Environmental Product Declaration

In accordance with ISO 14025 for:

BARRIER[®] Clean Air Suit

from

Mölnlycke Health Care AB

Programme: Programme operator: EPD registration number: Publication date: Validity date: Geographical scope: The International EPD® System www.environdec.com EPD International AB S-P-01340 2018-07-10 2021-06-25 Sweden **'EPD**®







About the company

Mölnlycke is a world-leading medical solutions company. We're here to advance performance in healthcare across the world, and we aspire to equip everybody in healthcare with solutions to achieve the best outcomes. We collaborate with customers to understand their needs. We design and supply medical solutions to enhance performance at every point of care – from the operating room to the home. Mölnlycke's headquarters are located in Gothenburg, Sweden.

Mölnlycke maintain a number of quality assurance certifications and registrations, including ISO 9001, ISO 13485 and the Medical Device Directive. In addition, the company is globally ISO 14001:2015 certified. The company has a global Code of Conduct, which governs the high ethical standards expected of the staff. A Supplier Standard covers expectations to suppliers, in terms of human rights, the environment and health and safety. There is a Supplier Performance Management system in place to monitor, improve and control supplier performance and conduct supplier audits on a regular basis.

For additional information about Mölnlycke , please visit the company web site at http://www.molnlycke.com/

Contact information: Mölnlycke Health Care AB, Box 130 80, 402 52 Göteborg, Sweden (visiting address Gamlestadsvägen 3c), Telephone: +46 31-722 30 00.

Product information

The BARRIER[®] Clean Air Suit is designed for functionality with several large pockets and an absorbent and soft inner layer, for increased comfort. The clean air suit should be worn in situations when bacterial spread from the human body's skin via the air contact is of concern. Such situations are e.g. the operating theatre, certain laboratories etc. The clean air suit is designed and constructed to encapsulate bacteria carrying particles been released from the wearer's skin.

Available in size range from XS to XXXL.

Product details

Colour: Blue Sterility: Non-sterile Size: M Reference number (shirt): 842200-30 Reference number (trousers): 843200-30 Reusability: Single use

Dimensions	
Clean Air Suit – Shirt	
Length, highest point at back:	75 cm
Chest width:	57 cm
Weight	77,5 g
Clean Air Suit – Trousers	
Inner leg length:	78 cm
Waist width:	52 cm
Weight	76,5 g

Fire reaction class (Test method CFR 1610): Class 1

UN CPC code: 35290 Other articles for medical or surgical purposes

Manufacturing site is in Bago, Myanmar







The materials contain no animal tissue, no human blood derivatives, no medicinal substances, no phthalates and no polyvinyl chloride.

The standards presented below is a selection of the most essential standards that are adhered to: EN 1041, EN 13795, EN 62366, EN ISO 9001, EN ISO 13485, EN ISO 10993-1, EN ISO 10993-5, EN ISO 15223-1, ISO 15223-2, EN ISO 10993-10 and ISO 14001.

Technical characteristics*

Characteristic	Test method	Unit	Requirement*	Value BARRIER [®] Clean Air Suit
Resistance to microbial penetration - dry	ISO 22612	CFU	≤300**	8
Cleanliness - microbial	ISO 11737-1	CFU/100 cm2	≤300	≤300
Cleanliness - particulate matter	ISO 9073-10	IPM	≤3,5	2,2
Linting	ISO 9073-10	log10	≤4	2,1
Bursting strength - dry	ISO 13938-1	kPa	≥40	137
Tensile strength dry	EN 29073-3	Ν	≥20	39

* Performance requirements for clean air suits according to EN13795. The requirements apply for all products areas of clean air suits The level of liquid barrier performance of the product, according to ANSI/AAMI PB70:2012 is not applicable for clean air suits.

** Test conditions: challenge concentration of 10⁸ CFU/g talc. and 30 min vibration time

Content declaration

Product

Materials	Weight (g)	%
Polypropylene	100,1	65
Polyester	22,2	14
Viscose	17,7	11
Cotton	10,4	7
Polyoxymethylene (POM)	1,3	1
Pigments, antistatic agents and other	2,3	1
Total	154,0	100

Packaging

The first packaging layer is a plastic bag, containing one individual garment. Second layers are one larger joint plastic bag containing 22 individual bags, and a corrugated board transport box containing one joint plastic bag. The transport boxes are designed to fit existing recovery systems. The packaging system complies with the Packaging Waste Directive of the European Union.

Mölnlycke recommends that the Clean Air Suits are stored under normal storage conditions. All layers of packaging should be kept intact until access to the underlying layers is needed.





LCA information

The underlying Life Cycle Assessment (LCA) is a cradle-to-grave assessment that has been conducted in accordance with ISO 14040 and ISO 14044. The study was also performed according to PCR 2017:01 Disposable surgical drapes, gowns and air suits, used for patients, clinical staff and equipment Version 1.0 and General Programme Instructions for the international EPD[®] System, version 2.5.

Functional unit: 1 piece of BARRIER® Clean Air Suit, size M, consisting of a shirt and pair of trousers.

<u>Technical Reference Service Life:</u> The technical reference service life is not applicable for this type of product as it is an inactive product, meaning that no impact occurs during its use phase. It is though recommended by Mölnlycke to be used for one working day, equal to 8 hours, and it has a shelf-life of 5 years.

Databases and LCA software used: Modelling and environmental impact calculations are performed with the LCA software GaBi (version 8.6), using life cycle inventory data from Thinkstep, Ecoinvent 3.4, selected EPDs and Ecoprofiles.

<u>System boundaries:</u> Figure 1 below is a simplified process tree with system boundaries for the BARRIER[®] Clean Air Suit (CAS) from Mölnlycke. All instances of the figure are included in the assessment. Excluded are, i.e., manufacturing of production equipment, buildings and pallets, travelling by personnel and research and development – all in accordance with the PCR.

In case of recycling or other recovery impacts are borne by the product until it enters the facility gate where the process takes place in accordance with the Polluter Pays Principle. Benefits and credits of recovery are outside the system boundaries.



Figure 1 Simplified process tree

The lifecycle is divided into the following modules:

Upstream module

The upstream process comprises impacts from extraction, transport and refinement of resources, electricity used as well as production of raw materials, semi-products, garment accessories (such as draw strings) and auxiliary products, along with manufacturing of primary and secondary packaging.

Core module

The core process comprises impacts from transportation of materials and semi-products to the core process, manufacturing and assembly of the final product, electricity used as well as end-of-life treatment of waste generated during manufacturing.





Downstream module

The downstream process comprises impacts from transportation from assembly to customer along with the endof-life treatment of both product and packaging waste.

Data categories and sources: the following types of data were used in the LCA study

Specific data

Specific data has been used for the production process and packaging of the products related to the core module. An exception is the electricity consumption at the assembly, where the contracted manufacturer was not able to provide the information; consequently selected generic data has been used.

Selected generic data and proxy data

Selected generic data from Thinkstep, Ecoinvent 3.4, selected EPDs and Ecoprofiles have been used for the upstream and downstream processes, as collection of specific data was not possible. Proxy data is used when specific and selected generic data were not available and the environmental impacts associated to proxy data do not exceed 10% of the overall environmental impact from the product system.





Environmental performance BARRIER[®] Clean Air Suit

Potential environmental impact

PARAMETER	UNIT	Upstream	Core	Downstream	TOTAL
Global Warming Potential	kg CO2-eq.	6,38E-01	8,41E-02	3,51E-01	1,07E+00
Acidification Potential	kg SO ₂ -eq.	2,24E-03	3,48E-04	5,67E-04	3,15E-03
Formation potential of tropospheric ozone (POCP)	kg Ethene-eq.	2,12E-04	1,68E-05	2,63E-05	2,55E-04
Eutrophication Potential	kg Phosphate-eq.	7,16E-04	4,57E-05	6,34E-05	8,25E-04

Characterization factors used are the latest baseline characterization factors from CML for all impact categories but acidification, where the non-baseline characterization from CML is used.

Use of resources

PARAMETER	UNIT	Upstream	Core	Downstream	TOTAL
Non-renewable material resource	es				
Gravel, stone & sand	g	1,05E+03	5,10E+01	1,05E+01	1,11E+03
Limestone	g	7,61E+00	3,48E-01	2,39E+00	1,03E+01
Soil	g	3,78E+00	3,59E+00	2,21E-01	7,59E+00
Other	g	2,53E+01	1,34E+00	9,66E-01	2,76E+01
Renewable material resources					
Wood	g	6,43E+01	0,00E+00	0,00E+00	6,43E+01
Oxygen	g	8,20E-01	1,98E-03	0,00E+00	8,09E-01
Other	g	1,33E+00	6,36E-12	5,43E-04	1,34E+00
Non-renewable energy resources	5				
Crude oil (resource) ^a	g	1,78E+02	3,10E+00	7,21E+00	1,88E+02
Hard coal (resource)	g	9,62E+01	1,85E+00	4,18E-01	9,84E+01
Lignite (resource)	g	4,54E+01	1,24E-01	7,11E-01	4,63E+01
Natural gas (resource)	g	1,00E+02	1,64E+01	1,31E+00	1,18E+02
Uranium (resource)	g	1,80E-03	2,35E-06	2,68E-05	1,83E-03
Uranium (primary energy)	MJ	9,87E-01	1,28E-03	1,46E-02	1,00E+00
Other	g	5,12E-01	6,46E-04	7,79E-03	5,21E-01
Renewable energy resources					
Bio mass	g	7,20E+01	0,00E+00	0,00E+00	7,20E+01
Energy from hydro	MJ	2,52E-01	3,98E-01	0,00E+00	6,46E-01
Energy from solar	MJ	5,35E-01	1,32E-03	5,61E-03	5,42E-01





Energy from wind	MJ	2,61E-01	3,51E-04	5,73E-04	2,62E-01			
Other	MJ	1,07E+00	8,69E-06	1,23E-16	1,07E+00			
Water use								
Total water resource use ^b	g	1,07E+06	1,24E+05	1,92E+03	1,20E+06			
Direct use in core process ^c	g	N/A	0,00E+00	N/A	0,00E+00			
Secondary resources ^d								
Material resources	g	0,00E+00	0,00E+00	0,00E+00	0,00E+00			
Energy resources	g	0,00E+00	0,00E+00	0,00E+00	0,00E+00			
Recovered energy flows	MJ	0,00E+00	0,00E+00	0,00E+00	0,00E+00			

^a Oil is also a material resource for polypropylene and polyester, however the entire amount is reported here as the data provider did not specify the amount used as a material versus energy resource.

^b Excluding sea water

^c There is no water involved in the assembly process. Site water is only used for cleaning, toilets, cooking and worker hand washing and is hence approximated to zero.

^d All upstream burdens have been included

Waste production

PARAMETER	UNIT	Upstream	Core	Downstream	TOTAL
Hazardous waste disposed	kg	8,47E-01	2,85E-02	7,84E-02	9,54E-01
Non-hazardous waste disposed	kg	6,53E-05	3,89E-10	5,50E-09	6,53E-05
Radioactive waste disposed	kg	3,14E-04	5,04E-07	5,28E-06	3,20E-04

Other environmental indicators

The energy content into some products is useful for end-of-life management. The BARRIER® Clean Air Suit's energy content is 5,90 MJ per product, which is equivalent to 38,3 MJ/kg.





Environmental performance BARRIER[®] Clean Air Suit – Shirt

Potential environmental impact

PARAMETER	UNIT	Upstream	Core	Downstream	TOTAL
Global Warming Potential	kg CO2-eq.	3,08E-01	4,81E-02	1,73E-01	5,29E-01
Acidification Potential	kg SO ₂ -eq.	1,23E-03	1,82E-04	2,88E-04	1,70E-03
Formation potential of tropospheric ozone (POCP)	kg Ethene-eq.	1,07E-04	9,25E-06	1,33E-05	1,30E-04
Eutrophication Potential	kg Phosphate-eq.	4,94E-04	2,43E-05	3,24E-05	5,51E-04

Characterization factors used are the latest baseline characterization factors from CML for all impact categories but acidification, where the non-baseline characterization from CML is used.

Use of resources

PARAMETER	UNIT	Upstream	Core	Downstream	TOTAL
Non-renewable material resource	es				
Gravel, stone & sand	g	5,59E+02	3,00E+01	5,29E+00	5,94E+02
Limestone	g	3,81E+00	2,03E-01	1,15E+00	5,16E+00
Soil	g	1,88E+00	2,10E+00	1,07E-01	4,09E+00
Other	g	1,40E+01	7,00E-01	4,70E-01	1,52E+01
Renewable material resources					
Wood	g	3,20E+01	0,00E+00	0,00E+00	3,20E+01
Oxygen	g	4,88E-01	1,17E-03	0,00E+00	4,83E-01
Other	g	6,84E-01	6,27E-12	2,63E-04	6,90E-01
Non-renewable energy resources	5				
Crude oil (resource) ^a	g	8,43E+01	1,56E+00	3,62E+00	8,95E+01
Hard coal (resource)	g	4,93E+01	1,09E+00	2,11E-01	5,06E+01
Lignite (resource)	g	2,62E+01	6,71E-02	3,55E-01	2,66E+01
Natural gas (resource)	g	4,84E+01	9,71E+00	6,71E-01	5,88E+01
Uranium (resource)	g	9,48E-04	1,29E-06	1,36E-05	9,63E-04
Uranium (primary energy)	MJ	5,21E-01	7,06E-04	7,41E-03	5,29E-01
Other	g	2,46E-01	3,65E-04	3,93E-03	2,50E-01
Renewable energy resources					
Bio mass	g	5,06E+01	0,00E+00	0,00E+00	5,06E+01
Energy from hydro	MJ	1,28E-01	2,36E-01	0,00E+00	3,63E-01
Energy from solar	MJ	2,99E-01	7,00E-04	2,82E-03	3,02E-01





Energy from wind	MJ	1,41E-01	1,86E-04	2,90E-04	1,42E-01		
Other	MJ	7,47E-01	4,42E-06	6,16E-17	7,49E-01		
Water use							
Total water resource use ^b	g	5,99E+05	7,34E+04	9,56E+02	6,73E+05		
Direct use in core process ^c	g	N/A	0,00E+00	N/A	0,00E+00		
Secondary resources ^d							
Material resources	g	0,00E+00	0,00E+00	0,00E+00	0,00E+00		
Energy resources	g	0,00E+00	0,00E+00	0,00E+00	0,00E+00		
Recovered energy flows	MJ	0,00E+00	0,00E+00	0,00E+00	0,00E+00		

^a Oil is also a material resource for polypropylene and polyester, however the entire amount is reported here as the data provider did not specify the amount used as a material versus energy resource.

^b Excluding sea water

^c There is no water involved in the assembly process. Site water is only used for cleaning, toilets, cooking and worker hand washing and is hence approximated to zero.

^d All upstream burdens have been included

Waste production

PARAMETER	UNIT	Upstream	Core	Downstream	TOTAL
Hazardous waste disposed	kg	4,62E-01	1,58E-02	3,92E-02	5,17E-01
Non-hazardous waste disposed	kg	3,87E-05	2,25E-10	2,76E-09	3,87E-05
Radioactive waste disposed	kg	1,61E-04	2,77E-07	2,67E-06	1,64E-04





Environmental performance BARRIER[®] Clean Air Suit – Trousers

Potential environmental impact

PARAMETER	UNIT	Upstream	Core	Downstream	TOTAL
Global Warming Potential	kg CO2-eq.	3,30E-01	3,60E-02	1,78E-01	5,44E-01
Acidification Potential	kg SO ₂ -eq.	1,01E-03	1,66E-04	2,79E-04	1,45E-03
Formation potential of tropospheric ozone (POCP)	kg Ethene-eq.	1,05E-04	7,56E-06	1,30E-05	1,25E-04
Eutrophication Potential	kg Phosphate-eq.	2,22E-04	2,14E-05	3,10E-05	2,74E-04

Characterization factors used are the latest baseline characterization factors from CML for all impact categories but acidification, where the non-baseline characterization from CML is used.

Use of resources

PARAMETER	UNIT	Upstream	Core	Downstream	TOTAL
Non-renewable material resources					
Gravel, stone & sand	g	4,92E+02	2,10E+01	5,25E+00	5,18E+02
Limestone	g	3,80E+00	1,45E-01	1,23E+00	5,18E+00
Soil	g	1,90E+00	1,50E+00	1,14E-01	3,51E+00
Other	g	1,13E+01	6,40E-01	4,96E-01	1,25E+01
Renewable material resources					
Wood	g	3,23E+01	0,00E+00	0,00E+00	3,23E+01
Oxygen	g	3,32E-01	8,12E-04	0,00E+00	3,27E-01
Other	g	6,43E-01	8,88E-14	2,81E-04	6,49E-01
Non-renewable energy resources	5				
Crude oil (resource) ^a	g	9,36E+01	1,54E+00	3,59E+00	9,87E+01
Hard coal (resource)	g	4,69E+01	7,60E-01	2,07E-01	4,79E+01
Lignite (resource)	g	1,93E+01	5,66E-02	3,56E-01	1,97E+01
Natural gas (resource)	g	5,18E+01	6,71E+00	6,42E-01	5,91E+01
Uranium (resource)	g	8,51E-04	1,06E-06	1,32E-05	8,65E-04
Uranium (primary energy)	MJ	4,67E-01	5,77E-04	7,22E-03	4,74E-01
Other	g	2,67E-01	2,81E-04	3,86E-03	2,71E-01
Renewable energy resources					
Bio mass	g	2,14E+01	0,00E+00	0,00E+00	2,14E+01
Energy from hydro	MJ	1,24E-01	1,62E-01	0,00E+00	2,84E-01
Energy from solar	MJ	2,36E-01	6,18E-04	2,80E-03	2,40E-01





Energy from wind	MJ	1,20E-01	1,65E-04	2,83E-04	1,21E-01
Other	MJ	3,19E-01	4,28E-06	6,11E-17	3,21E-01
Water use					
Total water resource use ^b	g	4,75E+05	5,04E+04	9,60E+02	5,26E+05
Direct use in core process ^c	g	N/A	0,00E+00	N/A	0,00E+00
Secondary resources ^d					
Material resources	g	0,00E+00	0,00E+00	0,00E+00	0,00E+00
Energy resources	g	0,00E+00	0,00E+00	0,00E+00	0,00E+00
Recovered energy flows	MJ	0,00E+00	0,00E+00	0,00E+00	0,00E+00

^a Oil is also a material resource for polypropylene and polyester, however the entire amount is reported here as the data provider did not specify the amount used as a material versus energy resource.

^b Excluding sea water

^c There is no water involved in the assembly process. Site water is only used for cleaning, toilets, cooking and worker hand washing and is hence approximated to zero.

^d All upstream burdens have been included

Waste production

PARAMETER	UNIT	Upstream	Core	Downstream	TOTAL
Hazardous waste disposed	kg	3,85E-01	1,27E-02	3,92E-02	4,37E-01
Non-hazardous waste disposed	kg	2,66E-05	1,65E-10	2,75E-09	2,66E-05
Radioactive waste disposed	kg	1,54E-04	2,27E-07	2,60E-06	1,56E-04





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 SE-100 31 Stockholm Sweden
	www.environdec.com info@environdec.com
EPD registration number:	S-P-01340
Published:	2018-07-10
Valid until:	2021-06-25
Product Category Rules:	PCR 2017:01 Disposable surgical drapes, gowns and air suits, used for patients, clinical staff and equipment Version 1.0; Date 2017-04-12
Product group classification:	UN CPC 35290 – Other articles for medical or surgical purposes
Reference year for data:	2017-2018
Geographical scope:	Sweden

Product category rules (PCR):

PCR 2017:01 Disposable surgical drapes, gowns and air suits, used for patients, clinical staff and equipment, Version 1.0; Date 2017-04-12 and UN CPC 35290 – Other articles for medical or surgical purposes

PCR review was conducted by:

Technical committee of the International EPD System, Chair: Hüdai Kara

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

 \Box EPD process certification \boxtimes EPD verification

Third party verifier:

Marcus Wendin, CEO, Life Cycle Assessment and Design For Environment, Miljögiraff AB

Approved by:

The International EPD® System

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

 \Box Yes \boxtimes No

EPDs within the same product category but from different programs may not be comparable.

EPDs based on the PCR 2017:01 but referred to different type of products (drapes, gowns, etc.) may not be comparable since the functional unit can change depending on the type of products.





References

PCR 2017:01 Disposable surgical drapes, gowns and air suits, used for patients, clinical staff and equipment, UN CPC 35290, Version 1.0; Date 2017-04-12

General Programme Instructions of the International EPD® System. Version 2.5

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