

Zinc Omadine™ 48% FPS for Personal Cleansing with Bar Soaps



Zinc Omadine™ FPS GECT
 INCI Name: Zinc Pyrithione
 SAP Codes #: 215711/215712

Zinc Omadine™ FPS PEO
 INCI Name: Zinc Pyrithione
 SAP Codes #: 215713/215714

Key Product Attributes:

- Targets odor causing bacteria on the skin
- Effective bactericidal and/or bacteriostatic active against specific bacteria linked to odor
- Allows for use in different rinse off personal cleansing applications

Efficacy Data

Minimum Inhibition Concentration (MICs)

Minimum inhibitory concentration (MIC) is an *in vitro* test that determines the lowest concentration of an antimicrobial that will inhibit the visible growth of a microorganism after overnight incubation. Minimum inhibitory concentrations are important because they can confirm resistance of microorganisms to an antimicrobial agent and also to monitor the activity of new antimicrobial agents.⁴ A MIC is generally regarded as the most basic laboratory measurement of the activity of an antimicrobial agent against an organism and Lonza uses this as an initial screening for determining efficacy.⁵ MIC studies were performed to determine the efficacy of Lonza's Zinc Omadine™ dispersion on numerous organisms that play a part in odor formation.

	Zinc Omadine™ (Active, ppm)
<i>S. epidermis</i>	15.6
<i>C. minutissimum</i>	7.81
<i>S. haemolyticus</i>	31.3
<i>C. xerosis</i>	3.91
<i>M. luteus</i>	15.6

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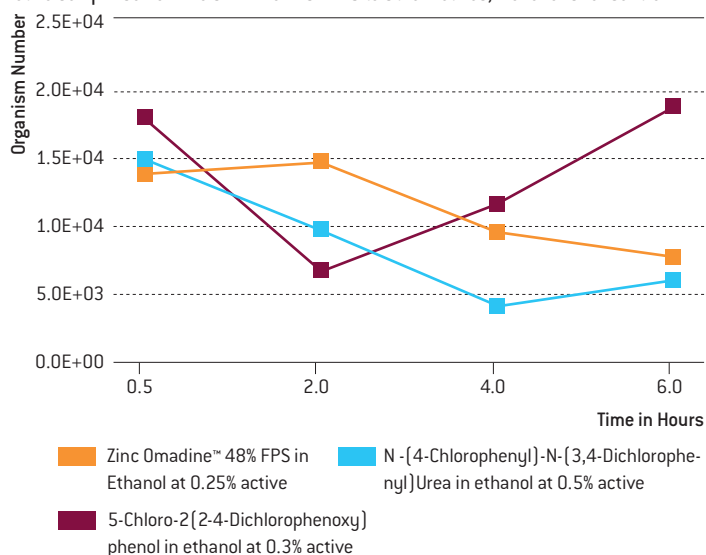
Microbiological Challenge Studies

In vitro pig skin tests were performed following a proprietary method in order to determine the efficacy of Lonza active Zinc Omadine™ 48% FPS dispersion. This zinc pyrithione active was compared to other commonly used actives for odor control; comparatives were done on the neat actives and in a bar soap.

Study 1

The first study shows how the various actives performed when tested on pig skin, neat.

Active Comparison of Zinc Omadine™ 48% FPS to Other Actives, Alone for Odor Control



Conclusion

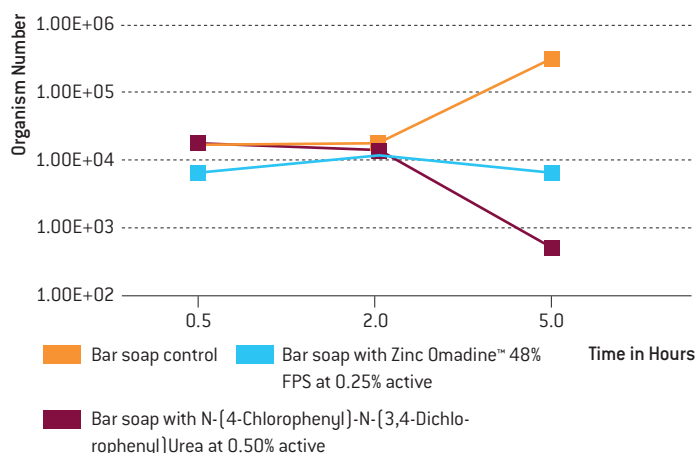
Results of the standalone actives after a 6 hour pig skin study show Zinc Omadine™ 48% FPS is effective in the long term decrease of the number of odor causing organisms.

Study 2

The second study shows how the actives performed when placed in a bar soap formulation. The ingredients of the formula are listed below.

Bar soap ingredients: Glycerin, Palm Oil, Coconut Oil, Lauric Acid, Aqua/Water/Eau, Sodium Hydroxide, Sodium Lauryl Sulfate, Sorbitol, Triethanolamine, Salt, EDTA

Comparison of Zinc Omadine™ 48% FPS Dispersion to Another Active for Odor Control in Bar Soap



Conclusion

Results of the actives in a bar soap after a 5 hour pig skin study show Zinc Omadine™ 48% FPS had a long term bacteriostatic effect on the number of odor causing organisms.

Regulatory Note

A finished formulation sold in the United States that contains Zinc Omadine™ 48% FPS cannot include any antimicrobial claims or reference the biocidal nature of the material against any particular organism. Zinc Omadine™ 48% FPS can be used in rinse-off deodorant applications but cannot be used as an active ingredient to make antimicrobial claims, including when used in cosmetic grade Deodorant or Antibacterial Handwash/Soap applications. FDA has classified deodorants as cosmetics and Zinc Omadine is not listed in FDA's Tentative Monograph: OTC Healthcare Antiseptic Drug Products.

In the EU, odor control is a cosmetic application not a biocidal application (BPR). Zinc pyrithione is a listed preservative in EU Cosmetic Reg Annex V and allowed in rinse off products only. For products other than those for hair, it is permitted up to 0.5%. Lonza recommends an upper use level of 0.25% zinc pyrithione for whole body rinse off products.

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