



Australian Government

Department of Health and Ageing
Therapeutic Goods Administration

Australian regulatory guidelines for prescription medicines

Appendix 22: Colourings permitted in medicines for oral use

June 2004

TGA Health Safety
Regulation



About the Therapeutic Goods Administration (TGA)

- The TGA is a division of the Australian Government Department of Health and Ageing, and is responsible for regulating medicines and medical devices.
- TGA administers the Therapeutic Goods Act 1989 (the Act), applying a risk management approach designed to ensure therapeutic goods supplied in Australia meet acceptable standards of quality, safety and efficacy (performance), when necessary.
- The work of the TGA is based on applying scientific and clinical expertise to decision-making, to ensure that the benefits to consumers outweigh any risks associated with the use of medicines and medical devices.
- The TGA relies on the public, healthcare professionals and industry to report problems with medicines or medical devices. TGA investigates reports received by it to determine any necessary regulatory action.
- To report a problem with a medicine or medical device, please see the information on the TGA website.

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Appendix 22: Colourings permitted in medicines for oral use

Colouring agents which may be used in orally administered medicines, without the requirement for sponsors to submit an application for evaluation by the Therapeutic Goods Administration (TGA), are listed on the TGA website¹.

Sponsors wishing to use new colours (that is, colours not included in the above list) in orally administered prescription medicines must lodge an application for evaluation by the Drug Safety and Evaluation Branch (DSEB). The requirements for this type of applications are detailed on the TGA website¹.

¹ <http://www.tga.gov.au/meds/colourings.pdf>

Historical document

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Reference/Publication #