Environmental Product Declaration

in accordance with ISO 14025 for

ALBUMIN 20% 50mL

from

KEDRION BIOPHARMA

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

Programme operator/
EPD International AB

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Global

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Programme information

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Programme/	The International EPD® System EPD International AB Box 210 60 SE-100 31 Stockholm Sweden www.environdec.com info@environdec.com

Accountabilities for PCR, LCA and independent, third-party verification

Product Category Rules (PCR)/

PCR: *Blood and blood derived products for therapeutic or prophylactic uses, 2016:07, v.2, 2022-03-14; UN CPC 35270*

PCR review was conducted by: The Technical Committee of the International EPD® System. A full list of members available on www.environdec.com. The review panel may be contacted via info@environdec.com. Review chair: Maurizio Fieschi

Life Cycle Assessment (LCA)/

LCA accountability: INDACO2 srl
via Roma 21B, 53034 Colle Val d'Elsa (SI) - ITALY

Third-party verification/

Independent third-party verification of the declaration and data, according to ISO 14025:2006, via:

☒ EPD verification by accredited certification body

Third-party verification: SGS Italia S.p.A. is an approved certification body accountable for the third-party verification

The certification body is accredited by: Accredia n.006H

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

☒ yes ☐ no

Company information

Owner of the EPD:

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

More info at http://www.kedrion.it/

Description of the organisation:

Kedrion plant of Bolognana site (Lucca - IT)

Product information

Product name:

ALBUMIN 20% 50mL

Product identification and description:

UMAN ALBUMIN 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.

ALBUMIN 50 ml vial contains human albumin equal to 20g.

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.

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.

Content declaration:

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)

The Albumin single dose kit (FU) contains:

tab. 1
Content of single dose (ALBUMIN 20%.50mL)

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

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).

A single dose kit (fig.1) includes:

- Albumin 20% 50mL vial; leaflet; cardboard box.

tab. 2
Components of single dose kit (ALBUMIN 20%.50mL)

Components			Materials	Quantity	Units
Auxiliary materials	Vial	Bottle	Glass	57	g
		Stopper	Bromobutyl rubber	8	g
		Aluminium overseal	Aluminium	1	g
		Plastic flip-off top cap	Polypropylene	1	g
Packaging materials	Leaflet		Paper	2.5	g
	Paper box		Paper	9	g
	Distribution box		Cardboard	9	g

UN CPC code:

CPC code Ver.2: 35270 - Other pharmaceutical products

Geographical scope:

Global

fig. 1
Components of single dose kit (ALBUMIN 20%.50mL)

LCA information

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 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:

A single dose kit of ALBUMIN including: Albumin 20% 50mL vial; stopper; leaflet; cardboard box, produced by Kedrion S.p.A. in the Bolognana site (Lucca – IT).

Time representativeness:

Data refer to the year 2021.

Database(s) and LCA software used:

EcoInvent Database v.3.8. and SimaPro 9.3.

System diagram:

Figure 2 shows the flow chart and system boundaries diagram of the ALBUMIN, divided into Upstream, Core and Downstream.

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 of raw materials used in the core process (e.g. plastic and chemical products);
- production of packaging of materials used in the core process (e.g. PVC, cardboard boxes)
- production of materials for the final product packaging (e.g. glass vial, cardboard boxes)
- transport of raw materials and components along the upstream supply chain to a distribution point (e.g. a stockroom or warehouse)

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, 2022-03-14, v. 2).

CORE PROCESS

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

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 Transport, 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%).

3 **Fractioning**: specific sequence of processes, including multiple filtering, centrifugations, extractions and separations, for the production of Fraction V.
From this sub-section to the packaging, collected data on material use were directly referred to the production of ALBUMIN (any allocation avoided).

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 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 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 materials were assessed coherently to the current state of waste treatment in Italy (EUROSTAT, 2023). 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.
- End of life treatment of materials used and packaging. Waste that includes contaminated materials (all the materials kept in touch with organic substances) and mono-dose vials were addressed to incineration. Non contaminated materials were assessed coherently to the current state of waste treatment in EU27 (EUROSTAT, 2023). 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.

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:

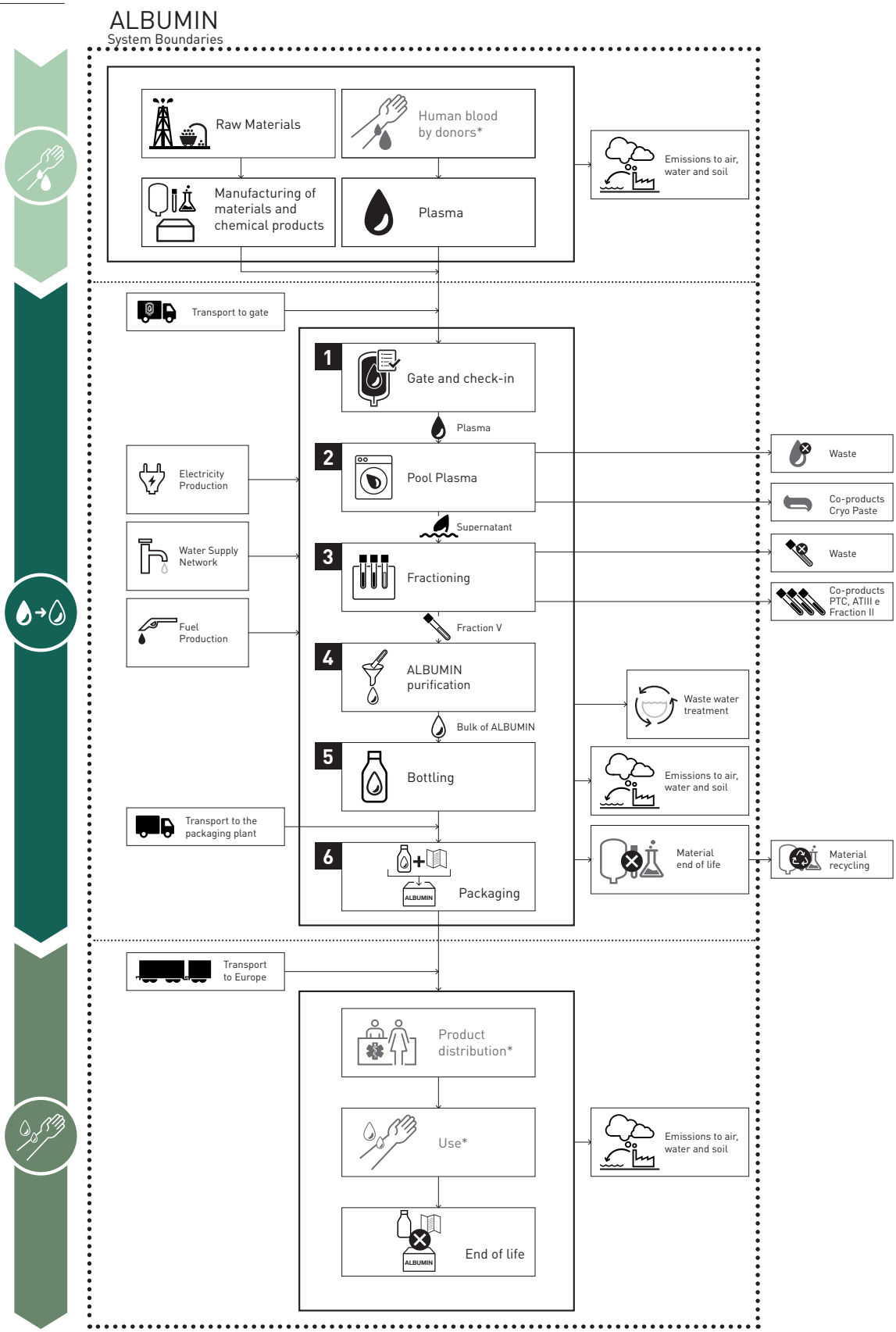
- construction of buildings and machineries in the Bolognana site;
- production and maintenance of machineries with more than 5 years estimated lifetime;
- technical materials reused in an indefinite number of production cycles;
- activity and travels of employers;
- blood withdrawing and plasma production in transfusion centres and transport to reception centres;
- transport to the end user (in case of distribution in pharmacy);
- the use of the product.

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, 2022-03-14, v.2 and GPI 2021-03-29 v.4.0. The included inventory data (not including inventory data of processes that are explicitly outside the system boundary as described in Section 4.3 of the PCR) give rise to 99% of the results of any of the environmental impact categories. Also, 99% of the mass of the product content and 99% of the energy use of the product life cycle is accounted for.

Not significant data were neglected, such as energy use for the final packaging, because this plant 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.

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

* not included



KEDRION BIOPHARMA

Environmental Product Declaration

ALBUMIN 20% 50mL

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), 2021-03-29 v.4.0.

The LCA refers to the PCR UN CPC 35270 (2022-03-14, v. 2) 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, 2022). 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 2022 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%). 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%). 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.3.8. The LCA has been performed based on the SimaPro 9.3 software, selected method EN15804+A2. 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 Gaia Esposito INDACO2 srl (Siena – Italy). Because of the updating of GPI and PCR and changes of materials and energy supply in the Bolognana site, it was considered appropriate to modify the previous EPD version (i.e. S-P- 01595 2019-06-05) to the new one.

Environmental performance

Potential environmental impact

The assessed potential environmental impacts are reported in table 3, detailed into upstream, core and downstream processes. Values refer to the functional unit (ALBUMIN 20% 50mL single dose kit).

tab. 3
Environmental Impact Potentials referred to the ALBUMIN 20% 50mL production system per FU (2021)

UPSTREAM
CORE
DOWNSTREAM
[redacted]
Downstream scenario: distribution to Europe (railway)

Environmental Impact Potentials/ ALBUMIN 20% 50mL

		Unit			[redacted] EU	Total
Global warming potential (GWP)	Fossil	kg CO2 eq	8.89E-01	2.63E+00	4.17E-02	**3.56E+00**
	Biogenic	kg CO2 eq	-1.46E-02	4.64E-03	2.06E-02	**1.06E-02**
	Land use and land transformation	kg CO2 eq	1.03E-02	2.88E-04	1.16E-05	**1.06E-02**
	TOTAL	kg CO2 eq	8.85E-01	2.64E+00	6.23E-02	**3.59E+00**
Ozone layer depletion (ODP)		kg CFC 11 eq	2.13E-07	3.88E-07	2.33E-09	**6.03E-07**
Acidification potential (AP)		mol H+ eq	4.12E-03	4.64E-03	1.17E-04	**8.88E-03**
Eutrophication potential (EP)	Aquatic freshwater	kg P eq	3.76E-04	3.03E-04	3.00E-06	**6.83E-04**
	Aquatic marine	kg N eq	8.48E-04	2.25E-03	4.69E-05	**3.14E-03**
	Aquatic terrestrial	mol N eq	8.34E-03	1.38E-02	5.05E-04	**2.26E-02**
Photochemical oxidant creation potential (POCP)		kg NMVOC eq	3.70E-03	2.48E-02	1.50E-04	**2.87E-02**
Abiotic depletion potential (ADP)	Metals and minerals	kg Sb eq	9.10E-06	2.56E-06	4.22E-08	**1.17E-05**
	Fossil resources	MJ, net calorific value	2.29E+01	2.75E+01	1.76E-01	**5.05E+01**
Water deprivation potential (WDP)		m^3 world eq deprived	7.08E-01	1.60E+00	1.30E-03	**2.31E+00**

Global Warming Potential: core processes generate the highest impact (73.6%), mainly due to the use of electricity (31.7%) and direct emission of refrigerant gases (12.4%), besides waste treatment (9.6%), transports (8.9%) and methane (6.3%). The upstream phase generates 24.7% of the total impact due to the production of chemical products (mainly ethanol, 14.5%). The downstream phase contributes with 1.7%, due to the end-life treatment of wasted materials for packaging.

Acidification Potential: the core phase generates highest impacts (52.3%), mainly due to the use of electricity (20.5%) and transport of plasma (18.8%). The upstream processes generate impacts for 46.4%, due to the use of chemical products and materials (mainly ethanol 21.6%). The downstream phase contributes to 1.3%, due to the end-life treatment of wasted materials and transport.

Eutrophication Potential: the upstream phase generates highest impacts 55.1%, due to the production of chemical products (mainly ethanol, 28.7%). The core phase generates 44.4% of the total impact, mainly due water and wastewater treatment (14.3% and 8% respectively), waste treatment (14.1%) and the use of electricity (5.5%). The downstream phase contributes less than 1% to the total impact.

Photochemical Oxidation Formation Potential: core processes generate the most of the impact (86.6%), mainly due to the use of chemical products (e.g. direct emission from ethanol, 72.6%). The upstream phase generates 12.9% of the total impact due to the use of chemical products (mainly ethanol). The downstream phase contributes less than 1% to the total impact.

Results are shown in Figure 3.

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

Global Warming Potential

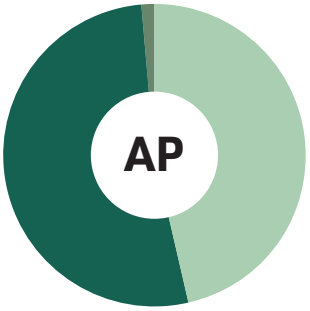
24.7% UPSTREAM
73.6% CORE
1.7% DOWNSTREAM

3.59 kg CO_2 eq

Acidification Potential

46.4% UPSTREAM
52.3% CORE
1.3% DOWNSTREAM

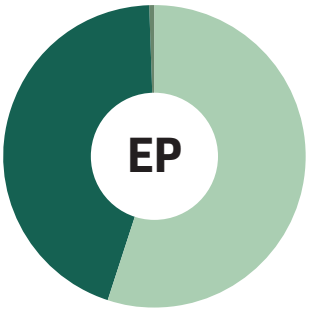
0.009 kg H+ eq



Eutrophication Potential

55.1% UPSTREAM
44.4% CORE
0.5% DOWNSTREAM

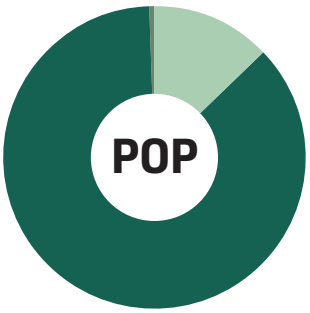
6.83*10^{-4} kg P eq



Photochemical Oxidation Potential

12.9% UPSTREAM
86.6% CORE
0.5% DOWNSTREAM

0.03 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 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.

Use of resources

tab. 3
Total renewable and non-renewable resources used in the ALBUMIN 20% 50mL production system (2021)

UPSTREAM
CORE
DOWNSTREAM

Renewable and non-renewable resources

Resources		Unit				Total
Primary energy resources - RENEWABLE	Used as ENERGY carrier	MJ, net calorific value	1.44E+00	4.12E-01	9.85E-03	**1.87E+00**
	Used as RAW MATERIALS	MJ, net calorific value	1.10E+00	1.81E-01	3.14E-03	**1.29E+00**
	total	MJ, net calorific value	2.55E+00	5.93E-01	1.30E-02	**3.15E+00**
Primary energy resources - NON RENEWABLE	Used as ENERGY carrier	MJ, net calorific value	2.58E+01	3.08E+01	2.09E-01	**5.68E+01**
	Used as RAW MATERIALS	MJ, net calorific value	6.02E-02	0.00E+00	0.00E+00	**6.02E-02**
	total	MJ, net calorific value	2.59E+01	3.08E+01	2.09E-01	**5.69E+01**
Secondary Material (optional)		kg	0	0	0	**0**
Renewable secondary fuels (optional)		kg	0	0	0	**0**
Non-Renewable secondary fuels (optional)		MJ	0	0	0	**0**
Net use of fresh water (optional)		m^3	1.32E-02	3.53E-02	1.27E-04	**4.86E-02**

Waste production and output flows (optional)

tab. 4
Total waste generation for the ALBUMIN 20% 50mL production system (2021)

Waste production

Parameter	Unit				Total
Hazardous waste disposed	kg	2.38E-05	7.02E-05	4.93E-07	**9.45E-05**
Non-hazardous waste disposed	kg	8.58E-02	1.55E-01	5.92E-02	**3.00E-01**
Radioactive waste disposed	kg	2.13E-05	5.69E-05	1.24E-06	**7.94E-05**

tab. 5
Total output flows for the ALBUMIN 20% 50mL production system (2021)

Output flows

Parameter	Unit				Total
Components for reuse	kg	0	0	0	**0**
Material for recycling	kg	0	1.59E-02	2.05E-02	**3.63E-02**
Materials for energy recovery	kg	0	0	0	**0**
Exported energy, electricity	MJ per energy carrier	0	0	0	**0**
Exported energy, thermal	MJ per energy carrier	0	0	0	**0**

Additional information

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 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

UNI ISO 45001 (Occupational Health and Safety System).

Differences Versus Previous Versions

2019-06-05 Version 1 first issue

2023-06-22 Version 2 **New verification**: Data and result update for one product (Albumin 20% 50mL) in accordance to the new version of the PCR and GPI 4.0. Validation date has been extended for five years.

References

EcoInvent, 2021. The ecoinvent® v3.8 database. The Swiss Centre for Life Cycle Inventories, Dübendorf (CH). https://ecoinvent.org/the-ecoinvent-database/

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ISO (2021), ISO 14040:2006, Environmental management – Life cycle assessment – Principles and framework.

ISO (2021), ISO 14044: 2006, Environmental management – Life cycle assessment – Requirements and guidelines.

ISO 14025:2006, Environmental labels and declarations – Type III Environmental declarations – Principles and procedures. The content of this standard is equivalent to EN ISO 14025:2010.

ISO 14067:2018, Greenhouse gases – Carbon footprint of products – Requirements and guidelines for quantification and communication

Kedrion SpA, 2022. Dichiarazione Ambientale EMAS - Stabilimento di Bolognana e sedi di Castelvecchio Pascoli (Lucca), Stabilimento di Sant'Antimo (Napoli). Kedrion Biopharma S.p.A., Castelvecchio Pascoli – Barga (Lucca, Italia).

PCR 2016:07. Blood and blood derived products for therapeutic or prophylactic uses. V.2. CPC 35270, publication date: 2022-03-14, available at: www.environdec.com

Prè Consultant - SimaPro LCA software
http://www.pre.nl/content/simapro-lca-software

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