

US EPA ARCHIVE DOCUMENT



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

May 10, 2005

ACTION MEMORANDUM

SUBJECT: Inert Ingredient Tolerance Reassessment – D&C Green No. 6, D&C Red No. 17, D&C Red No. 33, D&C Violet No. 2, and FD&C Yellow No. 6 Aluminum Lake

FROM: Dan Rosenblatt, Chief
Minor Use, Inerts, and Emergency Response Branch

TO: Lois A. Rossi, Director
Registration Division

I. FQPA REASSESSMENT ACTION

Action: Reassessment of eight (8) inert ingredient exemptions from the requirement of a tolerance.

Chemical and Use Summary: See table below.

Tolerance Exemptions Being Reassessed in this Document				
Tolerance Exemption Expression	CAS Reg No.	40 CFR §	Use Pattern (Pesticidal)	List Classification
D&C Green No. 6	128-80-3	180.920 ^{1/}	Dye	3
		180.930 ^{2/}	Dye, coloring agent	
D&C Red No. 17	85-86-9	180.920 ^{1/}	Dye	3
		180.930 ^{2/}	Dye, coloring agent	
D&C Red No. 33	3567-66-6	180.920 ^{1/}	Dye	3
D&C Violet No. 2	81-48-1	180.920 ^{1/}	Dye; Not more than 0.005% of pesticide formulation	3
		180.930 ^{2/}	Dye, coloring agent	

FD&C Yellow No. 6 Aluminum Lake	15790-07-5	180.930 ^{2/}	Pigment in animal tag and similar slow release devices; Not more than 2% by weight of pesticide formulation	3
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1. Residues listed in 40 CFR §180.920 [formerly 40 CFR§ 180.1001(d)] are exempted from the requirement of a tolerance when used as inert ingredients in pesticide formulations when applied to growing crops only.
2. Residues listed in 40 CFR §180.930 [formerly 40 CFR§ 180.1001(e)] are exempted from the requirement of a tolerance when used as inert ingredients in pesticide formulations when applied to animals.

List Classification Determination: D&C Green No. 6, D&C Red No. 17, D&C Red No. 33, D&C Violet No. 2, and FD&C Yellow No. 6 Aluminum Lake are all currently classified as List 3 inert ingredients. Based upon the reasonable certainty of no harm safety finding, D&C Green No. 6, D&C Red No. 17, D&C Red No. 33, D&C Violet No. 2, and FD&C Yellow No. 6 Aluminum Lake can each be classified as List 4B inert ingredients.

II. MANAGEMENT CONCURRENCE

I concur with the reassessment of the eight (8) exemptions from the requirement of a tolerance for the inert ingredients D&C Green No. 6, D&C Red No. 17, D&C Red No. 33, D&C Violet No. 2, and FD&C Yellow No. 6 Aluminum Lake, and with the List classification determination, as described above. I consider the exemptions from the requirement of a tolerance for D&C Green No. 6, D&C Red No. 17, D&C Red No. 33, and D&C Violet No. 2 established in 40 CFR §180.920 [formerly 40 CFR§180.1001(d)] and the exemptions from the requirement of a tolerance for D&C Green No. 6, D&C Red No. 17, D&C Violet No. 2, and FD&C Yellow No. 6 Aluminum Lake established in 40 CFR §180.930 [formerly 40 CFR§180.1001(e)] to be maintained and reassessed as of the date of my signature, below. A Federal Register Notice regarding this tolerance exemption reassessment decision will be published in the near future.

Lois A. Rossi

Lois A. Rossi, Director
Registration Division

Date: May 12, 2005

cc: Debbie Edwards, SRRD
Joe Nevola, SRRD



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

May 10, 2005

MEMORANDUM

SUBJECT: Reassessment of the Exemptions from the Requirement of a Tolerance for D&C Green No. 6, D&C Red No. 17, D&C Red No. 33, D&C Violet No. 2, and FD&C Yellow No. 6 Aluminum Lake

FROM: Kerry Leifer, Inerts Team Leader *Kerry Leifer*
Minor Use, Inerts and Emergency Response Branch
Registration Division (7505C)

THRU: Pauline Wagner, Inerts Coordinator *Pauline Wagner 5/11/05*
Registration Division (7505C)

TO: Dan Rosenblatt, Chief
Minor Use, Inerts and Emergency Response Branch
Registration Division (7505C)

Background

Attached is the science assessment for D&C Green No. 6, D&C Red No. 17, D&C Red No. 33, D&C Violet No. 2, and FD&C Yellow No. 6 Aluminum Lake. The purpose of this document is to reassess the eight existing exemptions from the requirement of a tolerance for residues of these inert ingredients as required under the Food Quality Protection Act (FQPA). This assessment summarizes available information on the use, physical/chemical properties, toxicological effects, exposure profiles and ecological effects of D&C Green No. 6, D&C Red No. 17, D&C Red No. 33, D&C Violet No. 2, and FD&C Yellow No. 6 Aluminum Lake.

Executive Summary

This report evaluates D&C Green No. 6, D&C Red No. 17, D&C Red No. 33, D&C Violet No. 2, and FD&C Yellow No. 6 Aluminum Lake. These substances are listed as safe for various uses as food, drug, and/or cosmetic color additives by the Food and Drug Administration (FDA). As pesticide inert ingredients these substances have exemptions from the requirement of a tolerance under 40 CFR §180.920 and 40 CFR §180.930 when used as inert ingredients in pesticide formulations applied to growing crops and animals.

The reliable available toxicity data on D&C Green No. 6, D&C Red No. 17, D&C Red No. 33, and D&C Violet No. 2, consist of mutagenicity studies on each of these substances and skin sensitization studies on D&C Green No. 6, D&C Red No. 17, and D&C Violet No. 2. None of the substances were determined to be mutagenic in bacterial reverse mutation (Ames) assays. D&C Violet No. 2 was found to be a skin sensitizer in guinea pigs but D&C Green No. 6 and D&C Red No. 17 were not. Additional secondary source data indicate that D&C Green No. 6 and D&C Red No. 33 did not demonstrate developmental or reproductive toxicity at any of the doses tested.

Structure activity relationship analyses of D&C Green No. 6, D&C Red No. 17, D&C Red No. 33, D&C Violet No. 2, and FD&C Yellow No. 6 Aluminum Lake were conducted by EPA's Office of Pollution Prevention and Toxics (OPPT) Structure Activity Team. The OPPT assessments concluded that absorption of these substances via all routes of exposure is poor to nil (with the exception of absorption via the lung for D&C Red No. 33) and there are no associated significant health concerns, with each of these substances being rated as "low" or "low-moderate" for human health effect concerns.

There are no available aquatic toxicity studies on D&C Green No. 6, D&C Red No. 17, D&C Red No. 33, D&C Violet No. 2, and FD&C Yellow No. 6 Aluminum Lake. The OPPT Structure Activity Team evaluated each of these substances for potential toxicity to fish, algae, and aquatic invertebrates, with concerns for chronic toxicity and/or algal effects at 1-200 ppb. Since estimated environmental concentrations of dyes in surface waters resulting from pesticide inert ingredient uses would not exceed 1 ppb, there are no risk concerns for nontarget aquatic organisms associated with the pesticide inert ingredient use of D&C Green No. 6, D&C Red No. 17, D&C Red No. 33, D&C Violet No. 2, and FD&C Yellow No. 6 Aluminum Lake. Based on available mammalian toxicity data, the potential for adverse effects to non-target terrestrial animals is unlikely.

Taking into consideration all available information on D&C Green No. 6, D&C Red No. 17, D&C Red No. 33, D&C Violet No. 2, and FD&C Yellow No. 6 Aluminum Lake, it has been determined that there is a reasonable certainty that no harm to any population subgroup will result from aggregate exposure to D&C Green No. 6, D&C Red No. 17, D&C Red No. 33, D&C Violet No. 2, and FD&C Yellow No. 6 Aluminum Lake when considering dietary exposure and

all other nonoccupational sources of pesticide exposure for which there is reliable information. Therefore, it is recommended that the exemptions from the requirement of a tolerance established for residues of D&C Green No. 6, D&C Red No. 17, D&C Red No. 33, D&C Violet No. 2, and FD&C Yellow No. 6 Aluminum Lake in/on raw agricultural commodities and animals can be considered reassessed as safe under section 408(q) of the FFDCA.

I. Introduction

The Food and Drug Administration (FDA) has regulatory oversight for color additives used in foods, drugs, cosmetics, and medical devices. A color additive, as defined by regulations promulgated under the Federal Food, Drug, and Cosmetic Act (FFDCA), is any dye, pigment, or other substance that can impart color to a food, drug, or cosmetic or to the human body. All color additives regulated by FDA fall into two categories: those that are subject to FDA's certification process and those that are exempt from the certification process. Color additives subject to batch certification are synthetic organic dyes, lakes, or pigments (e.g., FD&C Blue No.1). Color additives exempt from certification generally include those derived from plant or mineral sources (e.g., caramel).

The 1960 Color Additive Amendments to FFDCA defined "color additive" and required that only color additives (except coal-tar hair dyes) listed as "suitable and safe" for a given use could be used in foods, drugs, cosmetics, and medical devices. Under these amendments, the color additives that were in commercial use at the time were provisionally listed and could be used on an interim basis until they were either permanently listed or terminated due to safety concerns or lack of commercial interest. Permanently listing a color additive for a proposed use was prohibited unless scientific data established its safety.

The dyes D&C Green No. 6, D&C Red No. 17, D&C Red No. 33, and D&C Violet No. 2 are all permanently listed FDA-certified color additives. Lakes (metal salts) of permanently listed FD&C dyes such as FD&C Yellow No. 6 Aluminum Lake are pigments that are provisionally listed as color additives for general use in foods, drugs, and cosmetics.

II. Use Information

Pesticides

The tolerance exemptions for the inert ingredients D&C Green No. 6, D&C Red No. 17, D&C Red No. 33, D&C Violet No. 2, and FD&C Yellow No. 6 Aluminum Lake being reassessed in this document are given in Table 1 below.

Table 1. Tolerance Exemptions Being Reassessed in this Document				
Tolerance Exemption Expression	CAS Reg No.	40 CFR §	Use Pattern (Pesticidal)	List Classification

D&C Green No. 6	128-80-3	180.920 ^{1/}	Dye	3
		180.930 ^{2/}	Dye, coloring agent	
D&C Red No. 17	85-86-9	180.920 ^{1/}	Dye	3
		180.930 ^{2/}	Dye, coloring agent	
D&C Red No. 33	3567-66-6	180.920 ^{1/}	Dye	3
D&C Violet No. 2	81-48-1	180.920 ^{1/}	Dye; Not more than 0.005% of pesticide formulation	3
		180.930 ^{2/}	Dye, coloring agent	
FD&C Yellow No. 6 Aluminum Lake	15790-07-5	180.930 ^{2/}	Pigment in animal tag and similar slow release devices; Not more than 2% by weight of pesticide formulation	3

1. Residues listed in 40 CFR §180.920 [formerly 40 CFR§ 180.1001(d)] are exempted from the requirement of a tolerance when used as inert ingredients in pesticide formulations when applied to growing crops only.
2. Residues listed in 40 CFR §180.930 [formerly 40 CFR§ 180.1001(e)] are exempted from the requirement of a tolerance when used as inert ingredients in pesticide formulations when applied to animals.

Other Uses

D&C Green No. 6, D&C Red No. 17, D&C Red No. 33, D&C Violet No. 2, and FD&C Yellow No. 6 Aluminum Lake are used as FDA approved color additives in foods, drugs, cosmetics and/or medical devices. Table 2 below lists the FDA approved color additive uses. D&C Green No. 6 is also used as a dye in some wood stains, polymers and inks (Sigma-Aldrich 2004). D&C Red No. 17 has uses as a dye for plastics (Kirk-Othmer 1996). There are no other identified significant commercial uses for these substances (HSDB 2005).

Chemical	21 CFR §	Uses
D&C Green No. 6	74.1206	Externally applied drugs
	74.2206	Externally applied cosmetics
	74.3206	Various sutures not to exceed (NTE) specified levels; Contact lenses NTE 0.03%; Haptics of intraocular lenses NTE 0.1%
D&C Red No. 17	74.1317	Externally applied drugs
	74.3217	Externally applied cosmetics

Table 2. FDA Approved Color Additive Uses		
Chemical	21 CFR §	Uses
	74.3230	Contact lenses
D&C Red No. 33	74.1333	Ingested drugs, other than mouthwashes and dentifrices (NTE 0.75 mg/daily dose of drug); externally applied drugs, mouthwashes and dentifrices
	74.2333	Externally applied cosmetics; mouthwashes, dentifrices; cosmetic lip products (NTE 3% (by wt) of finished cosmetic product).
D&C Violet No. 2	74.1602	Externally applied drugs
	74.2602	Externally applied cosmetics
	74.3602	NTE 0.1- 0.3 percent by wt in various absorbable sutures; Contact lenses; NTE 0.2 percent of intraocular lens haptics; NTE 0.15 percent by weight of meniscal tacks
FD&C Yellow No. 6 Aluminum Lake	82.51	Provisionally listed FD&C Lakes—foods, drugs and cosmetics generally

III. Physical and Chemical Properties

D&C Green No. 6 and D&C Violet No. 2 are classified as anthraquinone dyes, while D&C Red No. 17 and D&C Red No. 33 are classified as azo dyes. FD&C Yellow No. 6 Aluminum Lake is a pigment precipitated from the reaction of the azo dye FD&C Yellow No. 6 with aluminum hydroxide. Some of the physical and chemical characteristics of D&C Green No. 6, D&C Red No. 17, D&C Red No. 33, D&C Violet No. 2, and FD&C Yellow No. 6 Aluminum Lake are given in Appendix A.

IV. Hazard Assessment

A. Hazard Profile

This hazard assessment relies upon the limited available toxicity data on D&C Green No. 6, D&C Red No. 17, D&C Red No. 33, D&C Violet No. 2, and FD&C Yellow No. 6 Aluminum Lake as well as structure activity relationship analyses of D&C Green No. 6, D&C Red No. 17, D&C Red No. 33, D&C Violet No. 2, and FD&C Yellow No. 6 Aluminum Lake performed by EPA's Office of Pollution Prevention and Toxics (OPPT) Structure Activity Team.

The reliable available toxicity data on D&C Green No. 6, D&C Red No. 17, D&C Red No. 33, and D&C Violet No. 2., consist of mutagenicity studies on each of these substances and

skin sensitization studies on D&C Green No. 6, D&C Red No. 17, and D&C Violet No. 2. Additional data are available from secondary sources, but due to the lack of complete information, the results of these studies can not be evaluated for reliability. A further discussion of both the reliable toxicity data and the additional toxicity data is given in section IV B

The dye from which the lake pigment FD&C Yellow No. 6 Aluminum Lake is formed is FD&C Yellow No. 6 (Sunset Yellow). The World Health Organization/Food and Agriculture Organization Joint Expert Committee for the Evaluation of Food Additives (JECFA) has evaluated the safety of FD&C Yellow No. 6 used as a coloring agent in food. An acceptable daily intake (ADI) of 0-2.5 mg/kg bw/day was established by JECFA in 1982 based on the extensive information available on FD&C Yellow No. 6 (IACM 2004). No other toxicological data were available for FD&C Yellow No. 6 Aluminum Lake itself.

Structure activity relationship analyses of D&C Green No. 6, D&C Red No. 17, D&C Red No. 33, D&C Violet No. 2, and FD&C Yellow No. 6 Aluminum Lake were conducted by EPA's Office of Pollution Prevention and Toxics (OPPT) Structure Activity Team. The OPPT assessments concluded that absorption of these substances via all routes of exposure is poor to nil (with the exception of absorption via the lung for D&C Red No. 33) and there are no associated significant health concerns, with each of these substance being rated as "low" or "low-moderate" for human health effect concerns. The OPPT Structure Activity Team report on D&C Red No. 33 did note health concerns associated with aniline, an azo reduction product of D&C Red No. 33, but rated D&C Red No. 33 as low-moderate concern overall as aniline would only be a minor product of azo reduction of D&C Red No. 33 and is not itself a potent enough carcinogen to raise risk concerns at the expected levels of formation. The OPPT Structure Activity Team assessment reports are included in Appendix B.

B. Toxicological Data

D&C Green No. 6 and Violet No.2 were non-mutagenic in Ames assay in *Salmonella typhimurium* strains TA98, TA100, TA1535, TA1537 and TA1538 with and without metabolic activation mix (Brown & Brown 1976; Muzzall & Cook 1979). D&C Red No. 17 was non-mutagenic in both the spot test and the plate incorporation assay in *S. typhimurium* test strains, TA98, TA100, TA1535, TA1537 and TA1538 with and without metabolic activation (Muzzall & Cook 1979). Pure samples of D&C Red No. 17 were tested for mutagenic activities in the Ames assay using *S. typhimurium* strains TA98 and TA100 with and without metabolic activation and showed no mutagenic response (Miyagoshi et al. 1985). D&C Red No.33 was not mutagenic in *S typhimurium* strains TA98, TA100, TA1535, TA1537 and TA1538 with and without metabolic activation at concentrations as high as 300 µg/plate (Rafii et al. 1997; Muzzall & Cook 1979).

D&C Red No. 17 was not found to be a skin sensitizer in a guinea pig maximization test (Xie et al. 2000). Pure forms of D&C Green No. 6 and D&C Violet No. 2 were also evaluated for skin sensitization potential in guinea pigs with D&C Green No. 6 not found to be a skin

sensitizer, but animals sensitized with D&C Violet No. 2 did exhibit a hypersensitivity response following challenge with D&C Violet No. 2 (Fujii 2003).

In studies on 25 colors used in foods, drugs and cosmetics, sponsored by the Inter-Industry Color Committee Task Force, D&C Green No. 6 and D&C Red No. 33 were among colors tested for developmental effects in rats and rabbits. The dyes were administered by gavage during organogenesis at doses based on the highest no-effect level in rats and dogs in 2-year feeding studies. D&C Green No. 6 and D&C Red No. 33 did not produce skeletal or soft tissue abnormalities in rat and rabbit fetuses. No further details were available (Burnett et al. 1974; Schardein 1993). Multigeneration reproductive toxicity studies were conducted by the same Task Force in which doses of D&C Green No. 6 and D&C Red No. 33 were administered to rats in the diet based on multiples of the ADI or the projected safe dose, with the highest dose tested not exceeding 1000 mg/kg/day. Data through the F_{2b} generation provided no indication of adverse effects on reproductive performance of rats; however no details regarding dose levels were provided (Pierce et al. 1974).

C. Metabolism And Pharmacokinetics

No studies on absorption, distribution, metabolism, and excretion of D&C Green No. 6, D&C Red No. 17, D&C Red No. 33, D&C Violet No. 2, and FD&C Yellow No. 6 Aluminum Lake were found. The OPPT Structure Activity Team assessments for D&C Green No. 6, D&C Red No. 17, D&C Red No. 33, D&C Violet No. 2, and FD&C Yellow No. 6 Aluminum Lake rate absorption for these substances via the skin and gastrointestinal (GI) tract as poor to nil.

D. Special Considerations for Infants and Children

Based on the lack of absorption and the low concern for human health effects, a safety factor analysis has not been used to assess the risks resulting from the use of D&C Green No. 6, D&C Red No. 17, D&C Red No. 33, D&C Violet No. 2, and FD&C Yellow No. 6 Aluminum Lake as pesticide inert ingredients and an additional tenfold safety factor for the protection of infants and children is also unnecessary.

V. Exposure Assessment

Absorption of D&C Green No. 6, D&C Red No. 17, D&C Violet No. 2, and FD&C Yellow No. 6 Aluminum Lake is poor to nil via all routes of exposure, therefore no further dermal, oral, or inhalation exposure assessment is necessary. D&C Red No. 33 is not absorbed via the skin or gastrointestinal tract, therefore no further dermal or oral exposure assessment is necessary. Based on the conclusions of the OPPT Structure Activity Team's assessment of D&C Red No. 33, lung absorption of D&C Red No. 33 is good, however, bystander inhalation exposure to D&C Red No. 33 resulting from its use as a pesticide inert ingredient is unlikely, therefore an inhalation exposure assessment is not required.

VI. Aggregate Exposures

In examining aggregate exposure, FFDCA section 408 directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures, including drinking water from ground water or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

For D&C Green No. 6, D&C Red No. 17, D&C Red No. 33, D&C Violet No. 2, and FD&C Yellow No. 6 Aluminum Lake, a qualitative assessment for all pathways of human exposure (food, drinking water, and residential) is appropriate given the lack of human health concerns associated with exposure to D&C Green No. 6, D&C Red No. 17, D&C Red No. 33, D&C Violet No. 2, and FD&C Yellow No. 6 Aluminum Lake.

VII. Cumulative Exposure

Section 408(b)(2)(D)(v) of the FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to D&C Green No. 6, D&C Red No. 17, D&C Red No. 33, D&C Violet No. 2, and FD&C Yellow No. 6 Aluminum Lake and any other substances and these materials do not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that D&C Green No. 6, D&C Red No. 17, D&C Red No. 33, D&C Violet No. 2, and FD&C Yellow No. 6 Aluminum Lake have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at <http://www.epa.gov/pesticides/cumulative/>

VIII. Environmental Fate Characterization/Drinking Water Considerations

The OPPT Structure Activity Team assessments of D&C Green No. 6, D&C Red No. 17, D&C Red No. 33, D&C Violet No. 2, and FD&C Yellow No. 6 Aluminum Lake noted that each of these substances is slightly soluble in water and strongly sorbed to soils and sediments resulting in negligible migration to ground water. Based on these conclusions, D&C Green No. 6, D&C Red No. 17, D&C Red No. 33, D&C Violet No. 2, and FD&C Yellow No. 6 Aluminum Lake are not expected to be present at concentrations much greater than 1 ppb in drinking water sources as a result of pesticide inert ingredient use.

IX. Human Health Risk Characterization

The OPPT Structure Activity Team has identified D&C Green No. 6, D&C Red No. 17, D&C Red No. 33, D&C Violet No. 2, and FD&C Yellow No. 6 Aluminum Lake as being of low or low-moderate concerns for human health effects, with no identified significant health concerns. The available toxicological data, while limited, do not indicate any effects of concern, with the only toxicological effect noted being skin sensitization with D&C Violet No. 2. Dermal sensitization testing is required to support the registration of all pesticide products under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). Any product that is a dermal sensitizer or which tests positive for dermal sensitization must bear the appropriate precautionary labeling statement. Any potential dermal sensitization concerns related to D&C Violet No. 2 would be addressed by the requisite dermal sensitization testing and, if necessary, mitigated through the use appropriate precautionary labeling.

Taking into consideration all available information on D&C Green No. 6, D&C Red No. 17, D&C Red No. 33, D&C Violet No. 2, and FD&C Yellow No. 6 Aluminum Lake, it has been determined that there is a reasonable certainty that no harm to any population subgroup will result from aggregate exposure to D&C Green No. 6, D&C Red No. 17, D&C Red No. 33, D&C Violet No. 2, and FD&C Yellow No. 6 Aluminum Lake when considering dietary exposure and all other nonoccupational sources of pesticide exposure for which there is reliable information. Therefore, it is recommended that the exemptions from the requirement of a tolerance established for residues of D&C Green No. 6, D&C Red No. 17, D&C Red No. 33, D&C Violet No. 2, and FD&C Yellow No. 6 Aluminum Lake in/on raw agricultural commodities and animals can be considered reassessed as safe under section 408(q) of the FFDCA.

X. Ecotoxicity and Ecological Risk Characterization

There are no available aquatic toxicity studies on D&C Green No. 6, D&C Red No. 17, D&C Red No. 33, D&C Violet No. 2, and FD&C Yellow No. 6 Aluminum Lake (ECOTOX 2002). The OPPT Structure Activity Team evaluated each of these substances for potential toxicity to fish, algae, and aquatic invertebrates. There were no concerns for D&C Green No. 6, with the other substances having concerns for chronic aquatic toxicity and/or algal effects at concern concentrations ranging from 1-200 ppb. A previous assessment on FD&C Blue No. 1, FD&C Red No. 40, and FD&C Yellow No. 5 utilized modeling data to determine that, on a worst-case basis, estimated environmental concentrations of dyes in surface waters resulting from pesticide inert ingredient uses would not exceed 1 ppb (EPA 2004). Therefore, based on this worst-case exposure estimate, there are no risk concerns for non-target aquatic organisms associated with the pesticide inert ingredient use of D&C Green No. 6, D&C Red No. 17, D&C Red No. 33, D&C Violet No. 2, and FD&C Yellow No. 6 Aluminum Lake.

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APPENDIX A

The table below lists some of the physical and chemical characteristics of D&C Green No. 6, D&C Red No. 17, D&C Red No. 33, D&C Violet No. 2, and FD&C Yellow No. 6 Aluminum Lake. These values are either measured (M) or estimated (E).

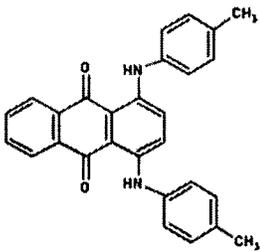
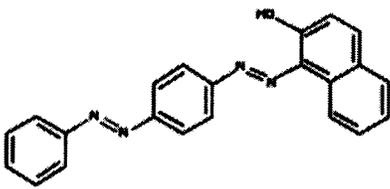
Table 3. Physical Chemical Properties		
Parameter	Value	Source
D&C Green No. 6 (CAS Reg. No. 128-80-3)		
Structure		ChemIDplus, 2005
Physical Form	Solid	EPA, 2005
Molecular Weight	418.494	ChemIDplus, 2005
Water Solubility	6.98×10^{-6} mg/L @ 25° C (E)	EPISuite, 2004
Melting Point	218° C (M)	
Vapor Pressure	7.05×10^{-13} mm Hg @ 25° C (E)	
Henry's Law Constant	1.47×10^{-16} atm-m ³ /mole @ 25° C (E)	
Octanol-Water Partition Coefficient (K _{ow})	log K _{ow} = 8.69 (E)	
D&C Red No. 17 (CAS Reg. No. 85-86-9)		
Structure		ChemIDplus, 2005

Table 3. Physical Chemical Properties		
Parameter	Value	Source
Physical Form	Solid	EPA, 2005
Molecular Weight	352.395	ChemIDplus, 2005
Water Solubility	0.01277 mg/L @ 25° C (E)	EPI Suite, 2004
Melting Point	195° C (M)	
Vapor Pressure	1.58×10^{-11} mm Hg @ 25° C (E)	
Henry's Law Constant	4.08×10^{-13} atm-m ³ /mole @ 25° C (E)	
Octanol-Water Partition Coefficient (K _{ow})	log K _{ow} =7.630 (E)	
D&C Red No. 33 (CAS Reg. No. 3567-66-6)		
Structure		ChemIDplus, 2005
Physical Form	Solid	EPA, 2005
Molecular Weight	467.389	ChemIDplus, 2005
Water Solubility	1.395 mg/L @ 25° C (E)	EPI Suite, 2004
Melting Point	349.84° C (E)	
Vapor Pressure	7.52×10^{-24} mm Hg @ 25° C (E)	
Henry's Law Constant	1.16×10^{-26} atm-m ³ /mole @ 25° C (E)	
Octanol-Water Partition Coefficient (K _{ow})	log K _{ow} =-2.09 (E)	
D&C Violet No. 2 (CAS Reg. No. 81-48-1)		

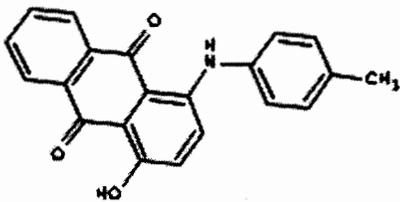
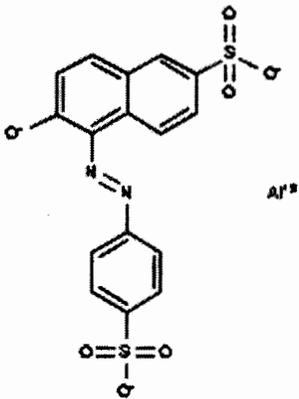
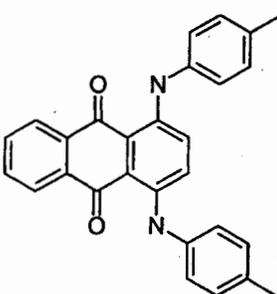
Table 3. Physical Chemical Properties		
Parameter	Value	Source
Structure		ChemIDplus, 2005
Physical Form	Solid	EPA, 2005
Molecular Weight	329.353	ChemIDplus, 2005
Water Solubility	0.003024 mg/L @ 25° C (E)	EPI Suite, 2004
Melting Point:	220.01° C (E)	
Vapor Pressure	1.08 x 10 ⁻¹¹ mm Hg @ 25° C (E)	
Henry's Law Constant	1.548 x 10 ⁻⁹ atm-m ³ /mole @ 25° C (E)	
Octanol-Water Partition Coefficient (K _{OW})	log K _{OW} = 6.24 (E)	
FD&C Yellow No. 6 Aluminum Lake (CAS Reg. No. 15790-07-5)		
Structure		ChemIDplus, 2005
Physical Form	Solid	EPA, 2005
Molecular Weight	432.368	ChemIDplus, 2005

Table 3. Physical Chemical Properties		
Parameter	Value	Source
Water Solubility	(not available)	
Melting Point	(not available)	
Henry's Law Constant	(not available)	
Octanol-Water Partition Coefficient (K_{ow})	(not available)	

APPENDIX B

STRUCTURE ACTIVITY TEAM REPORT		ver. 04/98	CBI? (YES/NO)
Case #:	Z-05-0013	DCN:	
SAT Date:	2/23/2005	SAT Chair: B. Jones	
Submitter:			
Chemical Name:			
9,10-Anthracenedione, 1,4-bis[(4-methylphenyl)amino]-			
CAS RN:	128-80-3	Trade Name: D & C Green no. 6; Solvent Green 3; Alizarin Cyanine Green, Fat Soluble	
Structure			
			
Molecular Formula:		C ₂₈ H ₂₂ N ₂ O ₂	
Molecular Wt.	418	WT% < 500:	WT% < 1000:
MP:	220.00 - 221.00	BP:	> 500
H2O Sol (g/L):	0.0009	V.P.	< 0.000001
Max. Prod. Volume (kg/yr):		Physical State:	Solid
USE:			
<p>Dye used to color fats, oils, waxes, hydrocarbon solvents, hydrocarbon-based wood stains, cellulose acetate, polystyrene and soap and in the preparation of oleic or steric acid rotogravure inks (Sigma Aldrich). Analog P-97-171 is a colorant for making petroleum products.</p>			
Related Case Numbers		Case Role	
Related Case Numbers		Case Role	
Related Case Numbers		Case Role	
Related Case Numbers		Case Role	
Focus	Date:	Results:	

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STRUCTURE ACTIVITY TEAM REPORT

CASE NUMBER: Z05-0013

RELATED CASES:

CONCLUSIONS/DISCUSSIONS

TYPE OF CONCERN:	HEALTH	ECOTOX
LEVEL OF CONCERN:	1	1

KEYWORDS:

SUMMARY OF ASSESSMENT

FATE: Solid
LogKow = 8.69(E); S (mg/L, 25°C) = 0.9(M); H < 1.00E-8(E)
MP (C) = 220-221(M); BP (C) > 400(E); VP @ 25C (mm) < 1.0E-6(E)
LogKoc = 5.60(E); LogBCF = 1.66(E);
POTW removal (%) = 90 via sorption
Time for complete ultimate aerobic biodeg = mo
PBT Potential: P2B1T1
Sorption to soils/sediments = v. strong
*CEB FATE: Migration to ground water = negl

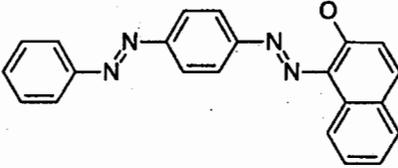
HEALTH: Absorption is nil all routes based on physical/chemical properties. No significant health concerns.
*CEB HEALTH: Low concern.

ECOTOX: Predicted (P) and measured (M) toxicity values in mg/L (ppm) are:

fish 96-h LC50	=	*	P
daphnid 48-h LC50	=	*	P
green algal 96-h EC50	=	*	P
fish chronic value	=	*	P
daphnid ChV	=	*	P
algal ChV	=	*	P

Predictions are based on SARs for neutral organic chemicals; SAR chemical class = dye-nonionic-anthraquinone-N-substituted; MW419; solid with mp 221 C (M); log Kow = 8.7 (EPI); S < 0.001 mg/L at 25 C (P); pH7; effective concentrations based on 100% active ingredients and nominal concentrations; hardness <150.0 mg/L as CaCO3; and TOC <2.0 mg/L;
low concern for toxicity;
assessment factor = 10.0
concern concentration = *
*CEB ECOTOX: No releases to water;

Becky Jones 564-8919

STRUCTURE ACTIVITY TEAM REPORT		ver. 04/98	CBI? (YES/NO)
Case #:	Z-05-0010	DCN:	
SAT Date:	2/23/2005	SAT Chair:	B. Jones
Submitter:			
Chemical Name:			
2-Naphthalenol, 1-[[4-(phenylazo)phenyl]azo]-			
CAS RN:	85-86-9	Trade Name:	
		SUDAN III; Solvent Red 23; C.I. 26100; D&C Red no. 17	
Structure			
			
Molecular Formula: $C_{22}H_{16}N_4O$			
Molecular Wt.	352	WT%<500:	WT%<1000:
MP:		BP:	>500 Eq. Wt:
H2O Sol (g/L):	0.000002	V.P.	<0.000001
Max. Prod. Volume (kg/yr):		Physical State:	Solid
USE:			
As a dye for plastics, externally applied drugs and externally applied cosmetics [Charvat RA. Colorants for Plastics. Kirk-Othmer Encyclopedia of Chemical Technology (Online posting date: March 19, 2004); Marmion D. Colorants for Foods, Drugs, Cosmetics and Medical Devices. Kirk-Othmer Encyclopedia of Chemical Technology (Online posting date: December 4, 2000)].			
Related Case Numbers	Case Role	Related Case Numbers	Case Role
Focus	Date:	Results:	

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STRUCTURE ACTIVITY TEAM REPORT

CASE NUMBER: Z05-0010

RELATED CASES:

CONCLUSIONS/DISCUSSIONS

TYPE OF CONCERN: HEALTH ECOTOX

LEVEL OF CONCERN: 1 3

KEYWORDS: AQUATOX-C

SUMMARY OF ASSESSMENT

FATE: Solid
LogKow = 7.63(E); S (mg/L, 25°C) = 0.003(E); H < 1.00E-8(E)
MP (C) = 199 Dec.(M); VP @ 25C (mm) < 1.0E-6(E)
LogKoc = 5.64(E); LogBCF = 1.00(E);
POTW removal (%) = 90 via sorption
Time for complete ultimate aerobic biodeg = mo
PBT Potential: P1B1T1
Sorption to soils/sediments = v. strong
*CEB FATE: Migration to ground water = negl

HEALTH: Absorption is nil all routes. No azo reduction is expected in the GI tract. No significant health concerns.
*CEB HEALTH: Low concern.

ECOTOX: Predicted (P) and measured (M) toxicity values in mg/L (ppm) are:

fish 96-h LC50	=	*	P
daphnid 48-h LC50	=	*	P
green algal 96-h EC50	=	*	P
fish 30-d ChV	=	0.020 or *	P
fish 90-d ChV	=	0.006 or *	P
daphnid ChV	=	0.020 or *	P
algal ChV	=	*	P

Predictions are based on SARs for phenols; SAR chemical class = dye-nonionic-phenol; MW352; solid with decomposition at 199 C (M); log Kow = 6.1 (ClogP), 7.6 (EPI); S between 0.002 and 0.020 mg/L at 25 C (P); pH7; effective concentrations based on 100% active ingredients and mean measured concentrations; hardness <150.0 mg/L as CaCO3; and TOC <2.0 mg/L; high concern for chronic toxicity;
assessment factor = 10.0
concern concentration = 0.001 mg/L (ppm)

*CEB ECOTOX: All releases to water with CC = 1 ppb if release days are greater than 90 days and CC = 2 ppb if release days are less than 90 d

Becky Jones 564-8919

STRUCTURE ACTIVITY TEAM REPORT		ver. 04/98	CBI? (YES/NO)
Case #:	Z-05-0011	DCN:	
SAT Date:	2/23/2005	SAT Chair:	B. Jones
Submitter:			
Chemical Name:			
2,7-Naphthalenedisulfonic acid, 5-amino-4-hydroxy-3-(phenylazo)-, disodium salt			
CAS RN:	3567-66-6	Trade Name:	D&C Red no. 33
Structure			
Molecular Formula: $C_{16}H_{11}N_3Na_2O_7S_2$			
Molecular Wt. 467	WT%<500:	WT%<1000:	
MP:	BP:	>500	Eq. Wt:
H2O Sol (g/L):	100	V.P.	<0.000001
Max. Prod. Volume (kg/yr):	Physical State: Solid (Est.)		
USE:			
Dye in soaps and detergents.			
Related Case Numbers	Case Role	Related Case Numbers	Case Role
Focus	Date:	Results:	

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STRUCTURE ACTIVITY TEAM REPORT

CASE NUMBER: Z05-0011

RELATED CASES:

CONCLUSIONS/DISCUSSIONS

TYPE OF CONCERN:	HEALTH	ECOTOX
LEVEL OF CONCERN:	1-2	2

KEYWORDS:

MUTA
ONCO
DEVEL
BLOOD
ALGAL SHADING

SUMMARY OF ASSESSMENT

FATE: Solid
S = Soluble(E); VP @ 25C (mm) < 1.0E-6(E); H < 1.00E-8(E)
POTW Removal (%) = 0
Time for complete ultimate aerobic biodeg = mo
Time for primary anaerobic biodeg (azo) ≤ da
PBT Potential: P1B1T2
Sorptions to soils/sediments = low
*CEB FATE: Migration to ground water = negl
Photolysis Direct = rapid

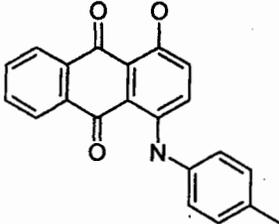
HEALTH: Absorption of the intact compound is nil through the skin and GI tract and good through the lungs. Expect azo reduction in the GI tract followed by absorption of both azo reduction products in the intestines. There is concern for mutagenicity, oncogenicity, developmental toxicity, and blood effects for the azo reduction product aniline. No concerns were identified for the naphthalenediamine derivative azo reduction product. Aniline is positive in the mouse micronucleus assay, ip and the mouse lymphoma assay, positive for binding to hemoglobin, causes maternal and developmental toxicity at 560 mg/kg when given orally to mice, and causes tumors of the circulatory system, multiple organ sites and spleen when administered in the feed.
*CEB HEALTH: Low moderate concern.

ECOTOX: Predicted (P) and measured (M) toxicity values in mg/L (ppm) are:

fish 96-h LC50	> 100.0	P
daphnid 48-h LC50	> 100.0	P
green algal 96-h EC50	= 20.0	P
fish chronic value	> 10.0	P
daphnid ChV	> 10.0	P
algal ChV	= 2.0	P

Predictions are based on SAR-nearest analog method for anionic dyes with 2 acid groups=S2: Acid Black 1 (CI#20470), and indirect effect of algal shading from the red dye color; SAR chemical class = dye-anionic-S2-phenol-aniline.Na; MW467; solid(P); S = 100 g/L at 25 C (P); pH7; effective concentrations based on 100% active ingredients and mean measured concentrations; hardness <150.0 mg/L as CaCO₃; and TOC <2.0 mg/L; moderate concern for indirect shading effects to green algae; assessment factor = 10.0
concern concentration = 0.200 mg/L (ppm) based on shading;
*CEB ECOTOX: No releases to water;

Becky Jones 564-8919

STRUCTURE ACTIVITY TEAM REPORT		ver. 04/98	CBI? (YES/NO)
Case #:	Z-05-0014	DCN:	
SAT Date:	2/23/2005	SAT Chair:	B. Jones
Submitter:			
Chemical Name:			
9,10-Anthracenedione, 1-hydroxy-4-[(4-methylphenyl)amino]-			
CAS RN:	81-48-1	Trade Name:	
Structure			
			
<i>Violet</i>			
Molecular Formula:		C ₂₁ H ₁₅ NO ₃	
Molecular Wt.	329	WT%<500:	WT%<1000:
MP:		BP:	> 500 Eq. Wt:
H ₂ O Sol (g/L):	0.000003	V.P.	< 0.000001
Max. Prod. Volume (kg/yr):		Physical State:	Solid (est.)
USE:			
Related Case Numbers		Case Role	
Related Case Numbers		Case Role	
Related Case Numbers		Case Role	
Focus	Date:	Results:	

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STRUCTURE ACTIVITY TEAM REPORT

CASE NUMBER: Z05-0014

RELATED CASES:

CONCLUSIONS/DISCUSSIONS

TYPE OF CONCERN:	HEALTH	ECOTOX
LEVEL OF CONCERN:	1-2	3

KEYWORDS:

MUTA
ONCO
SENS-DERMAL
AQUATOX-C

SUMMARY OF ASSESSMENT

FATE: Solid
LogKow = 6.24(E); S (mg/L, 25°C) = 0.003(E); H < 1.00E-8(E)
MP (C) = 220(E); BP (C) > 400(E); VP @ 25C (mm) < 1.0E-6(E)
LogKoc = 3.76(E); LogBCF = 3.26(E);
POTW removal (%) = 90 via sorption
Time for complete ultimate aerobic biodeg = mo
PBT Potential: P2B2T2
Sorption to soils/sediments = strong
*CEB FATE: Migration to ground water = slow

HEALTH: Absorption is nil all routes as the neat material and poor all routes when in solution if the material does not precipitate out of the solution. Although this chemical is negative in Salmonella, there is concern for mutagenicity based on a positive result in the micronucleus assay (studies submitted under TSCA Section 8d). Aminoanthraquinones are variously positive in mouse lymphoma, micronucleus, and DNA studies (SCEs). There is a marginal concern for oncogenicity based on the positive result in the micronucleus assay and concern for dermal sensitization based on information for other anthraquinones.
*CEB HEALTH: Low moderate concern.

ECOTOX: Predicted (P) and measured (M) toxicity values in mg/L (ppm) are:

fish 96-h LC50	=	*	P
daphnid 48-h LC50	=	*	P
green algal 96-h EC50	=	*	P
fish 30-d ChV	=	0.030 or *	P
fish 90-d ChV	=	0.010 or *	P
daphnid ChV	=	0.060 or *	P
algal ChV	=	*	P

Predictions are based on SARs for phenols; SAR chemical class =

dye-nonionic-anthraquinone-phenol-N-substituted; MW329; solid (P); log Kow = 5.2 (ClogP), 6.2 (EPI); S between 0.003 and 0.220 mg/L at 25 C (P); pH7; effective concentrations based on 100% active ingredients and mean measured concentrations; hardness <150.0 mg/L as CaCO3; and TOC <2.0 mg/L; high concern for chronic toxicity; assessment factor = 10.0 concern concentration = 0.001 mg/L (ppm)
*CEB ECOTOX: All releases to water with CC = 1 ppb if release days are greater than 90 days and CC = 3 ppb if release days are less than 90 d

Becky Jones 564-8919

STRUCTURE ACTIVITY TEAM REPORT		ver. 04/98	CBI? (YES/NO)
Case #:	Z-05-0012	DCN:	
SAT Date:	2/23/2005	SAT Chair:	B. Jones
Submitter:			
Chemical Name:			
C.I. Pigment Yellow 104 2-Naphthalenesulfonic acid, 6-hydroxy-5-[(4-sulfonylphenyl)azo]-, aluminum complex			
CAS RN:	15790-07-5	Trade Name:	FD&C Yellow no. 6 Aluminum Lake; C.I. Food Yellow 3
Structure			
Molecular Formula: C ₁₆ H ₉ AlN ₂ O ₇ S ₂			
Molecular Wt.	434	WT%<500:	WT%<1000:
MP:		BP:	>500
H2O Sol (g/L):	0.243	V.P.	<0.000001
Max. Prod. Volume (kg/yr):		Physical State:	Solid
USE:			
Food dye.			
Related Case Numbers	Case Role	Related Case Numbers	Case Role
Focus	Date:	Results:	

STRUCTURE ACTIVITY TEAM REPORT

CASE NUMBER: Z05-0012

RELATED CASES:

CONCLUSIONS/DISCUSSIONS

TYPE OF CONCERN:	HEALTH	ECOTOX
LEVEL OF CONCERN:	1-2	2

KEYWORDS:

ONCO
MUTA
DEVEL
SENS
IMMUNO
AQUATOX-A,C

SUMMARY OF ASSESSMENT

FATE: Solid; Estimations for neutral compound MW 408 $C_{16}H_{12}N_2O_7S_2$
LogKow = 1.40 (E); S (mg/L, 25°C) = 243 (E); H < 1.00E-8 (E)
MP (C) = 294 (E); BP (C) > 400 (E); VP @ 25C (mm) < 1.0E-6 (E)
LogKoc = 4.26 (E); LogBCF = 0.50 (E);
POTW removal (%) = 0
Time for complete ultimate aerobic biodeg = mo
PBT Potential: P1B1T2
Sorption to soils/sediments = low
*CEB FATE: Migration to ground water = negl

HEALTH: Absorption of the intact compound is nil through the skin and GI tract and poor through the lungs. Expect poor azo reduction in the GI tract with good absorption of the azo reduction products. There is concern for mutagenicity and a marginal concern for oncogenicity for the sulfonated beta-naphthylamine derivative azo reduction product to the extent that it is released via azo reduction. There is concern for developmental toxicity for the sulfonated aniline azo reduction product to the extent it is formed and concern for sensitization and immunotoxicity for the aluminum.
*CEB HEALTH: Low moderate concern.

ECOTOX: Predicted (P) and measured (M) toxicity values in mg/L (ppm) are:

fish 96-h LC50	= 180.0	P
daphnid 48-h LC50	= 91.0	P
green algal 96-h EC50	= 8.2	P
fish chronic value	= 500	P
daphnid ChV	= 16.0	P
algal ChV	= 1.6	P

Predictions are based on SAR-nearest analog analysis for AL compounds with MW adjustment and SAR-nearest analog analysis for anionic dyes with 2 acid groups-S2: CI Acid Red 1 = Lissamien Red 2G, and indirect effect of algal shading from the yellow dye color, however, the toxicity of the AL to green algae is greater than the indirect toxicity from shading; SAR chemical class = dye-anionic-S2-phenol-aniline.AL salt; MW432; solid; S = 240 mg/L at 25 C (P); pH7; effective concentrations based on 100% active ingredients and mean measured concentrations of dye via color and total AL; hardness <150.0 mg/L as CaCO3; and TOC <2.0 mg/L;

moderate concern for toxicity from the AL

assessment factor = 10.0

concern concentration = 0.200 mg/L (ppm) based on AL

*CEB ECOTOX: All releases to water with CC = 200 ppb

Becky Jones 564-8919