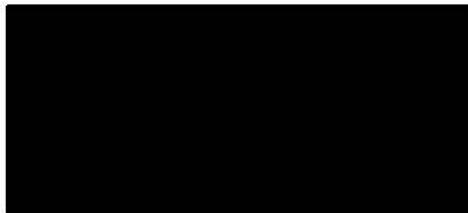




Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

TGAIN: 233555
FILE NO: 2006/000824



Dear Sir/Madam

The information you have submitted on behalf of [REDACTED] in support of the safety of **Butyloctyl salicylate** has been evaluated. On the basis of this information, **Butyloctyl salicylate** can be included in non-prescription products which are proposed for registration or listing in the Australian Register of Therapeutic Goods (ARTG) without the need for further evaluation of the safety of the substance *per se*. Subject to the following conditions:

- **Butyloctyl salicylate** is for dermal use only;
- The concentration of **Butyloctyl salicylate** is not to exceed 1.0%;
- **Butyloctyl salicylate** is not to be included in topical products intended for use in the eye.

This application is now concluded.

Yours sincerely

[REDACTED]
Principal Toxicologist
OTC Medicines Evaluation Section
Non-prescription Medicines Branch
30 October 2006