

Increase in concentration limit of butyloctyl salicylate to 5.0%

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NOTE FROM OTC MEDICINES SECTION

The OTC Medicines Section has completed a review of the data regarding the current use of butyloctyl salicylate as a topical excipient (dermal use only) in OTC products.

An increase in the allowable concentration (to 5%) is based on negative results in a series of toxicity studies at concentrations up to 50% butyloctyl salicylate, and no reported adverse events associated with the use of this excipient. Overseas experience (CIR review) with this excipient also supports the increase. The new concentration limit for butyloctyl salicylate has been set at 5.0%.

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