



Technical Bulletin

11/10/2017

Water Activity of Bedside-Care® EasiCleanse™

The purpose of this technical bulletin is to provide information on the low level of water activity in Bedside-Care® EasiCleanse™ and its ability to prevent microbial growth in the product.

There are many factors that can lead to contamination of products which may result in microbial growth that can be harmful to the user of the product. Reduced water activity (a_w) can greatly assist in the prevention of microbial growth in a product. Water activity is a measurement of the amount of “available” water versus “bound” water in a product. If there is little available water (low water activity) then microorganisms cannot proliferate. The following table shows the water activity required to support the growth of representative microorganisms.

Table 1. Water Activities (a_w) Required to Support the Growth of Representative Microorganisms

Bacteria	Water Activity (a_w)	Molds and Yeast	Water Activity (a_w)
<i>Pseudomonas aeruginosa</i>	0.97	<i>Rhizopus nigricans</i>	0.93
<i>Bacillus cereus</i>	0.95	<i>Mucor plumbeus</i>	0.92
<i>Clostridium botulinum</i> , Type A	0.95	<i>Rhodotorula mucilaginosa</i>	0.92
<i>Escherichia coli</i>	0.95	<i>Saccharomyces cerevisiae</i>	0.9
<i>Clostridium perfringens</i>	0.95	<i>Paecilomyces variotti</i>	0.84
<i>Lactobacillus viridescens</i>	0.95	<i>Penicillium chrysogenum</i>	0.83
<i>Salmonella</i> spp.	0.95	<i>Aspergillus fumigatus</i>	0.82
<i>Enterobacter aerogenes</i>	0.94	<i>Penicillium glabrum</i>	0.81
<i>Bacillus subtilis</i>	0.9	<i>Aspergillus flavus</i>	0.78
<i>Micrococcus lysodeketicus</i>	0.93	<i>Aspergillus niger</i>	0.77
<i>Staphylococcus aureus</i>	0.86	<i>Zygosaccharomyces rouxii</i> (osmophilic yeast)	0.62
<i>Halobacterium halobium</i> (halophilic bacterium)	0.75	<i>Xeromyces bisporus</i> (xerophilic fungi)	0.61
No microbial proliferation	<0.60		

Bedside Care EasiCleanse is a dry foam product that does not contain any preservatives due to the low water activity of the product. The water activity of Bedside Care EasiCleanse is on average 0.151, which does not support the growth of any microorganisms during the product’s shelf life

Reference:

Pharmacopeia USP 41 Section <1112> Application of Water Activity Determination to Nonsterile Pharmaceutical Products

Bedside Care EasiCleanse Water Activity Lab Report Veeva Doc. VV-0042472

Disclaimer - Provision of education information only - always seek professional advice

This letter is not a substitute for independent professional advice. Nothing contained in this letter is intended to be used as medical advice and it is not intended to be used to diagnose, treat, cure or prevent any disease, nor should it be used for therapeutic purposes or as a substitute for your own health professional's advice. Coloplast Corp. disclaims any liability for any injury, loss or damage incurred by use of or reliance on the information.