Zinc Omadine™ 48% FPS and Zinc Omadine™ Enhanced CP Dispersion for Personal Cleansing

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

Background

Lonza’s Zinc Omadine™ is extremely effective in eliminating the fungi, *Malassezia* spp., which is directly linked to the scalp condition, dandruff. An important characteristic of this molecule is that it is efficacious against numerous other organisms beyond *Malassezia*, including the various bacteria species associated with producing odor on the skin.

The market for body odor control and neutralization is expanding with ongoing research into how odor control on the body could be targeted differently. This research includes identifying various chemistries that can be active for this target as well as the mode of action for each chemistry. Lonza Consumer Care is dedicated to being able to offer solutions in this category beginning with Zinc Omadine™.
Odor Causing Bacteria

Body odor is influenced by the behavior of specific microorganisms found topically on the skin. There are certain bacteria that are more prone than others, to produce odor on the skin. These include *Corynebacterium minutissimum*, *Corynebacterium xerosis*, *Micrococcus luteus*, *Staphylococcus epidermis*, and *Staphylococcus haemolyticus*. These specific bacteria secrete enzymes extracellularly which react with lipids present in human sweat, breaking them down. The byproduct or breakdown product produced is what actually causes the odor to occur. Preventing these bacteria from initially growing on the skin is a critical step in preventing body odor, thus providing odor control.

Efficacy Data

**Minimum Inhibition Concentration (MICs)**

Minimum inhibitory concentration (MIC) is an *in vitro* test to 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. 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.

MIC studies were performed to determine the efficacy of Lonza’s *Zinc Omadine™* dispersion on numerous organisms that play a part in odor formation.

<table>
<thead>
<tr>
<th><em>Zinc Omadine™</em> (Active, ppm)</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>S. epidermis</em></td>
</tr>
<tr>
<td>15.6</td>
</tr>
<tr>
<td><em>C. minutissimum</em></td>
</tr>
<tr>
<td>781</td>
</tr>
<tr>
<td><em>S. haemolyticus</em></td>
</tr>
<tr>
<td>31.3</td>
</tr>
<tr>
<td><em>C. xerosis</em></td>
</tr>
<tr>
<td>3.91</td>
</tr>
<tr>
<td><em>M. luteus</em></td>
</tr>
<tr>
<td>15.6</td>
</tr>
</tbody>
</table>

**Microbiological Challenge Studies**

*In vitro* pig skin tests were performed following a proprietary method in order to determine the efficacy of two Lonza actives; *Zinc Omadine™ 48% FPS dispersion and Zinc Omadine™ Enhanced CP* (ZPT coated with palm oil). These zinc pyrithione actives were compared to other commonly used actives for odor control; comparatives were done on the neat actives, in a bar soap and incorporated in a body wash.

**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 and Zinc Omadine™ Enhanced CP Dispersion to Another Active for Odor Control in Bar Soap**

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

Study 3
The third study shows how the actives performed when placed in a body wash formulation. The formulation is provided below.

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>INCI Nomenclature</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water</td>
<td>Water</td>
<td>q.s to 100</td>
</tr>
<tr>
<td>Standapol WAQ-LC</td>
<td>Sodium Lauryl Sulfate</td>
<td>3.00</td>
</tr>
<tr>
<td>Steol</td>
<td>Sodium Lauryl Sulfate</td>
<td>10.00</td>
</tr>
<tr>
<td>CS 270</td>
<td>Sodium Laureth Sulfate</td>
<td>20.00</td>
</tr>
<tr>
<td>Lauramide MEA</td>
<td>Lauramide MEA</td>
<td>2.65</td>
</tr>
<tr>
<td>Polyaldo® 6-2-S</td>
<td>Polyglyceryl-6 Distearate</td>
<td>1.00</td>
</tr>
<tr>
<td>Cetearyl Alcohol</td>
<td>Cetearyl Alcohol</td>
<td>0.50</td>
</tr>
<tr>
<td>Active</td>
<td></td>
<td>0.52</td>
</tr>
<tr>
<td>Mikrokill® COS</td>
<td>Phenoxyethanol &amp; Caprylyl Glycol &amp; Chlorphenesin</td>
<td>0.75</td>
</tr>
<tr>
<td>Sodium Chloride</td>
<td>Sodium Chloride</td>
<td>1.00</td>
</tr>
<tr>
<td>Citric Acid 10 %</td>
<td>Citric Acid</td>
<td>q.s</td>
</tr>
<tr>
<td>Sodium Hydroxide 10 %</td>
<td>Sodium Hydroxide</td>
<td>q.s</td>
</tr>
</tbody>
</table>

Comparison of Zinc Omadine™ 48% FPS and Zinc Omadine™ Enhanced CP Dispersion to Another Active for Odor Control in Body Wash

Conclusion
Results of the actives in a body wash after a 5 hour pig skin study show Zinc Omadine™ Enhanced CP had a long term bacteriostatic effect on the number of odor causing organisms, similar to other actives used for odor control.
Formulating Tips with Zinc Omadine™

- Maintain pH between 5.0 and 8.5
- Maintain process temperatures which are normal to shampoo manufacturing; Zinc Omadine™ has shown to be stable for > 2 hours at 100°C
- Incorporate after blending of other ingredients, just prior to fragrance and preservative addition
- Complete homogenization is a critical and final step

Use of Suspending Agents in the Formulation

- It is important to include a suspending agent in the formulation in order to keep the Zinc Omadine™ consistently dispersed
  - Suspending agents include synthetic clays (Veegum, Laponite), Stepan TAB-Z, Stepan SAB-2
- Typically, suspending agents are used at half the Zinc Omadine™ (active) concentration
- If a suspending agent is not used, it is important to maintain viscosity >7000 cps

Use of Thickening Agents in the Formulation

- Use of thickening agent can help reduce required higher viscosity to prevent ZPT precipitation
- Thickening agents include:
  - Carbopol Aqua SF-1 [30% active liquid added at 3-5%]
  - Carbopol 2020 [Powdered thickener added at 0.1-0.3%]
  - Cellulosics, alkanoamides, sodium chloride or combinations
- It has been seen that hydroxypropyl methyl-cellulose or sodium chloride in combination with alkanoamide typically give good results

Incompatibilities with Zinc Omadine™

- Strong chelators, such as EDTA, can chelate the zinc forming soluable ionic pyrithione
- Cationic polymers can neutralize the negative charge on the ZPT molecule causing agglomeration. The positive charge of the cationic polymer must be neutralized by an anionic in the formulation prior to the addition of Zinc Omadine™
- Iron salts, even at trace levels, can cause a grey to purple color in a shampoo formulation due to the formation of ferric pyrithione

Regulatory Note

A finished formulation sold in the United States that contains Zinc Omadine™ 48% FPS or Zinc Omadine™ Enhanced CP Dispersion cannot include any antimicrobial claims or reference the biocidal nature of the material against any particular organism. Zinc Omadine™ 48% FPS or Zinc Omadine™ Enhanced CP Dispersion can be used in 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 (which supports antimicrobial hand washes and soaps).

References