

## **AOECS Public Statement on drugs, hygiene products and cosmetics**

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(under revision)**

### **About drugs:**

The European Pharmacopoeia<sup>1</sup> poses a limit to the total protein content of wheat starch present as excipient in drugs. The maximum total protein content is 0.3% (3.000 ppm) which correlates to the gluten content to be no more than 100 ppm.

The maximum quantity of gluten in drugs for oral use is therefore limited by this provision and it is completely harmless for the celiac taking into account the relatively small amount (weight) of medicinal products consumed daily.

All drugs can therefore be considered safe and suitable for people with celiac disease and Herpetiform Dermatitis patients except in cases of individual hypersensitivity that should be evaluated on a case-by-case basis.

See also: [https://www.ema.europa.eu/en/documents/report/wheat-starch-containing-gluten-used-excipient-report-published-support-questions-answers-wheat\\_en.pdf](https://www.ema.europa.eu/en/documents/report/wheat-starch-containing-gluten-used-excipient-report-published-support-questions-answers-wheat_en.pdf)

### **About hygiene and cosmetic products:**

As regards to materials that come in contact with the skin and mucosae including drugs, hygiene products and cosmetics, these are not a problem for coeliacs and Herpetiform Dermatitis patients even if containing gluten.

In fact, Gluten triggers an adverse reaction in coeliacs only when it comes in contact with the bowel.

Also, toothpaste and lipsticks are safe for coeliacs, even if containing gluten, taking into account the very small amount (traces) of products that could be ingested.

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<sup>1</sup> [https://www.edqm.eu/en/european\\_pharmacopoeia\\_10th\\_edition](https://www.edqm.eu/en/european_pharmacopoeia_10th_edition)

The AOECS European Licensing System for pre-packaged food products does not grant Crossed Grain Trademark licence for drugs, cosmetics and hygiene products.

Members of the AOECS Scientific Advisory List who have contributed to this communication:

Jorge Amil Dias, Portugal  
Rute Cerqueira, Portugal  
Raanan Shamir, Israel  
Martin Zarnkow, Germany