

Additional Note for GP-04-Instrument disinfectant VIREX BASIC conc. ID 200-03-08-01-ZA01_Master label


instrument disinfectant VIREX BASIC concentrate ID 200

Example label with mandatory details, area of validity: European Union




Classified as a class IIb medical product

	Description	Text	Legal basis	Evidence for the statement
1	Product name	Instrument disinfectant VIREX BASIC concentrate ID 200	1272/2008/EC	
2	Product description and intended purpose ¹	<p>Type of application: Product for the manual cleaning and prophylactic disinfection of thermostable and thermolabile instruments in immersion bath procedures. Not suitable for the terminal disinfection of semi-critical and critical medical devices!</p> <p>Notes on application: Dilute the concentrate with warm water (at least drinking water quality) of 10°C to 30°C (use a dispensing bottle or system) and insert the instruments into the working solution as soon as they are used, in an open condition. All surfaces and cavities to be disinfected have to be covered in full by the solution. Depending on the level of contamination, the working solution may have to be replaced (RKI recommendation: replace at least once per working day). After disinfection, the instruments should be rinsed with drinking water (demineralised water is recommended) and dried thoroughly. Do not mix with cleaning agents or other disinfectants! The treatment guidelines of the instrument manufacturer are to be observed. Semi-critical medical devices must be treated or sterilised with a viricidal disinfectant for terminal disinfection. Critical medical devices are to be sterilised last. First check the tolerance before using new materials. Suitable for use in an ultrasonic bath. The working solution can be disposed of with normal waste water. Dosage quantities and application times should be observed as precisely as possible and not be undercut.</p> <p>Application times: <u>Bacteria as per EN 13727, EN 14561 and VAH with high bio load:</u> 1,5% 15min. 1.0% 60min. <u>Candida albicans as per EN 13624, EN 14562 and VAH with high bio load:</u> 1,5% 15 min. 1.0% 60 min. <u>Membrane covered viruses viruses (e.g. HBV, HCV and HIV) as per DVV/RK with high bio load:</u> 1,5% 15 min. 1.0% 60 min. <u>TbB (<i>M. terrae</i>) as per EN 14348 and EN 14563. low bio load:</u> 4.0% 15 min. 2.0% 60 min.</p>	EEC 93/42 (Medical Device Law)	See assessments and test reports under 12.1 of the product documentation
3	Hazard statements	<p>Safety guidelines: H 302 Harmful if swallowed. H 314 Causes severe skin burns and eye damage. H 400 Very toxic to aquatic life. Avoid release to the environment. Wear protective gloves/eye protection. IN CASE OF CONTACT WITH THE SKIN (or hair): Remove all contaminated clothing immediately. Wash/shower the skin with water. IN THE EVENT OF CONTACT WITH THE EYES: Rinse carefully for a long time with water. Remove any contact lenses if possible. Continue to rinse. Call a POISON CENTER or a doctor/physician immediately. Dispose of the contents/container in accordance with local/regional/national/international regulations. Contains didecylidimethylammonium chloride, N-(3-aminopropyl)-N-dodecylpropane-1.3-diamin.</p>	1272/2008/EC	
4	Contents as per 648/2004/EC	Directive 648/2004/EC: Contains 15-30% non-ionic surfactants, <5 cationic surfactants, <5% EDTA salts, fragrance.	648/2004/EC	
5	CE marking with the number of the nominated office*	CE 0124	EEC 93/42	
6	Contents (volume)	XXXXml / XXltr. e	1272/2008/EC, 76/211/EEC	

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7	Batch and best before date**	 See imprint	EEC 93/42; EN 15223-1, EN 980
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¹ Text can vary.

8	Hazard symbols and signal word	 Hazard	1272/2008/EC
9	Date of editing (in format CCYY-MM)	2017-12	EEC 93/42 (2007/47/EC)
10	Storage temperature range	40°C 0°C 	EN 15223-1, EN 980
11	Name, address and tel. no. of the distributor, incl. and symbol		1272/2008/EC, EEC 93/42; EN 15223-1, EN 980

* XXX = Filler text

** Best before: 42 months

Extra voluntary details:

12: Notice: Additional information for "product usage" can be copied from point 71. from technical documentation.

13: range of activity:
bactericidal (incl. MRSA) acc. EN 13724, EN 14561, VAH; yeasticidal (Candida albicans) acc. EN 13624, EN 14562, VAH; tuberculocidal (M.terrae) acc. EN 14348, EN 14563, partially virucidal (membrane covered viruses e.g. HBV, HIV, HCV) acc. DVV/RKI

14: "100g contain:": 4,4g Didecyldimethylammoniumchloride, 2,75g N-(3-Aminopropyl)-N-dodecyl-propan-1,3-diamin.

15: time of activity:

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Bacterias acc. EN 13727 (high bio load):

2% 5min.
1% 15min.

Candida albicans acc. EN 13624 (high bio load):

2% 5min.
1% 15min.
0,5% 60min.

Bacterias acc. EN 14561 (high bio load):

2% 5min.
0,5% 15min.

Candida albicans acc. EN 14562 (high bio load):

2% 5min.
1% 15min.
0,5% 60min.

Bacterias and Candida albicans acc. VAH (high bio load):

1% 15min.

TbB (*M. terrae*) acc. EN 14348 (low bio load):

4% 15min
3% 30min.
2% 60min

TbB (*M. terrae*) acc. EN 14563 (low bio load):

2,0% 15min
1,5% 30min.
1,0% 60min.

„partially virucidal“ (membrane covered viruses acc. RKI/DVV e.g. HBV, HCV, HIV), high bio load:

1% 15min.

16: If an article number is to be applied, this must have "REF" next to it (EN 15223-1, EN 980)

17: Barcode

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