MGF-400105
Bemotrizinol (BEMT)

# 2.5 Clinical Overview

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**List of Abbreviations**

| | |
|---|---|
| AE | Adverse Event |
| API | Active Pharmaceutical Ingredient |
| ASEAN | Association of Southeast Asian Nations |
| AUC | Area Under the Concentration-Time Curve |
| BEMT | Bemotrizinol |
| $C_{max}$ | Maximum concentration |
| CFR | Code of Federal Regulation |
| EC | European Commission |
| $EC_{50}$ | Effective Concentration (50% of the maximum possible effect) |
| EU | European Union |
| FDA | Food and Drug Administration |
| GRASE | Generally Recognized as Safe and Effective |
| GCP | Good Clinical Practice |
| GLP | Good Laboratory Practice |
| ICH | International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use |
| i.e. | id est (that means) |
| IND | Investigational New Drug |
| MEDLINE | Medical Literature Analysis and Retrieval System Online |
| MERCOSUR | Mercado Común del Sur |
| MUsT | Maximal Usage Trial |
| OMOR | OTC Monograph Order Request |
| OTC | Over the Counter |
| PubMED | Public MEDLINE |
| PK | Pharmacokinetic |
| PD | Pharmacodynamic |
| REACH | Registration, Evaluation, Authorisation and Restriction of Chemicals |
| SD | Standard Deviation |
| $t_{1/2}$ | Half-life |
| US | United States of America |
| USP | United States Pharmacopoeia |
| UV | Ultraviolet |
| UVA | Ultraviolet A |
| UVB | Ultraviolet B |
| vs. | Versus |

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## 2.5.1 Product Development Rationale

The purpose of this document is to support a Tier 1 OTC Monograph Order Request (OMOR) for the inclusion of BEMT 6% as a Generally Recognized as Safe and Effective (GRASE) active ingredient for use in OTC sunscreen products under FDA's Over-the-Counter Sunscreen Monograph M020, in accordance with the conditions and indications of use specified in 21 CFR Part 352 (link: 21 CFR Part 352). The inclusion of BEMT in the OTC sunscreen drug monograph aims to meet the unmet need for a photostable UVA and UVB filter in the U.S. market, thereby expanding consumer options and enhancing public health protection against harmful UV radiation.

### 2.5.1.1 Pharmacological Class

From a pharmacological perspective, Bemotrizinol (BEMT) is a photostable, broad-spectrum organic sunscreen ingredient (UV filter) that protects against both Ultraviolet A (UVA) and Ultraviolet B (UVB) radiation. BEMT prevents sunburn and reduces the risk of skin damage by absorbing UV radiation and converting it into heat, which is then released from the skin. As such, it is classified as an active pharmaceutical ingredient for use in OTC sunscreen products under the FDA's Over-the-Counter Sunscreen Monograph M020. According to 21 CFR Part 352, active ingredients under the FDA's OTC sunscreen monograph are intended to protect the skin from the harmful effects of ultraviolet (UV) radiation, specifically UVB (which primarily causes sunburn) and UVA (which contributes to skin aging and cancer).

### 2.5.1.2 Targeted Indications

BEMT 6% is indicated as a broad-spectrum organic active ingredient (UV filter) that protects against both Ultraviolet A (UVA) and Ultraviolet B (UVB) radiation intended for use in OTC sunscreen products for adults and children over 6 months of age, helping to prevent sunburn in accordance with the conditions and indications of use specified in 21 CFR Part 352 and under the FDA's Over-the-Counter Sunscreen Monograph M020.

### 2.5.1.3 Scientific background

Sunscreens work by absorbing or reflecting ultraviolet (UV) radiation to protect against UV-induced skin effects, including sunburns and signs of aging (Watson et al., 2016; CDC, 2020; AAD, 2020). Bemotrizinol is a highly effective, broad-spectrum UV filter used in sunscreens, providing protection across the UVB (280-320 nm) and UVA (320-400 nm) ranges. Its high photostability and synergistic compatibility with other sunscreen actives make it a valuable ingredient in modern formulations. Below are the key attributes associated with BEMT.

Broad-Spectrum UV Protection:

- UVB Protection (280-320 nm): Shields against UVB radiation, which is primarily responsible for sunburn.
- UVA Protection (320-400 nm): Covers both UVA II (320-340 nm) and UVA I (340-400 nm) regions, helping protect against deeper skin penetration, photoaging, and long-term skin damage.

Photostability: Bemotrizinol has exceptional photostability. Unlike some UV filters that degrade under sunlight, Bemotrizinol remains stable, ensuring long-lasting protection. It also

significantly stabilizes Avobenzone, a common UVA filter, by enhancing its photostability. This stabilization leads to more reliable and prolonged UVA protection in sunscreen formulations (Gholap et al., 2023; Chatelain & Gabard, 2001), contributing to overall broad-spectrum efficacy.

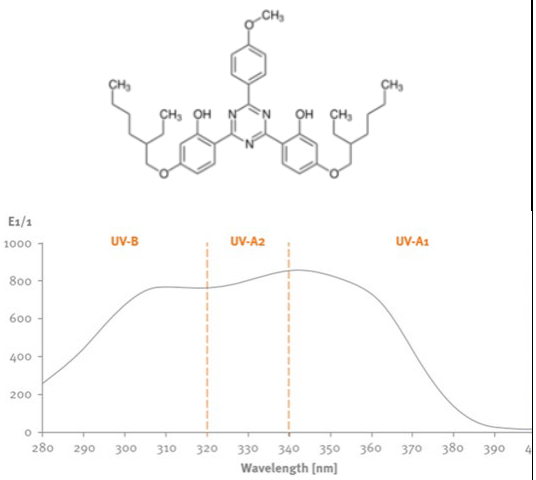
Compatibility with Other UV Filters: Bemotrizinol is highly compatible with other chemical and physical UV filters, enhancing the overall efficacy and photostability of sunscreen formulations. When combined with other filters, it can achieve higher SPF values and more robust protection.

Oil-Solubility: As an oil-soluble compound, Bemotrizinol integrates easily into the oil phase of sunscreen formulations, allowing for flexibility in products like creams, lotions, and sprays. Despite its oil solubility, it can be formulated to avoid a greasy or heavy feel, improving consumer comfort.

High Molecular Weight: With a high molecular weight of 627.81 g/mol, Bemotrizinol has reduced skin penetration, which enhances safety by minimizing systemic absorption. This property is particularly beneficial in sunscreens, where it is used as a UV filter.

Bemotrizinol's physical and chemical properties, including its high photostability, broad-spectrum UV protection, high molecular weight, and compatibility with other filters, make it a highly effective and versatile ingredient for use in sunscreen formulations. BEMT's physical and chemical characteristics are summarized in Table 1. Further details can be found here: https://pubchem.ncbi.nlm.nih.gov/compound/Bemotrizinol#section=Experimental-Properties.

*Table 1 BEMT Physical and Chemical Characteristics*

| Chemical Names and Synonyms | P-Chem Properties | BEMT Structure and UV Absorption Spectrum |
|---|---|---|
| CAS #: 187393-00-6<br><br>USAN: Bemotrizinol (BEMT)<br><br>UNII-PWZ1720CBH<br><br>Bis-ethylhexyloxyphenol Methoxyphenyl Triazine<br><br>2,4-Bis[(4-(2-ethyl-hexyloxy)-2hydroxy-phenyl]-6-(4-methoxyphenyl)-(1,3,5 triazine)<br><br>PARSOL® Shield<br><br>TINOSORB® S | Physical appearance: light yellow and coarse to fine powder<br><br>Molecular. Wt (MW): 627.81 g/mol<br><br>Melting point: ca. 80.4 °C (at 1,013 hPa; OECD Test Guideline 102)<br><br>Boiling Point: > 400 °C (at 1,013 hPa; OECD Test Guideline 103)<br><br>Flash Point: 284 °C (at 1,013 hPa; ISO 2719)<br><br>Vapor Pressure: < 0.0001 hPa (25 °C; OECD Test Guideline 104)<br><br>Octanol/Water Partition log $P_{o/w}$: > 5.7 (20 °C; OECD Test Guideline 107)<br><br>pH: 7 (1 g/l, 20 °C)<br><br>Polar Surface Area: 107 Å<br><br>Density: 1.17 g/cm3 (at 20 °C)<br><br>Solubility (water): < 0.014 mg/l (20 °C, pH 4.65; OECD Test Guideline 105) |  |

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### 2.5.1.4 Clinical Development Program

The product development process for BEMT adhered to FDA guidelines outlined in "Nonprescription Sunscreen Drug Products — Safety and Effectiveness Data" (FDA 2016), Guidance on Maximal Usage Trials for Topically Applied Active Ingredients (FDA 2019), and several relevant ICH guidelines referenced in this submission. This approach also incorporated the agreed upon tests and recommendations and advice received from the FDA at a BEMT pre-IND meeting in June 2019 and as part of our IND 146892 general investigational plan (Module 1.20), investigational brochure (Module 1.14.4.1) and subsequent IND annual report updates and serial submissions referenced in Module 1.4.

Completed studies have been registered with ClinicalStudies.gov and include an assessment of the human systemic absorption of sunscreen ingredients be made via the conduct of a pilot and pivotal Maximum Usage Trial (MUsT) in humans (NCT04355286 and NCT05277376) as well as skin irritation, sensitization (NCT05260359) and phototoxicity (NCT05254925) and photosensitization (NCT05254912) determinations. SPF efficacy studies for sunburn protection to human skin was also completed under standard clinical protocols to meet each of the FDA requirements supporting the BEMT determination as GRASE. Each of the completed controlled clinical studies followed standard, FDA recommended protocol designs using healthy subjects with intact skin to show clinical safety and effectiveness for the intended skin protective intervention.

Table 2 presents a summary of the studies conducted under our clinical development program (IND 146892) to support the safety and efficacy of BEMT 6% as an OTC sunscreen active ingredient.

*Table 2 Studies Conducted Under Clinical Development Program for BEMT*

| Study Type | Test Design and Objectives | Status |
|---|---|---|
| ***Clinical Studies*** | | |
| Human Repeated Insult Patch Test (HRIPT) - Dermal Irritation, Sensitization, and Cumulative Irritation<br>Study # CRLNJ2020-0493 | Primary objective: determine the potential of 6% BEMT (PARSOL® Shield) either in a basic sunscreen oil formulation or as dispersion in petrolatum to elicit dermal irritation and/or induce sensitization following repeated patch application.<br><br>Secondary objective: determine the cumulative irritation potential of 6% BEMT (PARSOL® Shield) either in a basic sunscreen oil formulation or as dispersion in petrolatum topically applied to the skin of human subjects over a 21-day period.<br><br>Study Summary submitted under IND 146892 Serial 0010, section 1.13.8.1.2.3. | Completed |
| Phototoxicity<br>Study # CRLNJ2020-0494 | The objective of this study was to evaluate the potential of 6% BEMT (PARSOL® Shield) in a suitable vehicle (i.e., sunscreen oil or petrolatum) to produce a phototoxic response after application to the skin of human subjects followed by exposure to UV radiation. Study summary submitted under IND 146892 Serial 0010, section 1.13.8.1.2.2. | Completed |
| Photoallergenicity<br>Study # CRLNJ2020-0495 | The objective of this study was to evaluate the potential of investigational product, 6% BEMT (PARSOL® Shield) in a suitable vehicle (i.e., sunscreen oil or petrolatum) to produce a photoallergic response after application to the skin of human subjects followed by exposure to UV radiation. Study summary submitted under IND 146892 Serial 0010, section 1.13.8.1.2.1. | Completed |
| BEMT Pilot Maximum Usage Trial (MUsT) Spaulding Study # BEMT-001 Part 1 | This was Part 1 of a single clinical MUsT study conducted in 2 parts (Part 1: pilot study and Part 2: pivotal study). | Completed |

| Study Type | Test Design and Objectives | Status |
|---|---|---|
| | Part 1 was an open-label, 1-arm study that had the following objectives:<br>• Primary: To explore whether Bemotrizinol (PARSOL® Shield), is absorbed into the systemic circulation from a high-penetrating sunscreen formulation including 6% BEMT when applied under maximal-use conditions.<br>• Secondary: To obtain information needed for a successful pivotal study such as preliminary pharmacokinetic (PK) data, validation of study and analytical procedures, and the number of subjects needed.<br><br>Study summary submitted under IND 146892 Serial 0008, section 1.13.8.2.1. | |
| BEMT Pivotal Maximum Usage Trial (MUsT) Spaulding Study # BEMT-001 Part 2 | This was Part 2 of a single clinical MUsT study conducted in 2 parts (Part 1: pilot study and Part 2: pivotal study).<br><br>Part 2 was an open-label, randomized, 3-arm study with the following objective:<br>• Primary: To assess the systemic absorption and pharmacokinetics of 6% BEMT from 3 market image sunscreen formulations under maximal-use conditions.<br>Study summary and report submitted under IND 146892 Serial 0011, section 5.3.3.1. | Completed |

### 2.5.1.5 Regulatory History

From a global perspective, Bemotrizinol has been commercially available since 2000, following its approval by the European Commission for use in cosmetic and sunscreen products at concentrations up to 10% in adults and children over six months old under Annex VI of the EU Cosmetics Regulation (EC) No 1223/2009 (https://health.ec.europa.eu/system/files/2016-11/cosmetic_1223_2009_regulation_en_0.pdf). This approval has facilitated its global adoption, with similar regulatory approvals in countries such as Australia, Japan, Canada, Korea, China and regions including MERCOSUR and ASEAN, as shown in Table 3.

*Table 3 Global Regulatory Status of BEMT*

| Current Global Regulatory Status of BEMT (Maximum Concentration (%) Permitted for Use in Sunscreen Products by Country/Region) | | | | | | |
|---|---|---|---|---|---|---|
| **EU** | **Canada** | **MERCOSUR** | **Australia** | **China** | **Korea** | **ASEAN** |
| 10.0 | 6.0 | 10.0 | 10.0 | 10.0 | 10.0 | 10.0 |

Bemotrizinol is also registered as a UV absorber for sunscreen use under the European Union's REACH regulation. Its data is available in the ECHA database as part of the REACH registration dossiers (https://echa.europa.eu/nl/registration-dossier/-/registered-dossier/12265).

In the U.S., Bemotrizinol (BEMT) has been under FDA review since 2005, following the submission of a Time and Extent Application (TEA). While BEMT was deemed eligible for review, additional data was required. The Sunscreen Innovation Act (SIA) of 2014 prompted the FDA to issue a Proposed Sunscreen Order (PSO) for BEMT, indicating it could be included in the OTC sunscreen monograph pending a GRASE determination. In June 2019, DSM met with the FDA to express interest in sponsoring PARSOL® Shield (BEMT) at 6% for OTC listing. An agreement was reached to address data gaps, and DSM established IND

146892 to provide the necessary data under the SIA pathway. With the 2020 CARES Act reforming the FDA's OTC regulatory program, the SIA was replaced, and the current OMOR pathway was established for incorporating new active ingredients under the Tier I OMOR process.

2.5.1.5.1 World-wide marketing experience:

Following the submission of a Time and Extent Application (TEA) for Bemotrizinol (BEMT) in 2005 and the FDA's confirmation of its eligibility for inclusion in the monograph, BEMT has been marketed extensively worldwide for 26 years in a variety of sunscreen formulations. These formulations align with the same conditions of use proposed in this OMOR for the U.S. market. The only exception is that DSM proposes a maximum concentration of 6% for the U.S., in contrast to 10% in other regions, due to BEMT's solubility profile, which makes use levels above 6% impractical from a formulation standpoint. This 6% concentration is consistent with the maximum dosage and strength approved by Health Canada.

Since its initial approval as a UV filter in the European Union in 2000, BEMT has been authorized for use in most countries and regions globally, mostly at concentrations up to 10%. It has gained extensive market presence, particularly in highly regulated markets such as the EU, Australia, Japan, and Canada, where it is valued for its dual UVA and UVB protection capabilities.

While there is no exact public figure for the number of sunscreen products worldwide that contain Bemotrizinol (BEMT), it is widely used in global markets, particularly in regions with strong regulatory frameworks such as the European Union, Japan, Australia, and Canada. Given its broad regulatory approvals and its inclusion in sunscreens for over 26 years, it is reasonable to estimate that there are several hundred, if not over a thousand sunscreen products globally that include BEMT as an active ingredient.

BEMT's long-standing global marketing experience, backed by comprehensive safety data and post-market surveillance, demonstrates its effectiveness and safety. This extensive history of use highlights BEMT's role as a preferred active ingredient in sunscreen formulations for both adults and children owing to its broad-spectrum protection and photostability, making it a key component in widely trusted and distributed sunscreen products. Examples of the types of products marketed for children in the EU are provided in Module 1.3.

In markets where it is available, BEMT has demonstrated a strong safety profile, supported by post-market surveillance data. The ingredient's ability to offer broad-spectrum protection, its photostability, and its favorable safety record have made it a key component in many widely distributed and trusted sunscreen products for both adults and children. This extensive international experience provides robust evidence of the long-standing safe and effective use of BEMT in sunscreen formulations.

There are no widely documented case reports or clinical data that specifically highlight any notable or significant adverse events related to the use of Bemotrizinol in adults or children. Post-market surveillance of the public literature, case reports, and adverse event databases such as the European Medicines Agency (EMA) pharmacovigilance reporting EudraVigilance system, the Australian Therapeutic Goods Administration (TGA) Database of Adverse Event Notifications reporting systems, and the Canada Vigilance Adverse Reaction Online Database

available in countries where Bemotrizinol is already approved do not indicate any safety concerns.

2.5.1.6 Compliance with Good Clinical Practice

All clinical and efficacy were undertaken in accordance with the principles of Good Clinical Practice requirements (International Council for Harmonisation harmonised tripartite guideline E6(R2): Good Clinical Practice). All studies were conducted with the approval of Ethics Committees or Institutional Review Boards. Informed consent was obtained for all subjects, and the studies were performed in accordance with the version of the Declaration of Helsinki that applied at the time the studies were conducted. All studies were conducted at clinical research organizations in the United States, except for two SPF efficacy studies conducted by Eurofins Dermatest (Australia) and at Institute Dr Schrader (Germany). Where required, regulatory approval was obtained from the relevant health authority.

## 2.5.2 Overview of Biopharmaceutics

Bemotrizinol is a hydrophobic compound, typically incorporated into the oil phase of sunscreen emulsions. Studies demonstrate that Bemotrizinol remains stable under light exposure and maintains its efficacy during prolonged sun exposure. Given its lipophilic nature, Bemotrizinol has a low potential for systemic absorption when applied topically.

## 2.5.3 Overview of Clinical Pharmacology

2.5.3.1 Pharmacodynamics

Mechanism of Action: Bemotrizinol works by absorbing harmful UV radiation, converting it into less harmful energy (heat). It provides a broad-spectrum photoprotection by absorbing UVB (290–320 nm) and UVA (320–400 nm) rays.

UV Protection Efficacy: In vivo studies have shown that Bemotrizinol significantly contributes to the Sun Protection Factor (SPF). Results from two adequate and well-controlled SPF studies, conducted in accordance with 21 CFR Parts 201 and 310, demonstrate that Bemotrizinol is effective at a maximum concentration of 6%, both alone and in combination with other US OTC sunscreen monograph UV filters.

2.5.3.2 Pharmacokinetics

2.5.3.2.1 Absorption

In vitro permeation tests (IVPTs) using human skin membranes, along with pilot and pivotal PK maximal usage trials (MUsTs), designed to assess the impact of maximal use on blood absorption through standard pharmacokinetic assessments in humans, have demonstrated low bioavailability and minimal systemic exposure to BEMT 6% following topical application of market-image sunscreen formulations.

IVPT results, utilizing market-image formulations of BEMT 6% in various forms showed that BEMT 6% exhibited no measurable skin penetration into the receptor chamber, irrespective of the formulation used. The absorbed dose was found to be below 2% of the applied dose.

The pivotal open-label, randomized, three-arm clinical MUsT study evaluated the systemic absorption and pharmacokinetics (PK) of BEMT 6% from three sunscreen treatments in 162 healthy American subjects. Conducted under maximal-use conditions, the sunscreen was applied four times daily for four days. Despite the use of a highly sensitive analytical method, the study demonstrated low bioavailability of BEMT 6%, with only 31.4% of PK samples (1,169/3,722) showing quantifiable concentrations (≥0.1 ng/mL). Notably, five subjects (3.1%) had no detectable BEMT concentrations, reinforcing the limited systemic absorption.

For all treatments, the geometric mean $C_{max}$ tended to be higher on Day 4 than on Day 1, suggesting drug accumulation. However, the geometric mean $C_{max}$ values on Day 4 remained below the FDA's regulatory threshold of 0.5 ng/mL for all treatments. Although only a limited number of subjects had sufficient data to estimate the half-life ($t_{1/2}$), plasma steady state was likely achieved by Day 4 for all treatments. Additionally, bioavailability of BEMT was not substantially different across formulations, based on 90% confidence interval evaluations for primary and secondary $C_{max}$, $AUC_{0-24}$, and $AUC_{0-last}$ on Days 1 and 4.

Although a small number (113 or 3.0%) of BEMT samples analyzed in the pivotal study had concentrations ≥0.5 ng/mL, the geometric mean $C_{max}$ did not exceed 0.5 ng/mL on either Day 1 or Day 4. These clinical results are pivotal indicators of the very low bioavailability of BEMT 6% when applied at maximum topical applications (6.66 g/day; 111 mg/kg body weight/day) in sunscreens.

2.5.3.2.2 Distribution

There is no evidence of significant systemic distribution.

2.5.3.2.3 Metabolism

In vitro metabolism testing of 14C-BEMT with human liver cells and enzymes showed no detectable BEMT metabolites or unique human conjugation products. This suggests that BEMT is stable in human metabolism, and human-specific metabolites are not expected after BEMT exposure.

The absence of radiolabeled BEMT metabolites indicates that Bemotrizinol remains stable in the liver, and no disproportionate human metabolites (exceeding 10% of the dose) were found or are expected after topical application of BEMT. These findings do not meet the criteria for further investigation as outlined by FDA guidelines.

Additionally, the nonclinical NOAELs (No Observed Adverse Effect Levels) confirm that any potential BEMT metabolites in animals have already been adequately evaluated. Therefore, further testing for BEMT metabolites in human plasma is not necessary, supporting the relevance of nonclinical studies in assessing human safety for BEMT exposure.

2.5.3.2.4 Excretion

Due to negligible systemic absorption and based on nonclinical studies, it can be inferred that any absorbed material is likely excreted primarily via the biliary route.

## 2.5.4 Overview Efficacy

Two independent clinical SPF studies, conducted according to the FDA's "Labeling and Effectiveness Testing: Sunscreen Drug Products for Over-The-Counter Human Use, 21 CFR Parts 201 and 310, June 2011" guidance, confirmed the efficacy of BEMT at concentrations of 1.0% to 4.5% in providing SPF values above 2, effectively protecting skin from UV radiation. A clear concentration-related increase in SPF values was observed with BEMT. Control formulations without BEMT did not exceed SPF 1.1, and the standard SPF reference material performed as expected. Table 4 provides a summary of the SPF studies conducted.

*Table 4 SPF Clinical Studies Conducted on BEMT 6%*

| ***Efficacy Studies*** | Test Design and Objectives | Status |
|---|---|---|
| In vivo SPF (Sun Protection Factor) Efficacy Study: Eurofins Dermatest: Project DSM PC2022-231, Reports 22288 through 22299 | These one of two adequate and well-controlled SPF studies completed in accordance with 21 CFR Parts 201 and 310, June 2022, to demonstrate that Bemotrizinol is effective at a maximum concentration of 6%. The results of this SPF study are included in IND 146892 Serial Amendment 0011, section 5.3.5.1.2.2. | Completed |
| In vivo SPF Efficacy Study: Institute Dr Schrader: reports HP-22-0682, HP-22-0683; HP-22-0684; HP-22-0685 | This second of two adequate and well-controlled SPF studies completed in accordance with 21 CFR Parts 201 and 310, June 2022, to demonstrate that Bemotrizinol is effective at a maximum concentration of 6%. The results of this SPF study are included in IND 146892 Serial Amendment 0011, section 5.3.5.1.2.1. | Completed |

## 2.5.5 Overview of Safety

**Preclinical Toxicology**:

- **Acute Toxicity**: Animal studies suggest low acute toxicity with no significant adverse effects observed at any doses.
- **Chronic Toxicity**: Long-term dermal application studies did not indicate any systemic toxicity, neoplastic changes, skin irritation, or sensitization.
- **Genotoxicity**: Bemotrizinol has not demonstrated any genotoxic potential in standard assays.

**Clinical Safety**:

- **Skin Irritation and Sensitization**: Clinical trials and post-market surveillance indicate a low incidence of skin irritation or sensitization with Bemotrizinol-containing products.
- **Phototoxicity and Photoallergenicity**: Bemotrizinol does not exhibit phototoxic or photoallergenic effects, making it suitable for long-term topical application in sunscreens.
- **Systemic Exposure**: Minimal systemic absorption suggests a low risk of systemic

Below is a brief overview of the dermal safety study results for BEMT. Further details are provided in Module 5.3.5.1.

1. In the clinical repeat insult patch test phase, none of the 185 subjects (18 to 74 years of age; 5 of 190 were lost to follow) completing the RIPT phase showed evidence of dermal irritation or sensitization after 9 induction and the challenge applications of 6% BEMT in a sunscreen oil with skin penetration enhancer formulation (SU E 101413 85). The cumulative skin irritation phase was completed by 30 subjects aged 22 to 74 years and none of them showed evidence of cumulative skin irritation after 21 daily patch applications of the drug formulation (SU E 101413 85). The respective control formulations and applications without BEMT gave their expected responses in each study phase (CRLNJ2020-0493).

2. The evaluation of 6% BEMT in a sunscreen oil with skin penetration enhancer formulation (SU E 101413 85) for phototoxic responses after application to the skin of human subjects followed by exposure to UV radiation. Vehicle and negative control formulations and an empty patch control were used in parallel on individual skin sites. Among the 34 male and female subjects aged 21 to 72 years none of them showed evidence of a phototoxic response to the 6% BEMT formulation (CRLNJ2020-0494).

3. Testing for photoallergenicity responses to 6% BEMT in a sunscreen oil with skin penetration enhancer formulation (SU E 101413 85) enrolled 50 male and female subjects (two discontinued) with ages of 21 to 72 years; over 20 days of clinic visits for 4 weeks in a 6-week period the six induction applications and skin response gradings were completed. Two weeks thereafter subjects returned for patch applications and 24h later UVA irradiation; sites were graded for skin responses at 24, 48 and 72h after UVA exposure. Evidence of photoallergic responses did not occur in any of the subjects at any time point; the negative and vehicle control formulations gave their expected responses (CRLNJ2020-0495).

In each of these clinical tests, 6% BEMT did not elicit signs or reactions indicating skin irritation, allergenicity, phototoxicity or photoallergenicity in any of the subjects completing the studies; non-completers were lost to follow-up or discontinued for reasons not related to the BEMT test formulation.

## 2.5.6 Benefits and Risks Conclusions

### 2.5.6.1 Therapeutic Context

The main purpose of active ingredients used FDA OTC sunscreen products is to prevent skin damage caused by UV radiation from the sun, which can lead to skin cancer and early aging.

Sunscreens protect by absorbing, reflecting, or scattering UV rays. Bemotrizinol is a strong, stable, broad-spectrum organic UV filter that provides UVB protection in the 280-320 nm range, guarding against sunburn. BEMT also offers UVA protection in the 320-400 nm range, shielding the skin from deeper-penetrating UVA rays that cause aging and long-term skin damage.

2.5.6.1.1 Disease or Condition Treated

- Prevention of Sunburn: Sunburn is an acute reaction to excessive UV exposure, leading to redness, pain, and inflammation. The use of BEMT as an active ingredient in sunscreens helps prevent this condition.

Other permitted labeling uses for finished sunscreen products: If used as directed with other sun protection measures (see Directions), decreases the risk of skin cancer and early skin aging caused by the sun (see Module 1.14)

2.5.6.1.2 Current Therapies

The FDA's sunscreen drug monograph specifies approved active ingredients and concentrations for sunscreens, which help prevent UV-induced skin damage, skin cancer, and early aging.

Sunscreens, classified as OTC drugs, come in various forms like lotions, creams, sprays, and sticks, and must meet efficacy and safety standards. Broad-spectrum sunscreens protect against both UVA (aging) and UVB (burning) rays.

To further reduce UV exposure, it's advised to use protective clothing, hats, sunglasses, and avoid the sun during peak hours (10 AM to 4 PM).

2.5.6.2 Benefits

The benefits of BEMT as an active ingredient for use in OTC sunscreen drugs are as follows:

- Safety Profile – The data gaps identified by FDA as necessary to make a GRASE determination for BEMT have been addressed according to FDA's GRASE safety and efficacy guidelines. Test results show that Bemotrizinol has low risk of systemic toxicity due to minimal absorption; a favorable safety profile with minimal skin irritation or sensitization; is generally well-tolerated by most skin types, making it suitable for a wide range of consumers; has been tested extensively and results show that it is safe for long term use in adult and pediatric populations.
- Provides effective broad-spectrum UV protection - Bemotrizinol provides effective protection against both UVA and UVB rays, which helps prevent sunburn, skin cancer, and photoaging. Its ability to cover a wide range of UV radiation makes it a valuable component in sunscreen formulations.
- High photostability - Unlike some other UV filters, Bemotrizinol is highly photostable, meaning it does not degrade significantly under sunlight. This ensures prolonged protection during sun exposure, reducing the need for frequent reapplication.
- Synergistic Effect: Bemotrizinol works well with other UV filters, enhancing the overall effectiveness of sunscreens. This synergistic effect allows for better formulation flexibility and can lead to more comprehensive UV protection.
- Precedent setting – BEMT would be the first sunscreen active ingredient reviewed under the OMOR Tier 1 process established by 505G of the FD&C Act. A positive GRASE determination could encourage further sunscreen innovation.
- The addition of BEMT to the sunscreen monograph will allow the U.S. sun care industry to innovate and better meet today's consumers needs and preferences for different skin tones and types - In the United States, sunscreen manufacturers currently have access to

16 ultraviolet (UV) filters to create sunscreen products and truly utilize only seven of these. Comparatively, European nations have up to 30 approved UV filters for consumer product companies to formulate a variety of sunscreen products. The lack of approved UV filters in America, including and especially more advanced sunscreen technologies, severely hampers the ability to bring forward a broader selection of safe and effective sunscreen products that help protect Americans from skin cancer and the harmful effects of overexposure to the sun. The addition of BEMT to the OTC sunscreen monograph will allow sunscreen manufacturers to create additional more innovative sunscreen products that provide more comprehensive protection against harmful ultraviolet rays with reduced degradation over time.

### 2.5.6.3 Risks

- Potential for very rare cases of skin irritation or allergic reactions, though these were not observed in the safety studies conducted and are not commonly reported (see section 2.5.8)

### 2.5.6.4 Benefit-Risk Assessment

The overall safety of BEMT for use in consumer sun protection products has been demonstrated through pivotal nonclinical and clinical safety studies included in this Tier 1 OMOR. The conservative, large margin of safety calculation presented in Module 2.4 indicates a sufficient difference between human systemic exposure and the no observed adverse effect level (NOAEL) in animals, ensuring safety for all age groups, including pediatric populations (6 months and older).

Therefore, the benefits of Bemotrizinol as an OTC sunscreen ingredient outweigh the risks. Its broad-spectrum protection, high photostability, and strong safety and efficacy profile make it a safe and effective UV filter. With minimal systemic absorption and low toxicity, it is well-suited for widespread and long-term use in sun protection products that help protect the public from the harmful effects of ultraviolet (UV) radiation, specifically UVB (which primarily causes sunburn) and UVA (which contributes to skin aging and cancer).

## 2.5.7 Literature References

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### 2.5.8 Tables and Figures

Two additional tables are included in this section to provide further details on the Adverse Events discussed in **section 2.7.4.3** Global experience with BEMT. Most of these adverse events are mild, not serious or life threatening, and similar to the common reactions associated with sunscreens in general, typically involving skin sensitivities or irritations, which can range from mild to severe.

**Table 1. Occurrence of Adverse Events Suspected Associated with Medicines Containing BEMT and Other UV Filters: Number of Case Reports (38 Total) TGA Database of Adverse Event Notifications**

(https://daen.tga.gov.au/medicines-terms-condition :Reported 10-Jun-2020 thru 14-Mar-2023 232906)

| MedDRA system organ class | MedDRA reaction term | Number of cases | Cases with a single suspected medicine | Cases where death was a reported outcome |
|---|---|---|---|---|
| Injury, poisoning and procedural complications | Sunburn | 16 | 16 | 0 |
| Skin and subcutaneous tissue disorders | Erythema | 9 | 8 | 0 |
| Immune system disorders | Hypersensitivity | 7 | 6 | 0 |
| General disorders and administration site conditions | Drug ineffective | 7 | 6 | 0 |
| Skin and subcutaneous tissue disorders | Blister | 6 | 6 | 0 |
| General disorders and administration site conditions | Pain | 6 | 6 | 0 |
| Skin and subcutaneous tissue disorders | Rash | 3 | 3 | 0 |
| Skin and subcutaneous tissue disorders | Skin irritation | 3 | 3 | 0 |
| Product issues | Product quality issue | 3 | 3 | 0 |
| Nervous system disorders | Burning sensation | 3 | 3 | 0 |
| Eye disorders | Eye swelling | 3 | 2 | 0 |
| Skin and subcutaneous tissue disorders | Pruritus | 2 | 2 | 0 |
| Skin and subcutaneous tissue disorders | Skin exfoliation | 2 | 2 | 0 |

| | | | | |
|---|---|---|---|---|
| Product issues | Product complaint | 2 | 2 | 0 |
| Injury, poisoning and procedural complications | Burns third degree | 2 | 2 | 0 |
| Injury, poisoning and procedural complications | Recalled product administered | 2 | 2 | 0 |
| Injury, poisoning and procedural complications | Thermal burn | 2 | 2 | 0 |
| General disorders and administration site conditions | Swelling face | 2 | 1 | 0 |
| General disorders and administration site conditions | Therapeutic product ineffective | 2 | 2 | 0 |
| Skin and subcutaneous tissue disorders | Dermatitis allergic | 1 | 1 | 0 |
| Skin and subcutaneous tissue disorders | Dermatitis contact | 1 | 1 | 0 |
| Skin and subcutaneous tissue disorders | Pain of skin | 1 | 0 | 0 |
| Skin and subcutaneous tissue disorders | Rash erythematous | 1 | 1 | 0 |
| Skin and subcutaneous tissue disorders | Rash macular | 1 | 1 | 0 |
| Skin and subcutaneous tissue disorders | Rosacea | 1 | 1 | 0 |
| Skin and subcutaneous tissue disorders | Skin erosion | 1 | 1 | 0 |
| Skin and subcutaneous tissue disorders | Skin lesion | 1 | 1 | 0 |
| Skin and subcutaneous tissue disorders | Urticaria | 1 | 1 | 0 |
| Product issues | Product physical consistency issue | 1 | 1 | 0 |
| Nervous system disorders | Paraesthesia | 1 | 1 | 0 |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | Skin cancer | 1 | 0 | 0 |
| Metabolism and nutrition disorders | Dehydration | 1 | 1 | 0 |
| Injury, poisoning and procedural complications | Burns second degree | 1 | 1 | 0 |

| | | | | |
|---|---|---|---|---|
| Injury, poisoning and procedural complications | Chemical burn of skin | 1 | 1 | 0 |
| Injury, poisoning and procedural complications | Third degree chemical burn of skin | 1 | 1 | 0 |
| Infections and infestations | Burn infection | 1 | 1 | 0 |
| Immune system disorders | Allergy to chemicals | 1 | 1 | 0 |
| General disorders and administration site conditions | Application site hypersensitivity | 1 | 1 | 0 |
| General disorders and administration site conditions | Concomitant disease aggravated | 1 | 1 | 0 |
| General disorders and administration site conditions | Condition aggravated | 1 | 0 | 0 |
| General disorders and administration site conditions | Face oedema | 1 | 1 | 0 |
| General disorders and administration site conditions | Peripheral swelling | 1 | 1 | 0 |
| Gastrointestinal disorders | Nausea | 1 | 1 | 0 |

**Table 2. Products (Medicines) in List of Reports of Adverse Events**
**TGA Database of Adverse Event Notifications**
(https://daen.tga.gov.au/medicines-terms-condition :Reported 10-Jun-2020 thru 14-Mar-2023 232906)

| Case number | Report entry date | Age (years) | Gender | Medicines reported being taken | MedDRA reaction terms |
|---|---|---|---|---|---|
| 511312 | 2020-11-05 00:00:00 | 69 | Female | • Ultra UV Protective Daily Moisturiser SPF50+ - AUST L 237094 (bemotrizinol; butyl methoxydibenzoylmethane; octocrylene; octyl methoxycinnamate; phenylbenzimidazole sulfonic acid) - Suspected | • Hypersensitivity |
| 512609 | 2020-11-20 00:00:00 | 54 | Female | • EGO SUNSENSE ANTI-AGEING FACE (193124) (octyl methoxycinnamate; diethylamino hydroxybenzoyl hexyl benzoate; bemotrizinol) - Suspected | • Erythema |
| 512811 | 2020-11-23 00:00:00 | 69 | Female | • Ultra UV Protective Daily Moisturiser SPF50+ - AUST L 237094 (bemotrizinol; butyl methoxydibenzoylmethane; octocrylene; octyl methoxycinnamate; phenylbenzimidazole sulfonic acid) - Suspected | • Erythema |
| 513195 | 2020-11-27 00:00:00 | 46 | Female | • Banana Boat Ultra SPF50+ (octocrylene; 4-methylbenzylidene camphor; butyl methoxydibenzoylmethane; bemotrizinol) - Suspected | • Drug ineffective<br>• Sunburn |
| 514912 | 2020-12-18 00:00:00 | 18 | Female | • LA ROCHE-POSAY LABORATOIRE DERMATOLOGIQUE ANTHELIOS XL DRY TOUCH GEL-CREAM AUST L 308621 (octyl salicylate; homosalate; octocrylene; titanium dioxide; ethylhexyl triazone; butyl methoxydibenzoylmethane; bemotrizinol; Ecamsule; Drometrizole trisiloxane) - Suspected | • Face oedema<br>• Paraesthesia<br>• Sunburn |
| 516049 | 2021-01-07 00:00:00 | 4 | Male | • Banana Boat Ultra SPF50+ (octocrylene; 4-methylbenzylidene camphor; butyl methoxydibenzoylmethane; bemotrizinol) - Suspected | • Blister<br>• Burns third degree<br>• Pain<br>• Sunburn |
| 516900 | 2021-01-18 00:00:00 | '- | Male | • NIVEA Sun Ultra Sport Cooling SPF50+ AUST L 234675 (bemotrizinol; butyl methoxydibenzoylmethane; homosalate; octocrylene; octyl salicylate) - Suspected | • Product quality issue<br>• Sunburn |
| 517076 | 2021-01-20 00:00:00 | 48 | Female | • LA ROCHE-POSAY LABORATOIRE DERMATOLOGIQUE ANTHELIOS XL ULTRA LIGHT TINTED FLUID (AUST L 268394) (octocrylene; | • Burning sensation<br>• Erythema<br>• Skin exfoliation |

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|---|---|---|---|---|---|
| | | | | titanium dioxide; ethylhexyl triazone; butyl methoxydibenzoylmethane; bemotrizinol; Ecamsule; Drometrizole trisiloxane) - Suspected | |
| 517224 | 2021-01-22 00:00:00 | '- | Female | • Nivea Sun Protect & Moisture Moisturising Sunscreen Lotion SPF50 - AUST L 270877 (bemotrizinol; butyl methoxydibenzoylmethane; homosalate; octocrylene; octyl salicylate) - Suspected | • Sunburn |
| 517351 | 2021-01-25 00:00:00 | '- | Not Specified | • NIVEA Sun Ultra Beach Sunscreen Spray SPF50+ AUST L 234687 (octyl salicylate; homosalate; octocrylene; butyl methoxydibenzoylmethane; bemotrizinol) - Suspected | • Drug ineffective<br>• Product quality issue<br>• Sunburn |
| 517892 | 2021-01-31 00:00:00 | 53 | Male | • Nivea Sun Protect & Moisture Moisturising Sunscreen Lotion SPF50 - AUST L 270877 (bemotrizinol; butyl methoxydibenzoylmethane; homosalate; octocrylene; octyl salicylate) - Suspected | • Sunburn |
| 518532 | 2021-02-08 00:00:00 | 29 | Female | • Ultra UV Protective Daily Moisturiser SPF30 Hydrating - AUST L 236265 (octyl methoxycinnamate; octocrylene; phenylbenzimidazole sulfonic acid; butyl methoxydibenzoylmethane; bemotrizinol) - Suspected | • Skin irritation |
| 519256 | 2021-02-15 00:00:00 | 3 | Male | • BANANA BOAT KIDS SPF50+ ROLL ON SUNSCREEN AUST L 196672 (4-methylbenzylidene camphor; bemotrizinol; butyl methoxydibenzoylmethane; octocrylene) - Suspected | • Erythema<br>• Eye swelling<br>• Hypersensitivity<br>• Pruritus<br>• Rash |
| 519480 | 2021-02-17 00:00:00 | 17 | Female | • Banana Boat Ultra SPF50+ (octocrylene; 4-methylbenzylidene camphor; butyl methoxydibenzoylmethane; bemotrizinol) - Suspected | • Hypersensitivity<br>• Urticaria |
| 519606 | 2021-02-18 00:00:00 | '- | Female | • Nivea Sun Protect & Moisture Moisturising Sunscreen Lotion SPF50 - AUST L 270877 (bemotrizinol; butyl methoxydibenzoylmethane; homosalate; octocrylene; octyl salicylate) - Suspected | • Product quality issue<br>• Sunburn |
| 531700 | 2021-04-06 00:00:00 | 62 | Female | • LA ROCHE-POSAY LABORATOIRE DERMATOLOGIQUE ANTHELIOS XL ULTRA LIGHT TINTED FLUID (AUST L 268394) (octocrylene; titanium dioxide; ethylhexyl triazone; butyl methoxydibenzoylmethane; bemotrizinol; Ecamsule; Drometrizole trisiloxane) - Suspected | • Rosacea |

| | | | | | |
|---|---|---|---|---|---|
| 546766 | 2021-05-03 00:00:00 | 46 | Male | • Ultra UV Protective Daily Moisturiser SPF 30 Mattifying - AUSTL 251012 (bemotrizinol; butyl methoxydibenzoylmethane; octocrylene; octyl methoxycinnamate; phenylbenzimidazole sulfonic acid) - Suspected | • Application site hypersensitivity |
| 615027 | 2021-08-31 00:00:00 | 3 | Female | • NIVEA Sun Kids Protect & Play Caring Roll-On SPF 50 (4-methylbenzylidene camphor; bemotrizinol; methylene bis-benzotriazolyl tetramethylbutylphenol; zinc oxide) - Suspected | • Burning sensation<br>• Rash erythematous<br>• Skin irritation |
| 624871 | 2021-09-15 00:00:00 | 46 | Male | • Ultra UV Protective Daily Moisturiser SPF50+ - AUST L 237094 (bemotrizinol; butyl methoxydibenzoylmethane; octocrylene; octyl methoxycinnamate; phenylbenzimidazole sulfonic acid) - Suspected | • Allergy to chemicals<br>• Erythema<br>• Pruritus<br>• Skin exfoliation |
| 638629 | 2021-10-06 00:00:00 | <1 | Female | • Banana Boat Baby SPF50+ Roll On Sunscreen (4-methylbenzylidene camphor; bemotrizinol; butyl methoxydibenzoylmethane; octocrylene) - Suspected | • Blister<br>• Erythema<br>• Eye swelling<br>• Skin erosion<br>• Swelling face<br>• Third degree chemical burn of skin |
| 648959 | 2021-10-22 00:00:00 | '- | Male | • LA ROCHE-POSAY LABORATOIRE DERMATOLOGIQUE ANTHELIOS XL WET SKIN KIDS GEL CREAM SPF50+ (bemotrizinol; butyl methoxydibenzoylmethane; drometrizole trisiloxane; ethylhexyl triazone; homosalate; octyl salicylate) - Suspected | • Burning sensation<br>• Rash |
| 688705 | 2021-12-31 00:00:00 | 36 | Female | • Nivea Sun Protect & Moisture Moisturising Sunscreen Lotion SPF50 - AUST L 270877 (bemotrizinol; butyl methoxydibenzoylmethane; homosalate; octocrylene; octyl salicylate) - Suspected | • Sunburn |
| 690195 | 2022-01-06 00:00:00 | '- | Female | • NIVEA Sun Ultra Sport Cooling SPF50+ AUST L 234675 (bemotrizinol; butyl methoxydibenzoylmethane; homosalate; octocrylene; octyl salicylate) - Suspected | • Blister<br>• Erythema<br>• Pain<br>• Product complaint<br>• Product physical consistency issue<br>• Sunburn |
| 696947 | 2022-01-19 00:00:00 | 29 | Female | • Ultimate UV Protective Daily Moisturiser SPF 50 Mattifying AUSTL 343257 (bemotrizinol; butyl methoxydibenzoylmethane; octocrylene; octyl methoxycinnamate; phenylbenzimidazole sulfonic acid) - Suspected | • Dermatitis contact |

| | | | | | |
|---|---|---|---|---|---|
| 709696 | 2022-02-14 00:00:00 | 10 | Female | • Banana Boat Sport Very High Protection Sunscreen Lotion SPF 50+ AUST L 196376 (4-methylbenzylidene camphor; bemotrizinol; butyl methoxydibenzoylmethane; octocrylene) - Suspected | • Burns third degree<br>• Drug ineffective<br>• Pain<br>• Recalled product administered |
| 715479 | 2022-03-01 00:00:00 | 33 | Female | • Banana Boat Sport Very High Protection Sunscreen Lotion SPF 50+ AUST L 196376 (4-methylbenzylidene camphor; bemotrizinol; butyl methoxydibenzoylmethane; octocrylene) - Suspected | • Blister<br>• Burn infection<br>• Burns second degree<br>• Dehydration<br>• Drug ineffective<br>• Erythema<br>• Nausea<br>• Pain<br>• Peripheral swelling<br>• Sunburn |
| 717793 | 2022-03-06 00:00:00 | 2 | Male | • BANANA BOAT KIDS VERY HIGH PROTECTION SUNSCREEN LOTION SPF 50+ AUST L 205791 (4-methylbenzylidene camphor; bemotrizinol; butyl methoxydibenzoylmethane; octocrylene) - Suspected | • Drug ineffective<br>• Hypersensitivity<br>• Pain<br>• Rash<br>• Rash macular<br>• Skin lesion<br>• Sunburn |
| 720327 | 2022-03-15 00:00:00 | '- | Female | • NIVEA Sun Ultra Sport Cooling SPF50+ AUST L 234675 (bemotrizinol; butyl methoxydibenzoylmethane; homosalate; octocrylene; octyl salicylate) - Suspected | • Product complaint<br>• Sunburn |
| 732056 | 2022-04-28 00:00:00 | 2 | Not Specified | • BANANA BOAT KIDS VERY HIGH PROTECTION SUNSCREEN LOTION SPF 50+ AUST L 205791 (4-methylbenzylidene camphor; bemotrizinol; butyl methoxydibenzoylmethane; octocrylene) - Suspected | • Recalled product administered<br>• Thermal burn |
| 733636 | 2022-05-06 00:00:00 | '- | Female | • Ultra UV Protective Daily Moisturiser SPF50+ - AUST L 237094 (bemotrizinol; butyl methoxydibenzoylmethane; octocrylene; octyl methoxycinnamate; phenylbenzimidazole sulfonic acid) - Suspected | • Blister<br>• Hypersensitivity |
| 737399 | 2022-05-26 00:00:00 | '- | Female | • LA ROCHE POSAY LABORATOIRE DERMATOLOGIQUE ANTHELIOS ULTRA COMFORT NON PERFUMED CREAM SPF50+ AUST L 307004 (bemotrizinol; drometrizole trisiloxane; ecamsule; ethylhexyl triazone; octyl salicylate) - Suspected | • Hypersensitivity<br>• Skin irritation |

| | | | | | |
|---|---|---|---|---|---|
| 744193 | 2022-07-11 00:00:00 | 25 | Female | • DermaVeen Regenerating Night Cream - Not on ARTG (alkyl (C12-15) benzoate; Avena sativa; ceteareth-20; Cetearyl Alcohol; cetyl alcohol; coco-caprylate; Cocos nucifera; Dimethicone; ethylhexylglycerin; glycerol; glyceryl monostearate; Hydroxypropyl methacrylate; medium chain triglycerides; phenoxyethanol; polysorbate 60; propanediol; Shea butter; sodium gluconate; sodium hyaluronate; squalene; stearic acid; Tocopheryl acetate; xanthan gum) - Suspected<br>• DermaVeen Ultra Light Day Lotion SPF50+ (AUST L 380592) (bemotrizinol; butyl methoxydibenzoylmethane; ethylhexyl triazone; homosalate; octyl salicylate; phenylbenzimidazole sulfonic acid) - Suspected | • Condition aggravated<br>• Drug ineffective<br>• Erythema<br>• Eye swelling<br>• Hypersensitivity<br>• Pain of skin<br>• Swelling face |
| 757596 | 2022-11-09 00:00:00 | 19 | Female | • Ultimate UV Protective Daily Moisturiser SPF 50 Mattifying AUSTL 343257 (bemotrizinol; butyl methoxydibenzoylmethane; octocrylene; octyl methoxycinnamate; phenylbenzimidazole sulfonic acid) - Suspected | • Dermatitis allergic |
| 759091 | 2022-11-24 00:00:00 | '- | Female | • Neutrogena Ultra Sheer Body Mist SPF30+ AUST L 157580 (butyl methoxydibenzoylmethane; homosalate; octocrylene; octyl salicylate; oxybenzone) - Suspected<br>• Neutrogena Ultra Sheer Body Mist Sunscreen Spray - AUST L Unknown (bemotrizinol; butyl methoxydibenzoylmethane; ethylhexyl triazone; homosalate; octocrylene) - Suspected | • Skin cancer |
| 764567 | 2023-01-17 00:00:00 | 28 | Female | • Nivea Sun Protect & Moisture Moisturising Sunscreen Lotion SPF50 - AUST L 270877 (bemotrizinol; butyl methoxydibenzoylmethane; homosalate; octocrylene; octyl salicylate) - Suspected | • Sunburn<br>• Therapeutic product ineffective |
| 765500 | 2023-01-30 00:00:00 | 73 | Female | • Ultra UV Protective Daily Moisturiser SPF 50 Mattifying - AUSTL 343242 (bemotrizinol; butyl methoxydibenzoylmethane; octocrylene; octyl methoxycinnamate; phenylbenzimidazole sulfonic acid) - Suspected | • Concomitant disease aggravated |
| 766401 | 2023-02-10 00:00:00 | 5 | Female | • BANANA BOAT KIDS VERY HIGH PROTECTION SUNSCREEN LOTION SPF 50+ AUST L 205791 (4-methylbenzylidene camphor; bemotrizinol; butyl methoxydibenzoylmethane; octocrylene) - Suspected | • Blister<br>• Chemical burn of skin<br>• Drug ineffective<br>• Pain<br>• Sunburn<br>• Thermal burn |

| | | | | | |
|---|---|---|---|---|---|
| 767287 | 2023-02-22 00:00:00 | '- | Female | • Nivea Sun Protect & Moisture Moisturising Sunscreen Lotion SPF50 - AUST L 270877 (bemotrizinol; butyl methoxydibenzoylmethane; homosalate; octocrylene; octyl salicylate) - Suspected | • Sunburn<br>• Therapeutic product ineffective |