Environmental Product Declaration

in accordance with ISO 14025 for

Emoclot 500 IU/10ml

KEDRION BIOPHARMA

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

Programme operator/
EPD International AB

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2024-04-08

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 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).

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 Emoclot in Kedrion's Bolognana plant.

Product information

Product name:

Emoclot

Product identification and description:

Emoclot is a concentrated solution of the anti-haemorrhagic factor VIII containing the essential protein for blood coagulation. It is a human plasma derived product for intravenous injection, lyophilized after a double viral inactivation.

Emoclot is used in: haemorrhages treatment and prophylaxis of patients with congenital deficit of factor VIII (haemophilia A); treatment of acquired deficit of factor VIII; treatment of haemophilic patients with developed antibody against factor VIII (inhibitors). The therapy can be both "on demand" for treating haemorrhages and for prophylaxis by continuous administration to prevent haemorrhages.

Emoclot is provided in 500IU[1]/10ml bottles containing 80IU/mg specific activity proteins. Components in Emoclot are: human plasma derived factor VIII (active substance), sodium chloride, glycine, calcium chloride and trisodium citrate (excipient). For intravenous injection, this is combined with a bottle of solvent containing water for injection.

A single dose kit (Fig.1) includes:

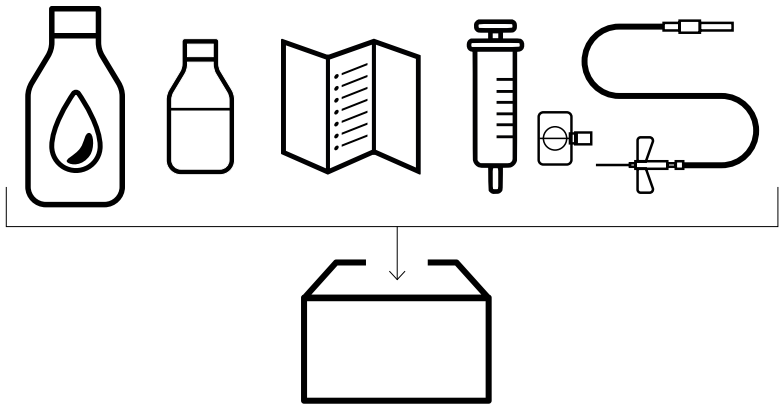
20ml vial containing 500IU/10ml Factor VIII; syringe; butterfly valve; pipe; needle; 10ml vial solvent; leaflet; cardboard box.

UN CPC code:

CPC code Ver.2: 35270 - Other pharmaceutical products

Geographical scope:

Global



1 The number of units of factor VIII administered is expressed in International Units (IU), which are related to the current WHO standard for factor VIII products. Factor VIII activity in plasma is expressed either as a percentage (relative to normal human plasma) or in International Units (relative to an international standard for factor VIII in plasma). One International Unit of factor VIII activity is equivalent to that quantity of factor VIII in 1ml of normal human plasma.

fig. 1
Components of a single dose kit

Components	Materials	Units	Quantity per 500 UI/ 10 ml
factor VIII vial (20ml)	glass vial	g	20
	bromobutyl cap	g	2
	aluminium cap	g	0.2
	polypropylene cap	g	0.3
	human plasma coagulation Factor VIII	UI	500
solvent vial (10 ml)	glass vial	g	10
	bromobutyl cap	g	2
	aluminium cap	g	0.2
	polypropylene cap	g	0.3
	solvent (injectable water)	ml	10
syringe	polypropylene	g	10
needle	steel	g	3
butterfly valve	polypropylene	g	2.5
	steel	g	2
pipe	polypropylene	g	10
leaflet	paper	g	3
paper box	paper	g	32.5

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Content declaration

Emoclot is a freeze-dried mass that contains the blood coagulation Factor VIII and low amounts of protein contaminants. Factor VIII is a protein which has an anti-haemorrhagic action. The product is manufactured using human venous plasma which meets the specification of the Ph. Eur. current ed., monograph 0853 "Human plasma for fractionation". Emoclot meets the specification of European Pharmacopoeia (Ph. Eur.) current ed., monograph 0275 "Human coagulation Factor VIII". Sodium chloride is added to achieve iso-osmolality suitable for intravenous administration. Glycine, calcium chloride and tribasic sodium citrate are added as excipients.

The Emoclot dose kit (FU) contains:

tab. 1
Content of Factor VIII single dose

Materials / chemical substances	Quantity	Unit
Factor VIII	500	IU
Water for injections	10	mL

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 Emoclot 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. In this document the terms "Emoclot" and "Factor VIII" will be used as synonymous.

A comprehensive quantitative evaluation of environmental performances in the Factor VIII 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 biological production, bottling and packaging of Factor VIII, until its use and end-use treatment.

Functional Unit

The Functional Unit (FU) is a single dose kit of Emoclot 500 IU including: 20ml vial containing 10ml/500IU Emoclot; syringe; butterfly valve; pipe; needle; 10ml vial solvent; 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 Emoclot 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. The cryopaste is almost 1% of the plasma and is used to produce the Factor VIII. The remaining part of plasma is used for the production of other products.

Material use in sections 0, 1 and 2 is allocated to the mass of plasma specifically addressed to the production of Emoclot to which was added the reattribution of waste jointly produced along the whole process of Bolognana (i.e. 2.82%). See Neri and Pulselli, 2019 for detailed description of allocation procedures.

3 **Biological production of Factor VIII**: specific sequence of processes, including fragmentation, solubilisation, centrifugation, dilution and multiple filtration, for the production of bulks of Factor VIII.

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

4 **Bottling**: sterilisation, lyophilisation and hermetic closing of 20ml glass vial containing 500IU/10ml factor VIII. Afterwards, bottles of Factor VIII, each one is coupled with a 20ml vial of solvent (produced in the Kedrion plant of S. Antimo – NA), are sent to the packaging.

5 **Packaging**: semi-manual assembling and packaging of the Emoclot single dose kit containing: 500IU/10ml Emoclot vial; syringe; butterfly valve; pipe; needle; 10ml solvent vial; 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 Emoclot from the production plant to the packaging plant) were also considered.

DOWNSTREAM PROCESS

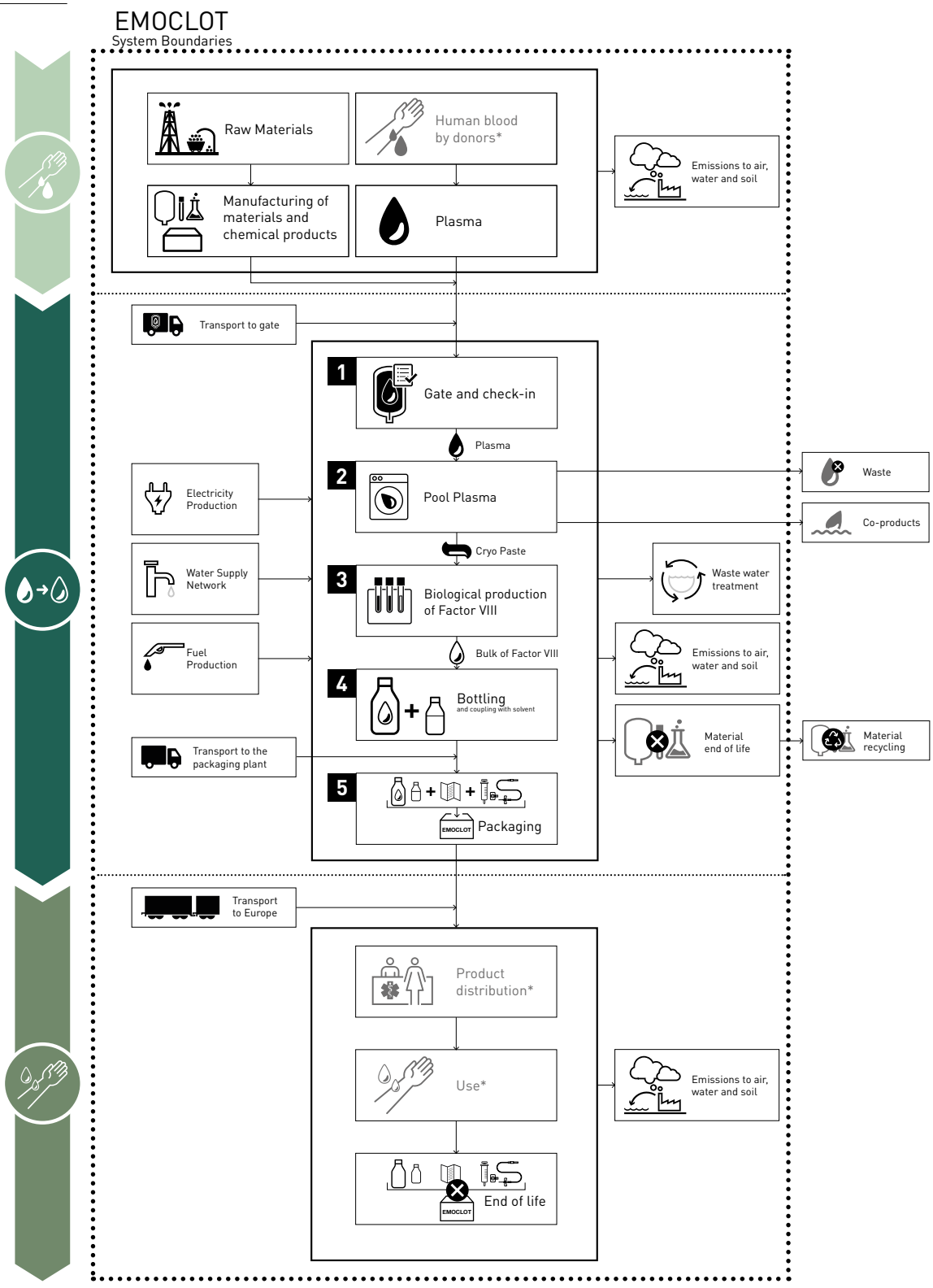
it consists in the "from gate to grave" set of processes that includes:

- 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 Emoclot 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 Emoclot 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)
- use of the product.

Not significant data were neglected, such as energy use for the packaging of solvent in vials (S. Antimo, Naples) and for the final packaging, because this plants is not specifically dedicated to the production of Emoclot 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 1.1) 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 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, 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 Factor VIII to which was added the reattribution of waste jointly produced along the whole process of Bolognana (i.e. 2.82%). 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. 22.6%). 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).

Because of the updating of GPI (v.2.5 to v.3.0), modification on PCR 2016:07 (v.1.0 to v.1.1) and in-depth analysis of collateral production processes concerning the Bolognana site, it was considered appropriate to modify the previous EPD version (i.e. S-P-00888 del 2018-01-24) to the new one.

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 (Emoclot 500IU single dose kit).

tab. 2a
Environmental Impact Potentials referred to the Emoclot production system per FU (2017)

UPSTREAM
CORE
DOWNSTREAM
EU

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						
		Unit			EU	Total
Global warming potential (GWP)	Fossil	kg CO_2 eq	1.50E+00	3.48E+01	8.69E-02	**3.64E+01**
	Biogenic	kg CO_2 eq	4.63E-02	2.28E-01	3.11E-04	**2.75E-01**
	Land use and land transformation	kg CO_2 eq	5.98E-03	1.03E-03	7.61E-06	**7.02E-03**
	total	kg CO_2 eq	1.56E+00	3.51E+01	8.72E-02	**3.67E+01**
Depletion potential of the stratospheric ozone layer (ODP)		kg CFC 11 eq	2.68E-06	3.87E-06	2.25E-09	**6.55E-06**
Acidification potential (AP)		kg SO_2 eq	2.50E-03	3.06E-02	9.79E-05	**3.32E-02**
Eutrophication potential (EP)		kg PO_4^{3-} eq	8.84E-04	5.61E-03	2.98E-05	**6.53E-03**
Formation potential of tropospheric ozone (POFP)		kg NMVOCeq	2.22E-03	3.60E-02	1.31E-04	**3.84E-02**
Abiotic depletion potential – Elements		kg Sb eq	2.01E-06	2.34E-06	1.69E-08	**4.36E-06**
Abiotic depletion potential – Fossil resources		MJ net calorific value	1.33E+01	3.38E+02	1.96E-01	**3.52E+02**
Water scarcity potential		m^3 eq	4.60E-01	2.49E+00	2.66E-03	**2.95E+00**

Global Warming Potential: core processes generate the highest impact (95.5%), mainly due to the use of natural gas for thermoelectricity production (48.4%) and vapour production (9.1%), besides direct emission of refrigerant gases (32.6%) and grid electricity absorption (4.4%). The upstream phase generates 4.24% of the total impact due to the production of chemical products (mainly refrigerant gases, 2.5%) The downstream phase contributes with 0.2%, due to the end-life treatment of wasted materials for packaging.

Acidification Potential: the core processes generate highest impacts (92.2%), mainly due to the use of natural gas for thermoelectricity (55.1%) and vapour (7.2%) production, grid electricity absorption (26.9%). The upstream phase generates 7.5% of the total impact, due to the use of plastic (2.4%) and chemical products (mainly ethanol, 2.0%). The downstream phase contributes to 0.3%, due to the end-life treatment of wasted materials.

Eutrophication Potential: core processes generate the highest impact (86.0%) due to the use of natural gas (38.0%), grid electricity absorption (31.0%) and wastewater treatment (6.3%). The upstream phase generates 13.5% of the total impact, mainly due to the production of chemical products (ethanol, 4.5%) and plastic (3.0%) and packaging materials (2.0%). The downstream phase contributes to 0.5%, due to the end-life treatment of wasted materials.

Photochemical Formation Oxidation Potential: core processes generate the most of the impact (93.9%), mainly due to the use of methane (61.8%), chemical products (direct emission from ethanol, 21.9%) and grid electricity absorption (7.8%). The up-stream phase generates 5.8% of the total impact due to the use of chemical products (mainly ethanol, 1.9%).

Results are shown in Figure 3.

fig. 3
LCA based estimated values of environmental impacts of Emoclot 500IU

Global Warming Potential

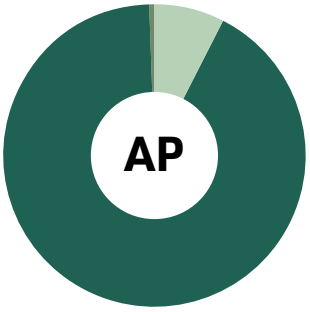
4.3% UPSTREAM
95.5% CORE
0.2% DOWNSTREAM

36.7 kg CO_2 eq

Acidification Potential

7.5% UPSTREAM
92.2% CORE
0.3% DOWNSTREAM

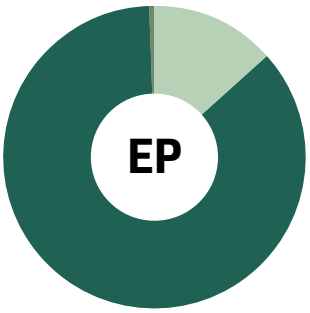
$3.32*10^{-2}$ kg SO_2 eq



Eutrophication Potential

13.5% UPSTREAM
86% CORE
0.5% DOWNSTREAM

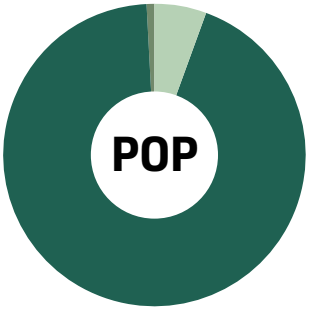
$6.53*10^{-3}$ kg PO_4^{3-} eq



Photochemical Formation Oxidation Potential

5.8% UPSTREAM
93.6% CORE
0.6% DOWNSTREAM

$3.84*10^{-2}$ 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 Emoclot 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 Emoclot 500IU production system (2017)

UPSTREAM
CORE
DOWNSTREAM

Renewable and non-renewable resources						
Resources		Unit				Total
Primary energy resources - RENEWABLE	Used as ENERGY carrier	MJ, net calorific value	1.05E+00	6.36E+00	9.37E-03	**7.42E+00**
	Used as RAW MATERIALS	MJ, net calorific value	9.87E-01	1.52E+00	3.73E-03	**2.51E+00**
	total	MJ, net calorific value	2.04E+00	7.88E+00	1.31E-02	**9.93E+00**
Primary energy resources - NON RENEWABLE	Used as ENERGY carrier	MJ, net calorific value	1.41E+01	3.80E+02	2.36E-01	**3.95E+02**
	Used as RAW MATERIALS	MJ, net calorific value	1.27E+00	0.00E+00	0.00E+00	**1.27E+00**
	total	MJ, net calorific value	1.54E+01	3.80E+02	2.36E-01	**3.96E+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	4.48E-03	1.07E-01	8.71E-05	**1.12E-01**

Waste production

tab. 4
Total waste generation for the Emoclot 500IU production system (2017)

Waste				
Parameter	Unit			Total
Hazardous waste disposed	kg	1.10E-05	7.09E-02	2.75E-02	**9.84E-02**
Non-hazardous waste disposed	kg	5.77E-02	3.18E-01	9.81E-02	**4.74E-01**
Radioactive waste disposed	kg	1.47E-05	1.46E-04	1.46E-06	**1.62E-04**

Output flows

tab. 5
Total output flows for the Emoclot 500IU production system (2017)

Output flows					
Parameter	Unit				Total
Components for reuse	kg	0	0	0	**0**
Material for recycling	kg	0	1.32E-02	5.20E-02	**6.52E-02**
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**

Output flows

tab. 5
Total output flows for the Emoclot 500IU production system (2017)

Output flows					
Parameter	Unit				Total
Components for reuse	kg	0	0	0	**0**
Material for recycling	kg	0	1.32E-02	5.20E-02	**6.52E-02**
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).

tab. 6
Environmental Impact Potentials referred to the Emoclot 500IU production system (2017). Compared downstream scenarios: distribution to Italy (roadway) and USA (airway)

Environmental Impact Potentials (only downstream)				
Parameter		Unit		
Global warming potential (GWP)	Fossil	kg CO_2 eq	IT	1.13E-01
			USA	9.19E-01
	Biogenic	kg CO_2 eq	IT	2.49E-04
			USA	1.23E-03
	Land use and land transformation	kg CO_2 eq	IT	1.62E-05
			USA	6.30E-05
	total	kg CO_2 eq	IT	1.13E-01
			USA	9.21E-01
Depletion potential of the stratospheric ozone layer (ODP)		kg CFC 11 eq	IT	1.67E-04
			USA	3.68E-03
Acidification potential (AP)		kg SO_2 eq	IT	3.90E-05
			USA	5.97E-04
Eutrophication potential (EP)		kg PO_4^{3-} eq	IT	2.02E-04
			USA	4.22E-03
Formation potential of tropospheric ozone (POFP)		kg NMVOCeq	IT	7.02E-09
			USA	1.55E-07
Abiotic depletion potential – Elements		kg Sb eq	IT	1.81E-07
			USA	9.06E-08
Abiotic depletion potential – Fossil resources		MJ net calorific value	IT	5.91E-01
			USA	1.21E+01
Water scarcity potential		m^3 eq	IT	4.60E-03
			USA	5.16E-02

UPSTREAM

CORE

DOWNSTREAM

Downstream scenario: distribution to ITA (roadway)

Downstream scenario: distribution to USA (airway)

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. 7
Environmental Impact Potentials referred to the Emoclot 500IU production system per FU (2017). Other assessed impact categories

Other assessed impact categories

Parameter	Unit				Total
Human Toxicity Potential	kg DCB e	3.10E-01	9.44E-01	7.93E-02	**1.33E+00**
Fresh-water Toxicity Potential	kg DCB e	1.79E-01	6.67E-01	2.96E-01	**1.14E+00**
Marine Toxicity Potential	kg DCB e	6.45E+02	2.20E+03	2.25E+02	**3.07E+03**

tab. 8
Energy content of Emoclot 500IU, 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

Paperboard	MJ/FU	**0.93**
Plastics	MJ/FU	**0.81**

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

EPD International AB
Box 210 60
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www.environdec.com

EPD registration number/ S-P-00888

Published/ 2018-01-23

Valid until/ 2024-04-08

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

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

Company

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