Food and Agriculture Organization of the United Nations

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82nd JECFA - Chemical and Technical Assessment (CTA), 2016

ALLURA RED AC

Chemical and Technical Assessment (CTA)

Prepared by Julie N. Barrows, Ph.D., and Reviewed by Harriet Wallin, Ph.D.

1. Summary

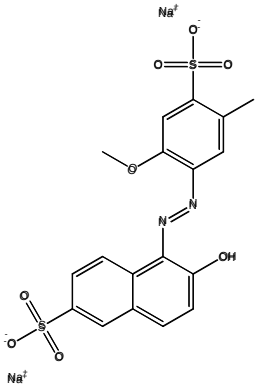
This Chemical and Technical Assessment summarizes data and information on Allura Red AC (INS No. 129), a synthetic colouring agent that belongs to the class of monoazo dyes. It is allowed as a food colour in the EU, Japan, USA, and other regions. The safety, dietary intake, and specifications for Allura Red AC were re-evaluated at the 82nd meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA).

2. Description

Allura Red AC is a synthetic colouring agent that belongs to the class of monoazo dyes. The dye was developed for use as a food colour by Allied Chemical Corporation, which trademarked the name Allura Red AC (Marmion, 1971).

Allura Red AC consists of disodium 6-hydroxy-5-[(2-methoxy-5-methyl-4-sulfophenyl)azo]-2-naphthalenesulfonate (Figure 1) and subsidiary colouring matters together with sodium chloride and/or sodium sulfate as the principal uncoloured components. The calcium and potassium salts are also permitted (EC, 2008). The disodium salt is certifiable by the USA as FD&C Red No. 40 (CFR, 2016).

Structure of the primary dye component of Allura Red AC



3. Manufacturing process

Allura Red AC is manufactured by coupling diazotized 5-amino-4-methoxy-2-toluenesulphonic acid (also called 4-amino-5-methoxy-2-methylbenzenesulfonic acid or *p*-cresidine sulfonic acid, *p*-CSA) with 6-hydroxy-2-naphthalene sulphonic acid (the sodium salt is called Shaeffer's salt) (HSDB, 2006). The resulting dye is purified and isolated as the sodium salt.

Allura Red AC may be converted to the corresponding aluminium lake under aqueous conditions by reacting aluminium oxide with the colouring matter. Undried aluminium oxide is usually freshly prepared by reacting aluminium sulfate or aluminium chloride with sodium carbonate or sodium bicarbonate, or aqueous ammonia. Following lake formation, the product is filtered, washed with water, and dried (JECFA, 2004).

4. Chemical characterization

Chemical and technical information for Allura Red AC, including information provided to JECFA by the International Association of Color Manufacturers (IACM, 2016), is summarized in Table 1.

Table 1. Chemical and technical information for Allura Red AC.

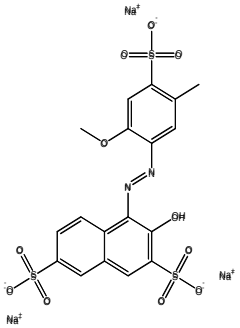
Molecular formula	$C_{18}H_{14}N_2Na_2O_8S_2$
Formula weight	496.43
CAS Registry Number	25956-17-6
Chemical name	Disodium 6-hydroxy-5-[(2-methoxy-5-methyl-4-sulfophenyl)azo]-2-naphthalenesulfonate
Synonyms	Allura Red, Allura Red AC, INS No. 129, CI Food Red 17, CI 16035 (Colour Index, 1975), Food Red No. 40, E 129, certified by USA as FD&C Red No. 40
Assay	Not less than 85% total colouring matters
Description	Dark red powder or granules
Functional uses	Colour
Solubility	Freely soluble in water and slightly soluble in 50% ethanol

Specifications for Allura Red AC have been established by JECFA (JECFA, 2006), EU (Commission Directive 2008/128/EC) (EC, 2008), and Japan Ministry of Health, Labour and Welfare (Japan, 2007) and for FD&C Red No. 40 by US FDA (CFR, 2016). The specifications are summarized in Table 2.

The purity of Allura Red AC is specified as not less than 85% of total colouring matters, calculated as the disodium salt, and not more than 15% total amount of volatile matter (loss on drying at 135 ^{o}C), sodium chloride, and sodium sulfate. Specified impurities include uncombined intermediates and reaction by-products originating from the manufacturing process.

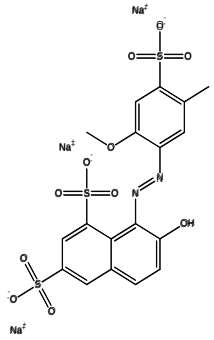
Subsidiary colouring matters include the following higher and lower subsidiary colours as their sodium salts.

- 3-Hydroxy-4-[(2-methoxy-5-methyl-4-sulfophenyl)azo]-2,7-naphthalenedisulfonic acid, trisodium salt, which is diazotized *p*-cresidine sulfonic acid (*p*-CSA) coupled with disodium salt of 3-hydroxy-2,7-naphthalenedisulfonic acid (R Salt) (Marmion, 1971; Bell, 1976):



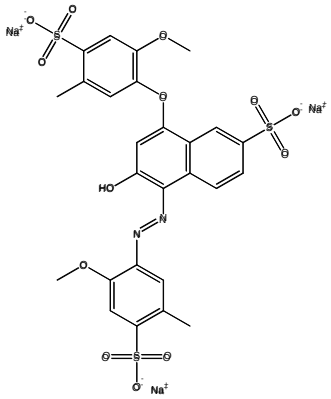
p-CSA + R Salt

- 7-Hydroxy-8-[(2-methoxy-5-methyl-4-sulfophenyl)azo]-1,3-naphthalenedisulfonic acid, trisodium salt, which is diazotized p cresidine sulfonic acid (p-CSA) coupled with disodium salt of 3-hydroxy-5,7-naphthalenedisulfonic acid (G Salt) (Marmion, 1971; Bell, 1976):



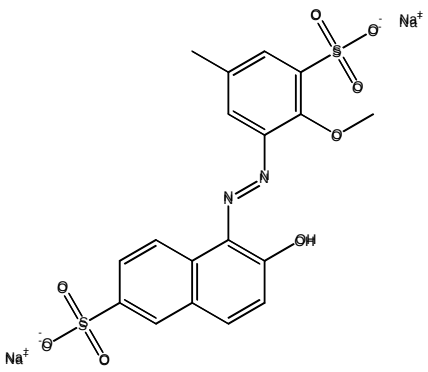
p-CSA + G Salt

- SC-NTR ("subsidiary colour – non-toxic red"), originally predicted as (6-hydroxy-5-[(2-methoxy-5-methyl-4-sulfophenyl)azo]-8-(2-methoxy-5-methyl-4-sulfophenoxy)-2-naphthalenesulfonic acid, disodium salt (Marmion, 1971):



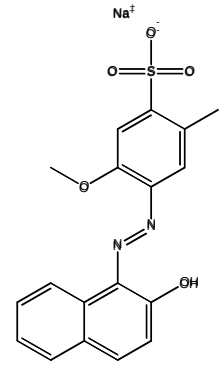
SC-NTR (Marmion, 1971)

- SC-NTR was subsequently shown to be an isomer of Allura Red AC (Takeda, 1994):



SC-NTR (Takeda, 1994)

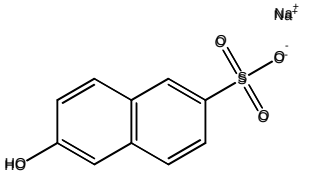
- Lower sulfonated subsidiary colours as their sodium salts, including diazotized *p*-CSA coupled with 2-naphthol (2N) (Marmion, 1971; Bell, 1976):



p-CSA + 2N

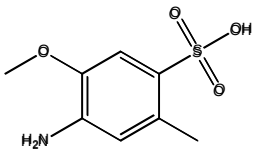
Organic compounds other than colouring matters include the following impurities:

- 6-Hydroxy-2-naphthalenesulfonic acid, sodium salt (Shaeffer's salt)



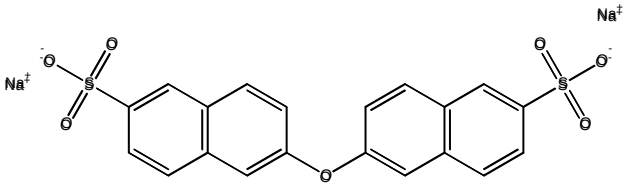
Shaeffer's salt

- 4-Amino-5-methoxy-2-methylbenzenesulfonic acid (*p*-cresidine sulfonic acid, *p*-CSA)



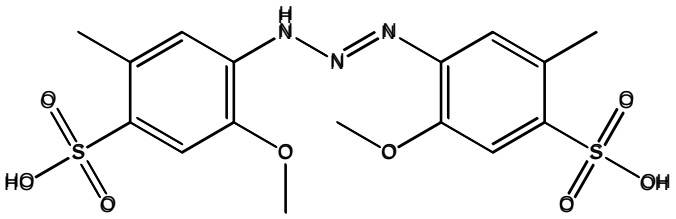
p-CSA

- 6,6-Oxybis(2-naphthalenesulfonic acid) disodium salt (DONS)



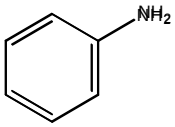
DONS

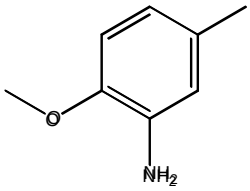
- Good manufacturing practice impurity in FD&C Red No. 40: 4,4'-(Diazoamino)bis[5-methoxy-2-methylbenzenesulfonic acid], disodium salt (DMMA) (Bailey and Cox, 1976; Richfield-Fratz, 1984

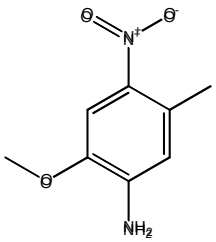


DMMA

Primary aromatic amines include the following (Richfield-Fratz et al., 1989; Richfield-Fratz and Bailey, 1987; Lancaster and Lawrence, 1991):

- Aniline 

- *p*-Cresidine 

- 4-Nitro-*p*-cresidine 

5. Functional use

Allura Red AC is allowed as a food colour in the EU, Japan, Australia, USA, and other regions. It is used in various types of foods including beverages, frozen treats, powder mixes, gelatin products, candies, icings, jellies, spices, dressings, sauces, baked goods, and dairy products (Petigara Harp et al., 2013; Doell et al., 2016).

6. Reactions and fate in foods

Allura Red AC is not light or air sensitive and is chemically stable when used in foods.

7. References

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Richfield-Fratz and Bailey (1987) Richfield-Fratz, N., and Bailey, J. E., "Determination of p-cresidine in FD&C Red No. 40 by the diazotization and coupling procedure followed by reversed-phase high-performance liquid chromatography," Journal of Chromatography, vol. 405, pp. 283-294, 1987.

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Table 2. Specifications for Allura Red AC.

Purity	**JECFA**	**Commission Directive 2008/128/EC**	**Japan**	**USA**
Assay Identification of colouring matters (Vol. 4)	Not less than 85% total colouring matters Passes test	Not less than 85% total colouring matters -	The equivalent of not less than 85% dye component	Total color, not less than 85.0 percent -
Loss on drying (Vol. 4) - Volatile matter - Salts	Not more than 15% at 135 °C together with chloride and sulfate calculated as sodium salts	-	Not more than 10.0% loss on drying Not more than 5.0% total chloride and sulfate	Sum of volatile matter (at 135 °C) and chlorides and sulfates (calculated as sodium salts), not more than 14.0 percent
Water-insoluble matter (Vol. 4)	Not more than 0.2%	≤ 0.2 %	Not more than 0.20%	Not more than 0.2%
Subsidiary colouring matters (Vol. 4)	Not more than 3.0% - - -	≤ 3.0 % - - -	- Lower sulfonated subsidiary colours, not more than 1.0% - Higher sulfonated subsidiary colours, not more than 1.0%	- Lower sulfonated subsidiary colours (as sodium salts), not more than 1.0% - Higher sulfonated subsidiary colours (as sodium salts), not more than 1.0% - 6-Hydroxy-5-[(2-methoxy-5-methyl-4-sulfophenyl) azo] -8-(2-methoxy-5-methyl-4-sulfophenoxy)-2-naphthalenesulfonic acid, disodium salt (SC-NTR),not more than 1.0% *(may actually be an isomer)*
Organic compounds other than colouring matters (Vol. 4) - 6-Hydroxy-2-naphthalene sulfonic acid, sodium salt (Shaeffer's salt) - 4-Amino-5-methoxy-2-methylbenzene sulfonic acid (cresidine sulfonic acid) - 6,6-Oxybis(2-naphthalene sulfonic acid) disodium salt	 Not more than 0.3% Not more than 0.2% Not more than 1.0% -	 ≤ 0.3 % ≤ 0.2 % ≤ 1.0 % -	 Not more than 0.3% Not more than 0.2% Not more than 1.0% -	 Not more than 0.3% Not more than 0.2% Not more than 1.0% - 4,4'-(Diazoamino)bis[5-methoxy-2-methylbenzenesulfonic acid], disodium salt (DMMA), not more than 0.1% *(GMP specification)*
Unsulfonated primary aromatic amines (Vol. 4)	Not more than 0.01% calculated as aniline	≤ 0.01 % (calculated as aniline)	- Not more than 0.01% as aniline - Not more than 10 µg/g as *p*-cresidine	-
Ether extractable matter (Vol.4)	Not more than 0.2%	≤ 0.2 % (from a solution of pH 7)	-	-
Heavy metals (Vol. 4) - Lead - Arsenic - Mercury - Cadmium - Heavy metals (as Pb)	 Not more than 2 mg/kg - - - -	 ≤ 10 mg/kg Pb ≤ 3 mg/kg As ≤ 1 mg/kg Hg ≤ 1 mg/kg Cd ≤ 40 mg/kg as Pb	 Not more than 10 µg/g Pb Not more than 4.0 µg/g as As_2O_3 Not more than 20 µg/g as Pb	 Not more than 10 ppm Pb Not more than 3 ppm As Not more than 1 ppm Hg *(GMP specification)*