

Pre-coat Filtration BECO® PR ENDURA® and BECO PR ENDURA S

Support Sheets for the Pharmaceutical Industry

BECO PR ENDURA range of support sheets is specially developed for the exacting requirements of the pharmaceutical industry. Low endotoxin content is ensured through the use of particularly pure raw materials and a special production process. BECO PR ENDURA support sheets can be used for pre-coat filtration in combination with all common filter aids.

The specific advantages of BECO PR ENDURA support sheets:

- Extremely low content of extractable components.
- Low endotoxin content through special production technique.
- Comprehensive quality assurance for all raw and auxiliary materials and intense in-process controls ensure consistent quality of the finished products.
- The filter material meets the guidelines of FDA, CRF 21 § 177.2260.
- Prior to delivery, a LAL test (Limulus Amebocyte Lysate) is used to verify the endotoxin content of BECO PR ENDURA products. A certificate is available on request.

Special Low-Endotoxin Filter Sheet for Pre-coat Filtration with Minimum Loss of Product

BECO PR ENDURA S

The application of BECO PR ENDURA S in pre-coat filtration, particularly for cake harvesting as part of plasma fractionation, ensures safe and economic filtration results.

Product loss during cake harvesting is minimized due to the extremely smooth and hydrophobic surface of BECO PR ENDURA S. The high wet bursting strength further simplifies cake harvest through secure handling.

Even if the intention is to extract the filtrate as a resource substance during pre-coat filtration, product loss is minimized due to the low suction volume (small thickness and hydrophobic matrix) of BECO PR ENDURA S.



Standard Support Sheet in Low-Endotoxin Design

BECO PR ENDURA

The BECO PR ENDURA support sheet combines the positive mechanical and filtration characteristics according to the requirements of the pharmaceutical industry.

This support sheet is suitable for pre-coating with a variety of filter aids. It is frequently used for the separation of activated carbon, for example, the decolorization of antibiotics. A high chemical resistance, even for solutions with extreme pH values, is the result of the high synthetic fiber content in BECO PR ENDURA support sheets.

Pyrogens/Endotoxins

In a medical sense, pyrogen means fever pathogen. Examples are endotoxins of gram-negative bacteria. These are cell wall constituents that consist of a lipid and a polysaccharide component and are embedded in the outer membrane.

Quantitative proof of endotoxins can be established using the LAL test (Limulus Amebocyte Lysate), for example, which is also used for the routine examination of the BECO PR ENDURA range of support sheets. This method is an efficient and economical alternative to the rabbit fever test. The support sheets are examined by an independent institute.

The endotoxin content of the samples is specified in EU/ml (endotoxin unit).

Physical Data

This information is intended as a guideline for the selection of BECO support sheets.

Type	Article no.	Thickness in (mm)	Ash content %	Bursting strength wet		Water throughput at	
				psi	(kPa)	$\Delta p = 14.5$ psi gpm/ft ²	($\Delta p = 100$ kPa* l/m ² /min)
PR ENDURA S	29450	0.06 (1.5)	< 1.0	> 58.0	(400)	18.9	(770)
PR ENDURA	29451	0.13 (3.4)	< 1.0	> 101.5	(700)	105.3	(4290)

The water throughput is a laboratory value characterizing the different BECO support sheets. It is not the recommended flow rate.

* 100 kPa = 1 bar

Chemical Data

BECO support sheet meets the requirements of LFGB*, Recommendation XXXVI/1 issued by BfR**, and the test criteria of FDA*** Directive CFR 21 § 177.2260.

Chemical resistance of the BECO depth filter sheets to different solvents over a contact time of 3 hours at 68 °F (20 °C). The chemical compatibilities listed in the table below are a guide only.

Solvent	Me- chan- ical strength	Solvent appear- ance	Solvent	Me- chan- ical strength	Solvent appear- ance	Solvent	Me- chan- ical strength	Solvent appear- ance
Aqueous solutions:						Organic solvents:		
Sugar solution, 10%	r	nc	Hydrochloric acid, 1%	r	nc	Methanol	r	nc
With 1% free chlorine	r	nc	Hydrochloric acid, 3%	r	nc	Ethanol	r	nc
With 1% hydrogen peroxide	r	nc	Hydrochloric acid, 5%	r	nc	Isopropanol	r	nc
With 30% formaldehyde	r	nc	Hydrochloric acid, 10%	r	nc	Toluene	r	nc
With 10% ethanol	r	nc	Nitric acid, 1%	r	nc	Xylene	r	nc
With 40% ethanol	r	nc	Nitric acid, 3%	r	nc	Acetone	r	nc
With 98% ethanol	r	nc	Nitric acid, 5%	r	nc	Methyl ethyl ketone	r	nc
Caustic soda, 1%	r	nc	Nitric acid, 10%	r	nc	n-hexane	r	nc
Caustic soda, 2%	r	nc	Sulfuric acid, 1%	r	nc	Dioxan	r	nc
Caustic soda, 4%	r	0	Sulfuric acid, 3%	r	nc	Cyclohexane	r	nc
Ammonia solution, 1%	r	nc	Sulfuric acid, 5%	r	nc	Tetrachloroethylene	r	nc
Ammonia solution, 3%	r	nc	Sulfuric acid, 10%	r	nc	Ethylene glycol	r	nc
Ammonia solution, 5%	r	nc	Acetic acid, 1%	r	nc	Dimethyl sulfide	r	nc
			Acetic acid, 3%	r	nc	N, N-Dimethyl formamide	r	nc
			Acetic acid, 5%	r	nc			
			Acetic acid, 10%	r	0			
<i>r = resistant</i>			<i>nc = no change</i>			<i>0 = slight opalescence</i>		

* = German Food, Commodity, and Feed Act

** = Federal Institute of Risk Assessment

*** = Food and Drug Administration; USA

Endotoxin Content of BECO PR ENDURA Support Sheet Range

To determine the endotoxin content, rinse support sheets with endotoxin-free water.

Filtration speed: 12.3 gal/ft²/h (500 l/m²/h)

Sampling after: 1.23 gal/ft² (50 l/m²)

Support sheet type	Endotoxin content EU/ml
BECO PR ENDURA S	< 0.08
BECO PR ENDURA	< 0.125

Components

BECO PR ENDURA support sheets are made from particularly pure materials. Finely fibrillated cellulose fibers from deciduous and coniferous trees, cationic charge carriers, and synthetic fibers are used.

Instructions for Correct Use

When inserting the support sheets into the sheet filters, handle carefully. Avoid knocks, distortion or abrasion. Never use a damaged support sheet.

Insertion

BECO support sheets have one rough side and one smooth side each. The rough side faces the liquid to be filtered (upstream). The smooth side is the filtrate side of the support sheet (downstream). When inserting take care to ensure that the smooth side is facing the filtrate plate.

Filter Preparation

Prior to the first filtration, Eaton recommends pre-rinsing the closed filter with 1.23 gal/ft² (50 l/m²) of water at 1.25 times the flow rate. As a rule, this equals a rinsing time of 10 to 20 minutes depending on the application. Test the entire filter for leakage at maximum operating pressure.

High-proof alcohol solutions and chemical products that cannot be used with water for pre-rinsing should be circulated for 10 to 20 minutes. Dispose of the solution after rinsing.

Sterilization (Optional)

BECO PR ENDURA support sheets may be sterilized with saturated steam of **249.8 °F (121 °C)**. The pressed packed filter has to be slightly loosened. Make sure to sterilize the entire filtration system thoroughly. Final pressure should be applied to the filter package once the entire filter has cooled down.

Sterilizing with Hot Water

The flow velocity should at least equal the filtration capacity. The water should be softened and free of impurities.

Temperature: 185 °F (85 °C)

Duration: 30 minutes after the temperature has reached 185 °F (85 °C) at all valves.

Pressure: At least 7.2 psi (50 kPa, 0.5 bar) at the filter outlet.

Sterilization with Steam

Steam quality: Steam has to be free of foreign particles and impurities

Temperature: max. **249.8 °F (121 °C)**
(saturated steam)

Duration: Approx. 20 minutes after steam has exited from all filter valves

Important Notice:

All vent and discharge valves must be slightly opened for optimal sterilization effect and to avoid the steam shock.

Safety

When used and handled correctly, there are no known unfavorable effects associated with this product.

Further safety information can be found in the relevant Material Safety Data Sheet, which can be downloaded from our website.

Waste Disposal

Due to their composition, BECO PR ENDURA support sheets can be disposed of as harmless waste. Comply with relevant current regulations, depending on the filtered product.

Storage

Support sheets consist of strongly adsorbing materials. Careful handling is necessary during transportation and storage. Support sheets must be stored in a dry and odor-free place that is well aerated.

Do not expose the support sheets in direct sun light.

BECO PR ENDURA support sheets are intended for immediate use and should be used within 36 months after production date.

Available Formats

BECO PR ENDURA support sheets can be supplied for all current filter sizes, square or round. Special formats are available at request.

Quality Assurance According to DIN EN ISO 9001

The Quality Management System of Eaton Technologies GmbH has been certified according to DIN EN ISO 9001.

The certification confirms the functioning of the total system of Quality Assurance from product development through contract controls, choice of suppliers as well as acceptance controls, production and final examination all in the way to storage and dispatch.

Extensive quality assurance measures comprise the adherence to technical criteria regarding the function as well as the confirmation of chemical purity and quality recognized as safe under the German law governing the production of foodstuffs and beverages.

All information is given to the best of our knowledge. However, the validity of the information cannot be guaranteed for every application, working practice and operating condition. Misuse of the product will result in all warranties being voided.

Subject to change in the interest of technical progress.

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