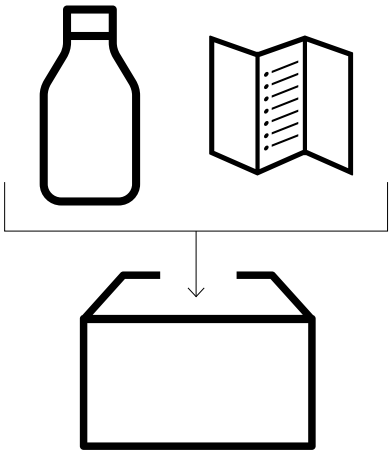
Albumin 20% 50mL, 25% 50mL, 20% 100mL or 5% 250mL vial; stopper; leaflet; cardboard box

UN CPC code:

CPC code Ver.2: 35270 - Other pharmaceutical products

Geographical scope:

Global



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Albumin 20% 50mL, **25%** 50mL, **20%** 100mL, **5%** 250mL

fig. 1
Components of a single dose kit

Components		Materials	Units	Quantity per			
				20% 50 ml	25% 50 ml	20% 100 ml	5% 250 ml
	**vial**	bottle/glass	g	57	57	92	158
		stopper/ bromobutyl rubber	g	8	8	8	8
		aluminium overseal/ aluminium	g	1	1	1	1
		plastic flip-off top cap/ polypropylene	g	1	1	1	1
	**leaflet**	paper	g	2.5	2.5	3	3
	**paper box**	paper	g	9	9	11	16

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Content declaration

UMAN ALBUMIN is a sterile liquid preparation of a plasma protein fraction containing human albumin.

It is obtained from plasma that complies with European Pharmacopoeia (Ph. Eur.) monograph *Human plasma for fractionation* (0853), current edition.

The product complies with the requirements of Ph. Eur. monograph Human albumin solution (0255), current edition.

Components in UMAN ALBUMIN are:

- Human albumin (active substance)
- Sodium chloride (added to adjust the ionic strength)
- Sodium caprylate (used as stabilizers)
- N-Acetyltryptophan (used as stabilizers)
- Water for injections (solvent medium of the pharmaceutical preparation)

UMAN ALBUMIN solution can be directly administered by the intravenous route, or it can also be diluted in an isotonic solution (e.g. 5% glucose or 0.9% sodium chloride). Albumin solutions must not be diluted with water for injections as this may cause haemolysis in recipients.

tab. 1
Content of ALBUMIN single dose

Albumin 20% **Materials/ chemical substances**	[Unit] %
Human Albumin	20%
Sodium chloride	4.52%
Sodium caprylate	2.66%
N-Acetyltryptophan	3.94%
Water for injections	68.88%

Albumin 25% **Materials/ chemical substances**	[Unit] %
Human Albumin	25%
Sodium chloride	3.52%
Sodium caprylate	3.32%
N-Acetyltryptophan	4.92%
Water for injections	63.24%

Albumin 5% **Materials/ chemical substances**	[Unit] %
Human Albumin	5.00%
Sodium chloride	8.39%
Sodium caprylate	0.66%
N-Acetyltryptophan	0.98%
Water for injections	84.97%

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 ALBUMIN 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 ALBUMIN 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 ALBUMIN, until its use and end-use treatment.

Functional Unit

The Functional Unit (FU) is a single dose kit of ALBUMIN including: Albumin 20% 50mL, 25% 50mL, 20% 100mL, 5% 250mL vial; stopper; 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 ALBUMIN 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. Ig Vena, PTC, ATIII), including the ALBUMIN. 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 ALBUMIN to which was added the reattribution of waste jointly produced along the whole process of Bolognana (i.e. 64.4%). 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 V.

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

5 **Bottling**: filtering in sterile room and hermetic closing of glass vial containing 20% 50mL, 25% 50mL, 20% 100mL, 5% 250mL of ALBUMIN. Afterwards, capped vials are sent to the packaging.

6 **Packaging**: semi-manual assembling and packaging of the ALBUMIN single dose kit containing: 20% 50mL, 25% 50mL, 20% 100mL, 5% 250mL ALBUMIN; 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 ALBUMIN from the production plant to the packaging plant) were also considered.

DOWNSTREAM PROCESS

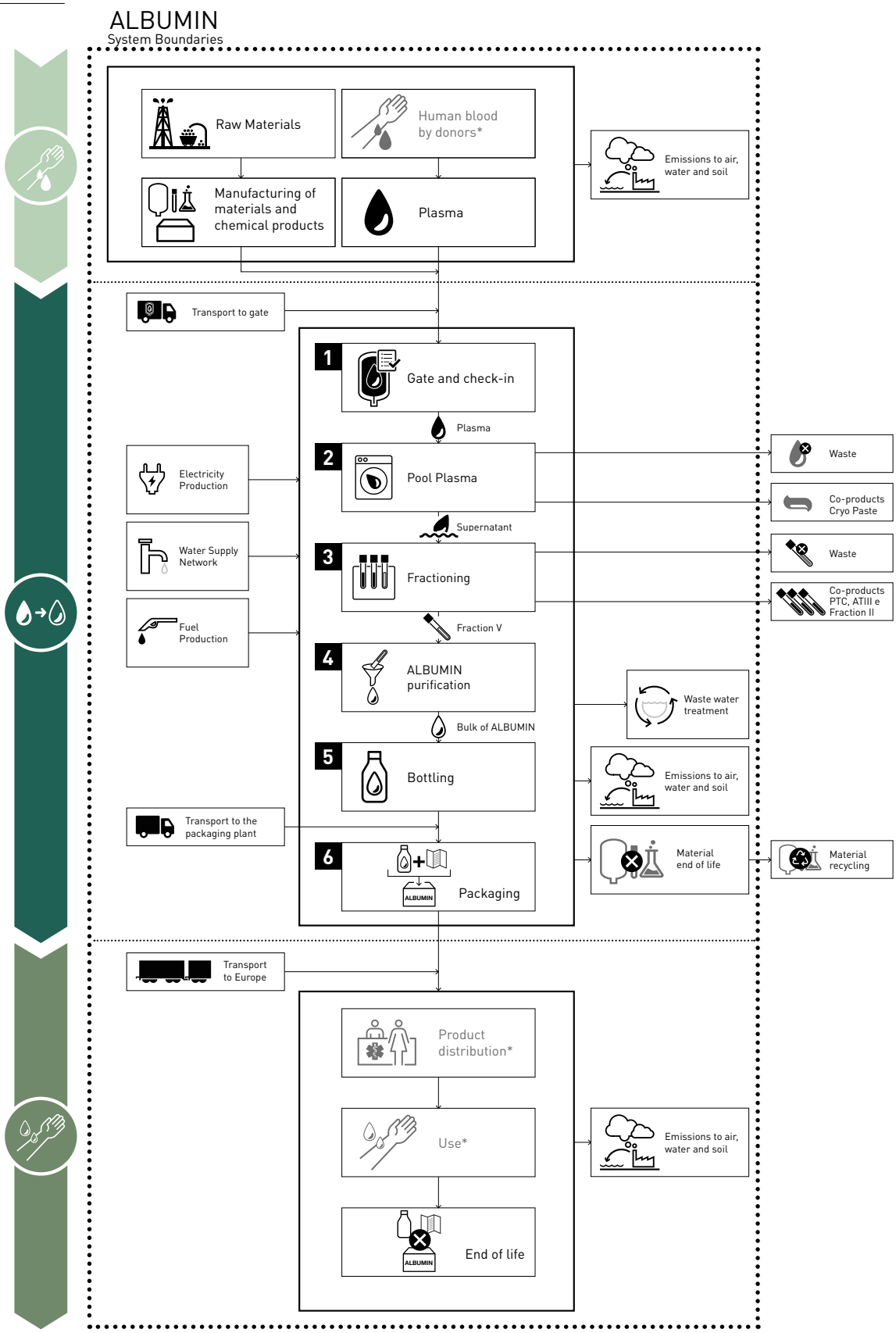
it consists in the "from gate to grave" set of processes that includes:

- 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 ALBUMIN production, divided into Upstream, Core and Downstream

* not included



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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 ALBUMIN 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 ALBUMIN 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 2016:07 UN CPC 35270 -39931, 2019-01-30, v. 1.1 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 are constituted by 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, refrigerant 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 ALBUMIN to which was added the reattribution of waste jointly produced along the whole process of Bolognana (i.e. 64.4%). 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. 28.2%). 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 POP 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 (ALBUMIN 20% 50mL single dose kit).

tab. 2a
Environmental Impact Potentials referred to the ALBUMIN 20% 50mL production system per FU (2017)

Environmental Impact Potentials/ ALBUMIN 20% 50mL

		Unit	UPSTREAM	CORE	DOWNSTREAM EU	Total
Global warming potential (GWP)	Fossil	kg CO_2 eq	9.49E-01	4.70E+00	3.64E-02	**5.68E+00**
	Biogenic	kg CO_2 eq	4.48E-02	5.76E-02	3.65E-04	**1.03E-01**
	Land use and land transformation	kg CO_2 eq	1.08E-02	3.14E-04	8.90E-06	**1.12E-02**
	total	kg CO_2 eq	1.01E+00	4.75E+00	3.68E-02	**5.80E+00**
Depletion potential of the stratospheric ozone layer (ODP)		kg CFC 11 eq	3.34E-07	5.30E-07	2.24E-09	**8.66E-07**
Acidification potential (AP)		kg SO_2 eq	3.34E-03	6.43E-03	9.49E-05	**9.86E-03**
Eutrophication potential (EP)		kg PO_4^{3-} eq	1.26E-03	2.17E-03	3.00E-05	**3.46E-03**
Formation potential of tropospheric ozone (POFP)		kg NMVOCeq	3.09E-03	2.76E-02	1.22E-04	**3.08E-02**
Abiotic depletion potential – Elements		kg Sb eq	2.60E-06	1.08E-06	1.86E-08	**3.70E-06**
Abiotic depletion potential – Fossil resources		MJ net calorific value	2.12E+01	4.50E+01	1.91E-01	**6.64E+01**
Water scarcity potential		m^3 eq	5.24E-01	1.88E+00	2.66E-03	**2.40E+00**

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

Global Warming Potential: core processes generate the highest impact (82%), mainly due to the use of natural gas for thermoelectricity production (33%) and vapour production (6%), besides direct emission of refrigerant gases (22%) and grid electricity absorption (3%). The upstream phase generates 17% of the total impact due to the production of chemical products (mainly ethanol, 9%) The downstream phase contributes with 0.6%, due to the end-life treatment of wasted materials for packaging.

Acidification Potential: the core phase generates highest impacts (65%), mainly due to the use of natural gas for thermoelectricity production (20%), grid electricity absorption (10%), transport of plasma from USA (12%) and hazardous waste treatment (8%). The upstream processes generate impacts for 34%, due to the use of chemical products (ethanol and glass, 18% and 5% respectively). The downstream phase contributes to 1%, due to the end-life treatment of wasted materials.

Eutrophication Potential: the core phase generates highest impacts (63%) mainly due to processes or wastewater treatment (16%), hazardous waste treatment (13%), the use of wfi water (9%) and natural gas (8%), grid electricity absorption (6%) and transport of plasma from USA (5%).
The upstream phase generates 36% of the total impact, due to the production of chemical products (mainly ethanol, 22%). 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 (90%), mainly due to the use of chemical products (mainly direct emission from ethanol, 70%). The upstream phase generates 10% of the total impact due to the use of chemical products (mainly ethanol, 6%).

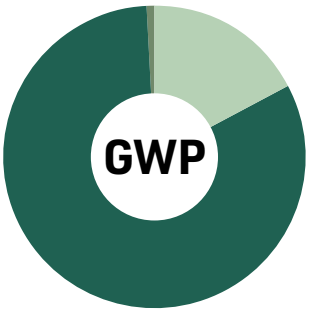
Results are shown in Figure 3.

fig. 3
LCA based estimated values of environmetal impacts of of ALBUMIN 20% 50mL

Global Warming Potential

17.4% UPSTREAM
82% CORE
0.6% DOWNSTREAM

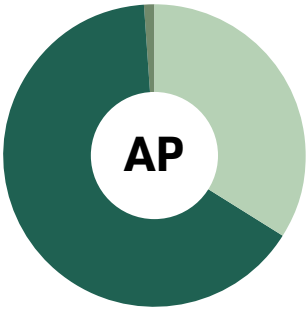
5.80 kg CO_2 eq



Acidification Potential

34% UPSTREAM
65% CORE
1% DOWNSTREAM

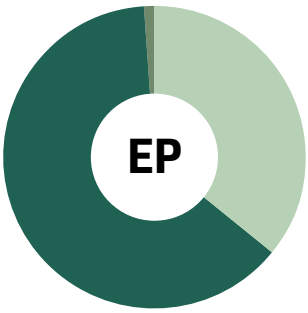
9.86*10^{-3} kg SO_2 eq



Eutrophication Potential

36% UPSTREAM
63% CORE
1% DOWNSTREAM

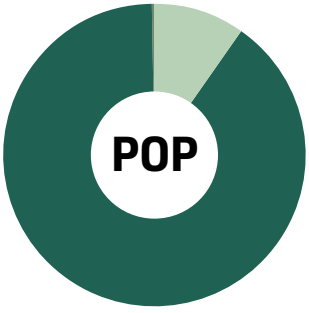
3.46*10^{-3} kg PO_4^{3-} eq



Photochemical Formation Oxidation Potential

9.9% UPSTREAM
90% CORE
0.1% DOWNSTREAM

3.08*10^{-2} kg NMVOC eq



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

Considering that ALBUMIN 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 (25% 50mL; 20% 100mL; 5% 250mL)

tab. 2b
Environmental Impact Potentials referred to the the ALBUMIN 25% 50mL production system per FU (2017)


UPSTREAM


CORE


DOWNSTREAM


Downstream scenario:
distribution to Europe (railway)

Environmental Impact Potentials/ ALBUMIN 25% 50mL

Parameter		Unit			EU	Total
Global warming potential (GWP)	Fossil	kg CO_2 eq	1.32E+00	6.53E+00	3.64E-02	**7.89E+00**
	Biogenic	kg CO_2 eq	5.76E-02	8.02E-02	3.65E-04	**1.38E-01**
	Land use and land transformation	kg CO_2 eq	1.51E-02	4.24E-04	8.90E-06	**1.55E-02**
	total	kg CO_2 eq	1.40E+00	6.61E+00	3.68E-02	**8.04E+00**
Depletion potential of the stratospheric ozone layer (ODP)		kg CFC 11 eq	4.83E-07	7.37E-07	2.24E-09	**1.22E-06**
Acidification potential (AP)		kg SO_2 eq	4.62E-03	8.85E-03	9.50E-05	**1.36E-02**
Eutrophication potential (EP)		kg PO_4^{3-} eq	1.78E-03	3.00E-03	3.00E-05	**4.81E-03**
Formation potential of tropospheric ozone (POFP)		kg NMVOCeq	4.26E-03	3.84E-02	1.22E-04	**4.28E-02**
Abiotic depletion potential – Elements		kg Sb eq	3.71E-06	1.43E-06	1.86E-08	**5.16E-06**
Abiotic depletion potential – Fossil resources		MJ net calorific value	2.93E+01	6.25E+01	1.91E-01	**9.20E+01**
Water scarcity potential		m^3 eq	7.51E-01	2.61E+00	2.66E-03	**3.36E+00**

tab. 2c
Environmental Impact Potentials referred to the ALBUMIN 20% 100mL production system per FU (2017)


UPSTREAM


CORE


DOWNSTREAM


Downstream scenario:
distribution to Europe (railway)

Environmental Impact Potentials/ ALBUMIN 20% 100mL

Parameter		Unit			EU	Total
Global warming potential (GWP)	Fossil	kg CO_2 eq	1.88E+00	9.36E+00	2.61E-02	**1.13E+01**
	Biogenic	kg CO_2 eq	7.98E-02	1.14E-01	5.76E-04	**1.95E-01**
	Land use and land transformation	kg CO_2 eq	2.15E-02	6.10E-04	1.36E-05	**2.21E-02**
	total	kg CO_2 eq	1.98E+00	9.47E+00	2.67E-02	**1.15E+01**
Depletion potential of the stratospheric ozone layer (ODP)		kg CFC 11 eq	6.84E-07	1.05E-06	3.16E-09	**1.74E-06**
Acidification potential (AP)		kg SO_2 eq	6.57E-03	1.27E-02	1.37E-04	**1.94E-02**
Eutrophication potential (EP)		kg PO_4^{3-} eq	2.52E-03	4.30E-03	3.99E-05	**6.86E-03**
Formation potential of tropospheric ozone (POFP)		kg NMVOCeq	6.04E-03	5.49E-02	1.72E-04	**6.11E-02**
Abiotic depletion potential – Elements		kg Sb eq	5.27E-06	2.07E-06	2.75E-08	**7.37E-06**
Abiotic depletion potential – Fossil resources		MJ net calorific value	4.17E+01	8.94E+01	2.81E-01	**1.31E+02**
Water scarcity potential		m^3 eq	1.04E+00	3.72E+00	5.90E-03	**4.77E+00**

tab. 2d
Environmental Impact Potentials referred to the ALBUMIN 5% 250mL production system per FU (2017)


UPSTREAM


CORE


DOWNSTREAM


Downstream scenario:
distribution to Europe (railway)

Environmental Impact Potentials/ ALBUMIN 5% 250mL

Parameter		Unit			EU	Total
Global warming potential (GWP)	Fossil	kg CO_2 eq	1.44E+00	6.25E+00	6.39E-02	**7.76E+00**
	Biogenic	kg CO_2 eq	7.16E-02	7.61E-02	1.14E-03	**1.49E-01**
	Land use and land transformation	kg CO_2 eq	1.45E-02	4.75E-04	2.70E-05	**1.50E-02**
	total	kg CO_2 eq	1.53E+00	6.33E+00	6.51E-02	**7.92E+00**
Depletion potential of the stratospheric ozone layer (ODP)		kg CFC 11 eq	4.76E-07	7.11E-07	5.90E-09	**1.19E-06**
Acidification potential (AP)		kg SO_2 eq	5.51E-03	8.96E-03	2.61E-04	**1.47E-02**
Eutrophication potential (EP)		kg PO_4^{3-} eq	1.95E-03	3.03E-03	8.05E-05	**5.07E-03**
Formation potential of tropospheric ozone (POFP)		kg NMVOCeq	4.73E-03	3.82E-02	3.25E-04	**4.32E-02**
Abiotic depletion potential – Elements		kg Sb eq	4.01E-06	1.79E-06	5.31E-08	**5.85E-06**
Abiotic depletion potential – Fossil resources		MJ net calorific value	3.05E+01	6.04E+01	5.22E-01	**9.15E+01**
Water scarcity potential		m^3 eq	7.78E-01	2.46E+00	9.37E-03	**3.25E+00**

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Use of resources

tab. 3a
Total renewable and non-renewable resources used in the ALBUMIN 20% 50mL production system (2017)

UPSTREAM
CORE
DOWNSTREAM

Renewable and non-renewable resources/ ALBUMIN 20% 50mL

Resources		Unit				Total
Primary energy resources - RENEWABLE	Used as ENERGY carrier	MJ, net calorific value	1.11E+00	8.79E-01	1.11E-02	**2.00E+00**
	Used as RAW MATERIALS	MJ, net calorific value	1.02E+00	2.42E-01	4.43E-03	**1.27E+00**
	total	MJ, net calorific value	2.14E+00	1.12E+00	1.55E-02	**3.27E+00**
Primary energy resources - NON RENEWABLE	Used as ENERGY carrier	MJ, net calorific value	2.41E+01	5.04E+01	2.36E-01	**7.47E+01**
	Used as RAW MATERIALS	MJ, net calorific value	0	0	0	**0.00E+00**
	total	MJ, net calorific value	2.41E+01	5.04E+01	2.36E-01	**7.47E+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^3	4.90E-03	7.82E-02	7.76E-05	**8.32E-02**

tab. 3b
Total renewable and non-renewable resources used in the ALBUMIN 25% 50mL production system (2017)

UPSTREAM
CORE
DOWNSTREAM

Renewable and non-renewable resources/ ALBUMIN 25% 50mL

Resources		Unit				Total
Primary energy resources - RENEWABLE	Used as ENERGY carrier	MJ, net calorific value	1.46E+00	1.22E+00	1.11E-02	**2.69E+00**
	Used as RAW MATERIALS	MJ, net calorific value	1.26E+00	3.35E-01	4.43E-03	**1.60E+00**
	total	MJ, net calorific value	2.72E+00	1.55E+00	1.55E-02	**4.29E+00**
Primary energy resources - NON RENEWABLE	Used as ENERGY carrier	MJ, net calorific value	3.34E+01	7.00E+01	2.36E-01	**1.04E+02**
	Used as RAW MATERIALS	MJ, net calorific value	0	0	0	**0.00E+00**
	total	MJ, net calorific value	3.34E+01	7.00E+01	2.36E-01	**1.04E+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^3	6.82E-03	1.08E-01	7.76E-05	**1.15E-01**

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tab. 3c
Total renewable and non-renewable resources used in the ALBUMIN 20% 100mL production system (2017)


UPSTREAM


CORE


DOWNSTREAM

Renewable and non-renewable resources/ ALBUMIN 20% 100mL

Resources		Unit				Total
Primary energy resources - RENEWABLE	Used as ENERGY carrier	MJ, net calorific value	2.02E+00	1.74E+00	1.72E-02	**3.78E+00**
	Used as RAW MATERIALS	MJ, net calorific value	1.74E+00	4.80E-01	6.99E-03	**2.23E+00**
	total	MJ, net calorific value	3.76E+00	2.22E+00	2.42E-02	**6.01E+00**
Primary energy resources - NON RENEWABLE	Used as ENERGY carrier	MJ, net calorific value	4.74E+01	1.00E+02	3.49E-01	**1.48E+02**
	Used as RAW MATERIALS	MJ, net calorific value	0	0	0	**0.00E+00**
	total	MJ, net calorific value	4.74E+01	1.00E+02	3.49E-01	**1.48E+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^3	9.63E-03	1.55E-01	1.72E-04	**1.65E-01**

tab. 3d
Total renewable and non-renewable resources used in the ALBUMIN 5% 250mL production system (2017)


UPSTREAM


CORE


DOWNSTREAM

Renewable and non-renewable resources/ ALBUMIN 5% 250mL

Resources		Unit				Total
Primary energy resources - RENEWABLE	Used as ENERGY carrier	MJ, net calorific value	1.81E+00	1.19E+00	3.42E-02	**3.03E+00**
	Used as RAW MATERIALS	MJ, net calorific value	1.71E+00	3.29E-01	1.37E-02	**2.06E+00**
	total	MJ, net calorific value	3.52E+00	1.52E+00	4.79E-02	**5.08E+00**
Primary energy resources - NON RENEWABLE	Used as ENERGY carrier	MJ, net calorific value	3.48E+01	6.76E+01	6.57E-01	**1.03E+02**
	Used as RAW MATERIALS	MJ, net calorific value	0	0	0	**0.00E+00**
	total	MJ, net calorific value	3.48E+01	6.76E+01	6.57E-01	**1.03E+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^3	7.74E-03	1.02E-01	2.74E-04	**1.10E-01**

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Waste production

tab. 4a
Total waste generation for the ALBUMIN 20% 50mL production system (2017)

Waste/ ALBUMIN 20% 50mL

Parameter	Unit				Total
Hazardous waste disposed	kg	2.62E-03	2.05E-01	6.88E-02	**2.76E-01**
Non-hazardous waste disposed	kg	9.17E-02	2.23E-01	3.63E-02	**3.51E-01**
Radioactive waste disposed	kg	1.97E-05	7.02E-05	1.52E-06	**9.14E-05**

tab. 4b
Total waste generation for the ALBUMIN 25% 50mL production system (2017)

Waste/ ALBUMIN 25% 50mL

Parameter	Unit				Total
Hazardous waste disposed	kg	2.66E-03	2.60E-01	6.95E-02	**3.32E-01**
Non-hazardous waste disposed	kg	9.51E-02	3.01E-01	4.08E-02	**4.37E-01**
Radioactive waste disposed	kg	2.27E-05	9.53E-05	1.82E-06	**1.20E-04**

tab. 4c
Total waste generation for the ALBUMIN 20% 100mL production system (2017)

Waste/ ALBUMIN 20% 100mL

Parameter	Unit				Total
Hazardous waste disposed	kg	4.17E-03	3.84E-01	1.06E-01	**4.93E-01**
Non-hazardous waste disposed	kg	1.34E-01	4.34E-01	5.22E-02	**6.21E-01**
Radioactive waste disposed	kg	3.22E-05	1.37E-04	2.77E-06	**1.72E-04**

tab. 4d
Total waste generation for the ALBUMIN 5% 250mL production system (2017)

Waste/ ALBUMIN 5% 250mL

Parameter	Unit				Total
Hazardous waste disposed	kg	6.54E-03	3.64E-01	1.70E-01	**5.41E-01**
Non-hazardous waste disposed	kg	1.12E-01	3.44E-01	6.20E-02	**5.19E-01**
Radioactive waste disposed	kg	2.95E-05	1.02E-04	3.34E-06	**1.35E-04**

Output flows

tab. 5a
Total output flows for the ALBUMIN 20% 50mL production system (2017)

Waste/ ALBUMIN 20% 50mL

Parameter	Unit				Total
Components for reuse	kg	0	0	0	**0**
Material for recycling	kg	0	1.50E-2	2.08E-02	**3.58E-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 ALBUMIN 25% 50mL production system (2017)

Waste/ ALBUMIN 25% 50mL

Parameter	Unit				Total
Components for reuse	kg	0	0	0	**0**
Material for recycling	kg	0	1.82E-2	2.35E-02	**4.17E-2**
Materials for energy recovery	kg				
Exported energy, electricity	MJ	0	0	0	**0**
Exported energy, thermal	MJ	0	0	0	**0**

tab. 5c
Total output flows for the ALBUMIN 20% 100mL production system (2017)

Waste/ ALBUMIN 20% 100mL

Parameter	Unit				Total
Components for reuse	kg	0	0	0	**0**
Material for recycling	kg	0	2.99E-2	2.49E-02	**5.48E-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. 5d
Total output flows for the ALBUMIN 5% 250mL production system (2017)

Waste/ ALBUMIN 5% 250mL

Parameter	Unit				Total
Components for reuse	kg	0	0	0	**0**
Material for recycling	kg	0	1.97E-2	4.05E-02	**6.02E-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**

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 POP.

tab. 6
Environmental Impact Potentials referred to the ALBUMIN 20% 50mL, 25% 50mL, 20% 100mL, 5% 250mL production system (2017). Compared downstream scenarios: distribution to Italy (roadway) and USA (airway)


UPSTREAM


CORE


DOWNSTREAM


Downstream scenario: distribution to ITA (roadway)

Downstream scenario: distribution to USA (airway)

Environmental Impact Potentials/ Ig Vena 100,50 and 200mL (only downstream)

Parameter		Unit		20% 50 mL	25% 50 mL	20% 100 mL	5% 250 mL
Global warming potential (GWP)	Fossil	kg CO_2 eq	IT	6.73E-02	6.73E-02	7.52E-02	1.62E-01
			USA	1.01E+00	1.02E+00	1.58E+00	3.18E+00
	Biogenic	kg CO_2 eq	IT	2.92E-04	2.92E-04	4.60E-04	9.06E-04
			USA	1.45E-03	1.45E-03	2.29E-03	4.57E-03
	Land use and land transformation	kg CO_2 eq	IT	1.90E-05	1.90E-05	2.97E-05	5.93E-05
			USA	7.40E-05	7.40E-05	1.17E-04	2.34E-04
	total	kg CO_2 eq	IT	6.76E-02	6.76E-02	7.57E-02	1.63E-01
			USA	1.02E+00	1.02E+00	1.58E+00	3.18E+00
Depletion potential of the stratospheric ozone layer (ODP)		kg CFC 11 eq	IT	8.33E-06	7.84E-09	1.21E-08	2.37E-08
			USA	1.59E-04	1.81E-07	2.88E-07	5.75E-07
Acidification potential (AP)		kg SO_2 eq	IT	9.94E-03	1.36E-02	1.95E-02	1.50E-02
			USA	1.41E-02	1.78E-02	2.61E-02	2.81E-02
Eutrophication potential (EP)		kg PO_4^{3-} eq	IT	1.45E-04	4.08E-05	5.71E-05	1.15E-04
			USA	3.46E-03	6.97E-04	1.10E-03	2.20E-03
Formation potential of tropospheric ozone (POFP)		kg NMVOCeq	IT	2.05E-04	2.05E-04	3.04E-04	5.89E-04
			USA	4.93E-03	4.93E-03	7.81E-03	1.56E-02
Abiotic depletion potential – Elements		kg Sb eq	IT	7.84E-09	2.11E-07	3.34E-07	6.66E-07
			USA	1.81E-07	1.05E-07	1.65E-07	3.29E-07
Abiotic depletion potential – Fossil resources		MJ net calorific value	IT	2.11E-07	6.56E-01	1.02E+00	2.00E+00
			USA	1.05E-07	1.42E+01	2.26E+01	4.52E+01
Water scarcity potential		m^3 eq	IT	3.06E+00	3.36E+00	4.78E+00	3.26E+00
			USA	1.66E+01	3.42E+00	4.86E+00	3.43E+00

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)

tab. 7a
Environmental Impact Potentials referred to the ALBUMIN 20% 50mL production system per FU (2017). Other assessed impact categories

Other assessed impact categories / ALBUMIN 20% 50mL

Parameter	Unit				Total
Human Toxicity Potential	kg DCB e	2.88E-01	5.23E-01	1.55E-02	**8.26E-01**
Fresh-water Toxicity Potential	kg DCB e	1.98E-01	3.66E-01	4.12E-02	**6.05E-01**
Marine Toxicity Potential	kg DCB e	7.21E+02	7.45E+02	3.49E+01	**1.50E+03**

tab. 7b
Environmental Impact Potentials referred to the ALBUMIN 25% 50mL production system per FU (2017). Other assessed impact categories

Other assessed impact categories / ALBUMIN 25% 50mL

Parameter	Unit				Total
Human Toxicity Potential	kg DCB e	4.02E-01	7.19E-01	1.55E-02	**1.14E+00**
Fresh-water Toxicity Potential	kg DCB e	2.81E-01	5.04E-01	4.12E-02	**8.27E-01**
Marine Toxicity Potential	kg DCB e	9.99E+02	1.02E+03	3.49E+01	**2.06E+03**

tab. 7c
Environmental Impact Potentials referred to the ALBUMIN 20% 100mL production system per FU (2017). Other assessed impact categories

Other assessed impact categories / ALBUMIN 20% 100mL

Parameter	Unit				Total
Human Toxicity Potential	kg DCB e	5.70E-01	1.04E+00	1.40E-02	**1.62E+00**
Fresh-water Toxicity Potential	kg DCB e	3.94E-01	7.28E-01	3.71E-02	**1.16E+00**
Marine Toxicity Potential	kg DCB e	1.40E+03	1.47E+03	3.40E+01	**2.91E+03**

tab. 7d
Environmental Impact Potentials referred to the ALBUMIN 5% 250mL production system per FU (2017). Other assessed impact categories

Other assessed impact categories / ALBUMIN 5% 250mL

Parameter	Unit				Total
Human Toxicity Potential	kg DCB e	4.76E-01	7.21E-01	2.80E-02	**1.23E+00**
Fresh-water Toxicity Potential	kg DCB e	3.13E-01	4.91E-01	5.18E-02	**8.56E-01**
Marine Toxicity Potential	kg DCB e	1.22E+03	1.04E+03	5.98E+01	**2.32E+03**

tab. 8
Energy content of the ALBUMIN 20% 50mL, 25% 50mL, 20% 100mL, 5% 250mL, 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 / ALBUMIN 20% 50mL

Paperboard	MJ/FU	**0.21**
Plastics	MJ/FU	**0.11**

Energy content / ALBUMIN 25% 50mL

Paperboard	MJ/FU	**0.21**
Plastics	MJ/FU	**0.11**

Energy content / ALBUMIN 20% 100mL

Paperboard	MJ/FU	**0.25**
Plastics	MJ/FU	**0.11**

Energy content / ALBUMIN 5% 250mL

Paperboard	MJ/FU	**0.43**
Plastics	MJ/FU	**0.11**

KEDRION BIOPHARMA

Environmental Product Declaration

Albumin 20% 50mL, **25%** 50mL, **20%** 100mL, **5%** 250mL

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.

Programme/ The International EPD® System

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Box 210 60
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EPD registration number/ S-P-01595

Published/ 2019-06-05

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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

Product group classification/ UN CPC 35270

Reference year for data/ 2017

Geographical scope/ Global

Product category rules (PCR)/
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PCR review was conducted by/
The Technical Committee of the The International® EPD System.
Chair: Lars-Gunnar Lindfors

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

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

Third party verifier/ SGS Italia S.p.A

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Accredited by/
ACCREDIA - Registration n.006H

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

☒ yes ☐ no

KEDRION BIOPHARMA

Environmental Product Declaration

Albumin 20% 50mL, **25%** 50mL, **20%** 100mL, **5%** 250mL

Company

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