

# Zinc Omadine® 48%

## Aqueous Dispersion FPS (Fine Particle Size)

### Safe & Effective Dandruff Relief



Zinc Omadine® 48% Aqueous Dispersion FPS

INCI Name: Zinc Pyrithione

SAP Code#: 100645

Preservative: DMDM Hydantoin

## Key Product Attributes:

- Relieves flaking symptoms of dandruff
- Targets scalp with a slow release for highest efficacy
- Effective dispersion because it is not soluble
- Enhances substantivity to the skin and hair
- Maintains efficacy over long-term use without resistance

## Product Background

Zinc Omadine® is the most popular anti-dandruff ingredient in the world, offering bactericide-fungicide efficacy in shampoos, conditioners and leave-on products. Lonza's Zinc Omadine® products have been providing dandruff relief and improved scalp health for over 50 years.

# Regulatory Compliance

## Globally

Regulatory Compliance - Anti-dandruff shampoo is considered a cosmetic in Europe but it is classified a drug in the US and a quasi-drug in Japan.

## Europe

Lonza maintains REACH and BPD registrations for all Zinc Omadine® products offered.

## United States

Zinc Omadine® 48% Aqueous Dispersion FPS complies with the current FDA OTC monograph for use as an anti-dandruff agent in a shampoo or hair dressing. US FDA allowed concentrations for Zinc Pyrithione for anti-dandruff applications are as follows:

- Rinse-off Applications 0.30 – 2.0% active
- Leave-in Applications 0.1 – 0.25% active

New Drug Application (NDA) not required to add Zinc Pyrithione to shampoo at levels recommended in monograph

# Formation of Dandruff

*Malassezia spp.* yeast are the primary factor in the development of dandruff on the scalp. These lipophilic yeasts are generally considered to be normal and inhabit the surface of all scalp. It is not known if there are any beneficial effects from hosting these organisms but since these yeasts use sebum as a nutrient source, their presence may in some way help minimize scalp oiliness.

*Malassezia* hydrolyze sebum, releasing a mixture of saturated and unsaturated fatty acids. They utilize the saturated fatty acids and leave behind the unsaturated fatty acids like oleic acid. In normal scalp, they inhabit the surface and live symbiotically with the human host.

The precise triggers for dandruff are unknown, however it is known that individuals vary in their susceptibility and it is not just the level of yeast colonization that is a factor. A greasy scalp will supply an overabundance of lipid to the *Malassezia* and will likely lead to an excess of fatty acids on the scalp. These acids are known to penetrate the stratum corneum inducing an irritation response or hyperproliferation. This increased rate of epidermal cell division results in sloughing and scaling. Dandruff sufferers have altered stratum corneum ultrastructure, resulting in weaker barrier function and increased sensitivity to irritants.

## Potential Triggers for Dandruff:

- Excessive oily scalp
- Cold, dry winter weather
- Stress or fatigue
- Mechanical stress on the hair and follicles during braiding or the addition of extensions can lead to the enhanced generation of sebum
- Some aftercare products can be loaded with humectants such as glycerin or propylene glycol, which impart short-term gloss to the hair, but can be very drying to the scalp

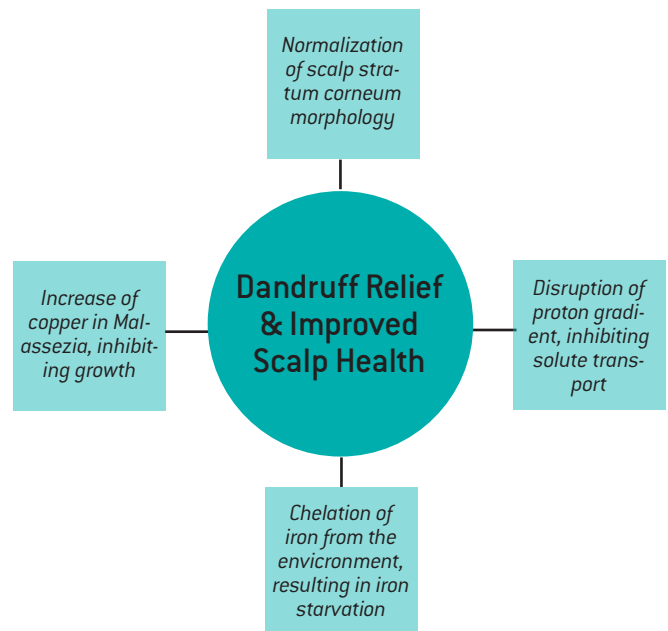
# Treatment of Dandruff

Many anti-dandruff actives work on the cell membrane by inhibiting enzyme (ergosterol) synthesis. When this takes place, the microbe changes the enzyme synthesis pathway, rendering the cell wall more impervious to the anti-microbials and to become increasingly resistant.

Unlike other actives, Zinc Pyrithione does not allow for resistance over time and continues to offer effective protection against dandruff with continual use. It works differently in that it acts as an antimicrobial through disruption of the proton gradient across the cell membrane. By moving freely in and out of the cell membrane and taking ions with it, Zinc Pyrithione carries potassium and magnesium out of the microbe until the microbe is completely depleted of these nutrients and is unable to function normally and dies. This mode of action does not interfere with cell wall enzymes, which means the organism does not mutate and become resistant to the continued use of the antimicrobial.

We now know that Zinc Pyrithione has additional properties that play into its efficacy. This molecule is an efficient chelator of iron and has been shown to deplete the cells of this essential nutrient<sup>1</sup>. Furthermore, it has been demonstrated that Zinc Pyrithione can increase cellular copper in *Malassezia*, which will also cause inhibition of growth<sup>2</sup>. Research has shown that Zinc Pyrithione is not only highly effective in reducing the level of viable yeast cells on the scalp but also works by normalizing scalp morphology<sup>3</sup>.

# Zinc Pyrithione Mode of Action



## Clinical Efficacy

- FDA Advisory Review Panel citations
- 13 clinical trials (1223 subjects) found 1.0% ZPT-based shampoo safe and effective
- 31 (of 33 total) clinical trials found 2.0% ZPT-based shampoo safe and effective

## Toxicology

- Extensive studies conducted by Lonza
  - Acute Oral LD50 in rats is 270 mg/kg
  - Irritating to eyes
  - Mildly irritating to skin (Dermal LD50: >2.0g/kg)
  - Minimal skin absorption
  - Not a skin sensitizer
  - Not a mutagen
  - Not a carcinogen
  - Not a teratogen

## Incompatibilities

- Oxidizing agents
- Strong chelators (EDTA)
- Presence of soluble iron
- Some cationics and amphoteric may form insoluble complexes with Zinc Pyrithione

## Formulating Tips

### Zinc Omadine® 48% Aqueous Dispersion FPS in Suspension

- Suspending agents
  - Synthetic clays (Veegum, Laponite)
  - Stepan TAB-2, Stepan SAB-2
  - Carbopol ETD 2020
- Viscosity
  - Maintain >7000 cps if suspending agent not used
- Homogenization
  - Beneficial final step

## General Properties

### Zinc Omadine® 48% Aqueous Dispersion FPS

- Mixture in water of very fine particles of Zinc Pyrithione, a dispersant, and viscosity control agent
- Effective anti-dandruff agent
- Exhibits pronounced growth inhibiting activity against a broad spectrum of both Gram positive and Gram negative bacteria in cosmetic preparations
- Inhibits the growth of fungi, both yeast & mold, in cosmetic preparations

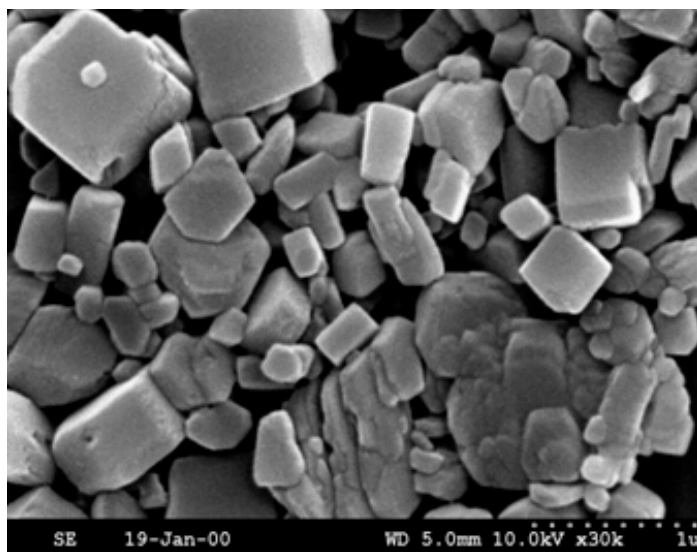


Fig. 1

Zinc Omadine® 48% Aqueous Dispersion FPS

Specifications	
Zinc Pyrithione (%)	48 - 50
pH 5% active slurry in pH 7 water	6.5 - 8.5
Particle Size (HORIBA LA 910)	
Less than or equal to 1 micron (%)	90
Less than 5 microns (%)	100

Typical Properties	
Molecular Weight (Zinc Pyrithione)	317.7
Color	off-white
Bulk Density (lb./gal.)	10
Zinc (%)	9.3 - 11.3

## References

1. Yasokawa D., et al. J. Biosci. Bioeng. (2010) 109: 479–486
2. Reeder et al. Antimicrob Agents Chemother. (2011) 55(12):5753-60
3. Warner et al. J. Amer. Acad. Dermatol. (2001) 45, (6) 897-903

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