

01 January 2023

To Our Valued Customers:

This statement is regarding the European Commission's (EU) Scientific Committee on Consumer Safety (SCCS) Opinion on Butylated Hydroxytoluene (BHT). BHT is a synthetic antioxidant used in multiple applications such as food additives, pharmaceutical and cosmetic and personal care products. In early 2019 the EU Cosmetics Regulation prioritized a list of 28 substances that had the potential to be endocrine disruptors (ED). BHT was one of these substances.

In 2019 the SCCS was asked to give their scientific opinion on the ED concerns of BHT used in tooth paste, rinse-off and leave-on products.

https://ec.europa.eu/health/sites/health/files/scientific_committees/consumer_safety/docs/sccs_o_257.pdf

The SCCS performed dermal, *in vitro* and oral studies regarding BHT as an endocrine disruptor. The SCCS concluded:

- "Although the evidence on skin sensitization in animals is limited, from a range of human experience there is no evidence to suggest that BHT is a significant human skin sensitizer or contact allergen."
- "On the basis of a safety assessment and considering the safety concerns related to the potential endocrine disrupting properties of BHT, the SCCS is of the opinion that BHT is safe as an ingredient up to a maximum concentration of 0.8% in other leave-on and rinse-off products."
- "The SCCS concurs with the conclusions of EFSA (European Food Safety Authority) (2012) and VKM (Norwegian Scientific Committee for Food and Environment) (2019) that BHT is not of concern with regard to genotoxicity."

SCCS's opinion is that BHT is safe as an ingredient up to a maximum concentration of 0.8% for leave-on and rinse-off products. In November 2022 EU accepted SCCS's opinion publishing Regulation 2022/2195 in the Official Journal of the European Union under the new conditions for use:

- "In light of the SCCS opinion, it can be concluded that there is a potential risk to human health arising from the use of Butylated Hydroxytoluene in mouthwash, toothpaste and other leave-on and rinse off products when the concentration of that substance exceeds certain levels. Therefore, the use of Butylated Hydroxytoluene in those products should be restricted to a maximum concentration of 0,001 %, 0,1 % and 0,8 % respectively."

Calumet adds BHT to products such as Versagel and Petrolatum at levels up to 0.05% and 0.002%. Calumet is aligned with this Regulation 2022/2195 for its personal care, pharma and cosmetic products that contain BHT. Keep in mind as our product is added to the customers final formulations it is likely to be diluted further.

Calumet products containing BHT include but are not limited to:

Product	Typical Concentration of BHT: ppm (%)
Petrolatum EP	<20 ppm (<0.002%)
White Petrolatum EP	<20 ppm (<0.002%)
USP Ointment Bases	<20 ppm (<0.002%)
Mineral Jellies	<20 ppm (<0.002%)
Versagel® M 200, 500, 750, 1600	<200 ppm (0.02%)
Versagel® MC 750, MC 1600	<200 ppm (0.02%)
Versagel® MD 500, MD 1600	<200 ppm (0.02%)
Versagel® ME 500, 750, 1600, 2000	<200 ppm (0.02%)
Versagel® ML 750, ML 1600	<500 ppm (0.05%)
Versagel® MN 750, MN 1600	<500 ppm (0.05%)
Versagel® MP 750, MP 1600	<500 ppm (0.05%)
Versagel® MX 750	<500 ppm (0.05%)
Versagel® P 200	<500 ppm (0.05%)

Please contact Calumet's Product Support Team at technical@clmt.com should you have further questions.