

Dear Dermatologist

It was great seeing you again in Cape Town at the Congress. Thank you for raising your concerns regarding various ingredients mentioned by Dr John English.

Kindly see below the answers to your questions. The response has been received from our Global Medical Affairs department:

1) **Linalool:**

- a. Pure linalool is a very weak allergen. In its air oxidized format (e.g. linalool hydroperoxide) it does have contact allergenic potential. Linalool is required to become oxidized with air first, before it can become a contact allergen. To develop a significant enough of a concentration to be an allergen would require air exposure for a minimum of 20 weeks to a maximum of 45 weeks (at which time 30% of pure linalool still exists). *Ref: SCCS 102 p47, Brared Christensson CD 2010: 67: p249*
- b. Concentrations of 6% oxidized linalool are required to produce an allergenic effect in 5.3% of test subjects (n=1725). At 2%, it was only able to produce an allergic response in 0.83% of test subjects (n=1693) *Ref: SCCS 102 p35, Brared Christensson CD 2010: 62: p35*
- c. Linalool is a part of the components that make up the Masking Fragrance Mixture in DERMACONTROL Foam Wash. The concentration of the fragrance mixture is 0.25% of total mixture, of which Linalool is a smaller component.
- d. **CONCLUSION: The concentration of Linalool in DERMACONTROL Foam Wash is extremely low and therefore it is unlikely to produce a contact allergy effect. As it is part of a masking fragrance formulation in the Foam wash, it is not designed to bind to human skin, but is only to reduce the unpleasant fragrance(s) of some of the other ingredients. It is washed off when rinsed and does not leave a residue afterwards.**
The results of the following clinical studies (SPR 18200, 18201, 18224 & 40135 – HRIPT) conducted by Galderma conclude that Cetaphil DERMACONTROL Foam Wash is well tolerated, does not induce any irritation or allergic reaction and does not demonstrate any sensitizing potential.

2) **Methylisothiaolamine (MI):**

- a. The first identified Contact Dermatitis to MI was reported in 2004 – this was due to exposure in occupational circumstances as MI was used as a biocide in a number of industrial applications (e.g. paints, inks, glues, etc.) *Ref: Editorial Whilst Rome Burns 2013 CD 2013: 68: p257*
- b. In 2010 the first non-occupational sensitivity to MI was reported. *Ref: Editorial Whilst Rome Burns 2013 CD 2013: 68: p257*
- c. In 2013, there is no agreement in the establishment of the correct concentration of MI to establish sensitivity testing for Contact Dermatitis *Ref: Urwin & Williamson CD 2013: 68: p254/5*

d. **CONCLUSION: Cosmetic products formulated to contain concentrations of MI at 100 ppm (0.01%) or less would not be expected to pose a sensitization risk. Ref: Urwin & Williamson CD 2013: 68: p254**

MI is not the preservative of Cetaphil Restoraderm Body Wash but the preservative of one of the ingredients. For this reason, there are only traces of it in the body wash. The final concentration of MI in the body wash is approximately 0.0011% to 0.0015% (11 to 15ppm), which means about ten times less than the concentration considered to be of negligible risk for a leave-on cosmetic.

In the recommended mode of use, the product is rinsed shortly after application on the skin. Therefore, because of the very low concentration of MI in the body wash and the short contact, the traces of MI present in Cetaphil Restoraderm Body Wash, are not considered to represent a significant risk of sensitization.

In clinical studies conducted by Galderma (SPR 18151, 40085 & 40086 – HRIPT), RESTORADERM Body Wash was shown to be well tolerated, in both Dermatologist and AD patient assessments, would not induce an allergic reaction or demonstrate sensitization potential.

3) **Sodium Lauryl Sulphate: (SLS):**

a. **in Cetaphil Restoraderm.**

b. Please see attached the ingredient lists for both the wash and moisturizers as well as the latest article published in the JDD- July2013 stating there is **NO SLS in Cetaphil Restoraderm.**

c. **In Cetaphil Gentle Cleanser:**

- o Contains Cetylstearyl alcohol-sodium lauryl sulphate complex
- o whilst containing a low SLS concentration within this complex, the detergent effect of sodium lauryl sulphate on the skin and skin barrier is suppressed while still cleansing effectively.

4) **The article of Del Rosso discusses the unique properties of Cetaphil Restoraderm and that Cetaphil Restoraderm wash and moisturiser which are specifically formulated to help AD patients, and which I'm sure will be of interest to you.**

As a final note: All ingredients that are used in products developed and manufactured by Galderma are permitted by EU and other Health Authorities and in permitted concentrations. Galderma constantly monitors the safety of their products and is regularly monitored at regulatory level.

Please feel free to come back to us with your comments or further questions you may have.

ATTACHMENTS:

- [Brared Christensoon linalool CD Contact Dermatitis 2012](#)
- [Cetaphil RESTORADERM Ingredients List](#)
- [Christensen Linalool contact dermatitis Contact dermatitis 2010](#)
- [Del Rosso - The Integration of Physiologically Targeted Skincare in the Management of Atopic Dermatitis](#)
- [MCT and MIT Contact Allergy - A New Epidemic](#)

Kindest Regards

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