



Zinc Omadine® Enhanced CP Dispersion (patented)

Enhanced Dandruff Relief and Hair Appearance



INCI Name: Water (and) Zinc Pyrithione (and) *Elaeis guineensis* (Palm) Oil

SAP Code#: 100670 & 100439

Preservative: DMDM Hydantoin

Key Product Attributes

- 46% Aqueous Dispersion
- Fine particles enhanced with palm oil coating
- Relieves flaking symptoms of dandruff
- Enhances substantivity to the skin and hair
- Offers weightless styling

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. Our most recent introduction of Zinc Omadine® Enhanced CP Dispersion is a patent-pending advancement that enhances the anti-dandruff efficacy and the cosmetic performance attributes of our benchmark ingredient Zinc Omadine®. The palm oil coating provides a way to 'target' the delivery of the Zinc Omadine® to the *Malassezia* spp. yeast, which are the primary factor in the development of dandruff on the scalp. *Malassezia* are lipid loving organisms and are therefore attracted to the lipophilically coated Zinc Pyrithione, offering enhanced efficacy of the Zinc Omadine®, as well as counteracting some negative effects of shampooing such as dry scalp and residue build up on the hair.

Regulatory Compliance

Globally

Anti-dandruff shampoo is considered a cosmetic in Europe but is classified as 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® Enhanced CP Dispersion 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.

Ex-vivo Efficacy

Corneofungimetry Study

Corneofungimetry is an *ex-vivo* bioassay that was used to determine the efficacy of the new Zinc Omadine® Enhanced CP Dispersion aqueous dispersion as compared to our regular grade Zinc Omadine® 48% FPS aqueous dispersion against *Malassezia furfur*. This method uses skin strippings as the growth medium for the yeast to simulate the growth conditions on the scalp. The skin strippings are treated with the test compound and then inoculated with a suspension of *M. furfur* and allowed to incubate at 27° C for 9 days. The samples are stained and viable yeast cells counted by computerized image analysis to determine growth of the *M. furfur*; the fewer viable yeast found, the greater the efficacy of the active to kill the organisms. Corneofungimetric evaluation of both the actives alone as well as in a shampoo formulation was performed. The results are shown in Fig. 1 and 2.

	Physiological Saline control (no antifungal)	Zinc Omadine® 48% FPS Dispersion (uncoated)	Zinc Omadine® Enhanced CP Dispersion
viable yeasts/cm2 of stratum corneum	810	457	339
% killing compared to saline control	—	44	58
Efficacy improvement over uncoated control (%)	—	—	25

Fig.1

Corneofungimetry bioassay results comparing the activity of Zinc Omadine® 48% FPS Dispersion to Zinc Omadine® Enhanced CP Dispersion at a concentration of 1% active ingredient. The results represent the mean values for 20 replicates for each treatment.

	Physiological Saline control	Shampoo with uncoated Zinc Omadine® 48% FPS Dispersion	Shampoo with Zinc Omadine® Enhanced CP Dispersion
viable yeasts/cm2 of stratum corneum	756	363	286
% killing compared to saline control	—	52	62
Efficacy improvement over uncoated control (%)	—	—	21

Fig. 2

Comparative corneofungimetry bioassay of a shampoo formulated with 1% active Zinc Pyrithione added either as our FPS dispersion or as Zinc Omadine® Enhanced CP Dispersion-dispersion. The results represent the mean values for 20 replicates for each treatment.

Corneofungimetry bioassay results demonstrate that Zinc Omadine® Enhanced CP Dispersion offers a 25% efficacy improvement over the uncoated control. The results also indicate that there is a 21% efficacy improvement over the uncoated control when Zinc Omadine® Enhanced CP Dispersion is formulated into a shampoo.

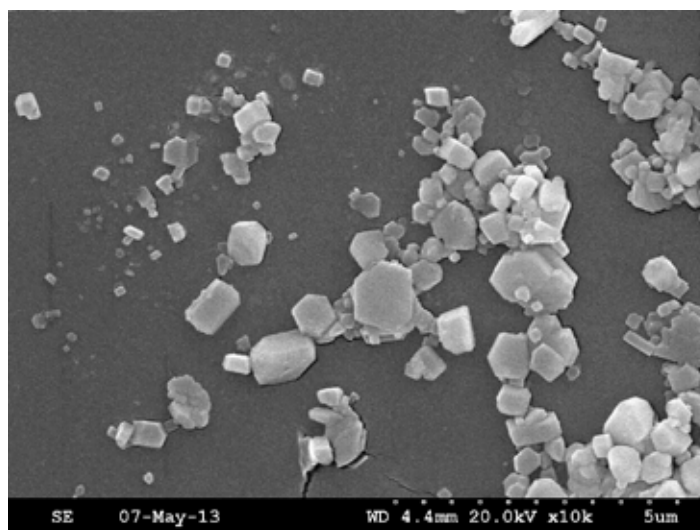


Fig. 3

Scanning electron microscope (SEM) image of Zinc Omadine® Enhanced CP Dispersion

In-vivo Beauty-Enhancement Study

Salon Comparison of Shampoos

A salon study was used to evaluate the attributes provided by the palm oil coating, specifically minimizing some of the side effects generally associated with anti-dandruff treatments. The beauty enhancement properties of Zinc Omadine® Enhanced CP Dispersion were evaluated by conducting an *in-vivo* study on 30 subjects looking at the appearance of curls, shine and presence of residue on the hair. The study was a double blind protocol where informed participants applied either a control shampoo containing 1% [active] Zinc Omadine® 48% FPS Dispersion to their hair, or a test shampoo containing 1% active ingredient

[a.i.] Zinc Omadine® Enhanced CP Dispersion. Application was done once daily for one week. Subjective evaluation of the effect of the effect of the shampoo was determined by assessment questionnaires, comparing the effect before and after product use for one week.

The one week salon study results are shown in Figure 4 as the percentage of panelists who agreed with the comments identified in the figure below.

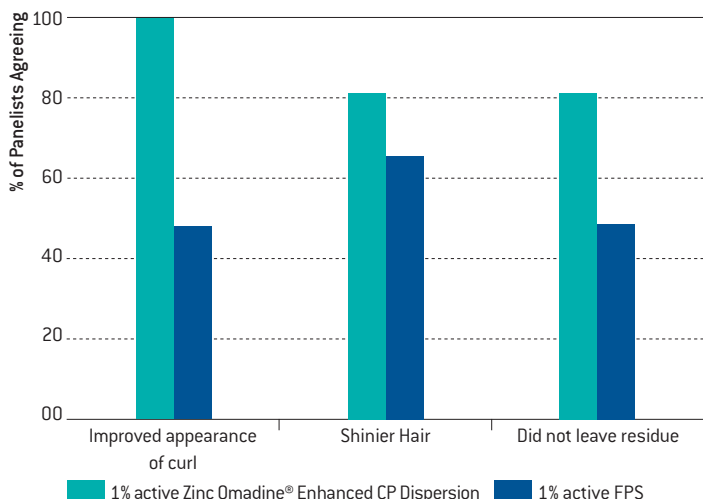


Fig. 4
Effect of Zinc Omadine® Enhanced CP Dispersion vs. ZPT in Anti-Dandruff Shampoo

Conclusions

The results in Figure 4 confirm that using our Zinc Omadine® Enhanced CP Dispersion to deliver 1% Zinc Pyrithione to a shampoo, offers enhanced properties over the standard uncoated Zinc Omadine® 48% FPS. Even at the low level of palm oil [0.12%], consumer perception substantiates there is an improvement in the hair feel.

The lack of residue is a key finding in this study, as the after-feel of a residue deposited on hair is a drawback to some anti-dandruff shampoos. The ability of Zinc Omadine® Enhanced CP Dispersion to give an improved appearance of curls allows for weightless styling claims and notable improvement in hair shine is a key attribute for any hair type.

Incompatibilities

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

Formulating Tips

Keeping Zinc Omadine® Enhanced CP Dispersion 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
- Cationic, polymeric conditioners are compatible with ZPT, but formulation changes may be necessary.

Typical Properties

Appearance	Creamy, off-white dispersion
Free from foreign matter	
Assay, % zinc pyrithione	44–48
Palm Oil (calculated % based on addition)	4.0–6.0
Recommended Use Levels (according to FDA allowed concentrations):	
- Rinse-off applications (0.3–2% active)	0.65–4.35%
- Non Rinse-off applications (0.1–2.25% active)	0.27–0.54%

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