

Color Additive Analysis

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Executive Summary

The U.S. Food and Drug Administration (FDA) and the U.S. Department of Health and Human Services recently announced the elimination of six petroleum-based synthetic dyes — Red 40, Yellow 5, Yellow 6, Blue 1, Blue 2, and Green 3 from the nation’s food supply chain by the end of 2026 [1].

Analysis of more than 441,000 branded food products included in the Global Branded Food Products Database (GBFPD) ¹ [2] published by the U.S. Department of Agriculture (USDA) provides estimates of the prevalence of these dyes. The GBFPD is processed using Large Language Model (LLM)-based pipeline to allow search for the presence of ingredients and additives, as well as nutritional values.

1 Red 40

Red 40 (common name Allura Red AC) is a synthetic red azo dye officially listed in the U.S. as FD&C Red No.40 and labeled as E129 in Europe. Red 40 is widely used as a color additive in beverages, candies, baked products, chewing gum, etc.

Health Impact. Multiple studies in the past several decades asserted that Red 40 may cause hyperactivity issues for children [3], as well as having toxicity and carcinogenic effects [4] [5] [6]. A well-known UK clinical trial published in *The Lancet* [3] found that a mix of food colorings (including Red 40, Yellow 5 and Yellow 6) increased hyperactive behavior in children. In a 2001 animal study [4], the authors reported colon DNA damage in mice at a low dose of Red 40 intake. Recently, a study [5] shows that Red 40 causes DNA damage in vitro and in vivo in mice, supporting the hypothesis that it disrupts key biological processes involved in early-onset colorectal cancer (EOCRC). Another recent animal study published in *Nature Communications* [6] also found that chronic Red 40 exposure exacerbates colitis in mice.

Regulatory Status. While Red 40 was banned in several Western and Northern Europe countries [7] prior to the 2008 harmonization of food additive approvals [8], currently, no countries or regions strictly prohibit the use of Red 40 as a food additive [EU, UK, Canada, China, Israel, Australia, New Zealand, Japan and Singapore investigated] [9] [10] [11] [12] [13] [14] [15] [16]. In 2009, the European Food Safety Authority (EFSA) re-evaluated Red 40 as a food additive, but chose to continue using the Acceptable Daily Intake (ADI) of 7 mg/kg body weight per day, citing a lack of sufficient evidence in the studies suggesting its potential carcinogenic and behavioral impacts [17]. EU did, however, require that all foods sold in the region containing Red 40 (as well as Yellow 5 and Yellow 6) must display a warning label stating ‘*[Name or E number of the colour]: may have an adverse effect on activity and attention in children*’ [18]. This requirement is still in effect today.

Prevalence. Red 40 appears in **37,771** unique branded foods in the GBFPD dataset, which equates to **8.6%** of the 441,466 foods. The table below presents the nine major categories of branded foods within which Red 40 appears in more than 20% of products (prevalence $\geq 20\%$) registered in the dataset. The categories are arranged in descending order based on the number of branded foods listing Red 40 among their ingredients.

Table 1: Percentage of Branded Foods Containing **Red 40** by categories

Category	with Red 40	Total Branded Foods	Percentage (%)
Candy	13,168	22,728	57.9
Cakes, Cupcakes, Snack Cakes	2,608	9,389	27.8
Baking Decorations & Dessert Toppings	1,691	4,114	41.1
Soda	1,690	7,940	21.3
Powdered Drinks	991	4,280	23.2
Croissants, Sweet Rolls, Muffins & Other Pastries	575	2,805	20.5
Chewing Gum & Mints	544	1,672	32.5
Gelatin, Gels, Pectins & Desserts	506	885	57.2
Liquid Water Enhancer	318	774	41.1

¹The Global Branded Food Products Database (GBFPD), published by the U.S. Department of Agriculture (USDA), contains the ingredient list and nutrition label information of approximately 441,000 branded sold in the U.S. The product information in the GBFPD is voluntarily submitted by food industry organizations and manufacturers, while the USDA and its partner institutions reformat and standardize the data.

2 Yellow 5

Yellow 5 (common name Tartrazine) is a synthetic lemon-yellow azo dye officially listed in the U.S. as FD&C Yellow No.5 and labeled as E102 in Europe. Yellow 5 is widely used as color additive in candies, baked products, desserts, etc.

Health Impact. Past studies suggest a potential link between Yellow 5 and allergic reactions [19], hyperactivity in children [3] [20], and potential genotoxicity (damage to DNA that may lead to mutations and possibly cancer) [21]. Less than 0.12% of the general population are estimated to be intolerant to Yellow 5. However, the risk of allergic reactions to tartrazine is much higher among individuals with asthma, allergies, and sensitivity to acetylsalicylic acid (aspirin) [19]. Yellow 5 was also linked with hyperactivity in sensitive children in the 2007 UK study [3] mentioned above. More recently, after reviewing related past studies and clinical trials, California Office of Environmental Health Hazard Assessment (OEHHA) also concluded that Yellow 5 may contribute to adverse neurobehavioral effects including inattentiveness and hyperactivity in sensitive children [20]. The famous 2002 animal study by a Japanese research team [21] reported DNA damage in gastrointestinal organs of mice after moderate Yellow 5 intake. The authors thus suggested regulatory bodies to re-assess the use of dyes as food additives.

Regulatory Status. Currently, no countries or regions strictly prohibit the use of Yellow 5 as food additives. However, decades ago, it was banned in several European countries, including Norway and Finland [22]. In the 2009 re-evaluation, the EFSA continued to permit E102 (Yellow 5) as a food additive with unchanged ADI of 7.5 mg/kg bw/day after finding lack of genotoxicity evidence in the concurrent studies [23]. Similar to Red 40, a warning "*may have an adverse effect on activity and attention in children*", has also been required for foods containing Yellow 5 sold in the EU [18]. In 2012, Canadian regulations also began to require that 'Tartrazine' (Yellow 5) be explicitly named on labels (rather than just "color") because of its potential to cause allergic reactions [24].

Prevalence. Yellow 5 appears in **34,170** unique branded foods in the GBFPD dataset, with an overall prevalence of **7.7%**. The table below presents the six major branded food categories within which Yellow 5 has a prevalence higher than 20%. The categories are arranged in descending order based on the number of branded foods listing Yellow 5 among their ingredients.

Table 2: Percentage of Branded Foods Containing **Yellow 5** by categories

Category	with Yellow 5	Total Branded Foods	Percentage (%)
Candy	10,857	22,728	47.8
Cakes, Cupcakes, Snack Cakes	2,429	9,389	25.9
Baking Decorations & Dessert Toppings	1,550	4,114	37.7
Puddings & Custards	552	1,240	44.5
Chewing Gum & Mints	474	1,672	28.3
Gelatin, Gels, Pectins & Desserts	277	885	31.3

3 Yellow 6

Yellow 6 (common name Sunset Yellow FCF), is a synthetic yellow azo dye officially listed in the U.S. as FD&C Yellow No.6 and labeled as E110 in Europe. Yellow 6 is commonly found in soft drinks, candies, gelatins and baked goods.

Health Impact. Toxicological concerns about Yellow 6 have surfaced for decades, as several studies have reported developmental toxicity, oxidative stress, DNA damage and allergic reactions [25]. Zebrafish model studies [26] [27] suggested a possible link between Yellow 6 consumption and several birth defects. Other animal studies [28] [29] reported liver and kidney damage, increased apoptosis (a type of cell death), and inflammation after high-dose exposure, while genotoxic effects were also observed in human lymphocytes exposed to Yellow 6 [30]. In terms of allergies, Yellow 6 is tolerated by most people, but on occasion it has been implicated in severe hypersensitivity [31]. As comparison, FDA has not mandated special labeling for Yellow 6 in drugs (unlike Yellow 5) [32], reflecting its lower incidence of reactions.

Regulatory Status. While Yellow 6 remains approved in all major markets (it was previously banned in Norway), its regulatory status has been under increasing scrutiny. In 2009, the EFSA temporarily lowered the Acceptable Daily Intake (ADI) of Yellow 6 to 1 mg/kg bw/day, following concerns about reproductive and developmental toxicity [33]. However, based on new data and alignment with the Joint FAO/WHO Expert Committee on Food Additives (JECFA)'s 2011 evaluation, the EFSA increased the ADI in 2014 to 4 mg/kg bw/day [34]. Nevertheless, the EU still mandates labeling on foods containing E110 (Yellow 6), requiring the warning, "*may have an adverse effect on activity and attention in children*", the same requirement that applies to Red 40 and Yellow 5 under Regulation (EC) No 1333/2008 [18].

Prevalence. Yellow 6 appears in **25,034** unique branded foods in the GBFPD dataset, with an overall prevalence of **5.7%**. The table below presents the five major branded food categories within which Yellow 6 has a prevalence higher than 20%. The categories are arranged in descending order based on the number of branded foods listing Yellow 6 among their ingredients.

Table 3: Percentage of Branded Foods Containing **Yellow 6** by categories

Category	with Yellow 6	Total Branded Foods	Percentage (%)
Candy	7,595	22,728	33.4
Cakes, Cupcakes, Snack Cakes	1,886	9,389	20.1
Baking Decorations & Dessert Toppings	985	4,114	23.9
Puddings & Custards	419	1,240	33.8
Gelatin, Gels, Pectins & Desserts	256	885	28.9

4 Blue 1

Blue 1 (common name Brilliant Blue FCF), is a blue synthetic triarylmethane dye officially listed in the U.S. as FD&C Blue No.1, and labeled as E133 in Europe. Blue 1 is widely used as a color additive in candies, baked goods, beverages, desserts, etc.

Health Impact. A small number of studies suggest the potential risk of cytotoxicity (cell damage) and genotoxicity [35] [36], however, much less evidence exists on possible health impacts of Blue 1, especially at moderate doses, compared to Red 40, Yellow 5 or Yellow 6.

Regulatory Status. Toxicological evaluations by EFSA and JECFA established an ADI of 6 mg/kg bw/day [37] [38] based on a No-observed-adverse-effect level (NOAEL) of 631 mg/kg in chronic rat studies, applying an uncertainty factor of 100. At dietary exposure levels, Blue 1 is poorly absorbed and there is limited evidence linking it to hyperactivity or adverse behavioral effects [39] — so no jurisdiction requires special warning labels for E133 (Blue 1) in EU. All major markets currently still allow the use of Blue 1 as a food additive.

Prevalence. Blue 1 appears in **29,587** unique branded foods in the GBFPD dataset, with an overall prevalence of **6.7%**. The table below presents the six major branded food categories within which Blue 1 has a prevalence higher than 20%. The categories are arranged in descending order based on the number of branded foods listing Blue 1 among their ingredients.

Table 4: Percentage of Branded Foods Containing **Blue 1** by categories

Category	with Blue 1	Total Branded Foods	Percentage (%)
Candy	11,389	22,728	50.1
Baking Decorations & Dessert Toppings	1,484	4,114	36.1
Chewing Gum & Mints	656	1,672	39.2
Gelatin, Gels, Pectins & Desserts	413	885	46.7
Liquid Water Enhancer	195	774	25.2
Sport Drinks	161	750	21.5

5 Blue 2

Blue 2 (common name Indigo carmine), is a dark blue synthetic dye officially listed in the U.S. as FD&C Blue No.2 and labeled as E132 in Europe. Blue 2 is widely used as a color additive in candies, baked goods, desserts, etc.

Health Impact. Toxicological evaluations of Blue 2 have consistently found little risk of health impacts because the dye is poorly absorbed [40]. Long term animal studies also reported no evidence of toxicity at tested doses [41]. Blue 2 is not capable of inducing genetic mutations [42], and not classified as carcinogenic by the International Agency for Research on Cancer (IARC) [43]. Similar to Blue 1, there is limited evidence linking Blue 2 to hyperactivity or adverse behavioral effects [39]. However, several recent in vitro studies suggest that Blue 2 is capable of penetrating human fibroblast cells (important for wound healing and tissue repair) and demonstrating toxic effects [44] [45].

Regulatory Status. Blue 2 remains approved by EFSA and JECFA, with an ADI of 5 mg/kg bw/day [46] [42]. No major market in the world currently prohibit the use of Blue 2 as a color additive and EU does not require a special warning label for E132 (Blue 2) either.

Prevalence. Blue 2 appears in **6,729** unique branded foods in the GBFPD dataset, with an overall prevalence of **1.5%**. The table below presents the seven major branded food categories within which Blue 2 has a prevalence higher than 5%. The categories are arranged in descending order based on the number of branded foods listing Blue 2 among their ingredients.

6 Green 3

Green 3, with the common name Fast Green FCF, is a green synthetic dye officially listed in the U.S. as FD&C Green No.3.

Table 5: Percentage of Branded Foods Containing **Blue 2** by categories

Category	with Blue 2	Total Branded Foods	Percentage (%)
Candy	2,323	22,728	10.2
Cookies & Biscuits	1,046	13,297	7.9
Cakes, Cupcakes, Snack Cakes	534	9,389	5.7
Baking Decorations & Dessert Toppings	275	4,114	6.7
Chewing Gum & Mints	87	1,672	5.2
Frozen Pancakes, Waffles, French Toast & Crepes	73	926	7.9
Sweet Bakery Products	32	570	5.6

Health Impact. JECFA concluded that Green 3 has low toxicity and is not carcinogenic or genotoxic in its 2017 food additive re-evaluation report [47].

Regulatory Status. Multiple regions and countries prohibit the use of Green 3 as food additive, including EU, UK and China. Instead, Green S (E142) — another green synthetic dye is usually served as alternative to Green 3 in these countries and regions.

Prevalence. Green 3 only appears in **195** unique branded foods in the GBFPD dataset, with an overall prevalence of **0.04%**.

7 Summary

There are **54,780** unique branded foods in the GBFPD dataset containing at least one of the six above additives, with an overall prevalence of **12.4%**. The table below presents the major branded food categories within which synthetic dyes have a prevalence higher than 20%. The categories are arranged in descending order based on the number of branded foods listing at least one of the six petroleum-based color additives among their ingredients.

Table 6: Percentage of Branded Foods Containing **any of the six color additives** by categories

Category	with color additive	Total Branded Foods	Percentage (%)
Candy	15,380	22,728	67.7
Cakes, Cupcakes, Snack Cakes	3,650	9,389	38.9
Cookies & Biscuits	3,160	13,297	23.8
Soda	2,586	7,940	32.6
Baking Decorations & Dessert Toppings	2,329	4,144	56.6
Powdered Drinks	1,292	4,280	30.2
Chewing Gum & Mints	1,032	1,672	61.7
Gelatin, Gels, Pectins & Desserts	770	885	87.0
Croissants, Sweet Rolls, Muffins & Other Pastries	744	2,805	26.5
Cake, Cookie & Cupcake Mixes	699	3,406	20.5
Puddings & Custards	607	1,240	49.0
Liquid Water Enhancer	440	774	56.8
Sport Drinks	341	750	45.5

References

- [1] U.S. Department of Health and Human Services and U.S. Food and Drug Administration. Hhs, fda to phase out petroleum-based synthetic dyes in nation’s food supply. <https://www.fda.gov/news-events/press-announcements/hhs-fda-phase-out-petroleum-based-synthetic-dyes-nations-food-supply>, April 2025.
- [2] U.S. Department of Agriculture (USDA), Agricultural Research Service. Fooddata central: Usda global branded food products database. <https://fdc.nal.usda.gov>, 2024. Version Current: April 2024.
- [3] Donna McCann, Angelina Barrett, Alison Cooper, Debbie Crumpler, Lindy Dalen, Kate Grimshaw, Elizabeth Kitchin, Kris Lok, Lucy Porteous, Emily Prince, Edmund Sonuga-Barke, John O Warner, and Jim Stevenson. Food additives and hyperactive behaviour in 3-year-old and 8/9-year-old children in the community: a randomised, double-blinded, placebo-controlled trial. *The Lancet*, 370(9598):1560–1567, November 2007.
- [4] Shuji Tsuda, Masako Murakami, Nobuaki Matsusaka, Koji Kano, Katsuyuki Taniguchi, and Yu Fumio Sasaki. Dna damage induced by red food dyes orally administered to pregnant and male mice. *Toxicological Sciences*, 61(1):92–99, 2001.

- [5] Qi Zhang, Alexander A. Chumanevich, Ivy Nguyen, Anastasiya A. Chumanevich, Nora Sartawi, Jake Hogan, Minou Khazan, Quinn Harris, Bryson Massey, Ioulia Chatzistamou, Phillip J. Buckhaults, Carolyn E. Banister, Michael Wirth, James R. Hebert, E. Angela Murphy, and Lorne J. Hofseth. The synthetic food dye, red 40, causes dna damage, causes colonic inflammation, and impacts the microbiome in mice. *Toxicology Reports*, 11:221–232, December 2023.
- [6] Yun Han Kwon, Suhrid Banskota, Huaqing Wang, Laura Rossi, Jensine A. Grondin, Saad A. Syed, Yeganeh Yousefi, Jonathan D. Schertzer, Katherine M. Morrison, Michael G. Wade, Alison C. Holloway, Michael G. Surette, Gregory R. Steinberg, and Waliul I. Khan. Chronic exposure to synthetic food colorant Allura Red AC promotes susceptibility to experimental colitis via intestinal serotonin in mice. *Nature Communications*, 13(1):7617, December 2022.
- [7] Sajjad Esmaeili, Mohammad Reza Ashrafi-Kooshk, Koestan Khaledian, Hadi Adibi, Shohre Rouhani, and Reza Khodarahmi. Degradation products of the artificial azo dye, Allura red, inhibit esterase activity of carbonic anhydrase II: A basic in vitro study on the food safety of the colorant in terms of enzyme inhibition. *Food Chemistry*, 213:494–504, December 2016.
- [8] Regulation (ec) no 1331/2008 of the european parliament and of the council of 16 december 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings, 2008.
- [9] European Commission. Food additives database. <https://ec.europa.eu/food/food-feed-portal/screen/food-additives/search>, 2025.
- [10] Food Standards Agency, Government of the United Kingdom. Approved additives and e numbers. <https://www.food.gov.uk/business-guidance/approved-additives-and-e-numbers>, 2025.
- [11] Health Canada, Government of Canada. List of permitted food colours (lists of permitted food additives). <https://www.canada.ca/en/health-canada/services/food-nutrition/food-safety/food-additives/lists-permitted/3-colouring-agents.html>, 2024.
- [12] National Health Commission and State Administration for Market Regulation, People’s Republic of China. National food safety standard—standard for uses of food additives (gb 2760-2024), 2024.
- [13] Ministry of Health, state of Israel. List of permitted food additives in israel, 2024.
- [14] Food Standards Australia New Zealand. Food standards code legislation — compilation of australia new zealand food standards and schedules, March 2025.
- [15] Japan Food Chemical Research Foundation. List of designated additives, 2024.
- [16] Singapore Food Agency. Food additives permitted under the singapore food regulations, 2024.
- [17] EFSA Panel on Food Additives and Nutrient Sources Added to Food (ANS). Scientific opinion on the re-evaluation of allura red ac (e 129) as a food additive. *EFSA Journal*, 7(11):1327, 2009.
- [18] Regulation (ec) no 1333/2008 of the european parliament and of the council of 16 december 2008 on food additives, 2008.
- [19] Food, drug, and cosmetic dyes. In J.K. Aronson, editor, *Meyler’s Side Effects of Drugs (Sixteenth Edition)*, pages 433–436. Elsevier, Oxford, sixteenth edition edition, 2016.
- [20] Office of Environmental Health Hazard Assessment (OEHHA). Health effects assessment: Potential neurobehavioral effects of synthetic food dyes in children. Technical report, California Environmental Protection Agency, April 2021. Children’s Environmental Health Center.
- [21] Yu F Sasaki, Satomi Kawaguchi, Asako Kamaya, Miyuki Ohshita, Kazumi Kabasawa, Kayoko Iwama, Kazuyuki Taniguchi, and Shuji Tsuda. The comet assay with 8 mouse organs: results with 39 currently used food additives. *Mutation Research/Genetic Toxicology and Environmental Mutagenesis*, 519(1–2):103–119, August 2002.
- [22] James Meikle. The colour of a curry may make it look better – but is it good for you? *The Guardian*, March 2004.
- [23] EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS). Scientific opinion on the re-evaluation tartrazine (e 102). *EFSA Journal*, 7(11):1327, 2009.
- [24] Food colours in beverages, condiments, soups, pickled vegetables, dried spices and mixes, and oils – april 1, 2014 to march 31, 2015. Technical report, Canadian Food Inspection Agency, 2019. Food chemistry – Targeted surveys – Final report.
- [25] Petra Amchova, Frantisek Siska, and Jana Ruda-Kucerova. Food safety and health concerns of synthetic food colors: An update. *Toxics*, 12(7):466, 2024.
- [26] Ling-Ling Jiang, Kang Li, Dong-Lin Yan, Mi-Fang Yang, Lan Ma, and Li-Zhe Xie. Toxicity assessment of 4 azo dyes in zebrafish embryos. *International Journal of Toxicology*, 39(2):115–123, January 2020.

- [27] Vani Joshi and Katti Pancharatna. Food colorant sunset yellow (e110) intervenes developmental profile of zebrafish (danio rerio). *Journal of Applied Toxicology*, 39(4):571–581, November 2018.
- [28] Xiunan Kong, Xiu Wang, Yumei Qin, and Jianzhong Han. Effects of sunset yellow on proliferation and differentiation of intestinal epithelial cells in murine intestinal organoids. *Journal of Applied Toxicology*, 41(6):953–963, October 2020.
- [29] Latifa I. Khayyat, Amina E. Essawy, Jehan M. Sorour, and Ahmed Soffar. Sunset yellow and allura red modulate bcl2 and cox2 expression levels and confer oxidative stress-mediated renal and hepatic toxicity in male rats. *PeerJ*, 6:e5689, September 2018.
- [30] Anja Haverić, Sanin Haverić, Maida Hadžić, Naida Lojo-Kadrić, and Slavka Ibrulj. Genotoxicity and cytotoxicity analysis of curcumin and sunset yellow in human lymphocyte culture. *Cellular and Molecular Biology*, 64(3):87–91, February 2018.
- [31] EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA). Scientific opinion on the appropriateness of the food azo-colours tartrazine (e 102), sunset yellow fcf (e 110), carmoisine (e 122), amaranth (e 123), ponceau 4r (e 124), allura red ac (e 129), brilliant black bn (e 151), brown fk (e 154), brown ht (e 155) and litholrubine bk (e 180) for inclusion in the list of food ingredients set up in annex iii a of directive 2000/13/ec. *EFSA Journal*, 8(10):1778, 2010.
- [32] 21 cfr § 201.20 - declaration of presence of fd&c yellow no. 5 and/or fd&c yellow no. 6 in certain drugs for human use. <https://www.ecfr.gov/current/title-21/chapter-I/subchapter-C/part-201/subpart-A/section-201.20>.
- [33] EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS). Scientific opinion on the re-evaluation of sunset yellow fcf (e 110) as a food additive. *EFSA Journal*, 7(11):1330, 2009.
- [34] EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS). Scientific opinion on the reconsideration of the temporary adi and refined exposure assessment for sunset yellow fcf (e 110). *EFSA Journal*, 12(7):3765, 2014.
- [35] Elena Bonciu, Mirela Paraschivu, Nicoleta Anca Şuţan, and Aurel Liviu Olaru. Cytotoxicity of sunset yellow and brilliant blue food dyes in a plant test system. *Caryologia*, 75(2):143–149, 2022.
- [36] Dilek Pandir. Dna damage in human germ cell exposed to the some food additives in vitro. *Cytotechnology*, 68(4):725–733, December 2014.
- [37] EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS). Scientific opinion on the re-evaluation of brilliant blue fcf (e 133) as a food additive. *EFSA Journal*, 8(11):1853, 2010.
- [38] International Association of Color Manufacturers. Brilliant blue fcf (fdc blue no. 1) – color profile, 2025. Accessed: 2025-05-06.
- [39] Rachel M Rambler, Erica Rinehart, Wendy Boehmler, Prerna Gait, Joan Moore, Melissa Schlenker, and Rahul Kashyap. A review of the association of blue food coloring with attention deficit hyperactivity disorder symptoms in children. *Cureus*, September 2022.
- [40] Petra Amchova, Hana Kotolova, and Jana Ruda-Kucerova. Health safety issues of synthetic food colorants. *Regulatory Toxicology and Pharmacology*, 73(3):914–922, December 2015.
- [41] J.F. Borzelleca, G.K. Hogan, and A. Koestner. Chronic toxicity/carcinogenicity study of fd amp; c blue no. 2 in rats. *Food and Chemical Toxicology*, 23(6):551–558, June 1985.
- [42] EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS). Scientific opinion on the re-evaluation of indigo carmine (e 132) as a food additive. *EFSA Journal*, 12(4):3768, 2014.
- [43] International Agency for Research on Cancer. List of classifications – iarc monographs on the identification of carcinogenic hazards to humans. <https://monographs.iarc.who.int/list-of-classifications/>, 2025.
- [44] Ardalan Pasdaran, Negar Azarpira, Reza Heidari, Simin Nourinejad, Maryam Zare, and Azadeh Hamed. Effects of some cosmetic dyes and pigments on the proliferation of human foreskin fibroblasts and cellular oxidative stress; potential cytotoxicity of chlorophyllin and indigo carmine on fibroblasts. *Journal of Cosmetic Dermatology*, 21(9):3979–3985, January 2022.
- [45] Patrícia Christina Genázio Pereira, Roberta Valoura Reimão, Thelma Pavesi, Enrico Mendes Saggiaro, Josino Costa Moreira, and Fábio Veríssimo Correia. Lethal and sub-lethal evaluation of indigo carmine dye and byproducts after tio2 photocatalysis in the immune system of eisenia andrei earthworms. *Ecotoxicology and Environmental Safety*, 143:275–282, September 2017.
- [46] EFSA Panel on Food Additives and Flavourings (FAF). Follow-up of the re-evaluation of indigo carmine (e 132) as a food additive. *EFSA Journal*, 21, July 2023.
- [47] World Health Organization. *Evaluation of Certain Food Additives: Eighty-fourth Report of the Joint FAO/WHO Expert Committee on Food Additives*. World Health Organization, Geneva, 2017.