

DSM Nutritional Products LLC
45 Waterview Boulevard
Parsippany, NJ 07054-1298, USA
+1 201.400.9376
Carl.d-ruiz@dsm-firmenich.com

22 September 2025

CDR Trang Tran, PharmD, MBA, BCPS, Senior Regulatory Project Manager
Shannon Liu, DPT, Regulatory Project Manager
Division of Regulatory Operations for Nonprescription Drugs I
Office of Regulatory Operations
Center for Drug Evaluation and Research
10903 New Hampshire Avenue
Silver Spring, MD 20993

Subject: MGF 400105 – Response to IR #22 [3971]

Dear Trang and Shannon,

We acknowledge receipt of FDA's Information Request (IR) letter dated September 15, 2025, and appreciate the continued review of our submission, including our December 9, 2024, response to the Agency's correspondence dated November 20, 2024.

Further reference is made to our submissions received on September 23, 27, and 30, 2024, in support of a Tier 1 Over-the-Counter (OTC) Monograph Order Request (OMOR) for a Generally Recognized as Safe and Effective (GRASE) determination for bemotrizinol (BEMT) 6% as a new sunscreen active ingredient under FDA's OTC Monograph M020: Sunscreen Drug Products for OTC Human Use.

In response to the FDA's request for examples of aerosol drug products containing BEMT and a propellant, including complete product formulation and release and stability testing results, we have conducted an exhaustive review of publicly available sources. While ingredient compositions and shelf-life claims are accessible for several marketed products, detailed formulation and stability testing data remain proprietary to the respective manufacturers and are not publicly disclosed.

Bemotrizinol (BEMT)

The solubility profile of BEMT presents formulation challenges in propellant-based systems, which has precluded the development of in-house aerosol formulations to date. Nevertheless, the identification of 465 continuous spray products containing BEMT and propellants, launched globally over the past six years, demonstrates the feasibility and widespread acceptance of such formulations. Shelf-life information, where available, is provided as a proxy for stability data (see Table 1 below). As such, our response is limited to publicly available data to support the GRASE evaluation.

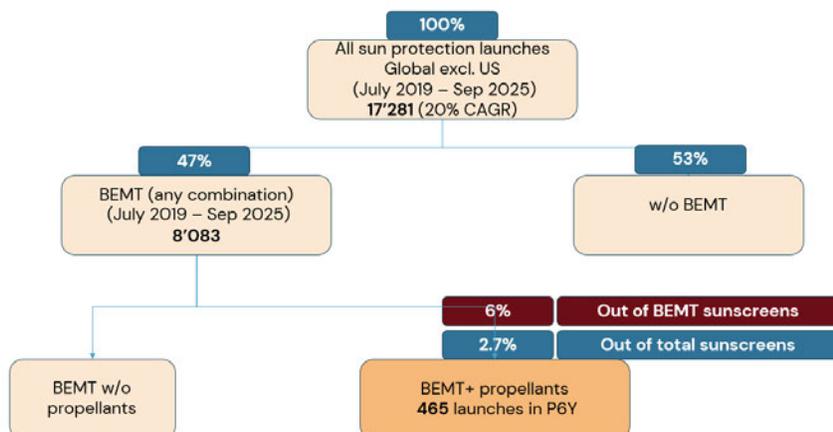
The publicly available resource to assess drug products containing BEMT with focus on aerosol sprayable dosage forms, we used Mintel GNPD with the following search criteria:

- where Sub-Category matches Sun - Sun/Sunbed Exposure,
- and Date Published is between Jun 2019 and current date (Sep 2025),
- and Ingredient Search matches one or more of [all of (Bis-ethylhexyloxyphenol Methoxyphenyl Triazine; Propane) together; all of (Bis-ethylhexyloxyphenol Methoxyphenyl Triazine; Butane) together; all of (Dimethyl Ether; Bis-ethylhexyloxyphenol Methoxyphenyl Triazine) together] as the Ingredients.

This research on sunscreen market products over the last 6 years contains Bemotrizinol (INCI Bis-ethylhexyloxyphenol Methoxyphenyl Triazine) in the presence of a propellant representing continuous sprays, revealed a total of 465 products launched have been found.

Figure 1 below shows that, of the 17,281 new sunscreen products released in the last six years, 8,083 contain Bemotrizinol (BEMT), representing 47% of the total. In other markets, the percentage of continuous (aerosol) spray products is not as high as in the US. However, an increasing number of these products are launched each year, resulting in a total of 465 products across regions, years, and brands.

Figure 1: Mintel GNPD search results overview



Bemotrizinol (BEMT)

Of the 465 continuous spray applications containing Bemotrizinol, we selected ten representative examples, listed in Table 1 below. These examples span different brands and marketing countries to ensure broad representativeness. The publishing and expiration dates indicated for each product reflect the minimum stability period, under the assumption that the manufacturing date precedes the publication date. The representative products in Table 1 exhibit a remaining stability period ranging from 15 to 64 months after the publication date. In contrast, most continuous spray products guarantee a shelf life of 18 to 24 months.

Mintel GNPD data on marketed products shows that aerosol spray products containing Bemotrizinol are technically feasible and sufficiently stable.

Table 1: Selected Marketed Continuous Spray Sunscreen Products Containing BEMT and Propellants

Brand	Product Name	Market	Date published	Expire Date
Kruidvat Solait	Sport Sunspray SPF 30	Belgium	Sep 2025	Sep 2027
Babaria Adventure	Facial and Body Sunscreen Mist SPF 50	Colombia	Sep 2025	Jan 2030
Mentholatum Sunplay Water Kids	Sun Protection Spray SPF 50+ PA+++	China	Sep 2025	Dec 2026
Anessa (Shiseido)	Perfect UV Sunscreen Skincare Spray SPF 50+ PA++++	Vietnam	Sep 2025	18 months after opening
Skintific	Real Protection All Day Light Sunscreen Mist SPF 50+ PA++++	Malaysia	Sep 2025	Jun 2027
Babaria Kids	Protective Mist Sunscreen SPF 50	Portugal	Aug 2025	Jun 2029
La Roche-Posay Anthelios	Invisible Mist SPF+	Bulgaria	May 2025	Jun 2027
Eucerin Sun Protection Dry Touch Oil Control	Transparent Sun Mist SPF 30	Cambodia	Aug 2025	Apr 2027
Nivea Sun Protect & Dry Touch	Refreshing Mist SPF 50 +	Indonesia	May 2025	Jan 2027
Naos Bioderma Photoderm	Invisible Mist SPF 50+ PA++++	Morocco	Sep 2024	Jul 2027

The requested information is submitted via the CDER NextGen Portal by the due date of September 23, 2025, to facilitate FDA's ongoing evaluation of our OMOR.

Please do not hesitate to contact us should additional clarification or data be required.

Bemotrizinol (BEMT)

Sincerely,

A handwritten signature in black ink, appearing to read "Carl D'Ruiz". The signature is written in a cursive style with a large initial "C".

Carl D'Ruiz, MPH.

Senior NA Science, Advocacy and Business Development Manager, Beauty & Care