Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Colourings Permitted in Medicines for Oral Use

Version 1.2, May 2011

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.
- The 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. The 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.

Version history

Version	Description of change	Author	Effective date
V1.0	Initial publication	OCM	16/06/04
V1.1	Addition of D&C Red27	OCM	04/12/09
V1.2	Transferred to new template Updated links to external websites	OPSS OCM	04/05/11

Colourings permitted in medicines for oral use

The colouring agents detailed in the list below may be used in orally administered (prescription, over-the-counter and complementary) medicines, without the requirement for sponsors to submit an application for evaluation by the TGA.

Equivalents of the colours detailed below (such as the aluminium and calcium lakes (salts) of these substances) are also considered acceptable and do not require further evaluation. The synthetic equivalents must be manufactured from colours that comply with the specifications indicated below.

In the absence of a British Pharmacopoeia (BP) monograph, colours shall conform to either the specifications in the Food and Agriculture Organization (FAO) / World Health Organization (WHO) *Compendium of Food Additive Specifications*, as published by the Joint FAO / WHO Expert Committee on Food Additives (JECFA) on its website[1] or those defined in the European Commission Directive 95/45/EC[2] (specific purity criteria concerning colours for use in foodstuffs).

Where there is a BP monograph, the colour must comply with the BP specifications (unless otherwise justified[3]).

Australian Approved Name (AAN)	JECFA[1] name (if different)	CI[4] Number	INS[5] Number
Allura Red AC		16035	129
Amaranth		16185	123
Annatto	Annatto Extracts (Oil and Alkali-extracted) Annatto Extracts (Solvent-extracted)	75120	160b
Anthocyanins	Grape Skin Extract	-	163(ii)
Beet Red		-	162

[1] http://www.fao.org/docrep/009/a0691e/a0691e00.htm
[2] http://ec.europa.eu/food/fs/sfp/addit_flavor/flav13_en.pdf
[3] Sponsors attempting to justify non-compliance with a prescribed standard (e.g. BP) should apply to the TGA in writing, seeking an exemption under section 14 of the *Therapeutic Goods Act 1989*. Section 14 Exemption requests should explain why the standard cannot be met and detail what alternative is proposed and why. The delegate of the Secretary will review the request and sponsors will be advised in writing of the delegate's decision.
[4] CI is the code used in the Colour Index Volumes (for more information see http://www.colour-index.org/)
[5] International Numbering System for food additives. The INS has been prepared by the Codex Alimentarius Commission, Codex Committee on Food Additives and Contaminants, for the purpose of providing an agreed international numerical system for identifying food additives in ingredient lists. The INS will largely use 'E numbers (numerical designations developed within the European Community for declaration of foodstuff additives), but without the "E".

Australian Approved Name (AAN)	JECFA[1] name (if different)	CI[4] Number	INS[5] Number
Betacarotene		40800	160a(i)
Brilliant Black BN	Brilliant Black PN	28440	151
Brilliant Blue FCF		42090	133
Brilliant Scarlet 4R	Ponceau 4R	16255	124
Canthaxanthin		40850	161
Caramel	**Caramel Colours** Class I: Plain Caramel, caustic caramel Class II: Caustic sulfite caramel Class III: Ammonia caramel Class IV: Sulfite ammonia caramel	- 	 150a 150b 150c 150d
Carbon black	Vegetable carbon	77266	153
Carmoisine	Azorubine	14720	122
Carotenes	Carotenes (Algae) Carotenes (Vegetable)	75130	160a(ii)
Chlorophylls		75810	140
Chlorophyllins - Copper Complexes Sodium and Potassium Salts (previous AAN Chlorophyllin -Copper Complex)		75810	141(ii)
Chlorophylls - Copper Complexes		75810	141(i)
Chocolate Brown HT	Brown HT	20285	155
Cochineal		75470	120
Curcumin		75300	100(i)

Australian Approved Name (AAN)	JECFA[1] name (if different)	CI[4] Number	INS[5] Number
Erythrosine		45430	127
Fast green FCF		42053	143
Food Orange 6	Beta-apo-8'-carotenal	40820	160e
Food Orange 7	Beta-apo-8'-carotenoic Acid Ethyl Ether	40825	160f
Green S		44090	142
Indigo Carmine	Indigotine	73015	132
Iron Oxide Black		77499	172(i)
Iron Oxide Red		77491	172(ii)
Iron Oxide Yellow		77492	172(iii)
Patent Blue V		42051	131
Phloxine B[6]	(none allocated – see footnote)	45410	-
Quinoline Yellow		47005	104
Riboflavin		-	101(i)
Saffron		75100	-
Sunset Yellow FCF		15985	110
Red 27		45410	-
Titanium Dioxide		77891	171

A BP monograph exists for this colour. Compliance is required with BP specification.

[6] Because of the absence of a European specification, Phloxine B must comply with the specifications detailed in the United States Code of Federal Regulations (Volume 21) for D&C Red 28 – Part (b) of Section 74.1328

Indicative data requirements for new colours

Sponsors wishing to use new colours (that is, those not included in the previous table) in orally administered medicinal products must lodge an application for evaluation by the TGA. The requirements for applications of this type are detailed below.

All applications

A complete and unambiguous identification of the colour must be provided. This should include the chemical name, common names by which the chemical is known or identified in the technical literature, names under which the colour has been or will be marketed (including trade names), the Colour Index (CI) Number, International Number System (INS) number and the Chemical Abstract Service (CAS) Number.

Application for evaluation of a colour where Food Standards Australia New Zealand (FSANZ) has made an evaluation

Quality data (consistent with the Common Technical Document[7] (CTD) requirements for Module 3) should include:

- evidence as to the standard approved by FSANZ
- details of the test methods used during quality control of each batch and the limits for results
- evidence as to compliance with the standard approved FSANZ (e.g. at least two sample certificates of analysis).

Non-clinical data (consistent with the CTD requirements for Module 4) should include:

- FSANZ reports
- report of all toxicology studies completed after the FSANZ evaluation that are relevant to the assessment of the chemical.

Clinical data (consistent with the CTD requirements for Module 5) should include reports of all human studies (if any) completed after the FSANZ evaluation that are relevant to the assessment of the chemical.

Application for assessment of a colour for which an FSANZ evaluation is not available

Quality data should include:

- for colours included in EU Commission Directive 95/45/EC, evidence of compliance with the directive (e.g. at least two sample certificates of analysis)[8];
- for other new colours, quality data requirements as outlined in 2.2.2 of the EU Guideline - Excipients in the Dossier for Application for Marketing Authorisation of a Medical Product (3AQ9a)[9].

Non-clinical data should fulfil the following requirements.

- The toxicology and pharmacology of an excipient used for the first time in a therapeutic good should be investigated as if it were a new active substance.

[7] http://www.tga.gov.au/industry/pm-ctd.htm
[8] http://ec.europa.eu/food/fs/sfp/addit_flavor/flav13_en.pdf
[9] http://www.tga.gov.au/pdf/euguide/vol3a/3aq9aen.pdf [replaced in May 2010 by EMEA/CHMP/QWP/396951/2006]

- There may be extensive toxicological data based on other uses (for example, veterinary, agricultural and industrial chemicals). There also may be animal toxicological and human safety data arising from use as a food or food additive. Such data may be used to support the use of a new colour in a therapeutic good.

Clinical data should include reports of all clinical human studies of the colour.

Therapeutic Goods Administration

PO Box 100 Woden ACT 2606 Australia
Email: info@tga.gov.au Phone: 02 6232 8444 Fax: 02 6232 8605
www.tga.gov.au

Reference/Publication #