



Sterile, powdered concentrate based on active oxygen for disinfecting surfaces in cleanrooms

perform® sterile concentrate OXY

Our Plus

- sporicidal and material compatible
- sterile (X-Ray irradiated)
- convenient single use sachets
- colour free
- efficacy tested according to European norms (EN)

Application areas

Disinfection of surfaces and equipment/devices in cleanrooms. Especially for Grade A and B clean areas, according to:

- EU Guidelines to Good Manufacturing Practice for medicinal products, Annex 1: Manufacture of sterile medicinal products; March 2009
- FDA Guidance for Industry: Sterile drug products produced by aseptic processing - current Good Manufacturing Practice, U.S. Department of Health and Human Services; Food and Drug Administration; September 2004.

Instructions for use

To prepare the working solution, first add water (preferably hand-warm) to the tub or bucket, then sprinkle in and dissolve the product.

For example:

1 sachet (40 g) to 4 l = 1 % solution

Ensure complete wetting. Contact time has to be considered. Rinse surfaces intended to be in direct contact with final products. To prevent the build-up of residue on treated surfaces, keep residual moisture on surfaces to a minimum after wiping. perform® sterile concentrate OXY has excellent cleaning properties, therefore mixing it with cleaning boosters is not necessary. The composition of the active ingredient system in the use solution remains stable for one

working day. If the active solution becomes very dirty, replace it earlier.

Microbiological efficacy

Efficacy	Concentration	Contact time
bactericidal EN1276, EN13697	0.5 % (5 g/l)	30 min.
fungicidal EN1650, EN13697	1.5 % (15 g/l)	60 min.
virucidal against enveloped viruses <i>in accordance with DVV (German Registered Association for Combating Viral Diseases)//RKI Guideline</i>	0.5 % (5 g/l)	5 min.
Vaccinia virus	0.5 % (5 g/l)	5 min.
sporicidal EN13697	1 % (10 g/l)	2 h
sporicidal EN13704	2 % (20 g/l)	2 h



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Product data

Composition:

100 g powder contains the following active substances:

45 g Pentapotassium bis(peroximonosulphate) bis(sulphate).

Labelling according to Regulation (EC) No. 648/2004: 5 - 15 % anionic surfactants, < 5 % non-ionic surfactants, < 5 % soap, < 5 % phosphonates, perfumes

Chemical-physical data

Color	white
Flash point	Not applicable
Form	granular
pH	ca. 4 / 5 g/l / 20°C / in water
Viscosity, dynamic	Not applicable

Special advice

Use disinfectants safely. Always read the label and product information before use.

The bags are sterile (with radiation indicator) and doublewrapped in practical 5 sachets units. Do not store bags above room temperature.

The active solution may bleach textile dyes that are highly sensitive.

Environmental information

schülke manufactures products economically and with advanced, safe and environmentally friendly production processes while at the same time maintaining our high quality standards.

Expert opinion and information

Please visit our website for an overview of all available literature/reports on the product: www.schuelke.com.

For individual questions:

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Schülke & Mayr GmbH holds a Manufacturer's Authorisation according to sect 13 para 1 German Drug Law and Certificates of GMP Compliance for medicinal products.

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