Comparative Analysis of Skin Barrier Permeation Rates Between FDA-Approved and Third-Generation Chemical UV Filters for Sunscreen Formulations

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INTRODUCTION

Use of sunscreen is pivotal in reducing the harmful effects of ultraviolet (UV) light exposure on the skin which include sunburn, carcinogenesis and premature skin aging. In the US, only 16 UV filters are approved by the FDA for use in sunscreens, with no progress since 1999. Recently, a study of 6 FDA approved UV filters found that these filters were not only systemically absorbed but were also detected at plasma concentrations higher than the FDA threshold to be considered safe. More studies are needed to better understand the risk of these UV filters; FDA approval of more recently developed, well studied UV filters would additionally aid in making progress in this space. Meanwhile, the US market has become more interested in foreign skin care, particularly products from European Union (EU) and Asian countries. Notably, the EU and Asian countries have over 30 approved UV filters. Some of these filters, including third generation UV filters bemotrizinol (BEMT) and bisoctrizole (MBBT), have been submitted for but do not yet have FDA approval. As permeation and plasma concentration data is pivotal in determining the safety and candidacy for approval of these filters, this review aims to compare current US FDA approved filters to filters not currently approved in the US, but available to the consumer via foreign markets.

This literature review aims to examine the differences in skin barrier permeation rates of FDA-approved chemical UV filters and third-generation chemical UV filters BEMT and MBBT. Data extraction was completed using the Cochrane Review Template for Included Studies.

OBJECTIVES

- Review the literature for data on permeation of FDA approved and Non-FDA approved UV filters (BEMT and MBBT)
- Compare the permeation data of FDA approved and Non-FDA approve UV filters (BEMT and MBBT)

METHODS

Online databases were searched for articles containing information about the permeation rate of 6 of the most common FDA approved sunscreen filters (oxybenzone, avobenzone, homosalate, octisalate, octocrylene, ensulizole, and meradimate) and two of the most common third generation UV filters used in EU and Asian products (bemotrizinol and bisoctrizole).

- Human studies only were included for FDA approved sunscreen filters.
- Human and animal studies were included for EU/Asian sunscreen filters.
- Both categories included in-vitro and in-vivo permeation experiments.

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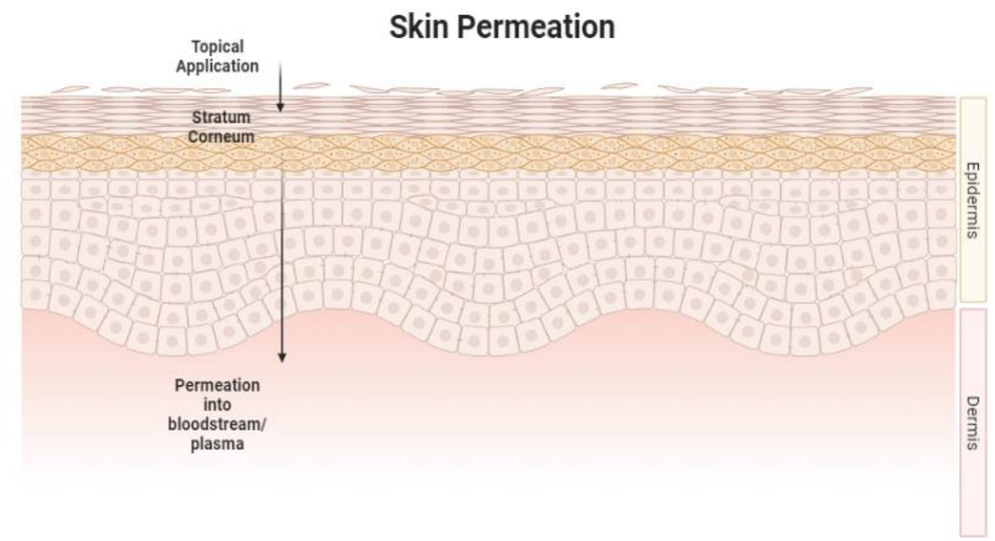
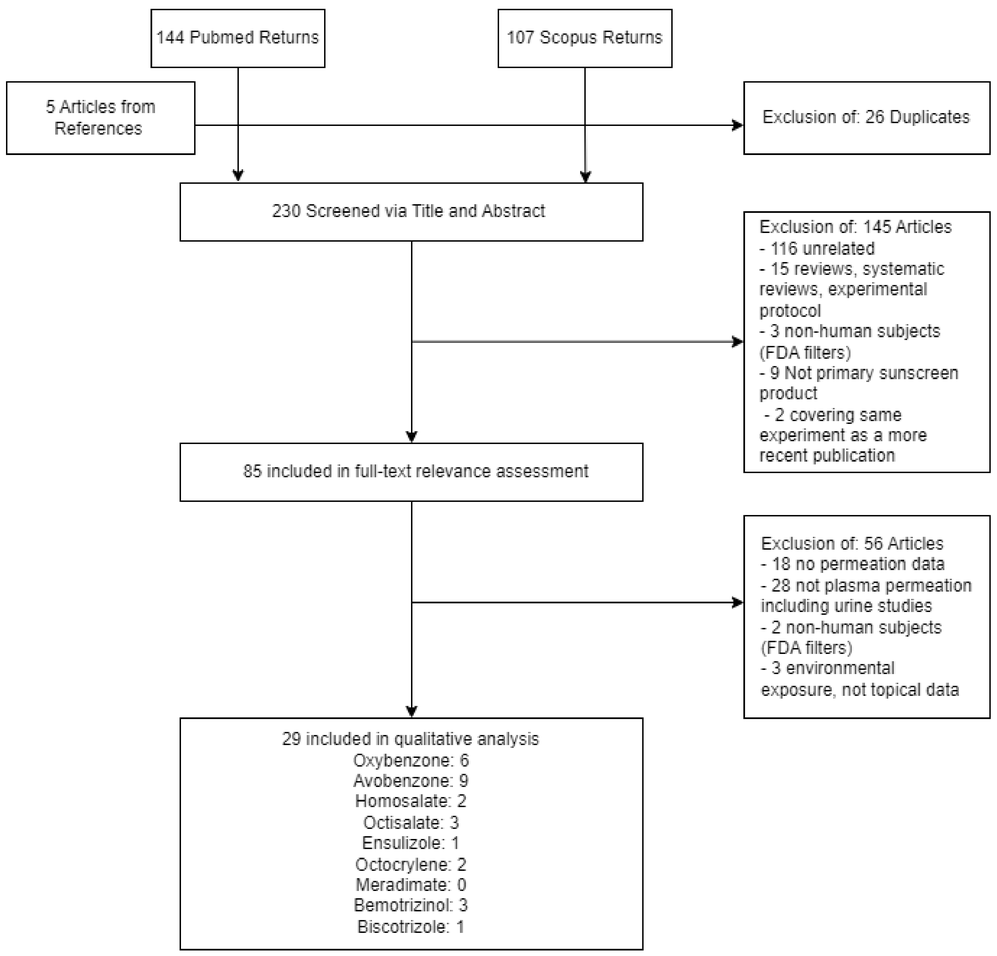


Figure 1. Topical application of sunscreens ideally stay within the outer epidermis (the stratum corneum) for maximum UV filtration effect. Penetration into the deeper layers or into systemic circulation do not offer UV protection and the effect of these filters in the plasma is not known.



RESULTS

A total of 29 published articles across PubMed, Scopus, and PubMed Compound were included. Due to variations in data and study parameters, direct comparison of each filter was not possible.

Bemotrizinol: no permeation (2 studies), exhibited concentrations that did not exceed FDA's defined threshold (1 maximum usage trial*)

Biscotrizole: did not reach measurable plasma concentrations (1 study)

Oxybenzone: permeation (6 studies, 1 maximum usage trial)

Avobenzone: no permeation into the plasma (3 studies), variable permeation (3 studies)

Homosalate: permeation (1 study), no permeation (1 study)

Octisalate: no permeation into the plasma (2 studies), permeation (1 maximum usage trial)

Ensulizole: permeation (1 study)

Octocrylene: permeation (2 studies including 1 maximum usage trial)

Meradimate: No published information

BEMT and MBBT permeation data suggest they are less absorbed than FDA approved UV filters. Concerns regarding permeation should not be barriers of FDA approval of these filters for use in the US market.

*A Maximum Usage Trial (MUST) is a controlled study conducted to assess product safety when used at a maximum recommended dose or application frequency.

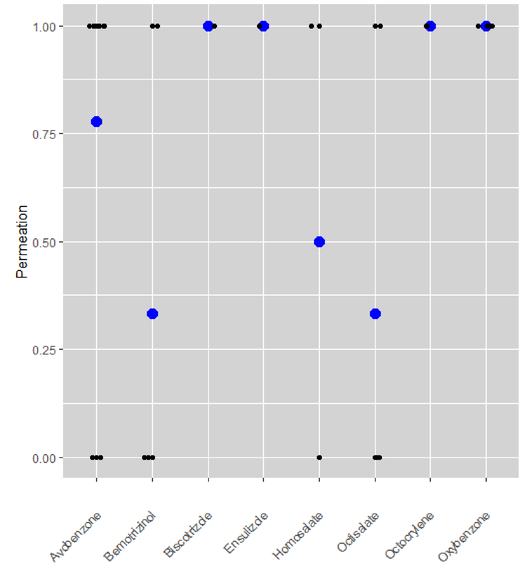


Figure 2. Included studies where sunscreen permeated (1) or did not permeate (0) (black). Each black data point represents one study. Average number of studies (blue) that permeated for each UV filter.

FUTURE DIRECTIONS

A similar study into other FDA approved and non-FDA approved UV filters could be performed. More standardized research on all UV filters, including FDA approved and non-FDA approved, is needed to determine degrees of permeation, which would allow comparison and hopefully support FDA approval of more UV filters in our armamentarium. Additional research into the effects of UV filters in the plasma would also help elucidate this controversial topic.

ACKNOWLEDGEMENTS

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