

Formulating High Efficacy Sunscreens with Bis-ethylhexyloxyphenol Methoxyphenyl Triazine (BEMT): A New Sunscreen Filter Expected to Be Approved in the United States

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Introduction, Objectives, and Methods

Introduction

- BEMT [Bis-ethylhexyloxyphenol methoxyphenyl triazine] is a broad-spectrum UV [Ultraviolet] filter active ingredient currently utilized globally for sun protection and projected to be generally recognized as safe and effective (GRASE) in the United States.¹
- More understanding is needed about the UV protective capacity of BEMT when used in combination with other FDA-approved UV filters to expand consumer choice of effective sunscreens.

Objective

- This study evaluates the potential impact of excipients (thickener, emulsifier, film former, and oil absorbent) and formula design on the in-vitro UV absorption efficacy, particularly UVA (320–400 nm), of sunscreens with BEMT.

Methods

- Oil-in-water emulsions of comparable sensorial attributes and viscosities (15,000-32,000 cPs) were formulated using maximum projected approved BEMT concentration of 6 wt.%, along with avobenzene and octisalate. The efficacy of these formulae were evaluated using in vitro UV spectroscopy.
- In vitro UV absorption was measured according to the FDA Over-The-Counter Monograph M020; §M020.90(a)(b) Broad Spectrum Test Procedure and sun protection factor (SPF) was calculated based on the principles of ISO:24443:2021.

FDA, US Food and Drug Administration

1. FDA Proposes Expanding Sunscreen Active Ingredient List, published on FDA News Release on December 11, 20205.

Results: In Vitro SPF Efficacy Demonstrates High Dependence on Choice of Key Structural Excipients (Thickener, Emulsifier, Film Former, and Oil Absorbent)

Figure 1. Average UV Absorbance Spectra of BEMT Sunscreens

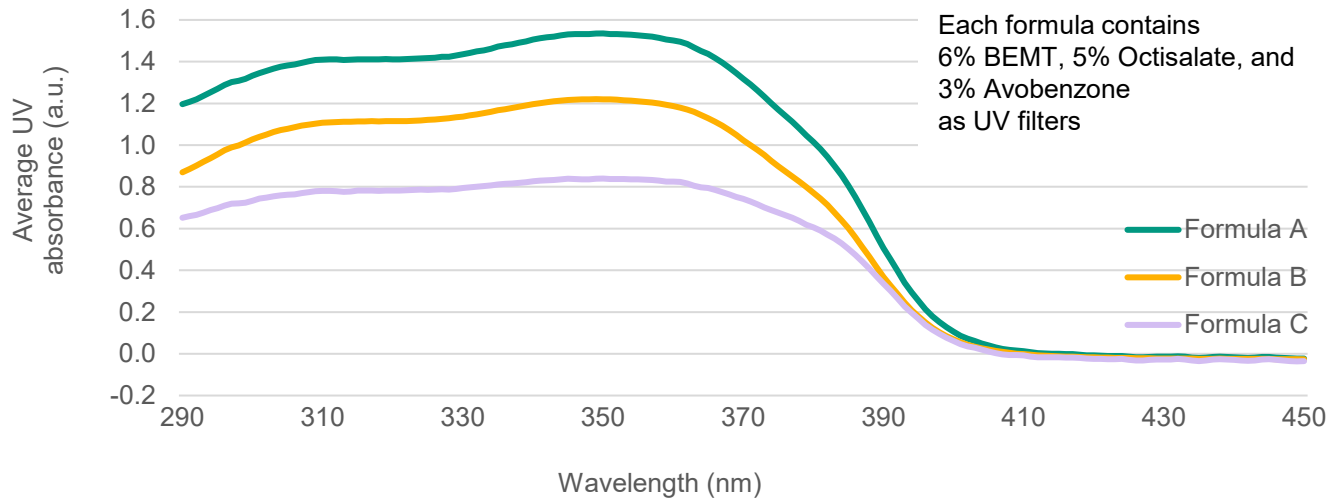
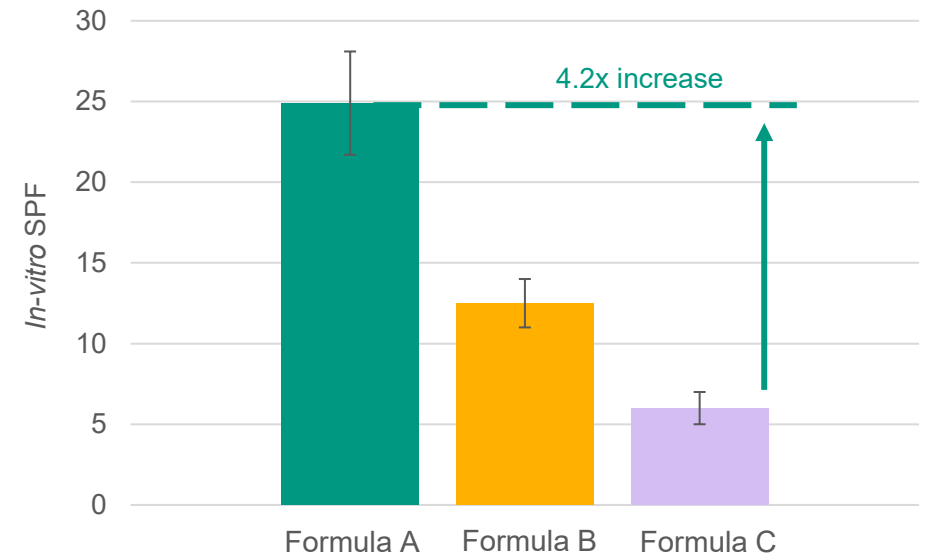


Table 1. Key Structural Ingredients of BEMT Sunscreens

Ingredient Category	Formula A (wt%)	Formula B (wt%)	Formula C (wt%)
UV Filter Solvent	10.00	10.00	10.00
Thickener	0.45	0.58	0.75
Emulsifier	2.30	3.10	2.90
Film Former	2.00	2.50	1.40
Oil Absorbent	3.00	2.00	1.20

Figure 2. In vitro SPF of BEMT Sunscreens



- Results demonstrated that both the chemical nature of the excipients as well as their concentration in the formula impact the in vitro SPF efficacy (**Figure 1** and **Table 1**).
- In vitro SPF efficacy is greatly dependent on the choice of key structural ingredients in the formulae with identical UV filter package and UV filter solubilizer (**Figure 2**).

Results: Large Variability in the UV Absorption in Formulae Containing 6% BEMT

Table 2. UVA and UVB Absorption of BEMT Sunscreens

Sample	In vitro SPF	CW	UVA:UVB Ratio	Viscosity (cP)	Viscosity (Pa*S)
Formula A	24.9 ± 3.2	376.8 ± 0.4	2.29	16,600	7.48
Formula B	12.5 ± 1.5	376.1 ± 0.3	2.31	30,000	17.3
Formula C	6.0 ± 1.0	378.0 ± 0.2	2.33	25,100	20.6

- Both UVA (320–400 nm) and UVB (290–320 nm) absorbance was observed to be highly dependent on formula composition; however, the balance between absorbance capacity in the 2 regions was highly consistent (**Table 2**).
- Optimization of excipients resulted in a 4-fold increase in in-vitro SPF (**Table 2**). This SPF increase was achieved while maintaining the broad-spectrum behavior, indicated by consistent critical wavelength (CW) values (376–378 nm) and UVA: ultraviolet B (UVB) absorption ratio (2.29–2.33).
- In-vitro SPF, CW, and UVA/UVB ratios were independent of variation in viscosity between the evaluated emulsions, containing 6% BEMT, 3% Avobenzone, 5% Octisalate, and 10% of UV filter solvent (**Table 2**).
- Viscosity of a sunscreen is generally correlated with numerous sensorial attributes of the formula and influencing the consumer choice of the product. Identifying an optimal viscosity range of the product can help promote the sunscreen usage and compliance.

Conclusions

- These findings demonstrate the importance of excipients in sunscreen formulations containing BEMT to achieve high levels of sun protection.
- Key structural formula ingredients, such as thickeners, emulsifiers, film formers, and solid oil absorbents, their chemical characteristics, and concentrations in the formula play a key role in achieving high UV protection efficacy sunscreen formula.
- The projected BEMT approval in the US will allow to expand the choice of sunscreen options. As shown in this study, carefully designed formulations will be essential to unlock the full UV protective potential of BEMT in sunscreens.