

MGF 400105
Bemotrizinol (BEMT)

1.14 Labeling

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1.14.1.1 Example of proposed labeling that reflects the OTC monograph condition(s) of use proposed in the OMOR for BEMT

Draft OTC Sunscreen Drug Finished Product Labeling

Bemotrizinol is proposed for use as an active ingredient in OTC sunscreen drug products at a maximum concentration of 6 percent. OTC sunscreen products containing BEMT as an active ingredient will need to comply with the FDA's "Drug Facts" labeling requirements and other effectiveness and compliance guidelines as outlined in the FDA's Over-the-Counter Monograph M020: Sunscreen Drug Products for Over-the-Counter Human Use and 21 CFR 352 and as amended by the FDA's Final Order for BEMT.

Below is an example of OTC sunscreen labeling proposed for Bemotrizinol 6% as an active ingredient. While it is anticipated that BEMT will be allowed in combination with other OTC sunscreen monograph ingredients, the example provided illustrates BEMT as the sole active ingredient.

Drug Facts

Active Ingredients:

- **Bemotrizinol 6%** (Sunscreen)

Uses:

- Helps prevent sunburn
- 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.

Warnings:

- **For external use only**
- **Do not use** on damaged or broken skin.
- **When using this product**, keep out of eyes. Rinse with water to remove.
- **Stop use and ask a doctor** if rash occurs.
- **Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

Directions:

- Apply generously 15 minutes before sun exposure.
- Reapply:
 - After 80 minutes of swimming or sweating
 - Immediately after towel drying
 - At least every 2 hours

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- **Sun Protection Measures:** Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a Broad-Spectrum SPF of 15 or higher and other sun protection measures including:
 - Limit time in the sun, especially from 10 a.m. – 2 p.m.
 - Wear long-sleeve shirts, pants, hats, and sunglasses.
- **Children under 6 months:** Ask a doctor.

Other Information:

- Protect this product from excessive heat and direct sunlight.

Inactive Ingredients: [List of inactive ingredients, e.g., water, glycerin, etc.]

Questions or comments? Call [Company's contact information].

Draft BEMT (Active Pharmaceutical Ingredient – API) API Bulk Drug Drum Labeling

Bemotrizinol (BEMT) will be sold as a USP-grade bulk drug substance (API) for use in the manufacturing, processing, or repackaging of OTC sunscreen products. Unlike finished OTC products, the labeling requirements for bulk drugs are tailored for further processing rather than direct consumer sale. BEMT will be drug listed per FDA requirements and packaged according to the drug substance container closure system as indicated in [section 3-2-s-6](#) . An example of the bulk drug labeling that will be used is provided below:

Example of a Drum Label for Bemotrizinol (Sunscreen Active Ingredient)

- **Product Name:** Bemotrizinol 6% USP
- **Tradename:** PARSOL® Shield
- **Batch/Lot Number:** 12345678
- **CAS Number:** 1314-13-2
- **Net Weight:** 25 kg
- **Purity:** 99.8%
- **Manufacturing Date:** August 2024
- **Expiration Date:** August 2026
- **Storage Conditions:** Store in a cool, dry place. Protect from moisture and sunlight.

Active Ingredient Information

- **Ingredient:** Bemotrizinol (Sunscreen Grade)
- **Purpose:** UV Filter for Sunscreen Formulations
- **Approved Use:** For sunscreen products per FDA Monograph 21 CFR 352. Maximum allowed concentration: 6%.

Safety Information

- **Hazard Statements:**
 - **Precautionary Statements:**
-

Regulatory Information

- **Country of Origin:**
 - **FDA Compliance:** Meets U.S. FDA OTC Monograph for Sunscreens (21 CFR 352).
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Manufacturer

- **Name:**
 - **Address:**
 - **Phone:**
 - **Email:**
-

Handling Instructions

Handle with care. Use proper PPE. Avoid direct contact with eyes, skin, and clothing.

Below is an example of a current global drum label for PARSOL® Shield that would be modified to reflect API drug substance requirements for Bemotrizinol as shown above.



PARSOL® Shield

INCI name: Bis-Ethylhexyloxyphenyl Methoxyphenyl Triazine

00001 3,000133

2,4-bis[[4-(2-ethyl-hexyloxy-2-hydroxy)-phenyl]-6-(4-methoxyphenyl)-(1,3,5)-triazine

<p>CAS EINECS</p>	<p>No.: No.:</p>	<p>187393-00-6 425-950-7</p>	
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<p>Caution For manufacturing, processing or repacking. Not for retail sale. For external use only.</p>	<p>Atención Para uso industrial no para venta directa. Para uso externo.</p>	<p>Remarque Destiné à l'utilisation industrielle et non à la vente au détail. Pour usage externe.</p>	<p>Avviso Da impiegare unicamente ai fini della produzione. Esclusa la vendita al dettaglio. Per uso esterno.</p>	<p>Hinweis Nur für die Weiterverarbeitung bestimmt, nicht für den Verkauf im Einzelhandel. Zur äusseren Anwendung.</p>
<p>Storage: Store in a dry place below 25°C and avoid from freezing. Keep package closed. Protect from light.</p>	<p>Almacenamiento: Almacene en un lugar seco a menos de 25°C y evite que se congele. Mantenga el paquete cerrado. Proteger de la luz.</p>	<p>Stockage: Conserver dans un endroit sec à moins de 25°C et éviter de geler. Gardez le paquet fermé. Protéger de la lumière.</p>	<p>Immagazzinamento: Conservare in luogo asciutto sotto i 25°C e evitare il congelamento. Tenere il pacchetto chiuso. Proteggere dalla luce.</p>	<p>Lagerung: An einem trockenen Ort unter 25°C lagern und nicht einfrieren lassen. Halten Sie die Verpackung geschlossen. Vor Licht schützen.</p>
<p>Safety information: WARNING May form combustible dust concentrations in air.</p>	<p>Información de seguridad: ATENCIÓN Puede formar concentraciones de polvo combustible en el aire.</p>	<p>Information sur la sécurité: ATTENTION Peut former des concentrations de poussières combustibles dans l'air.</p>	<p>Informazioni sulla sicurezza: ATTENZIONE Può formare polveri in concentrazioni combustibili in aria.</p>	<p>Sicherheitsinformationen: ACHTUNG Kann in Luft brennbare Staubkonzentrationen bilden.</p>

Manufactured for:
DSM Nutritional Products Ltd., Site Sisseln
Hauptstrasse 4, CH-4334 Sisseln, Switzerland
for sale by:
DSM affiliates & authorized distributors
Made in PR China

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EMERGENCY: +41 848 001 177 (Carechem 24 hr) | USECA for HAZMAT incidents ONLY: 1-800-424-8300 (CHEMTREC)



Manufacturing date: Fecha de fabricación: Date de fabrication: Data di produzione: Herstellungs-Datum:	Best use before: Fecha de caducidad: A utiliser avant: Data di scadenza: Mindestens haltbar:	Net weight: Peso neto: Poids net: Peso netto: Nettogewicht:
11-OCT-2023	09-OCT-2028	20kg

(01) 97630047287254 (17) 281009 (3102) 002000 (10) UT11102023



Code 5017835622

Lot UT11102023

1.14.1.2 Proposed OTC monograph that reflects the OTC monograph condition(s) of use proposed in the OMOR

Bemotrizinol 6% is proposed to be listed as an active ingredient for use in OTC sunscreen drug products that are sold in a form suitable for topical administration under FDA's Over-the-Counter Monograph M020: Sunscreen Drug Products for Over-the-Counter Human Use (21 CFR 352). (https://dps-admin.fda.gov/omuf/omuf/sites/omuf/files/primary-documents/2022-09/Final%20Administrative%20Order%20OTC000006_M020-Sunscreen%20Drug%20Products%20for%20OTC%20Human%20Use.pdf).