



Food and Agriculture Organization
of the United Nations

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

Chemical and Technical Assessment (CTA)

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1. Summary

This Chemical and Technical Assessment summarizes data and information on Tartrazine (INS No. 102), 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 Tartrazine were re-evaluated at the 82nd meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA).

2. Description

Tartrazine is a synthetic colouring agent that belongs to the class of monoazo pyrazolone dyes. The dye consists of trisodium 4,5-dihydro-5-oxo-1-(4-sulfophenyl)-4-[(4-sulfophenyl)azo]-1H-pyrazole-3-carboxylate (Figure 1) and subsidiary colouring matters together with sodium chloride and/or sodium sulfate as the principal uncoloured components. The calcium and potassium salts of Tartrazine are also permitted (EC, 2008). The trisodium salt is certifiable by the USA as FD&C Yellow No. 5 (CFR, 2016).

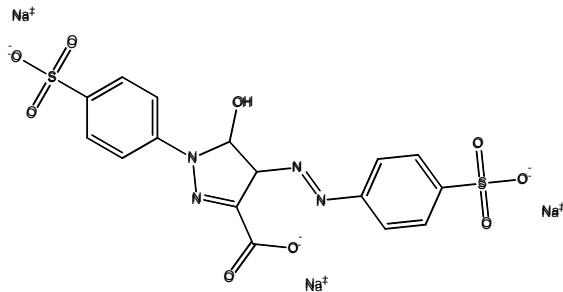
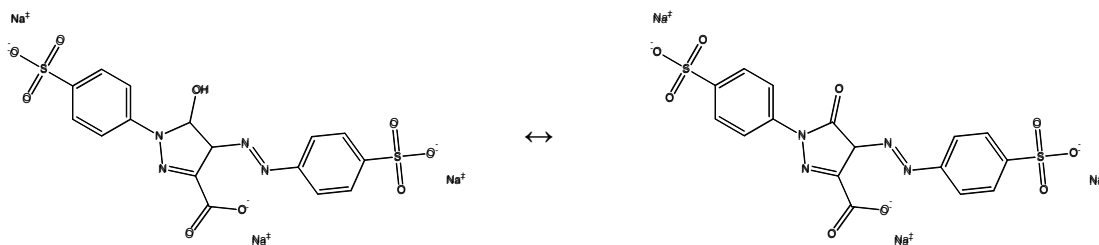


Figure 1. Structure of the primary dye component of Tartrazine.

Tartrazine is classified as an azo dye and both of the following structures, which show its acid-base equilibrium, are used to represent the dye.



¹⁵N NMR chemical shift data for the dye anion indicate the existence of azo-hydrazone, acid-base equilibria and suggest that the dye anion is present in the hydrazone form at pH 7 and the azo form at pH 12 (Bell et al., 1989).

3. Manufacturing

Tartrazine is manufactured by coupling diazotized 4-aminobenzenesulfonic acid (sulfanilic acid, SA) with 5-oxo-1-(4-sulfophenyl)-2-pyrazoline-3-carboxylic acid (Pyrazolone T, PyT) or with the methyl ester, the ethyl ester, or a salt of this carboxylic acid (HSDB, 2006; CFR, 2016). The resulting dye is purified and isolated as the sodium salt.

Tartrazine also may be manufactured by condensing phenylhydrazine-4-sulfonic acid (PHSA, also called phenylhydrazine-p-sulfonic acid or 4-hydrazinobenzenesulfonic acid) with dioxosuccinic acid or oxalacetic acid derivatives (Colour Index, 1924; Weisz, 2014). USA had a specification for PHSA of not more than 0.2% until 1986 (CFR, 1986), when the current identity and specifications were established (FDA, 1986; CFR, 2016). JECFA currently has specifications for 4-hydrazinobenzenesulfonic acid (i.e., PHSA) and tetrahydroxysuccinic acid, which is hydrated dioxosuccinic acid.

Tartrazine 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 Tartrazine, 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 Tartrazine.

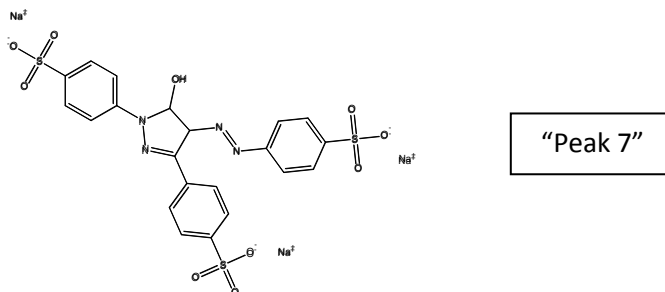
Molecular formula	C ₁₆ H ₉ N ₄ Na ₃ O ₉ S ₂
Formula weight	534.37
CAS Registry Number	25956-17-6
Chemical name	Trisodium 4,5-dihydro-5-oxo-1-(4-sulfophenyl)-4-[(4-sulfophenyl)azo]-1 <i>H</i> -pyrazole-3-carboxylate
Synonyms	Tartrazine, INS No. 102, CI Food Yellow 4, CI 19140 (Colour Index, 1971), E102, certified by USA as FD&C Yellow No. 5
Assay	Tartrazine: not less than 85% total colouring matters; FD&C Yellow No. 5: not less than 87% total color
Description	Light orange powder or granules
Functional uses	Colour
Solubility	Soluble in water; sparingly soluble in ethanol

Specifications for Tartrazine have been defined by JECFA (JECFA, 2006), the EU legislation (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.

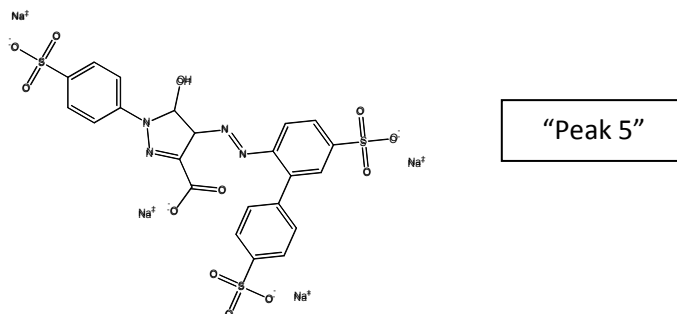
The purity of Tartrazine is specified as not less than 85% of total colouring matters, calculated as the trisodium salt, and not more than 15% total amount of volatile matter (loss on drying at 135 °C), sodium chloride, and sodium sulfate. Specified impurities include uncombined intermediates and reaction by-products originating from the manufacturing process. (The purity of FD&C Yellow No. 5 is specified as not less than 87% total color, calculated as the sodium salt.)

Subsidiary colouring matters include the following compounds.

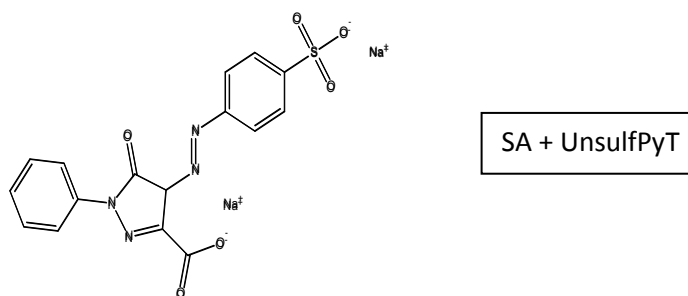
- 4,4'-[4,5-Dihydro-5-oxo-4-[(4-sulfophenyl)hydrazono]-1*H*-pyrazol-1,3-diyl]bis[benzenesulfonic acid], trisodium salt ("Peak 7," Weisz et al., 2014)



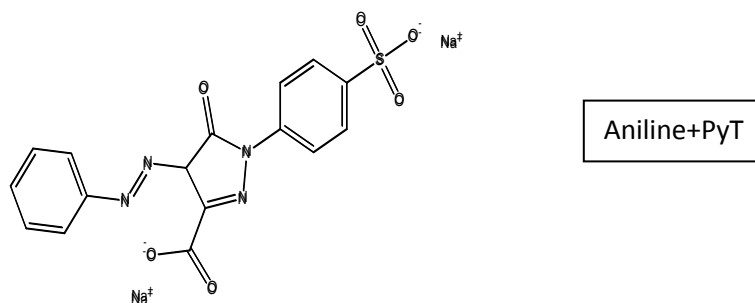
- 4-[(4',5'-Disulfo[1,1'-biphenyl]-2-yl)hydrazono]-4,5-dihydro-5-oxo-1-(4-sulfophenyl)-1H-pyrazole-3-carboxylic acid, tetrasodium salt ("Peak 5," Weisz et al., 2014)



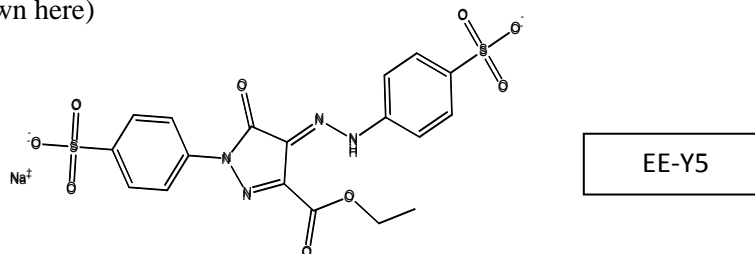
- 4,5-Dihydro-5-oxo-1-phenyl-4-[(4-sulfophenyl)azo]-1H-pyrazole-3-carboxylic acid, disodium salt, which is diazotized aminobenzenesulfonic acid (sulfonilic acid, SA) coupled with unsulfonated pyrazolone T (SA+UnsulPyT, also called SC-3 for "subsidiary color-3")



- 4,5-Dihydro-5-oxo-4-(phenylazo)-1-(4-sulfophenyl)-1H-pyrazole-3-carboxylic acid, disodium salt, which is diazotized aniline coupled with pyrazolone T (Aniline+PyT, also called SC-4 for "subsidiary color-4")

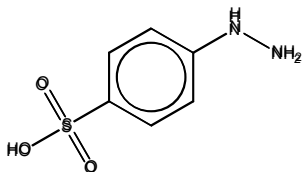


- Ethyl or methyl 4,5-dihydro-5-oxo-1-(4-sulfophenyl)-4-[(4-sulfophenyl)hydrazono]-1H-pyrazole-3-carboxylate, disodium salt (ethyl or methyl ester of FD&C Yellow No. 5 anion, EE-Y5 or ME-Y5) (the ethyl ester is shown here)



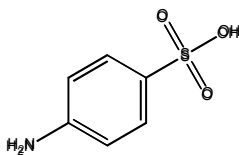
Organic compounds other than colouring matters include the following impurities:

- 4-Hydrazinobenzenesulfonic acid (diazotized sulfanilic acid)



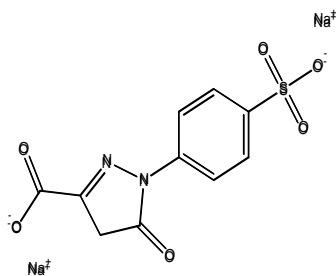
diazotized SA

- 4-Aminobenzenesulfonic acid (sulfanilic acid, SA)



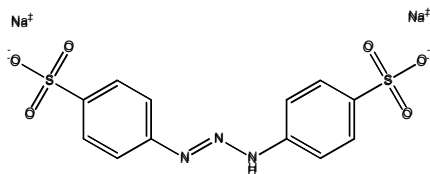
SA

- 5-oxo-1-(4-sulfophenyl)-2-pyrazoline-3-carboxylic acid, disodium salt (Pyrazolone T disodium salt, PyT-Na₂) (acid form also called 4,5-dihydro-5-oxo-1-(4-sulfophenyl)-1H-pyrazole-3-carboxylic acid)



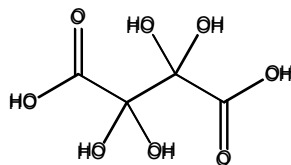
PyT-sodium salt

- 4,4'-(1-Triazene-1,3-diyl)bis[benzenesulfonic acid], disodium salt (disodium salt of 4,4'-diazoaminodibenzenesulfonic acid, DAADBSA)



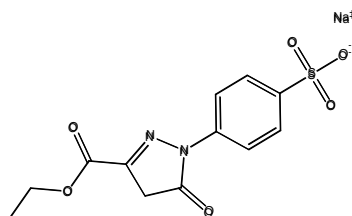
DAADBSA-sodium salt

- Tetrahydroxysuccinic acid (hydrated dioxosuccinic acid)



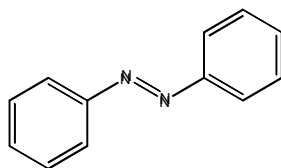
hydrated dioxosuccinic acid

- Ethyl or methyl 4,5-dihydro-5-oxo-1-(4-sulfophenyl)-1*H*-pyrazole-3-carboxylate, sodium salt (ethyl or methyl ester of Pyrazolone T, EE-PyT or ME-PyT) (ethyl ester is shown here)



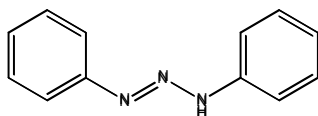
EE-PyT-sodium salt

- Azobenzene (AZB)



AZB

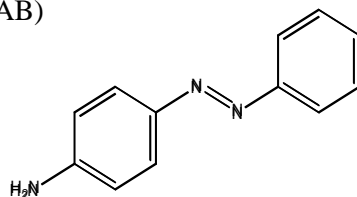
- 1,3-Diphenyltriazene (DPT)



DPT

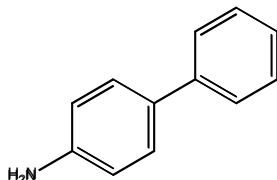
Primary aromatic amines include the following (Bailey and Bailey, 1985; Richfield-Fratz et al., 1985; FDA, 1986):

- 4-Aminoazobenzene (AAB)



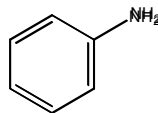
AAB

- 4-Aminobiphenyl (ABP)



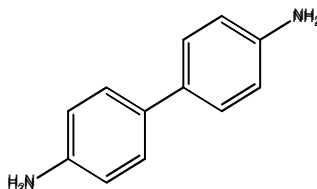
ABP

- Aniline (ANI)



ANI

- Benzidine (BNZ)



BNZ

5. Functional use

Tartrazine 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

Tartrazine is not light or air sensitive and is chemically stable when used in foods.

7. References

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Coupling Procedure Followed by Reversed-Phase High-Performance Liquid Chromatography,” *Journal of Chromatography*, vol. 331, pp. 109-123, 1985.

Weisz et al. (2014) Adrian Weisz, Clark D. Ridge, Jose A. Roque, Eugene P. Mazzola, and Yoichiro Ito, “Preparative Separation of Two Subsidiary Colors of FD&C Yellow No. 5 (Tartrazine) using Spiral High-Speed Counter-Current Chromatography,” *Journal of Chromatography A*, vol. 1343, pp. 91-100, 2014.

Table 2. Specifications for Tartrazine.

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 87.0 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 6.0% total chloride and sulfate	Sum of volatile matter (at 135 °C.) and chlorides and sulfates (calculated as sodium salts), not more than 13.0 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 1% - - -	≤ 1.0 % - - -	- Lower sulfonated subsidiary colours, not more than 1.0% - Higher sulfonated subsidiary colours, not more than 1.0%	- 4,4'-[4,5-Dihydro-5-oxo-4-[(4-sulfophenyl)hydrazono]-1H-pyrazol-1,3-diy]bis[benzene-sulfonic acid], trisodium salt, not more than 1.0% - 4-[[4',5-Disulfo[1,1'-biphenyl]-2-yl)hydrazono]-4,5-dihydro-5-oxo-1-(4-sulfophenyl)-1H-pyrazole-3-carboxylic acid, tetrasodium salt, not more than 1.0% - Ethyl or methyl 4,5-dihydro-5-oxo-1-(4-sulfophenyl)-4-[(4-sulfophenyl)hydrazono]-1H-pyrazole-3-carboxylate, disodium salt, not more than 1% - Sum of 4,5-dihydro-5-oxo-1-phenyl-4-[(4-sulfophenyl)azo]-1H-pyrazole-3-carboxylic acid, disodium salt, and 4,5-dihydro-5-oxo-4-(phenylazo)-1-(4-sulfophenyl)-1H-pyrazole-3-carboxylic acid, disodium salt, not more than 0.5 percent
Organic compounds other than colouring matters (Vol. 4)	Not more than 0.5% sum of: - 4-Hydrazinobenzenesulfonic acid - 4-Aminobenzenesulfonic acid - 5-Oxo-1-(4-sulfophenyl)-2-pyrazoline-3-carboxylic acid - 4,4'-Diazoaminodi-(benzenesulfonic acid) - Tetrahydroxysuccinic acid	≤ 0.5 % sum of: - 4-Hydrazinobenzenesulfonic acid - 4-Aminobenzenesulfonic acid - 5-Oxo-1-(4-sulfophenyl)-2-pyrazoline-3-carboxylic acid - 4,4'-Diazoaminodi-(benzenesulfonic acid) - Tetrahydroxysuccinic acid	Not more than 0.5% as the total of: 4-Aminobenzenesulfonic acid, 5-Hydroxy-1-(4-sulfophenyl)-3-pyrazolecarboxylic acid, 4-Hydrazinobenzenesulfonic acid, and Disodium 4,4'-(diazoamino)dibenzene-sulfonate -	- 4-Aminobenzenesulfonic acid, sodium salt, not more than 0.2% - 4,5-Dihydro-5-oxo-1-(4-sulfophenyl)-1H-pyrazole-3-carboxylic acid, disodium salt, not more than 0.2% - 4,4'-(1-triazene-1,3-diy]bis[benzenesulfonic acid], disodium salt, not more than 0.05% - Ethyl or methyl 4,5-dihydro-5-oxo-1-(4-sulfophenyl)-1H-pyrazole-3-carboxylate, sodium salt, not more than 0.1% - 4-Aminoazobenzene, not more than 75 ppb - 1,3-Diphenyltriazene, not more than 40 ppb
Unulfonated primary aromatic amines (Vol. 4)	Not more than 0.01% calculated as aniline	≤ 0.01 % (calc as aniline)	- Not more than 0.01% as aniline - Not more than 10 µg/g as <i>p</i> -cresidine	- 4-Aminobiphenyl, not more than 5 ppb - Aniline, not more than 100 ppb - Azobenzene, not more than 40 ppb - Benzidine, not more than 1 ppb
Ether extractable matter (Vol. 4)	Not more than 0.2%	≤ 0.2 % (under neutral conditions)	-	-
Heavy metals (Vol. 4) - Lead - Arsenic - Mercury - Cadmium - Heavy metals (as Pb)	Not more than 2 mg/kg - - - -	≤ 10 mg/kg ≤ 3 mg/kg ≤ 1 mg/kg ≤ 1 mg/kg ≤ 40 mg/kg	Not more than 20 µg/g Pb Not more than 4.0 µg/g as As ₂ O ₃ Not more than 20 µg/g as Pb	Not more than 10 ppm Not more than 3 ppm Not more than 1 ppm - -