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Bemotrizinol: A Next-Generation Broad-Spectrum Ultraviolet Filter Enters the United States Sunscreen Armamentarium

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Abstract

Background: The US sunscreen landscape has long lagged behind global counterparts, with no new organic ultraviolet (UV) filter approved since ensulizole in 1999. This regulatory stagnation has left American formulators with an inadequate toolkit for UVA protection, photostability, and cosmetic elegance.

Objective: To review the photochemistry, clinical safety, and dermatologic utility of bemotrizinol (bis-ethylhexyloxyphenol methoxyphenyl triazine; BEMT), the first new organic UV filter added to the US over-the-counter (OTC) sunscreen monograph in more than 2 decades.

Methods: Synthesis of published photobiological, pharmacokinetic, and clinical data submitted to and reviewed by the FDA, as well as peer-reviewed literature.

Results: BEMT is a photostable, oil-soluble, broad-spectrum UV filter with dual absorption peaks at approximately 310 nm (UVB) and 343 nm (UVA1), bridging the historically underprotected 320-nm transition gap. Its high molecular weight (627.8 g/mol) confers negligible systemic absorption. Across 472 participants in 4 clinical trials, BEMT demonstrated no contact sensitization, phototoxicity, photoallergenicity, or systemic accumulation. It photostabilizes avobenzone via triplet-triplet energy transfer, is compatible with all existing UV filters including zinc oxide and titanium dioxide, and provides transparent application with no white cast.

Conclusions: BEMT represents the most meaningful advance in US photoprotection in over 25 years, with particular relevance for patients with pigmentary disorders and individuals with skin of color. Its approval, effective August 9, 2026, warrants prompt integration into dermatologic practice.

Introduction

For more than 2 decades, US dermatologists have counseled patients on sun protection within the constraints of a sunscreen monograph that had effectively stood still. While the European Union, Australia, and many Asian markets have access to more than 29 approved UV filters, the US has permitted only 16 active sunscreen ingredients, with the last new organic (chemical) filter, ensulizole, approved in 1999.^{1,2}

The consequences of this regulatory gap have been clinically meaningful. Avobenzone, approved in 1988, remains the sole FDA-monographed filter with meaningful long-wavelength UVA1 (340–400 nm) coverage. Yet avobenzone is inherently photounstable and cannot be combined with mineral filters such as zinc oxide (ZnO) and titanium dioxide (TiO₂) in sunscreen formulations marketed in the US. Moreover, the existing US filter portfolio leaves an inadequately protected spectral zone near 310–340 nm, a transitional region between UVB and UVA2 wavelengths where photodamage, including DNA strand breaks and the stimulation of melanogenesis, is clinically relevant.²

The regulatory pathway itself was a barrier. Under the legacy OTC monograph system, new sunscreen active ingredients required exhaustive, multi-year data submissions with no defined timeline for agency action, a process that had effectively frozen US innovation since the 1990s. The Coronavirus Aid, Relief, and Economic Security (CARES) Act of 2020 changed the regulatory landscape, replacing it with an administrative order pathway that established clear timelines and review standards.¹

On June 9, 2026, the FDA issued final administrative order OTC000039, formally adding bemotrizinol (BEMT) to OTC sunscreen monograph M020, a milestone 25 years in the making. This order took effect August 9, 2026, initiating an 18-month marketing exclusivity period for DSM-Firmenich's proprietary brand, PARSOL Shield.¹

This review provides dermatologists with a comprehensive understanding of BEMT's photochemistry, clinical safety profile, formulation advantages, and practical implications for patient care.

The BEMT Molecule: Chemistry, Absorption Profile, and Photostabilization Mechanisms

Chemical Identity and Physical Properties

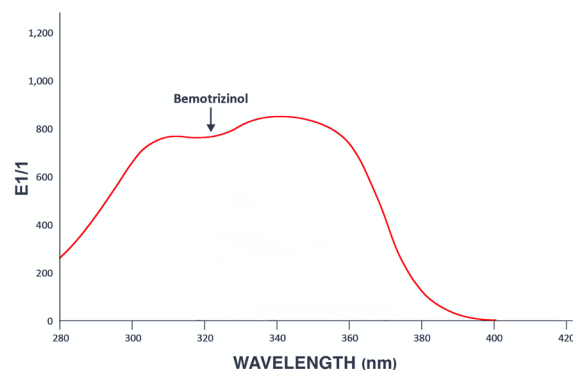
Bemotrizinol is chemically designated as bis-ethylhexyloxyphenol methoxyphenyl triazine (CAS 187393-00-6). Its structural core is a central 1,3,5-triazine ring symmetrically substituted with 3 aromatic moieties: one 4-methoxyphenyl group and two 2-hydroxyphenol groups, each etherified with 2-ethylhexyloxy chains at the 5-position.³ BEMT has a molecular weight of 627.8 g/mol and presents physically

as a pale yellow crystalline powder. It is highly lipophilic, insoluble in water but readily soluble in common cosmetic emollients, and is incorporated into the lipid phase of both oil-in-water and water-in-oil emulsions. Approved dosage forms include lotions, creams, oils, gels, butters, pastes, ointments, and sticks; non-aerosol sprays are permitted, while propellant-combined aerosol sprays and dry powders are not.¹

UV Absorption Profile and the 320-nm Gap

BEMT exhibits a broad, continuous UV absorption spectrum spanning approximately 280 to 400 nm, with 2 distinct absorption maxima: approximately 310 nm in the UVB range and 343 nm in the UVA1 range (Figure 1).^{2,3}

Figure 1. Ultraviolet absorption spectrum of bemotrizinol. Bemotrizinol (BEMT) demonstrates strong, continuous absorption across UVB and UVA, including UVA2 (320–340 nm) and UVA1 (340–400 nm).



This dual-peak profile is clinically significant. No currently available FDA-approved UV filter provides reliable, photostable coverage across both of these peaks simultaneously, a deficiency most conspicuous in the 310–340 nm transitional region between UVB and UVA2. This spectral zone has been termed the "320-nm gap" in the US filter portfolio.² Radiation in this range is biologically active: it contributes to cyclobutane pyrimidine dimer formation, oxidative DNA damage, and the initiation of melanogenic signaling pathways. BEMT's continuous absorption across this transition directly addresses a longstanding gap in US photoprotective coverage.

Intrinsic Photostability: The ESIPT Mechanism

Unlike some organic UV filters that degrade upon UV exposure, BEMT is intrinsically photostable by virtue of a rapid excited-state intramolecular proton transfer (ESIPT) mechanism.³

Upon absorbing a UV photon, the BEMT molecule transitions from its ground singlet state to an excited singlet state. Rather than degrading or generating reactive oxygen species (ROS), it dissipates this absorbed energy through a non-radiative intramolecular proton transfer: the phenolic hydroxyl proton is transferred to an adjacent nitrogen atom on the triazine ring, converting the enol tautomer to an excited keto tautomer. This keto form undergoes rapid internal conversion, releasing the absorbed energy as harmless heat and vibrational energy before the molecule returns to the stable enol ground state. The entire photocycle occurs on a picosecond timescale and does not involve covalent bond homolysis, ensuring that BEMT neither degrades nor sensitizes adjacent molecules over the product's lifetime.

Photostabilization of Avobenzone

Beyond its own photostability, BEMT serves as a potent photostabilizer for avobenzone—the most widely used UVA filter in the US market. Avobenzone is a dibenzoylmethane derivative that absorbs maximally at approximately 360 nm but is highly photolabile: upon UV exposure, it undergoes irreversible photodegradation, losing approximately 60% of its UVA-filtering capacity within 1 hour of sunlight exposure.⁴

BEMT prevents this degradation through a triplet-triplet energy transfer mechanism. When avobenzone enters its reactive triplet excited state, the precursor to homolytic cleavage, BEMT accepts the excitation energy through a collisional, non-radiative transfer and dissipates it via its own ESIP pathway. Formulations pairing BEMT with avobenzone retain more than 90% of avobenzone's UVA protection after prolonged sun exposure.⁴ Critically, BEMT also demonstrates compatibility with ZnO and TiO₂, which normally accelerate avobenzone photodegradation, an incompatibility that has severely constrained US mineral sunscreen formulation for decades.²

Safety Profile

Systemic Absorption and the 500 Dalton Rule

A defining safety advantage of BEMT is its negligible systemic absorption. The "500 Dalton rule" of dermal pharmacology holds that molecules exceeding 500 g/mol encounter significant resistance to penetrating the intact stratum corneum. BEMT's molecular weight of 627.8 g/mol places it well above this threshold, and this structural prediction is borne out clinically.²

In contrast, legacy UV filters such as oxybenzone (228.2 g/mol) are small enough to cross the dermal barrier. These filters have demonstrated systemic plasma concentrations exceeding the FDA's threshold of concern (0.5 ng/mL) under maximal use conditions in randomized clinical trials⁵, raising legitimate questions about chronic exposure. BEMT does not share this liability.

Clinical Trial Program

To support its GRASE determination, BEMT was evaluated in a 4-trial clinical development program enrolling 472 participants.¹

The pharmacokinetic program began with BEMT-001 Part 1 (Pilot Maximal Use Trial, MUSt), an open-label, single-arm study in 14 healthy adults (7 male, 7 female). Participants applied a model sunscreen containing 6% BEMT with 10% ethanol, a vehicle specifically designed to maximize potential skin penetration, multiple times daily for 4 days. Of the 299 plasma samples analyzed, 92.6% were below the limit of quantification (<0.1 ng/mL), and BEMT was entirely undetectable in 50% of participants, with no evidence of accumulation.³

The BEMT-001 Part 2 (Pivotal MUSt) trial randomized 162 healthy adults across 3 parallel arms to evaluate cream, lotion, and oil vehicles containing 6% BEMT, each applied to 75% or more of body surface area 4 times daily for 4 days, conditions explicitly designed to simulate worst-case real-world use. Plasma concentrations consistently remained below the FDA's 0.5 ng/mL threshold of concern across all 3 vehicles and throughout the treatment period, confirming negligible systemic bioavailability under maximal conditions.^{1,3}

Local Tolerability

Local tolerability of 6% BEMT was evaluated across a comprehensive battery of dermatologic safety studies. A human repeated insult patch test (HRIPT) and cumulative irritation study found no primary sensitization. Dedicated phototoxicity and photoallergenicity trials, both conducted under standardized solar-simulated UV light exposure, produced no phototoxic or photoallergic cutaneous reactions.¹

An independent study conducted at laboratories extended these findings in 54 adult participants (8 male, 46 female; age 18–65) subjected to occlusive patch application for 24 hours, 3 times weekly for 3 consecutive weeks, followed by a 10 to 14-day rest period and re-challenge. The study confirmed the absence of any irritant or sensitizing potential even under occlusive conditions, a rigorous standard that exceeds typical consumer use.¹

Long-term and Reproductive Safety

A 104-week dermal carcinogenicity study in rodents, using daily doses up to the highest feasible concentration, revealed no treatment-related systemic toxicity, target organ effects, or neoplastic changes. Multigenerational reproductive toxicity assays demonstrated no adverse effects on reproductive performance or offspring development. The FDA granted GRASE status for use in adults and children 6 months of age and older.¹

Key Advantages and Clinical Benefits

Formulation Versatility

BEMT's oil solubility and compatibility with the full spectrum of existing UV filters, including ZnO, TiO₂, avobenzone, octocrylene, homosalate, octisalate, and ensulizole, give formulators an unprecedented degree of flexibility. The ability to pair BEMT with mineral filters, historically precluded by avobenzone's incompatibility with ZnO and TiO₂, enables a new generation of hybrid sunscreens that can achieve high SPF values and superior UVA protection at lower overall active concentrations. Reducing mineral filter concentrations also directly improves cosmetic elegance by reducing visible whitening—a benefit with real-world adherence implications.²

BEMT's solubility in polar lipids and common cosmetic emollients (such as octisalate, homosalate) prevents recrystallization in formulation over the product's shelf life, contributing to consistent UV performance from first to last use.

Pigmentary Disorders: Melasma and Post-Inflammatory Hyperpigmentation

Melasma and post-inflammatory hyperpigmentation (PIH) represent among the most treatment-resistant conditions in clinical dermatology, with disproportionate impact on patients with Fitzpatrick phototypes III–VI. A key driver of therapeutic failure is the inability of currently available US sunscreens to provide comprehensive, durable protection across the full spectrum of melanogenic radiation.

UV-driven melanogenesis is not confined to UVB. Long-wavelength UVA1 radiation (340–400 nm) and high-energy visible light (HEVL, 400–440 nm) activate melanocytes through distinct signaling cascades. HEVL is detected by the opsin-3 (OPN3) receptor on melanocytes, triggering a transient receptor potential vanilloid 1 (TRPV1)-mediated calcium influx, downstream CaMKII activation, ERK pathway upregulation, and ultimately MITF-driven transcription of tyrosinase, resulting in pigment synthesis that can persist for up to 22 days after a single exposure. Mineral sunscreens can reduce HEVL but are limited by the cosmetic barrier of white cast in darker skin tones.

BEMT directly addresses the UVA1 component of this pathway. Its photostable absorption peak at 343 nm provides continuous, reliable coverage of the UVA1 spectrum without degrading over a day of outdoor exposure. Unlike formulations relying solely on avobenzone for UVA1 coverage, where photodegradation progressively erodes protection as the day advances, BEMT-containing formulations maintain their UVA1 filtering capacity throughout prolonged sun exposure.⁴

Perhaps equally important is BEMT's cosmetic profile. Patients with darker skin phototypes have historically cited the white cast of mineral-dominant sunscreens as a primary barrier to consistent daily use, and incomplete sunscreen use is a well-documented driver of melasma recurrence and treatment failure. BEMT is a chemical filter that applies completely transparently. Its incorporation into formulations enables high-SPF, broad-spectrum sunscreens that are cosmetically acceptable across all skin tones, reducing a structural barrier to compliance and, by extension, improving clinical outcomes for melasma and PIH.^{1,2}

Environmental Considerations

The environmental safety of sunscreen actives has attracted increasing social media attention, particularly following anecdotal reports that oxybenzone and octinoxate can induce coral bleaching, disrupt marine endocrine systems, and bioaccumulate in aquatic food chains. Hawaii and several other jurisdictions have banned the 2 above filters outright.

BEMT's physicochemical profile confers a meaningfully different environmental risk profile. Its high molecular weight and extreme water insolubility limit its ability to dissolve in and distribute through the water column, reducing the potential for marine bioaccumulation. Toxicological studies have shown that BEMT does not induce coral bleaching or DNA damage in marine organisms at environmentally relevant concentrations.¹

Based on a weight-of-evidence evaluation integrating environmental exposure, bioavailability, and ecotoxicological effects, the proposed use of bemotrizinol at concentrations up to 6% in over-the-counter sunscreen products is not expected to result in significant adverse effects on the quality of the human environment. All risk characterizations, including worst-case exposure scenarios, demonstrate adequate margins of safety.

Modernizing the US Formulation Toolkit

US sunscreen formulators have long operated with fewer UV filters that are available in other parts of the globe. While European manufacturers can draw on 29 approved UV filters to engineer formulations of varying elegance, SPF, and UVA protection, the US counterparts have been limited to approximately 7 commonly used active ingredients. This disparity has not merely been a commercial inconvenience; it has imposed real constraints on the quality of photoprotection available to American patients.^{1,2}

The approval of this new UV filter was by DSM-Firmenich, a project that was carried out over 8 years and cost millions of dollars. The initial market availability will be under DSM-Firmenich's PARSOL Shield branding, protected by an 18-month exclusivity period running through approximately February 2028. After exclusivity expires, broader uptake by competing manufacturers is expected, and BEMT-containing products will become widely available across price points.¹

From a business standpoint, DSM-Firmenich's decision to pursue this pathway is somewhat unconventional. Unlike a novel drug approval, which typically confers decades of patent-protected market exclusivity, the FDA's OTC monograph process affords no such durable protection; BEMT is not a novel, patentable molecule, and the resulting 18-month exclusivity window is brief relative to the multi-year investment and cost required to bring it through review. This process raises a broader question of precedent: will other UV filter manufacturers be willing to undertake a similarly resource-intensive regulatory odyssey, knowing that any competitive advantage gained will be short-lived? If not, it is conceivable that few, if any, additional internationally available UV filters will reach the US market unless another manufacturer is willing to make a comparable investment without the assurance of long-term exclusivity.

Viewed in this light, DSM-Firmenich's decision to proceed despite this asymmetry between investment and protection deserves recognition: the company appears to have advanced this filter through the regulatory process on the premise that expanding UV protection options serves public health in the US, rather than for the promise of durable commercial return.

Conclusion

Bemotrizinol's approval marks the end of a 25-year hiatus in US sunscreen innovation. For dermatologists and their patients, it arrives not as an incremental refinement but as a substantive expansion of the photoprotective toolkit, one that simultaneously addresses the spectral coverage gap at 310–340 nm, the chronic photostability limitations of avobenzone, the formulation incompatibilities between chemical and mineral UV filters, and the cosmetic elegance barrier that has undermined sunscreen adherence in patients with skin of color.

Its safety profile is robust. With a molecular weight far exceeding the 500 Dalton dermal penetration threshold, negligible systemic absorption across 4 clinical trials, and no evidence of sensitization, phototoxicity, or carcinogenicity, BEMT satisfies the stringent standards the FDA appropriately applies to topical drugs applied repeatedly to broad body surface areas.

Clinically, dermatologists should begin counseling appropriate patients—particularly those with high risks for skin cancers, melasma, PIH, or other conditions requiring reliable broad-spectrum UVA1 photoprotection, on the availability of BEMT-containing sunscreens as of August 9, 2026. Early products will carry the PARSOL Shield ingredient designation. As market exclusivity expires in early 2028, BEMT incorporation across the sunscreen market will expand significantly.

The BEMT approval represents a lengthy and costly undertaking, carried out under the CARES Act modernization pathway. While this pathway was designed to deliver rigorous, science-based decisions on novel UV filter candidates within a timeframe that does not discourage investment, the BEMT experience suggests that further refinement may be warranted. An 8-year, multi-million-dollar effort, yielding only a comparatively brief period of market exclusivity, may not provide sufficient incentive for other manufacturers to bring additional, well-characterized UV filters already in global use through the same process. The dermatologic community should advocate for continued evolution of this pathway, with the goal of building a US sunscreen landscape that more efficiently reflects the state of international photobiological science.

Disclosure

Dr Wang has served as a consultant for ISDIN, Kenvue, La Roche-Posay, and Coppertone. Mr Osterwalder and Ms Waske have no conflicts of interest to disclose.

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