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Retrospective Review of Dermal Safety Studies of the Organic Sun Filter Bemotrizinol

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INTRODUCTION

Bis-ethylhexyloxyphenol methoxyphenyl triazine (BEMT) is a UVA/UVB sun filter that has been approved for use in the European Union since 2000. In June 2026, the FDA approved BEMT as a new, safe, and effective UV filter for over-the-counter sunscreens in the US. BEMT was approved in the US at concentrations up to 6% in sunscreen products at maximum use and is used at concentrations of up to 10% in the Southern Common Market (Mercosur), China, and Europe, whereas in Japan BEMT is limited to 3%. We conducted a retrospective analysis of approximately 14,622 subjects who participated in clinical safety studies examining sunscreens formulated with BEMT for countries outside of the US.

MATERIALS AND METHODS

The test subjects included adult volunteers from 18 to 70 years old. These subjects did not have a known history of allergies, skin diseases, or lesions. Exclusion criteria included: pregnancy, currently breastfeeding or planning to become pregnant during the study, having a history of skin cancer within the past 5 years, recent use of corticosteroids or other medications, compromised skin, or existing skin irritations on the test area. Tests were supervised by dermatologists and conducted at an independent laboratory. All clinical safety studies were approved by an Institutional Review Board, and all test subjects signed written informed consent forms.

A total of 108 formulas were assessed, which ranged from 0.1% to 6% BEMT concentration. BEMT formulations in the dataset are also combined with other UV filters, which are not described. Sunscreens in the tested dataset included commercialized and noncommercialized formulations. The categories were further divided into product types (Cream/Lotion, Pump/Spray, Serum, or Stick).

The Human Repeat Insult Patch Test (HRIPT) determines the potential of a product to cause irritation and/or allergic contact dermatitis. The Cumulative Irritation Test (CIT) test assesses the potential of a product to cause cumulative skin irritation. The Photo Toxicity Test (PT) study evaluates an induced photo irritation response to a product. The Photo Allergy Test (PA) study evaluates an induced photosensitization response. One hundred and eight studies were performed in 3 study centers in Latin America, Europe, and Asia. Specific protocols followed for each safety test can be found in Wilson et al 2025.

RESULTS

A total of 14,622 subjects were evaluated in HRIPT, CIT, PT, or PA safety studies as summarized in Table 1. For HRIPT, 12,379 subjects evaluated 177 BEMT containing Cream/Lotion, Pump/Spray, Serum, or Stick formulations. These represent a range of commercial formulations that could contain BEMT. Of the 12,379 subjects in the HRIPT studies, there were no cases of

TABLE 1.

Summary of BEMT Safety Studies Assessed

	HRIPT		Photo Allergy		Photo Toxicity		Cumulative Irritation	
	# of Products	# of Subjects	# of Products	# of Subjects	# of Products	# of Subjects	# of Products	# of Subjects
Cream/ Lotion	66	7324	17	456	31	532	19	560
Spray	42	4444	7	173	10	158	11	285
Serum	9	387	0	0	1	27	0	0
Stick	2	224	2	52	0	0	0	0
Total	117	12379	24	681	42	717	30	845
Pass	--	12379 (100%)	--	681 (100%)	--	717 (100%)	--	845 (100%)
Fail	--	0 (0%)	--	0 (0%)	--	0 (0%)	--	0 (0%)

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sensitization observed from any formulation containing BEMT. For assessments of potential photoallergy, phototoxicity, or cumulative irritation, a total of 2243 subjects tested Cream/Lotion, Pump/Spray, Serum, or Stick formulations containing BEMT.

The results of the retrospective assessment demonstrated that there were no cases of photoallergy, phototoxicity or cumulative irritation, observed from any formulation containing BEMT. These clinical safety study results demonstrate that formulations containing BEMT have a robust safety profile.

DISCUSSION

Sun protection, including sunscreens, is essential for preventing skin cancer and the effects of photoaging such as mottled hyperpigmentation and wrinkles. We recently completed a retrospective assessment of the dermal safety of sunscreens containing existing organic UV filters (Wilson et al, 2025); this current retrospective assessment extends that work to include BEMT. Bis-ethylhexyloxyphenol methoxyphenyl triazine (BEMT), also known as bemotrizinol, is an oil-soluble organic compound used in sunscreens to absorb UV rays, protecting against both UVA and UVB rays. With a molecular weight of 627.80 g/mol and a solubility index, XLogP3 of 10.4, BEMT has unique physical/chemical properties that distinguish it from other sunscreen actives currently in use in the US market.[2] BEMT is a highly oil-soluble sun filter with a large relative molecular size which contributes to minimal, non-accumulative transdermal exposure and an ecological profile characterized by low environmental persistence, minimal bioaccumulation potential, and favorable ecotoxicity.[3,4] BEMT is an efficient broad-spectrum UV filter with multiple absorbance maxima reported: 310 nm in the UVB region and 343 nm in the UVA region of the solar radiation spectra[5], which results in broad-spectrum UV light protection.

The approval of BEMT by the FDA brings the first new organic UV filter to the US in over 20 years. BEMT is an efficient broad-spectrum UV filter, with protection from both UVA and UVB wavelengths. Furthermore, topical applications of BEMT containing sunscreen formulation containing 6% BEMT did not result in significant systemic exposure (D'Ruiz et al, 2023) likely a result of the large molecular weight of BEMT. The lack of systemic exposure further supports the safety profile of the new sun filter and also reinforces the importance of a robust assessment of dermal safety for BEMT.

The core hydroxyphenyl triazine structure of the BEMT chromophore exhibits extreme inherent photostability as well as an ability to photo-stabilize other more labile UV filters such as Avobenzone (Butyl Methoxydibenzoylmethane, BMDBM) when used in combination.[6] In addition, BEMT can combine with mineral sun filters such as Zinc Oxide and Titanium Dioxide, and will be generally regarded as safe and effective (GRASE) in the US, which can expand the range of sunscreen available.

The study shows no observed dermal irritation, sensitization, photoallergy, and photo irritation across a range of formulation types (ie, Cream/Lotion, Pump/Spray, Serum, or Stick), thereby reinforcing the overall safety profile of BEMT. One limitation of the current retrospective study supporting the safety of sunscreen formulations containing BEMT is extrapolating the results to other formulations. Although the study assessed safety in multiple forms of sunscreen formulations (creams, lotions, sprays, serums, and sticks), this extrapolation may not be applicable for every formulation form.

By analyzing data from over 14,000 subjects, this retrospective review provides strong evidence supporting the dermal safety of sunscreens containing BEMT. With these results, we aim to provide information to dermatologists and other medical professionals who may consult their patients on the safety and usage of BEMT products.

DISCLOSURES

CMR, MDS, JDW, and SE are employees of Kenvue, which manufactures sunscreen products.

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REFERENCES

1. PubChem. Bemotrizinol. Available at: https://pubchem.ncbi.nlm.nih.gov/20compound/bemotrizinol. Accessed 21 March 2026.
2. D'Ruiz CD, Plautz JR, Schuetz R, et al. Preliminary clinical pharmacokinetic evaluation of bemotrizinol - a new sunscreen active ingredient being considered for inclusion under FDA's over-the-counter (OTC) sunscreen monograph. *Regul Toxicol Pharmacol.* 2023;139:105344.
3. Tlili A, & Collard M. Environmental fate, hazard and risk assessment of the ultraviolet filter bemotrizinol in water and soil. In *SETAC Europe 35th Annual Meeting*. SETAC.
4. Shaath NA. (2007). *The encyclopedia of ultraviolet filters.* Carol Stream: Allured Publishing Corporation.
5. Sohn M, Baptiste L, Quass K, et al. (2021). Photokinetics of oil soluble 1, 3, 5-Triazine UV filters in combination with butyl methoxydibenzoylmethane or with diethylamino hydroxybenzoyl hexyl benzoate. *J Photochem Photobiol,* 8, 100073.
6. Wilson LT, Chu C, Wang SQ, et al. Retrospective review of dermal safety studies of organic sunscreens. *J Drugs Dermatol.* 2025;24(9):897-903.

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