

	<b>Multiple Fagron Derma Products, Microplastic Free</b>	Page : 1-2
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## Scope: Multiple Fagron Derma Products, see Annex A

Dear Valued Customer / Partner:

Fagron's line of topical creams and ointments have been carefully formulated for maximum compatibility with various active pharmaceutical or dermaceutical ingredients, and with a wide variety of skin types. In August of 2022, the European Commission released a draft proposal to restrict added microplastics in various products entitled [Annex to the Annex XV Restriction Report, Proposal for a Restriction: Substance Name\(s\): intentionally added microplastics](#). This 302 page proposal is the basis of the current analysis and statement.

The proposal (Table 1) gives over 15 individual definitions by regulatory bodies regarding what is a microplastic, with no full consensus. Three elements, however, are common across all the definitions, which are small, solid, and water insoluble. Biodegradability is also frequently cited. Some ingredients such as simethicone can be found in this document (Table 46), but this table also includes many components that are not solid, of limited solubility in water, and are generally considered biodegradable. We therefore do not consider these ingredients to be microplastics.

Based on a review of the composition of the vehicles noted in Annex A, Fagron declares that **none of these products contain intentionally or unintentionally added microplastics**.

Date:  
05 Jul 2023

Authorised by:  
Joshua Radke  
Director, North America Quality and  
Global Quality Support  
Fagron Group

This information is provided to the best of our knowledge and belief based on a review of current composition and information supplied by vendors. However, we do not specifically analyse each batch to confirm of the points above and cannot guarantee the absence or level of these substances to any specific limit or threshold value.



## **Annex A**

The following products have been reviewed and are considered to be in scope:

- Emolivan™
- Espumil™
- Fitalite™
- Phytobase™
- Nourisil™
- Nourivan™ Antiox
- Occluvan™
- Pentravan®
- Seraqua™
- Versatile™
- Versatile™ Rich