Safety Assessment of Basic Blue 7 as Used in Cosmetics

Status:	Tentative Report for Public Comment
Last Panel Review:	March 13 - 14, 2025
Release Date:	March 21, 2025

*All interested persons are provided 60 days from the above release date (i.e., by, **May 20, 2025**) to comment on this safety assessment, and to identify additional published data that should be included or provide unpublished data which can be made public and included. Information may be submitted without identifying the source or the trade name of the cosmetic product containing the ingredient. All unpublished data submitted to CIR will be discussed in open meetings, will be available for review by any interested party and may be cited in a peer-reviewed scientific journal. Please submit data, comments, or requests to the CIR Executive Director, Dr. Bart Heldreth.*

The Expert Panel for Cosmetic Ingredient Safety members are: Chair, Wilma F. Bergfeld, M.D., F.A.C.P.; Donald V. Belsito, M.D.; David E. Cohen, M.D.; Samuel M. Cohen, M.D., Ph.D.; Curtis D. Klaassen, Ph.D.; Allan E. Rettie, Ph.D.; David Ross, Ph.D.; Paul W. Snyder, D.V.M., Ph.D.; and Susan C. Tilton, Ph.D. The Cosmetic Ingredient Review (CIR) Executive Director is Bart Heldreth, Ph.D., and the Senior Director is Monice Fiume, M.B.A. This safety assessment was prepared by Christina Burnett, M.S., Senior Scientific Analyst/Writer, CIR.

555 13th Street, NW, Suite 300W, Washington, DC 20004
cirinfo@cir-safety.org

ABBREVIATIONS

CIR	Cosmetic Ingredient Review
Council	Personal Care Products Council
CPSC	Consumer Product Safety Commission
Dictionary	web-based *International Cosmetic Ingredient Dictionary and Handbook* (wINCI)
FDA	Food and Drug Administration
FD&C Act	Food, Drug, and Cosmetic Act
MoCRA	Modernization of Cosmetics Regulation Act
Panel	Expert Panel for Cosmetic Ingredient Safety
PI	propidium iodide
RLD	Registration and Listing Data
SCCNFP	Scientific Committee on Cosmetic Products and Non-Food Products Intended for Consumers
US	United States
VCRP	Voluntary Cosmetic Registration Program

ABSTRACT

The Expert Panel for Cosmetic Ingredient Safety (Panel) assessed the safety of Basic Blue 7, which is reported to function as a hair colorant in cosmetic products. The Panel reviewed the available data to determine the safety of this ingredient. The Panel concluded that the available data are insufficient to make a determination of safety for Basic Blue 7 under the intended conditions of use as a hair dye ingredient.

INTRODUCTION

This assessment reviews the safety of Basic Blue 7 as used in cosmetic formulations. According to the web-based *International Cosmetic Ingredient Dictionary and Handbook* (*Dictionary*), this ingredient is reported to function as a hair colorant in cosmetic products.[1]

This safety assessment includes relevant published and unpublished data that are available for each endpoint that is evaluated. Published data are identified by conducting an extensive search of the world's literature; a search was last conducted January 2025. A listing of the search engines and websites that are used and the sources that are typically explored, as well as the endpoints that the Panel typically evaluates, is provided on the Cosmetic Ingredient Review (CIR) website (https://www.cir-safety.org/supplementaldoc/preliminary-search-engines-and-websites; https://www.cir-safety.org/supplementaldoc/cir-report-format-outline). Unpublished data are provided by the cosmetics industry, as well as by other interested parties.

CHEMISTRY

Definition and Structure

Basic Blue 7 (CAS No. 2390-60-5) is classed chemically as a triarylmethane color.[1] It conforms to the structure in Figure 1.

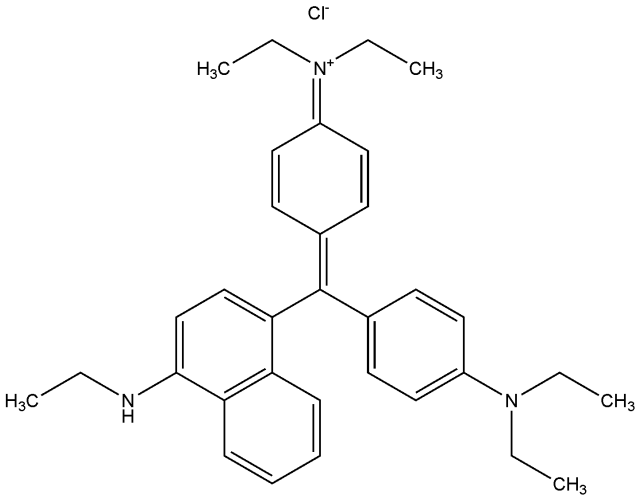

Figure 1. Basic Blue 7

Chemical Properties

Chemical properties for Basic Blue 7 are summarized in Table 1. Basic Blue 7 is a reddish-blue powder with a formula weight of 514.14 g/mol, and an estimated log K_{ow} of 4.06.[2-4]

Method of Manufacture

Triarylmethane dyes such as Basic Blue 7 may be manufactured via a multitude of synthetic methodologies; although, Friedel-Crafts is historically the most common method.[5] However, no method of manufacturing data specific to how cosmetic raw material manufacturers produce this ingredient were found in the published literature, and unpublished data were not submitted.

Impurities

Impurities data were not found in the published literature, and unpublished data were not submitted.

USE

Cosmetic

The safety of the cosmetic ingredient addressed in this assessment is evaluated based on data received from the US Food and Drug Administration (FDA) and the cosmetics industry on the expected use of Basic Blue 7 in cosmetics. Data included herein were obtained from the FDA and in response to a survey of maximum use concentrations conducted by the Personal Care Products Council (Council), and it is these values that define the present practices of use and concentration. Frequencies of use obtained from the FDA include data from the Voluntary Cosmetic Registration Program

(VCRP) database as well as Registration and Listing Data (RLD). As a result of the Modernization of Cosmetics Regulation Act (MoCRA) of 2022, the VCRP was discontinued in 2023 and, as of 2024, manufacturers and processors are required to register facilities and list their products (and ingredients therein) with the FDA (i.e., RLD). An exception is made for small businesses (average gross annual sales in the US of cosmetic products for the previous 3-year period is less than $1,000,000, adjusted for inflation), which are exempt from MoCRA reporting for most cosmetic product categories. Eye area products, injected products, internal use products, or products that alter appearance for more than 24 h, and the facilities that manufacture these products are not included in this exemption.[6] Please note, at this time, it is not appropriate to contrast data from the VCRP and RLD to determine a trend in frequency of use because there are numerous differences in the ways the data for the VCRP and the RLD were collected and processed, and because reporting frequency of use is now mandatory (as opposed to the past practice of voluntary reporting). Although the VCRP program is now defunct, trends in frequency of use from the RLD alone are not yet possible in that a baseline is currently not available.

According to RLD that CIR received in 2024, Basic Blue 7 is used in 11 formulations, which include non-coloring (1 use) and coloring hair preparations (10 uses; Table 2).[7] VCRP survey data received in 2023 reported Basic Blue 7 to be used in 1 nail polish and enamel product.[8] No uses of this ingredient were reported in response to the concentration of use survey submitted by the Personal Care Products Council in 2023.[9]

Some products containing Basic Blue 7 may be marketed for use with airbrush delivery systems. With the advent of MoCRA and the current product categories outlined by the FDA, it is now mandatory that cosmetic products used in airbrush delivery systems be reported as such for some, but not all, product categories in the RLD. In other words, a reliable source of frequency of use data regarding the use of cosmetic ingredients in conjunction with airbrush delivery systems is now available in some instances. None of the reported product categories for this ingredient as listed in the RLD include a designation using airbrush application, so it is possible that this ingredient is used with airbrush delivery systems, but not reported as such. Additionally, the Council currently surveys the cosmetic industry for maximum reported use concentrations of ingredients in products which may be used in conjunction with an airbrush delivery system; thus, this type of data may also be available, when submitted. Please note that no concentration of use data were provided indicating airbrush application. Nevertheless, no consumer habits and practices data or particle size data are publicly available to evaluate the exposure associated with this use type, thereby preempting the ability to evaluate risk or safety. Without information regarding the consumer habits and practices data or product particle size data (or other relevant particle data, e.g., diameter) related to this use technology, the data profile is incomplete, and the Panel is not able to determine safety for use in airbrush formulations. Accordingly, the data are insufficient to evaluate the exposure resulting from cosmetics applied via airbrush delivery systems.

This ingredient is considered a coal tar hair dye for which regulations require caution statements and instructions regarding patch tests in order to be exempt from certain adulteration and color additive provisions of the US Federal Food, Drug, and Cosmetic Act (FD&C Act). In order to be exempt, the following caution statement must be displayed on all coal tar hair dye products:

> Caution - this product contains ingredients which may cause skin irritation on certain individuals and a preliminary test according to accompanying directions should be made. This product must not be used for dyeing the eyelashes or eyebrows; to do so may cause blindness.

However, as of 2024, Basic Blue 7 is reported to be used in non-coloring hair preparations. Basic Blue 7 is exempt from certain adulteration and color additive provisions of the FD&C Act ***only*** when it is used as a coal tar hair dye ingredient. The FD&C Act mandates that color additives must be approved by FDA for their intended use before they are used. Basic Blue 7 is not an approved color additive in non-hair dye cosmetic products, and thereby, use in non-coloring hair products is not permitted.

Product labels shall also bear patch test instructions for determining whether the product causes skin irritation. However, whether or not patch testing prior to use is appropriate is not universally agreed upon. The Panel recommends that an open patch test be applied and evaluated by the beautician and/or consumer for sensitization 48 h after application of the test material and prior to the use of a hair dye formulation. Conversely, a report in Europe suggests that self-testing has severe limitations, and may even cause morbidity in consumers.[10,11] Hair dye products marketed and sold in the US, though, must follow the labeling requirements established by the FD&C Act.

Under European regulations for cosmetic ingredients, Basic Blue 7, when used as a substance in hair dye products, is **c**ategorized in Annex II, the list of substances prohibited in cosmetic products in Europe**.**[12] Historically, in 2000, the Scientific Committee on Cosmetic Products and Non-Food Products Intended for Consumers (SCCNFP) concluded that Basic Blue 7 can be used safely in hair tinting products at a maximum concentration of 0.2%.[13] It further stated that it could not be excluded that Basic Blue 7 is a contact allergen. No data accompanied the 2000 dossier and an update to this dossier could not be found.

Non-Cosmetic

Basic Blue 7 is commonly used to dye anionic substrates (e.g. wool, silk, cotton, leather, nylon, and acrylics).[2,14] It is also reported to be used as a stain in molecular biology and in stamping and flexographic printing inks.[2] Research has been

performed on its use in polymer films and optoelectronic applications.[2,14] The use of Basic Blue 7 as a photodynamic therapy for cancer treatment has also been studied.[15-19]

TOXICOKINETIC STUDIES

Toxicokinetics studies were not found in the published literature, and unpublished data were not submitted.

TOXICOLOGICAL STUDIES

Acute Toxicity Studies

Acute toxicity studies were not found in the published literature, and unpublished data were not submitted.

Short-Term, Subchronic, and Chronic Toxicity Studies

Short-term, subchronic, and chronic toxicity studies were not found in the published literature, and unpublished data were not submitted.

DEVELOPMENTAL AND REPRODUCTIVE TOXICITY STUDIES

Developmental and reproductive toxicity studies were not found in the published literature, and unpublished data were not submitted.

GENOTOXICITY STUDIES

Genotoxicity studies were not found in the published literature, and unpublished data were not submitted.

CARCINOGENICITY STUDIES

Carcinogenicity studies were not found in the published literature, and unpublished data were not submitted.

OTHER RELEVANT STUDIES

Cytotoxicity

Photodynamic induced cytotoxicity by Basic Blue 7 in 95% ethanol was studied using 2 human leukemic cell lines, K-52 and TF-1.[16] The cells were incubated with 1×10^{-8} to 1×10^{-6} M of the test material and irradiated with different doses of white light (530 - 650 nm). Cell survival was assessed by propidium iodide (PI) staining using flow cytometry analysis. A concentration of 5×10^{-8} M was found to kill 75% of cells, and a concentration of 1×10^{-7} M induced more than 99% of cell killing.

In a similar study, the photodynamic effect of Basic Blue 7 in 95% ethanol and photoirradiation was studied on normal peripheral blood mononuclear cells.[16] The cells were preincubated with 1×10^{-9} to 1×10^{-7} M of the test material followed by photoirradiation (550 - 650 nm for 0, 30, 60, or 120 min) and overnight culture. PI assay in flow cytometry was used to evaluate the cells. The highest percentage of dead cells were observed in the monocyte population. Lymphocytes had a lower sensitivity to the Basic Blue 7 photodynamic action than the monocytes (12% vs 80% of PI-positive cells). Further investigation evaluated the effects of Basic Blue 7 on phototreatment of lymphocyte function using a mitogen-induced proliferation assay. A decrease of mitogen response was observed. Leukemic cells from acute myeloid leukemia and B-cell precursor leukemia exhibited sensitivity to the photodynamic effects of Basic Blue 7.

DERMAL IRRITATION AND SENSITIZATION STUDIES

Dermal irritation and sensitization studies were not found in the published literature, and unpublished data were not submitted.

OCULAR IRRITATION STUDIES

Ocular irritation studies were not found in the published literature, and unpublished data were not submitted.

EPIDEMIOLOGICAL STUDIES

Hair dyes may be broadly grouped into oxidative (permanent) and direct (temporary or semi-permanent) dyes. The oxidative dyes consist of precursors mixed with developers to produce color, while direct hair dyes consist of preformed colors. Basic Blue 7 is reported to be used as a direct dye. While the safety of individual hair dye ingredients is not addressed in epidemiology studies that seek to determine links, if any, between hair dye use and disease, such studies do provide broad information. The Panel determined that the available hair dye epidemiology data do not provide sufficient evidence for a causal relationship between personal hair dye use and cancer. A detailed summary of the available hair dye epidemiology data is available at https://www.cir-safety.org/cir-findings.

SUMMARY

According to RLD that CIR received in 2024, Basic Blue 7 is used in 11 formulations, which include non-coloring (1 use) and coloring hair preparations (10 uses). VCRP survey data received in 2023 reported Basic Blue 7 to be used in 1 nail

polish and enamel product. No uses of this ingredient were reported in response to the concentration of use survey submitted by the Personal Care Products Council in 2023.

With regard to the reported use in non-coloring hair preparations, the US Federal FD&C Act mandates that color additives must be approved by FDA for their intended use before they are used. Basic Blue 7 is not an approved color additive in non-hair dye cosmetic products, and thereby, use in non-coloring hair products is not permitted. Under European regulations for cosmetic ingredients, Basic Blue 7, when used as a substance in hair dye products, is **c**ategorized in Annex II, the list of substances prohibited in cosmetic products in Europe**.**

The Panel determined that the available hair dye epidemiology data do not provide sufficient evidence for a causal relationship between personal hair dye use and cancer.

Impurities data, toxicokinetics studies, acute and repeated-dose toxicity studies, developmental and reproductive toxicity studies, genotoxicity studies, carcinogenicity studies, dermal irritation and sensitization studies, and ocular irritation studies on Basic Blue 7 were not found in a literature search, and unpublished data were not submitted.

DISCUSSION

This assessment reviews the safety of Basic Blue 7 as used in cosmetic formulations, in accordance with the product categories and concentrations of use identified in the Use section and Use table. The Panel concluded that the available data are insufficient for determining the safety of this ingredient under the intended conditions of use as a hair colorant. The Panel noted a lack of relevant safety data and determined that the data needs from the Insufficient Data Announcement issued following the September 2024 Panel meeting remain unmet. In order to come to a conclusion of safety for this hair dye ingredient, the following additional data are needed:

- Chemical properties data
- Method of manufacturing
- Composition/impurities data
- Concentration of use
- Dermal absorption data or 28-day dermal toxicity data
    - If absorbed, additional data, including developmental and reproductive toxicity data are needed
- Genotoxicity data

The Panel recognizes that hair dyes containing this ingredient, as coal tar hair dye products, are exempt from certain adulteration and color additive provisions of the Federal FD&C Act, when the label bears a caution statement and patch test instructions for determining whether the product causes skin irritation. The Panel expects that following this procedure will identify prospective individuals who would have an irritation/sensitization reaction and allow them to avoid significant exposures. The Panel considered concerns that such self-testing might induce sensitization, but agreed that there was not a sufficient basis for changing this advice to consumers at this time.

The Panel noted that Basic Blue 7 has been reported in non-coloring hair preparations. However, this ingredient is exempt from certain adulteration and color additive provisions of the FD&C Act ***only*** when it is used as a coal tar hair dye ingredient. Accordingly, because Basic Blue 7 is not an approved color additive in cosmetic products, use in non-coloring hair preparations is not permitted.

In considering hair dye epidemiology data, the Panel concluded that the available epidemiology studies are insufficient to scientifically support a causal relationship between hair dye use and cancer or other toxicological endpoints, based on lack of strength of the associations and inconsistency of findings. Use of direct hair dyes, while not the focus in all investigations, appears to have little evidence of any association with adverse events as reported in epidemiology studies.

As stated in the Use section, products containing this ingredient may be marketed for use with airbrush delivery systems. While it may be known in some (but not all) instances whether or not there is use in airbrush applications, information regarding the consumer habits and practices data, product particle size data, and/or other relevant particle data (e.g., diameter) related to this use technology are absent, and thus the data are insufficient to evaluate the exposure resulting from cosmetics applied via airbrush delivery systems.

CONCLUSION

The Expert Panel for Cosmetic Ingredient Safety concluded that the available data are insufficient to make a determination of safety for Basic Blue 7 under the intended conditions of use as a hair dye ingredient.

TABLES

Table 1. Chemical properties

Property	Value	Reference
Physical Form	Reddish-blue powder Blue liquid (solvated)	[2] [3]
Formula Weight (g/mol)	514.14	[2]
Density (g/ml @ 20 ºC)	1.05 - 1.2 (solvated)	[3]
Melting Point (ºC)	333.89 (MPBPVP v 1.43 estimated)	[4]
Boiling Point (ºC)	759.65 (MPBPVP v 1. 43 estimated)	[4]
Viscosity (kg/(m x s)@ 25 ºC)	< 0.1 (solvated)	[3]
Water Solubility	Slightly soluble in cold water; soluble in hot water, easily soluble in ethanol	[20]
log K_{ow}	4.06 (KOWWIN v 1.68 estimated)	[4]

Table 2. Frequency (RLD/VCRP) and concentration of use according to likely duration and exposure and by product category

	# of Uses		Max Conc of Use
	RLD (2024)[7]	VCRP (2023)[8]	% (2023)[9]
Totals*	**11**	**1**	**NR**
summarized by likely duration and exposure**			
Duration of Use			
Leave-On	***	*1*	*NR*
Rinse-Off	***	*NR*	*NR*
Diluted for (Bath) Use	***	*NR*	*NR*
Exposure Type			
Eye Area	***	NR	NR
Incidental Ingestion	***	NR	NR
Incidental Inhalation-Spray	***	NR	NR
Incidental Inhalation-Powder	***	NR	NR
Dermal Contact	***	NR	NR
Deodorant (underarm)	***	NR	NR
Hair - Non-Coloring	***	NR	NR
Hair-Coloring	***	NR	NR
Nail	***	1	NR
Mucous Membrane	***	NR	NR
Baby Products	***	NR	NR
as reported by product category			
Hair Preparations (non-coloring)	*1*		
Tonics, Dressings, and Other Hair Grooming Aids	1	NR	NR
Other Hair Preparations	1	NR	NR
Hair Coloring Preparations	*10*		
Hair Dyes and Colors (all types requiring caution statements and patch tests)	9	NR	NR
Hair Tints	1	NR	NR
Manicuring Preparations			
Nail Polishes and Enamels	NR	1	NR

NR – not reported

*The total FOU provided for RLD refers to the ingredient count supplied by FDA, and is not a summation of the number of uses per category because each product may be categorized under multiple ***product*** categories. For data supplied via the VCRP or by the Council survey, the sum of all exposure types may not equal the sum of total uses because each ingredient may be used in cosmetics with multiple ***exposure*** types.

**Likely duration and exposure are derived from VCRP and survey data based on product category (see Use Categorization https://www.cir-safety.org/cir-findings)

***In the RLD, each ingredient may be reported under several product categories, making a summation of RLD misleading in comparison to VCRP data. Accordingly, RLD are presented below by product category (as supplied by FDA), but are not summarized by likely duration and exposure.

REFERENCES

1. Nikitakis J, Kowcz A. 2025. Web-Based International Cosmetic Ingredient Dictionary and Handbook. https://incipedia.personalcarecouncil.org/ Last Updated: 2025. Date Accessed: January 20, 2025.
2. Hemalatha S, Rajagobalan B, Geethakrishnan T. Fabrication, characterization of Basic Blue 7 dye-doped PVA films and their third-order nonlinear optical properties. *J Fluoresc*. 2023;33(6):2295–2304.
3. Luoyang Taixue Dyes Co. L. 2024. Basic Blue 7. https://www.chinataixue.com/products/Basic_blue_7.html Last Updated: 2024. Date Accessed: August 7, 2024.
4. U.S. EPA. 2024. Estimation Programs Interface Suite™ for Microsoft® Windows, v 4.11. United States Environmental Protection Agency, Washington, DC, USA.
5. Kshatriya R, Jejurkar VP, Saha S. Advances in the catalytic synthesis of triarylmethanes (TRAMs). *Eur J Org Chem*. 2019;24:3818–3841.
6. U.S. Food and Drug Administration. Federal Food, Drug, and Cosmetic Act Section 612 Title 21.
7. U.S. Food and Drug Administration Office of the Chief Scientist. 2024. Registration and Listing Data - Frequency of Use of Cosmetic Products. College Park, MD [Obtained under the Freedom of Information Act from the Division of Freedom of Information, requested as "Frequency of Use Data" July 17, 2024; received July 30, 2024].
8. U.S. Food and Drug Administration Center for Food and Safety & Applied Nutrition. 2023. Voluntary Cosmetic Registration Program - Frequency of Use of Cosmetic Ingredients. College Park, MD [Obtained under the Freedom of Information Act from CFSAN; requested as "Frequency of Use Data" January 4, 2023; received February 2, 2023.].
9. Personal Care Products Council. 2023. Concentration of Use by FDA Product Category: Basic Blue 7. [Unpublished data submitted by the Personal Care Products Council on April 27, 2023].
10. Goossens A. Self-testing for contact sensitization to hair dyes. *Contact Dermatitis*. 2012;66(6):299.
11. Thyssen JP, Sosted H, Uter W, et al. Self-testing for contact sensitization to hair dyes - scientific considerations and clinical concerns of an industry-led screening programme. *Contact Dermatitis*. 2012;66(6):300.
12. EUR-Lex. 2024. Regulation (EC) No. 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (recast). (Test with EEA relevance). https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32009R1223&qid=1682529291932 Last Updated: 2024. Date Accessed: May 30, 2024.
13. Scientific Committee on Cosmetic Products and Non-Food Products Intended for Consumers, . 2000. Opinion Concerning Basic Blue 7 Colipa No. C46 Adopted By the SCCNFP During the 12th Plenary Meeting of 3 May 2000. http://ec.europa.eu/health/ph_risk/committees/sccp/docshtml/sccp_out118_en.htm Last Updated: 2000. Date Accessed: July 29, 2024.
14. Srinivasan Arunsankar N, Prabakaran A, Saravanan P, Vimalan M, Jeyaram S. Solvent media on nonlinear optical properties of triarylmethane dye via facile Z-scan method. *J Fluoresc*. 2023;Available online.
15. Fiedorowicz M, Galindo JR, Julliard M, Mannoni P, Chanon M. Efficient photodynamic action of Victoria Blue BO against the human leukemic cell lines K-562 and TF-1. *Photochem Photobiol*. 1993;58(3):356–361.
16. Fiedorowicz M, Pituch-Noworolska A, Zembala M. The photodynamic effect of Victoria Blue BO on peripheral blood mononuclear and leukemic cells. *Photochem Photobiol*. 1997;65(5):855–861.
17. Viola A, Lutz NW, Maroc C, Chabannon C, Julliard M, Cozzone PJ. Metabolic effects of photodynamically induced apoptosis in an erythroleukemic cell line. A 31P NMR spectroscopic study of Victoria-Blue-BO-sensitized TF-1 cells. *Int J Cancer*. 2000;85(5):733–739.
18. Morgan J, Potter WR, Oseroff AR. Comparison of photodynamic targets in a carcinoma cell line and its mitochondrial DNA-deficient derivative. *Photochem Photobiol*. 2000;71(6):747–757.
19. Kowaltowski AJ, Turin J, Indig GL, Vercesi AE. Mitochondrial effects of triarylmethane dyes. *J Bioenerg Biomembr*. 1999;31(6):581–590.
20. World Dye Variety. 2012. Basic Blue 7. https://www.worlddyevariety.com/basic-dyes/basic-blue-7.html Last Updated: 2012. Date Accessed: August 7, 2024.