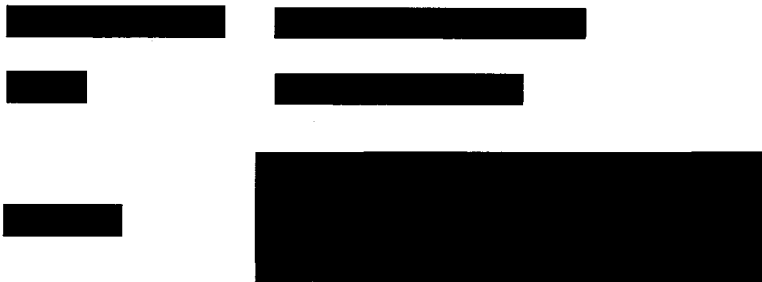


**COMMENTS ON PROPOSED REVISIONS TO CHAPTER 10
'SUNSCREENS IN THE AUSTRALIAN REGULATORY
GUIDELINES FOR OTC MEDICINES (ARGOM)'**



SECTION X.2.2 COSMETIC SUNSCREENS

DEFINITION OF COSMETICS WITH SECONDARY SUNSCREEN

1. The general cosmetic definition is broad I believe products with secondary sunscreen need stronger definition with some qualitative figures.
 - a. What percentage of tint in a formulation constitutes a 'tinted base or foundation'?
 - b. SPF factors allowed need to be defined as these differ for foundation (up to SPF 30+) and moisturiser (up to SPF 15). Note: I had to make a lot of phone calls to establish this fact to both TGA and NICNAS.
 - c. Products such as foundation primers with sunscreen do not fit into either category and need to be defined.

NOTE: I have recently submitted a formal request to NICNAS requesting NICNAS Advisory Board review of above points.

LABELLING OF COSMETICS WITH SECONDARY SUNSCREENS

2. Labelling requirements in the Cosmetic Act 2007 and ACCC Guidelines do not adequately cover cosmetics with secondary sunscreens.
 - a. I suggest the option of listing active ingredients; consumers have an interest in this. (I have confirmed with TGA OTC Sunscreens and NICNAS that this would not make the product therapeutic by presentation.) To accommodate this for cosmetic clients I list the actives, and then re-list in descending order (to meet NICNAS and ACCC regulations) providing an asteric (*) link so that it is evident the ingredient has been shown twice.

- b. There is not clear enough instruction of what IS allowed and what IS NOT allowed on labels. I had to make a lot of phone calls to both TGA and NICNAS to establish the correct parameters for a cosmetic with Secondary Sunscreen. The NICNAS Cosmetic Act (2007) needs to state:

ONLY THE FOLLOWING (related to sunscreen properties) MAY BE ON THE LABEL

- SPF factor
- SPF Category description (as per section 6.2 of AS/NZS 2604:1998.
- Active ingredients (optional)
- NO therapeutic claims (such as prevention of skin cancer). NO therapeutic instructions for use (such as re-apply after swimming, towelling or perspiration) may be on the label of cosmetic with secondary sunscreen.

INCONSISTENCY – a moisturiser offering broad spectrum protection may make representations in connection with the product in regards to premature skin aging (refer Cosmetic Standard 2007 Section 2.2(b); HOWEVER a foundation offering broad spectrum protection may NOT?

The Cosmetic Act 2007 needs to be more consistent OR state why this is not applicable to foundation products with secondary sunscreens.

REFERENCE DOCUMENT ISSUES

3. AS/NZS 2604:1998 is outdated.
 - a. It still refers to TGO 48, which was superseded by TGO 69 years ago.
 - b. AS/NZS 2604:1998 refers again to secondary sunscreens at section 8.2 but neither the Australian standard nor the Cosmetic Act 2007 SPECIFIES that this section is NOT applicable to cosmetics with secondary sunscreens. The labelling requirements if followed in Section 8.2 would make the cosmetic product therapeutic by representation as they request TGO 48 (one assumes TGO 69 now?) a requirement. However my phone calls to TGA OTC Sunscreen expert [REDACTED] indicated this level of labelling was not required for cosmetics with secondary sunscreen and was in fact to be avoided so that the product would not represent as 'therapeutic' by presentation.
4. Please state in ARGOM order of review of documents as when so many documents interface one may contradict another.

The following documents need to be referred to currently to do a full regulatory review on a cosmetic with secondary sunscreen:

- a. NICNAS Cosmetic Act 2007
- b. ACCC Cosmetics & toiletries – ingredient labelling
- c. NICNAS – AICS registry
- d. SUSPD – confirm no scheduled substances
- e. ACCC – Country of origin
- f. TGA ARGOM – confirm good is excluded
- g. AS/NZS 2604:1998 Sunscreen products – Evaluation and classification

ARGOM DRAFT GENERAL OTHER POINTS

5. Suggest separate section for Excluded cosmetic sunscreens under x.3.1 Exempt Sunscreens.

COSMETICS WITH SECONDARY SUNSCREENS OTHER POINTS

6. Cosmetic Standard 2007 or AS/NS 2608:1998 should state that SPF might be affected via formulation changes [as ARGOM draft does (page 14)] and encourage (or insist on) SPF re-test.
 7. ARGOM Draft states at X.10 Sun screening agents permitted as active ingredients (in listed therapeutics). Nothing in current regulation(s) would make this a requirement for cosmetic sunscreen actives? Was this the intent?
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