

STERYKLEAR ADM FREE—KSEA

- Materials free from substances of animal origin (ADM FREE Animal Derived Materials)
- · Food contact materials, according to EU and FDA requirements
- USP materials compliance
- High effective filtration area
- Thermowelded construction
- Integrity testable in situ
- Repeatedly steamable in situ or in autoclave
- Sanitizable
- Validation Guide available upon request



STERYKLEAR ADM FREE-KSEA filter is "Animal Free" as the materials used for its manufacturing are free from animal derived substances.

It is used as final sterilizing filter in food & beverage and pharmaceutical critical applications; PH and PHH grades are preflushed with pyrogen free water and with certification of quality. As it is free from animal derived substances, STERYKLEAR ADM FREE-KSEA is suitable for the newest and ever more increasing market requirements.

The manufacturing process is carried out in a certified clean room; every filter passes the integrity test which is correlated to the microbiological retention.

MATERIALS OF CONSTRUCTION

| Filter media | PES membrane | |
|-------------------|---------------|--|
| Support layers | polyester | |
| Internal core | polypropylene | |
| External cage | polypropylene | |
| End caps/Adapters | polyester | |

FOOD-SAFETY

STERYKLEAR KSEA filter element materials meet (EU) regulation 10/2011 and its amendments, regulations (EC) 1935/2004 and 1895/2005.

BIO-SAFETY

Filter media and components pass USP Biological Reactivity and Chemical-Physical tests for CLASS VI plastics.

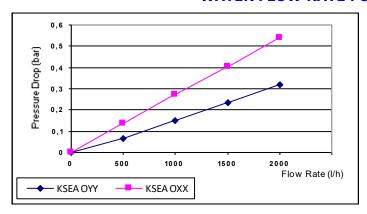
Specific for "PH" and "PHH" grade: the filter meets USP "Water for injection" requirements for particle release and the effluent is Non-Pyrogenic per USP Bacterial Endotoxins (< 0,25 EU/ml). Bacterial endotoxins are determined by LAL test.

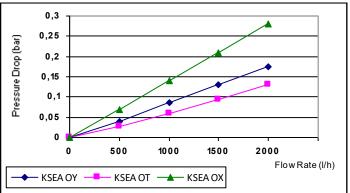
RECOMMENDED OPERATING CONDITIONS

| - max. continuous temperature | 80 °C | |
|--|--|--|
| - max. cumulative time of steam sterilization | 13 hours at 125 °C with cycles of 30 minutes | |
| - sanitization with hot water | 80 °C max | |
| - sanitization with chemicals | can be sanitized by standard chemical agents | |
| - max. differential pressure | 5,0 bar at 25 °C | |
| - recommended change out differential pressure | 2,0 bar at 25 °C | |

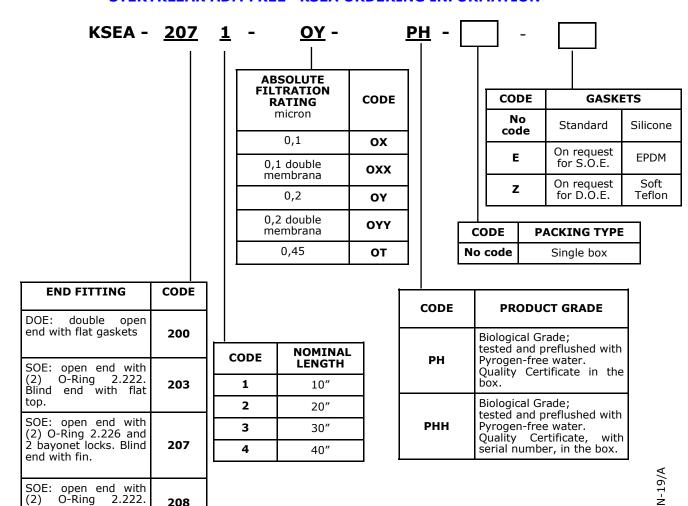
| CODE | ABSOLUTE FILTRATION RATING IN LIQUIDS | BACTERIAL RETENTION >10 ¹⁰ CFU/ 10" CARTRIDGE * | ACCEPTABLE LIMIT FOR DIFFUSION TEST WITH WATER FOR 10" CARTRIDGE (ml/min) |
|-------------------|--|---|--|
| ОХ | 0,1 μm | Acholeplasma laidlawii | ≤ 30 @ 3,5 bar |
| OXX | 0,1 µm double membrane | Acholeplasma laidlawii | ≤ 30 @ 3,5 bar |
| OY | 0,2 μm | Brevundimonas diminuta | ≤ 26 @ 2,7 bar |
| OYY | 0,2 µm double membrane | Brevundimonas diminuta | ≤ 26 @ 2,7 bar |
| ОТ | 0,45 μm | Serratia marcescens | ≤ 16 @ 1,7 bar |
| *as per ASTM F838 | | | |

WATER FLOW RATE FOR 10" CARTRIDGE





STERYKLEAR ADM FREE-KSEA ORDERING INFORMATION



Recommended rinse up volume in situ: 5 liters/10" cartridge

Data contained in this bulletin are informative and subject to change without notice. User is responsible for determining whether the product is fit for particular purpose and suitable for User's method of application.



Blind end with fin.

end with fin.

SOE: open end with (2) O-Ring 2.222 and

3 bayonet locks. Blind

208

212

DS-KSEA-565-EN-19/A