

18th May 2010

Dear Customer

**Discontinuation of Premier-WFI Klercide-CR Sterile
Filtered Biocide F Concentrate**

Due to a problem with validating the endotoxin recovery from Premier-WFI Klercide-CR Sterile Filtered Biocide F Concentrate we are unable to make an endotoxin claim for this product. Despite numerous changes to the test method due to the nature of the quaternary ammonium compound it has not been possible to validate the endotoxin test. This product is discontinued with immediate effect.

This product will be replaced with Premier Klercide-CR Sterile Filtered Biocide F Concentrate which is an identical product in terms of active ingredient so therefore very low residue but it will not have a guaranteed endotoxin limit as part of the release criteria for the product.

The concentrate will be blended with deionised water in the same way as the other products in our Premier range.

The new product will be :

Premier Klercide-CR Sterile Filtered Biocide F Concentrate Capped Code 3057850

The endotoxin claim will be removed from the product certificate. All other release criteria remain the same. A draft Certificate of Analysis is attached.

The new product will be available from the end of July.

If you have any queries about this change please do not hesitate to contact either your local business manager or our customer service department on +44 (0) 1252 717616.

Yours faithfully

A handwritten signature in black ink, appearing to read 'K. Rossington'. The signature is written in a cursive style with a long horizontal stroke at the end.

Karen Rossington
Marketing and Development Manager

DRAFT

Certificate of Analysis

Product: Premier Klercide-CR Sterile Filtered Biocide F Concentrate Capped

Product Code: 3057850

Product Description: Hard Surface Disinfectant Concentrate 5L Capped

Batch:

Manufacture Date:

Expiry Date:

Certificate of Analysis No:

<u>Test</u>	<u>Specification</u>	<u>Results</u>
Colour:	Colourless to pale yellow liquid	
Odour:	Aromatic	
Clarity:	Clear	
Filtration	to 0.2 microns	
SG @ 20°C:	0.988 – 1.000	
pH @ 20°C	5.5 – 7.5.	

We hereby certify that the above was manufactured via a Quality System certified to BS EN ISO 9001:2000, BS EN ISO 13485:2003 and where applicable the Medical Devices Directive 93/42/EEC, tested in accordance with documented quality procedures and approved as a result of meeting the required specifications.

Furthermore, all environmental monitoring data will have been recorded and actioned in line with SM.QMP.01– Environmental Monitoring of the clean rooms – thus ensuring that all relevant release criteria has been met in respect of any sterility work required and clean room monitoring results.

Authorised Signature: 1. _____ 2. _____

Position: 1. _____ 2. _____

Date: 1. _____ 2. _____

For and on behalf of Shield Medicare, a division of Ecolab

Shield Medicare Limited



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