Safety Assessment of Basic Blue 7 as Used in Cosmetics

Status:	Draft Report for Panel Review
Release Date:	September 6, 2024
Panel Meeting Date:	September 30 - October 1, 2024

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.; Curtis D. Klaassen, Ph.D.; Allan E. Rettie, Ph.D.; David Ross, Ph.D.; Thomas J. Slaga, 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.

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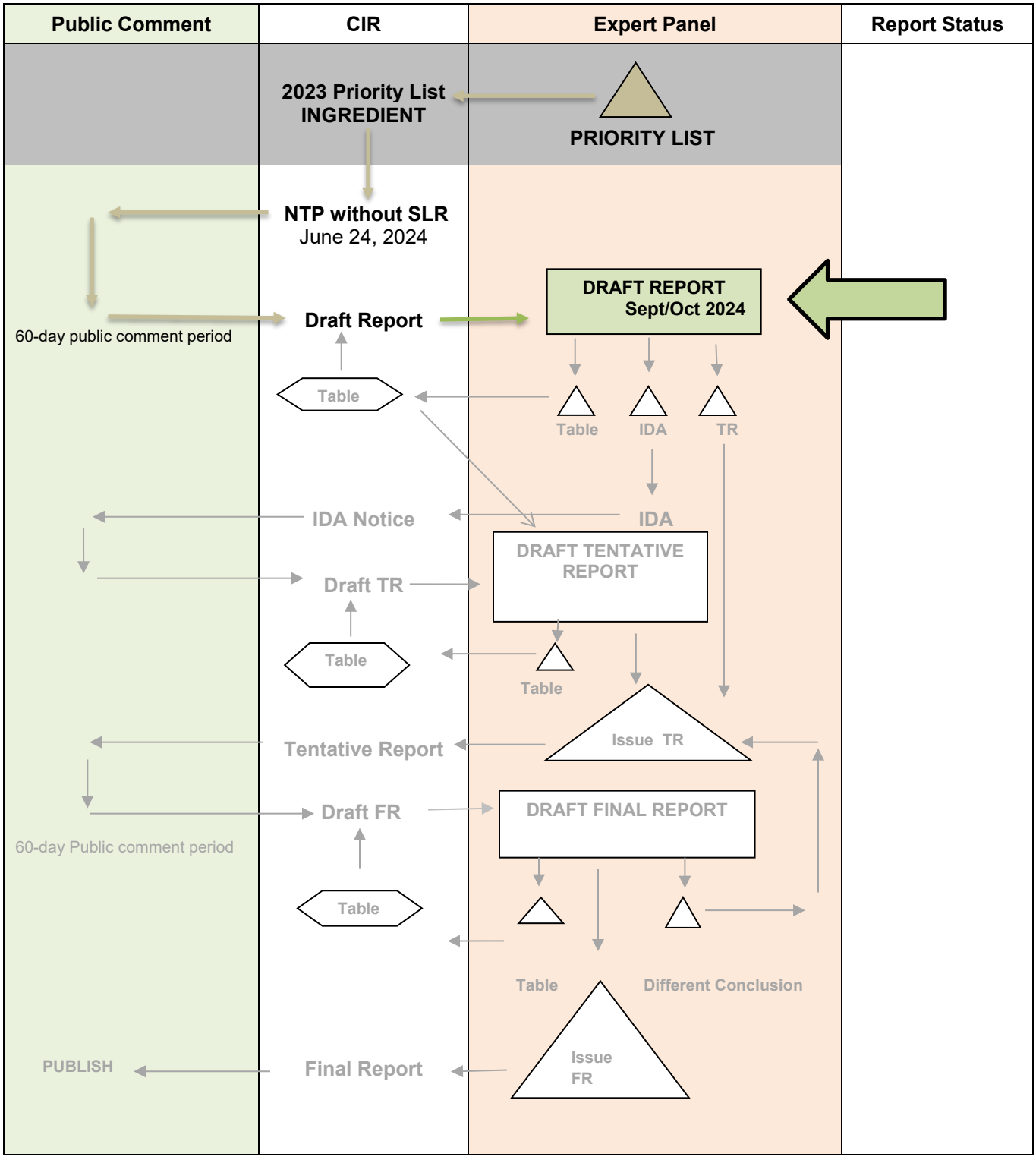
SAFETY ASSESSMENT FLOW CHART

INGREDIENT/FAMILY Basic Blue 7

MEETING September/October 2024



Cosmetic Ingredient Review

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Memorandum

To: Expert Panel for Cosmetic Ingredient Safety Members and Liaisons
From: Christina L. Burnett, M.S., Senior Scientific Analyst/Writer, CIR
Date: September 6, 2024
Subject: Safety Assessment of Basic Blue 7 as Used in Cosmetics

Enclosed is the Draft Report on the Safety Assessment of Basic Blue 7 as Used in Cosmetics. (It is identified as *report_BasicBlue7_092024* in the pdf document). This ingredient is reported to function as a hair colorant in cosmetic formulations.

In June 2024, CIR issued a Scientific Literature Review (SLR) Notice to Proceed (NTP) for Basic Blue 7 because an intensive search of information in the published scientific literature, online databases, and other sources on these ingredients provided insufficient information to justify the preparation of a formal SLR. It was found that under European regulations for cosmetic ingredients, Basic Blue 7, when used as a substance in hair dye products, is categorized in Annex II, the list of substances prohibited in cosmetic products in Europe. The other data identified in the published literature were information on non-cosmetic uses.

CIR issued the SLR NTP to alert interested parties that a safety assessment is being prepared and to request information in multiple areas, including:

- Chemistry information, including composition, method of manufacture, and impurity data;
- Toxicokinetics data relevant to routes of exposure expected with cosmetic use;
- General toxicity data;
- Developmental and reproductive toxicity data;
- Genotoxicity data;
- Carcinogenicity data;
- Dermal irritation and sensitization data;
- Inhalation toxicity data; and
- Any other relevant safety information that may be available

At the time of this transmittal memo, no unpublished data (other than concentration of use data; *data_BasicBlue7_092024*) have been received.

According to 2023 VCRP survey data, Basic Blue 7 was reported to be used in 1 nail polish and enamel product. No uses of this ingredient were reported in a concentration of use survey submitted by the Personal Care Products Council in 2023.

Additional supporting documents for this report package include a flow chart (*flow_BasicBlue7_092024*), report history (*history_BasicBlue7_092024*), a search strategy (*search_BasicBlue7_092024*), and a data profile (*dataprofile_BasicBlue7_092024*).

The Panel should consider the lack of information available on which to base a safety assessment of this ingredient, specify the data needed to complete the assessment, and issue an Insufficient Data Announcement.

Basic Blue 7 History

June 2024 – A Scientific Literature Review (SLR) Notice to Proceed (NTP) for Basic Blue 7 was issued.

Basic Blue 7 Data Profile* – September 2024 – Christina Burnett																															
				Toxicokinetics			Acute Tox			Repeated Dose Tox			DART		Genotox		Carci		Dermal Irritation			Dermal Sensitization				Ocular Irritation		Clinical Studies	
	Reported Use	Method of Mfg	Impurities	log P/log K_{ow}	Dermal Penetration	ADME	Dermal	Oral	Inhalation	Dermal	Oral	Inhalation	Dermal	Oral	In Vitro	In Vivo	Dermal	Oral	In Vitro	Animal	Human	In Vitro	Animal	Human	Phototoxicity	In Vitro	Animal	Retrospective/ Multicenter	Case Reports
Basic Blue 7 (CAS No. 2390-60-5)	X	X																													

* "X" indicates that data were available in a category for the ingredient

Basic Blue 7

Ingredient	CAS #	INCIpedia	PubMed	FDA	EU	ECHA	SCCS	SIDS	ECETOC	HPVIS	AICIS	NTIS	NTP	WHO	FAO	NIOSH	FEMA	Web
Basic Blue 7	2390-60-5	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√	√

Search Strategy

PubMed
((“basic blue 7”) OR (2390-60-5[EC/RN Number]) = 27 hits, most only useful for non-cosmetic use descriptions

ECHA
Dossier available as [4-[4-(diethylamino)-α-[4-(ethylamino)-1-naphthyl]benzylidene]cyclohexa-2,5-dien-1-ylidene]diethylammonium chloride, but there are no physical and chemical properties or toxicological data provided in the dossier.

EU
Annex II (entry 1328): List of substances prohibited in cosmetic products
SCCNFP Opinion 2000 (no dossier): ingredient can be safely used in hair tinting products at a maximum concentration of 0.2%.

LINKS

Search Engines

- Pubmed (- http://www.ncbi.nlm.nih.gov/pubmed)

appropriate qualifiers are used as necessary
search results are reviewed to identify relevant documents

Pertinent Websites

- wINCI - https://incipedia.personalcarecouncil.org/infobase/
- FDA databases http://www.ecfr.gov/cgi-bin/ECFR?page=browse
- FDA search databases: http://www.fda.gov/ForIndustry/FDABasicsforIndustry/ucm234631.htm;,
- Substances Added to Food (formerly, EAFUS): https://www.fda.gov/food/food-additives-petitions/substances-added-food-formerly-eafus
- GRAS listing: http://www.fda.gov/food/ingredientspackaginglabeling/gras/default.htm
- SCOGS database: http://www.fda.gov/food/ingredientspackaginglabeling/gras/scogs/ucm2006852.htm
- Indirect Food Additives: http://www.accessdata.fda.gov/scripts/fdcc/?set=IndirectAdditives
- Drug Approvals and Database: http://www.fda.gov/Drugs/InformationOnDrugs/default.htm
- FDA Orange Book: https://www.fda.gov/Drugs/InformationOnDrugs/ucm129662.htm
- (inactive ingredients approved for drugs: http://www.accessdata.fda.gov/scripts/cder/iig/
- HPVIS (EPA High-Production Volume Info Systems) - https://iaspub.epa.gov/oppthpv/public_search.html_page
- NIOSH (National Institute for Occupational Safety and Health) - http://www.cdc.gov/niosh/
- NTIS (National Technical Information Service) - http://www.ntis.gov/
  - technical reports search page: https://ntrl.ntis.gov/NTRL/
- NTP (National Toxicology Program) - http://ntp.niehs.nih.gov/

- Office of Dietary Supplements https://ods.od.nih.gov/
- FEMA (Flavor & Extract Manufacturers Association) GRAS: https://www.femaflavor.org/fema-gras
- EU CosIng database: http://ec.europa.eu/growth/tools-databases/cosing/
- ECHA (European Chemicals Agency – REACH dossiers) – http://echa.europa.eu/information-on-chemicals;jsessionid=A978100B4E4CC39C78C93A851EB3E3C7.live1
- ECETOC (European Centre for Ecotoxicology and Toxicology of Chemicals) - http://www.ecetoc.org
- European Medicines Agency (EMA) - http://www.ema.europa.eu/ema/
- OECD SIDS (Organisation for Economic Co-operation and Development Screening Info Data Sets)- http://webnet.oecd.org/hpv/ui/Search.aspx
- SCCS (Scientific Committee for Consumer Safety) opinions: http://ec.europa.eu/health/scientific_committees/consumer_safety/opinions/index_en.htm
- AICIS (Australian Industrial Chemicals Introduction Scheme)- https://www.industrialchemicals.gov.au/
- International Programme on Chemical Safety http://www.inchem.org/
- FAO (Food and Agriculture Organization of the United Nations) - http://www.fao.org/food/food-safety-quality/scientific-advice/jecfa/jecfa-additives/en/
- WHO (World Health Organization) technical reports - http://www.who.int/biologicals/technical_report_series/en/
- www.google.com - a general Google search should be performed for additional background information, to identify references that are available, and for other general information

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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
Panel	Expert Panel for Cosmetic Ingredient Safety
PI	propidium iodide
SCCNFP	Scientific Committee on Cosmetic Products and Non-Food Products Intended for Consumers
US	United States
VCRP	Voluntary Cosmetic Registration Program

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 August 2024. 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 Expert Panel for Cosmetic Ingredient Safety (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.

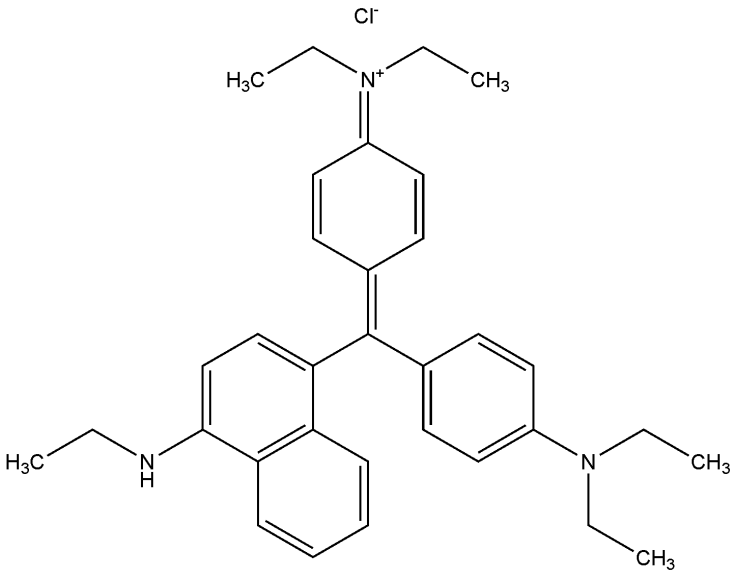

Figure 1. Basic Blue 7

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, an estimated log K_{ow} of 4.06, and a density of 1.05 - 1.2 g/ml.[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 this ingredient in cosmetics, and does not cover its use in airbrush delivery systems. Data included herein were obtained from the FDA's Voluntary Cosmetic Registration Program (VCRP) database in 2023 (frequency of use) and in response to a survey conducted by the Personal Care Products Council (Council) (maximum use concentrations). The data were provided by cosmetic product categories, based at that time on 21CFR Part 720. For most cosmetic product categories, 21CFR Part 720 does not indicate type of application and, therefore, airbrush application is not considered. Airbrush delivery systems are within the purview of the US

Consumer Product Safety Commission (CPSC), while ingredients, as used in airbrush delivery systems, are within the jurisdiction of the FDA. Airbrush delivery system use for cosmetic application has not been evaluated by the CPSC, nor has the use of cosmetic ingredients in airbrush technology been evaluated by the FDA. Moreover, 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.

According to 2023 VCRP survey data, Basic Blue 7 is reported to be used in 1 nail polish and enamel product.[6] No uses of this ingredient were reported in response to the concentration of use survey submitted by the Personal Care Products Council in 2023.[7]

Although products containing this ingredient may be marketed for use with airbrush delivery systems, this information is not available from the VCRP or the Council survey. Without information regarding the frequency and concentrations of use of these ingredients (and without consumer habits and practices data or particle size data related to this use technology), 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.

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.[8,9] 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**.**[10] 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%.[11] 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).[2,12] 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.[2,12] The use of Basic Blue 7 as a photodynamic therapy for cancer treatment has also been studied.[13-17]

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.[14] The cells were incubated with 1 x 10^{-8} to 1 x 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 x 10^{-8} M was found to kill 75% of cells, and a concentration of 1 x 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.[14] The cells were preincubated with 1 x 10^{-9} to 1 x 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 2023 VCRP survey data, Basic Blue 7 is reported to be used in 1 nail polish and enamel product. No uses of this ingredient were reported in response to a concentration of use survey submitted by the Council in 2023.

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

To be developed…

CONCLUSION

To be determined…

TABLES

Table 1. Chemical properties

Property	Value	Reference
Physical Form	Reddish-blue powder	[2]
Formula Weight (g/mol)	514.14	[2]
Density (g/ml @ 20 ºC)	1.05 - 1.2	[3]
Vapor pressure (mmHg@ 25 ºC)	1.29×10^{-18}	[4]
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	[3]
Water Solubility	Slightly soluble in cold water; soluble in hot water, easily soluble in ethanol	[18]
log K_{ow}	4.06 (KOWWIN v 1.68 estimated)	[4]

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Personal Care Products Council
Committed to Safety, Quality & Innovation

Memorandum

TO: Bart Heldreth, Ph.D.
Executive Director - Cosmetic Ingredient Review

FROM: Carol Eisenmann, Ph.D.
Personal Care Products Council (PCPC)

DATE: April 27, 2023

SUBJECT: Concentration of Use by FDA Product Category: Basic Blue 7

Basic Blue 7 was included in the March 2023 PCPC concentration of use survey. No uses of this ingredient were reported.