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

OFFICE OF
PREVENTION, PESTICIDES AND

TOXIC SUBSTANCES

December 21, 2004

ACTION MEMORANDUM

SUBJECT: Inert Ingredient Tolerance Reassessment – FD&C Blue No. 1, FD&C Red No. 40, and FD&C Yellow No. 5 (Tartrazine)

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 six (6) inert ingredient exemptions from the requirement of a tolerance

Chemical and Use Summary: See table below

Tolerance Exemptions Being Reassessed for FD&C Blue No. 1, FD&C Red No. 40, and FD&C Yellow No. 5				
Tolerance Exemption Expression	**CAS Reg No.**	**40 CFR §**	**Use Pattern (Pesticidal)**	**List Classification**
FD&C Blue No. 1	3844-45-9	180.910	Dye; Not more than 0.2% of pesticide formulation	3
		180.930	Dye, coloring agent	

FD&C Red No. 40	25956-17-6	180.910	Dye, coloring agent not to exceed 0.002% by weight of pesticide formulation	4B
		180.920	Dye, coloring agent for seed treatment use only. Not to exceed 2% by weight of pesticide formulation	
Tartrazine[1/]	1934-21-0	180.910	Dye	3
		180.930	Dye, coloring agent	
		180.940(b)	Ingredient in an antimicrobial pesticide formulation applied to: Dairy processing equipment, and food-processing equipment and utensils.	
		180.940(c)	Ingredient in an antimicrobial pesticide formulation may be applied to: Food-processing equipment and utensils.	

1/ also known as FD&C Yellow No. 5

List Reclassification Determination: FD&C Blue No. 1 and tartrazine (FD&C Yellow No. 5) are currently classified as List 3 inert ingredients; FD&C Red. No. 40 is currently classified as a List 4B inert ingredient. Based on the reasonable certainty of no harm safety finding and the use limitations present in the exemptions from the requirement of tolerance for FD&C Blue No. 1, FD&C Red No. 40, and FD&C Yellow No. 5 (tartrazine), these substances can all be reclassified as List 4B inert ingredients.

II. MANAGEMENT CONCURRENCE

I concur with the reassessment of six (6) exemptions from the requirement of a tolerance for FD&C Blue No. 1, FD&C Red No. 40, and FD&C Yellow No. 5 (tartrazine), and with the List reclassification determinations, as described above. I consider the exemptions from the requirement of a tolerance for FD&C Blue No. 1, FD&C Red No. 40, and FD&C Yellow No. 5 (tartrazine) established in 40 CFR §180.910 [formerly 40 CFR§180.1001(c)], the exemption from the requirement of a tolerance for FD&C Red No. 40 established in 40 CFR §180.920 [formerly 40 CFR§180.1001(d)], and the exemptions for FD&C Blue No. 1 and tartrazine (FD&C Yellow No. 5)

established in 40 CFR §180.930 [formerly 40 CFR§180.1001(e)] to each be 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, Director
Registration Division

Date: 12/30/04

cc: Debbie Edwards, SRRD
Joe Nevola, SRRD

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MEMORANDUM

SUBJECT: Reassessment of the Exemptions from the Requirement of a Tolerance for the FDA-Certified Color Additives FD&C Blue No. 1, FD&C Red No. 40, and FD&C Yellow No. 5 (Tartrazine)

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

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

Background

Attached is the Lower Risk Pesticide Chemical Focus Group's science assessment for the FDA-certified color additives FD&C Blue No. 1, FD&C Red No. 40, and FD&C Yellow No. 5 (also known as tartrazine). The purpose of this document is to reassess the existing exemptions from the requirement of a tolerance for residues of FD&C Blue No. 1, FD&C Red No. 40, and FD&C Yellow No. 5 as required under the Food Quality Protection Act (FQPA). This assessment summarizes available information on the use, physical/chemical properties, toxicological effects, and exposure profile, environmental fate and ecotoxicity of FD&C Blue No. 1, FD&C Red No. 40, and FD&C Yellow No. 5. In performing this assessment, EPA has relied upon peer-reviewed evaluations performed by the Food and Drug Administration (FDA) and the Joint Expert Committee on Food Additives of the Food and Agriculture Organization/World Health Organization (FAO/WHO).

Executive Summary

This report evaluates FD&C Blue No. 1, FD&C Red No. 40, and FD&C Yellow No. 5 (also known as tartrazine). These substances are each permanently listed as safe for general use as food, drug, and 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 §180.910 [formerly 40 CFR§ 180.1001(c)], 40 CFR §180.920 [formerly 40 CFR §180.1001(d)], and 40 CFR §180.930 [formerly 40 CFR §180.1001(e)] when used as inert ingredients in pesticide formulations applied to growing crops, raw agricultural commodities after harvest, and animals.

A combination of FD&C Blue No. 1 and FD&C Yellow No. 5 is utilized as the active ingredients in five currently registered pesticide products that are used as aquatic herbicides/algaecides. An exemption from the requirement of a tolerance for FD&C Blue No. 1 as an aquatic plant control agent is listed under 40 CFR §180.1074, however there are no registered food use aquatic herbicide products containing FD&C Blue No. 1 as an active ingredient. Pending a further review by HED in support of the RED for the combination of FD&C Blue No. 1 and FD&C Yellow No. 5, the tolerance exemption given at 40 CFR §180.1074 may be a candidate for revocation

In permanently listing FD&C Blue No. 1, FD&C Red No. 40, and FD&C Yellow No. 5 as color additives for use in foods, drugs and cosmetics, FDA concluded that these colorants were safe and determined a maximum acceptable daily intake for FD&C Blue No. 1 and FD&C Yellow No. 5. Similarly, the Joint Expert Committee on Food Additives of the Food and Agriculture Organization/World Health Organization (JECFA) has evaluated these of compounds for the purpose of establishing estimates of acceptable daily intakes (ADIs).

As color additives used in food, drugs, and cosmetics, there are no identified risk concerns for FD&C Blue No. 1, FD&C Red No. 40, and FD&C Yellow No. 5. The established ADIs were based upon studies in which adverse effects were not observed at any levels below the limit dose. No adverse effects have been associated with exposures resulting from the FDA-approved uses. As a result of these findings, OPP is conducting a qualitative approach to assessing human health risks from exposure to FD&C Blue No. 1, FD&C Red No. 40, and FD&C Yellow No. 5.

Taking into consideration all available information on FD&C Blue No. 1, FD&C Red No. 40, and FD&C Yellow No. 5 including the extensive toxicity database in which no adverse effects were noted, the low toxicity, the lack of risk concerns usage as color additives, and the low exposures likely to result from uses as pesticide inert ingredients, it has been determined that there is a reasonable certainty that no harm to any population subgroup will result from aggregate exposure to FD&C Blue No. 1, FD&C Red No. 40, and FD&C Yellow No. 5 when considering dietary exposure and all other non-occupational 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 FD&C Blue No. 1, FD&C Red No. 40, and FD&C Yellow No. 5 in/on raw agricultural commodities can be considered reassessed as safe under section 408(q) of the FFDCA.

The available toxicity information, fate properties and use information have been used to characterize potential ecological risks related to the use of FD&C Blue No. 1, FD&C Red No. 40, and FD&C Yellow No. 5 as inert ingredients in pesticide formulations. While no toxicity studies are available, modeling results indicate that potential risks to aquatic organisms and soil and sediment dwelling organisms resulting from the use of FD&C Blue No. 1, FD&C Red No. 40, and FD&C Yellow No. 5 as inert ingredients in pesticide formulations are low.

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 further 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. Each of these FDA-certified color additives (FD&C Blue No. 1, FD&C Red No. 40, and FD&C Yellow No. 5) has been permanently listed by FDA.

II. Use Information

Pesticides

The tolerance exemptions for the inert ingredients FD&C Blue No. 1, FD&C Red No. 40, and FD&C Yellow No. 5 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**
FD&C Blue No. 1	3844-45-9	180.910[1/]	Dye; Not more than 0.2% of pesticide formulation	3
		180.930[3/]	Dye, coloring agent	
FD&C Red No. 40	25956-17-6	180.910[1/]	Dye, coloring agent not to exceed 0.002% by weight of pesticide formulation	4B
		180.920[2/]	Dye, coloring agent for seed treatment use only. Not to exceed 2% by weight of pesticide formulation	
Tartrazine[4/]	1934-21-0	180.910[1/]	Dye	3
		180.930[3/]	Dye, coloring agent	
		180.940(b)	Ingredient in an antimicrobial pesticide formulation applied to: Dairy processing equipment, and food-processing equipment and utensils.	
		180.940(c)	Ingredient in an antimicrobial pesticide formulation may be applied to: Food-processing equipment and utensils.	

1. Residues listed in 40 CFR §180.910 [formerly 40 CFR§ 180.1001(c)] are exempted from the requirement of a tolerance when used as inert ingredients in pesticide formulations when applied to growing crops and raw agricultural commodities after harvest.
2. 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.

3. 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.
4. Also known as FD&C Yellow No. 5

A combination of FD&C Blue No. 1 and FD&C Yellow No. 5 is sometimes referred to as Aquashade. This combination is utilized as the active ingredients in five currently registered pesticide products that are used as aquatic herbicides/algaecides. An exemption from the requirement of a tolerance for FD&C Blue No. 1 as an aquatic plant control agent is listed under 40 CFR §180.1074, however there are no registered food use aquatic herbicide products containing FD&C Blue No. 1 as an active ingredient as none of the currently registered products are permitted for use on food crops or in potable water. It is therefore recommended that, pending a further review by HED in support of the RED for the combination of FD&C Blue No. 1 and FD&C Yellow No. 5, the tolerance exemption for FD&C Blue No. 1 given at 40 CFR §180.1074 be revoked.

Other Uses

FD&C Blue No. 1, FD&C Red No. 40, and FD&C Yellow No. 5 are used as FDA approved color additives in foods, drugs and cosmetics. Table 2 lists the FDA approved color additive uses. There are no identified other commercial uses for these substances (HSDB, 2004).

Table 2. FDA Approved Color Additive Uses

Chemical	21 CFR §	Uses
FD&C Blue No. 1	74.101	Foods generally
	74.1101	Ingested drugs generally; Externally applied drugs; Eye area use
	74.2101	Cosmetics generally; Eye area use
FD&C Red No. 40	74.340	Foods generally
	74.1340	Drugs generally; Eye area use
	74.2340	Cosmetics generally; Eye area use
FD&C Yellow No. 5	74.706	Foods generally
	74.1706	Drugs generally
	74.2706	Cosmetics generally

III. Physical and Chemical Properties

A summary of the physical and chemical characteristics of these compounds is given in Appendix A. These compounds are all water soluble and nonvolatile.

IV. Hazard Assessment

In permanently listing FD&C Blue No. 1, FD&C Red No. 40, and FD&C Yellow No. 5 as color additives for use in foods, drugs and cosmetics, FDA concluded that these colorants were safe and determined a maximum acceptable daily intake for FD&C Blue No. 1 and FD&C Yellow No. 5. (FDA 1982, 1985). Similarly, JECFA has evaluated these of compounds for the purpose of establishing estimates of acceptable daily intakes (ADIs) (JECFA 1964, 1969, 1980). Table 3 lists the respective FDA and JECFA ADIs for these substances.

Table 3. FDA and JECFA Acceptable Daily Intake (ADI) Values (in mg/kg- bw/day)

Color Additive	FDA ADI	JECFA ADI
FD&C Blue No. 1	12.0	0 - 12.5
FD&C Red. No. 40	N/A	0 - 7
FD&C Yellow No. 5	5.0	0 - 7.5

A. Hazard Profile/Toxicological Information

The FDA and JECFA evaluations of FD&C Blue No. 1, FD&C Red No. 40, and FD&C Yellow No. 5 include reviews of numerous animal toxicity studies involving dogs, hamsters, guinea pigs, rabbits, rats, and mice as part of toxicity endpoint selection process. Table 4 summarizes the studies upon which the FDA and JECFA ADIs were based.

Table 4. Studies utilized for establishment of Acceptable Dietary Intake (ADI) for FD&C Blue No. 1, FD&C Red No. 40, and FD&C Yellow No. 5

Substance	Study Type	Dose (mg/kg/day)	Endpoints	Reference
FD&C Blue No. 1	Chronic oral toxicity/carcinogenicity study in Charles River albino rats	NOAEL=1200 [1/] (HDT) *UF[2/]=100* ADI=12.0	--	FDA, 1982
	Chronic oral toxicity/carcinogenicity study in Osborne-Mendel rats	NOAEL=2500 (HDT) *UF=200* ADI=0 - 12.5	--	Hansen et al., 1964, as cited in JECFA, 1969

FD&C Red No. 40	Chronic oral toxicity/carcinogenicity study in CD-1 albino rats	NOAEL=695 LOAEL=2595 *UF=100* ADI= 0 - 7	Decreased mean body weight and growth rate	Serota et al., 1977, as cited in JECFA, 1980
FD&C Yellow No. 5[3/]	Chronic oral toxicity study in dogs	NOAEL=500 (HDT) UF=100 ADI=5.0	–	FDA, 1985

1/ No observed adverse effect level (NOAEL) in mg/kg/day converted from the reported value of 2.0% in the diet
2/ Uncertainty factor used in deriving the ADI
3/ Information on the derivation of the JECFA ADI of 0 - 7.5 mg/kg/day is unavailable

These substances were each determined to be of low acute oral toxicity and to not be dermal irritants or sensitizers (Sazaki et al, 2002; BIBRA, 1999). No treatment related maternal or fetal effects were reportedly observed at limit dose levels in two rat developmental toxicity studies with FD&C Yellow No.5 (Collins et al, 1990, 1992). In two rat developmental studies with FD&C Red No. 40, no treatment related maternal or fetal effects were reportedly observed at limit does levels in an oral (gavage) study (Collins et al, 1989a) and no treatment-related maternal or fetal effects were reportedly observed at the highest dose tested of 939 mg/kg/day in an oral (drinking water) study (Collins et al,1989b).

No adverse effects were observed in a three-generation reproduction study in rats with dietary doses of FD&C Blue No. 1 of up to about 1 g/kg/day (BIPRA, 1999). A reported NOAEL for reproductive effects in rats following administration of FD&C Red No. 40 in the diet was given as 13,900 ppm (IACM, 2003) which would be approximately equivalent to a NOAEL of 695 mg/kg/day (with a LOAEL of 2595 mg/kg/day based on pup growth suppression). FDA concluded that "a multigeneration study in rats in which the animals were exposed to FD&C Yellow No. 5 at 750 mg/kg/day for three generations . . . . revealed no adverse effects on reproduction" (FDA, 1985).

No evidence of carcinogenicity was observed in carcinogenicity studies in mice and rats with FD&C Blue No. 1, (Borzelleca and Hallagan, 1988a, 1988b), FD&C Red No. 40, (Borzelleca et al 1989, 1991) and FD&C Yellow No. 5 (Borzelleca et al, 1990). These substances are not mutagenic in the standard Ames assay with or without metabolic activation (Brown et al, 1978).

B. Special Considerations for Infants and Children

At this time, there is no concern for potential sensitivity to infants and children resulting from exposures to FD&C Blue No. 1, FD&C Red No. 40, and FD&C Yellow No. 5. There is no reported quantitative or qualitative evidence of increased susceptibility of rat fetuses to *in utero* exposure to FD&C Blue No. 1, FD&C Red No. 40, and FD&C Yellow No. 5. in developmental toxicity studies in rats. No quantitative or qualitative evidence of increased susceptibility has been reported following the pre/postnatal exposure to rats in 2-generation reproduction toxicity

studies in rats. A safety factor analysis has not been used to assess the risk. For these reasons the additional tenfold safety factor is unnecessary.

C. Endocrine Disruption

EPA is required under the Federal Food Drug and Cosmetic Act (FFDCA), as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) "may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or other such endocrine effects as the Administrator may designate." Following the recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there was scientific bases for including, as part of the program, the androgen and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that the Program include evaluations of potential effects in wildlife. For pesticide chemicals, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA has authority to require the wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP).

When the appropriate screening and/or testing protocols being considered under the Agency's EDSP have been developed, FD&C Blue No. 1, FD&C Red No. 40, and FD&C Yellow No. 5 may be subjected to additional screening and/or testing to better characterize effects related to endocrine disruption.

V. Exposure Assessment

Exposures to FD&C Blue No. 1, FD&C Red No. 40, and FD&C Yellow No. 5 would most likely be from their existing uses as food, drug and cosmetic color additives. Inert ingredient functional use category weight fraction data (PIRAT, 2004) show that color agents are incorporated into pesticide products at concentrations that are typically much less than 0.1%. Utilizing pesticide use rate information coupled with weight fraction data on colorants, estimates of dietary exposures (food only) resulting from the pesticide inert ingredient uses of FD&C Blue No. 1, FD&C Red No. 40, and FD&C Yellow No. 5 are several orders of magnitude lower than both the exposures resulting from the FDA-approved uses of these color additives in foods and the established ADIs for these color additives. Results of the dietary exposure analysis are given in Appendix B.

FD&C Blue No. 1, FD&C Red No. 40, and FD&C Yellow No. 5 are water soluble, mobile and not readily biodegradable. Volatilization from soils and water is not likely to be a transport process in the environment. There were no readily available data on the occurrence of FD&C Blue No. 1, FD&C Red No. 40, and FD&C Yellow No. 5 in ambient or treated drinking water. No ambient water quality criteria, drinking water maximum contaminant levels or health advisory levels have been established for these compounds by EPA's Office of Water. The potential for

transport into drinking water resulting from pesticide inert ingredient uses of these substances do exist, however highly conservative estimated upper bound drinking water concentrations from these substances' use as pesticide inert ingredients derived from the FQPA Index Reservoir Screening Tool (FIRST) would be around 1 ppb which translates to drinking water exposures that are several orders of magnitude below the established ADIs; actual drinking water exposures, if any, would be significantly lower. The results of the FIRST modeling analysis and the conservative assumptions utilized as inputs into the model are provided in Appendix C.

VI. Aggregate Exposure

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 FD&C Blue No. 1, FD&C Red No. 40, and FD&C Yellow No. 5 a qualitative assessment for all pathways of human exposure (food, drinking water, and residential) given the their low toxicity and low concerns for human health hazards associated with their use as FDA approved color additive and pesticide inert ingredient use.

VII. Risk Characterization

As color additives used in food, drugs and cosmetics, there are no identified risk concerns for FD&C Blue No. 1, FD&C Red No. 40, and FD&C Yellow No. 5. No adverse effects have been associated with exposures resulting from these FDA-approved uses of FD&C Blue No. 1, FD&C Red No. 40, and FD&C Yellow No. 5.

Taking into consideration all available information on FD&C Blue No. 1, FD&C Red No. 40, and FD&C Yellow No. 5 including the extensive toxicity database in which no adverse effects were noted, the low toxicity, the lack of risk concerns usage as color additives, and the low exposures likely to result from uses as pesticide inert ingredients, it has been determined that there is a reasonable certainty that no harm to any population subgroup will result from aggregate exposure to FD&C Blue No. 1, FD&C Red No. 40, and FD&C Yellow No. 5 when considering dietary exposure and all other non-occupational 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 FD&C Blue No. 1, FD&C Red No. 40, and FD&C Yellow No. 5 in/on raw agricultural commodities can be considered reassessed as safe under section 408(q) of the FFDCA.

VIII. Cumulative Risk

Section 408(b)(2)(D)(v) of 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."

EPA does not have, at this time, available data to determine whether FD&C Blue No. 1, FD&C Red No. 40, and FD&C Yellow No. 5 have a common mechanism of toxicity with other substances. 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 FD&C Blue No. 1, FD&C Red No. 40, and FD&C Yellow No. 5 and any other substances and, FD&C Blue No. 1, FD&C Red No. 40, and FD&C Yellow No. 5 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 FD&C Blue No. 1, FD&C Red No. 40, and FD&C Yellow No. 5 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's Office of Pesticide Programs 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/fedrgstr/EPA-PEST/2002/January/Day-16/.

IX . Ecological Risk Characterization

The available toxicity information, fate properties and use information have been used to characterize potential ecological risks related to the use of FD&C Blue No. 1, FD&C Red No. 40, and FD&C Yellow No. 5 as inert ingredients in pesticide formulations. The available aquatic toxicity data on FD&C Blue No. 1 and FD&C Yellow No 5. indicate low acute toxicity to fish and aquatic invertebrates (ECOTOX, 2002). While no other toxicity studies are available, modeling results indicate that expected potential risks to aquatic organisms and soil and sediment dwelling organisms resulting from the use of FD&C Blue No. 1, FD&C Red No. 40, and FD&C Yellow No. 5 as inert ingredients in pesticide formulations are low (ECOSAR, 2000).

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(November 28, 2004)

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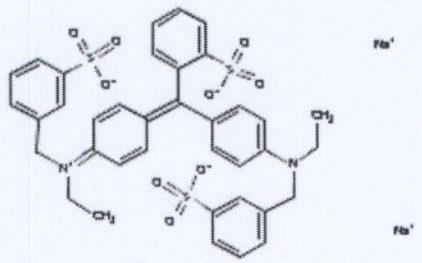
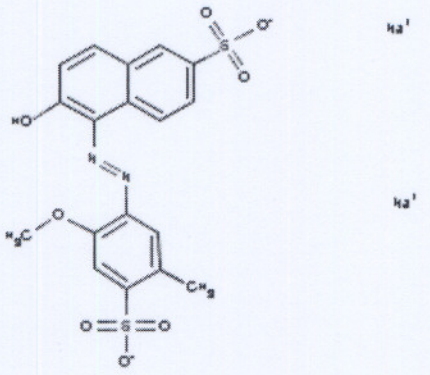
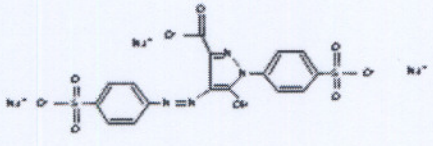
APPENDICES

APPENDIX A

Physical and Chemical Properties of FD&C Blue No. 1, FD&C Red No. 40 and FD&C Yellow No. 5. These values are either measured (M) or estimated (E).

Physical /Chemical Properties		
Parameter	**Value**	**Source**
FD&C Blue No. 1 (CAS Reg. No. 3844-45-9)		
Molecular Weight	792.859	SRC, 2004
Water Solubility	1374 mg/L @ 25° C (E)	EPI Suite, 2004
Melting Point	> 250° C (M)	BIBRA, 1999
Vapor Pressure	2.97×10^{-42} mm Hg @ 25° C (E)	EPI Suite, 2004
Henry's Law Constant	7.6×10^{-34} atm-m^3/mole @ 25° C (E)	EPI Suite, 2004
Octanol-Water Partition Coefficient (K_{OW})	log K_{OW}= -0.320 (E)	SRC, 2004
Structure		ChemIDplus, 2004
FD&C Red No. 40 (CAS Reg. No. 25956-17-6)		
Molecular Weight	496.427	SRC, 2004
Water Solubility	2.25×10^{5} mg/L @ 25° C (M)	SRC, 2004
Melting Point	350° C (E)	MPBPVPWIN EPI Suite, 2000 as cited by IACM, 2003
Vapor Pressure	1.25×10^{-23} mm Hg @ 25° C (E)	MPBPVPWIN EPI Suite, 2000 as cited by IACM, 2003
Henry's Law Constant	1×10^{-15} atm-m^3/mole @ 25° C (E)	MPBPVPWIN EPI Suite, 2000 as cited by IACM, 2003

Physical /Chemical Properties		
Parameter	**Value**	**Source**
Octanol-Water Partition Coefficient (K_{OW})	log K_{OW}= -0.550 (E)	SRC, 2004
Structure		ChemIDplus, 2004
FD&C Yellow No. 5 (CAS Reg. No. 1934-21-0)		
Molecular Weight	534.368	SRC 2004
pH	6-7 (10g/L @ 20° C (M)	BASF, 2003
Water Solubility	160 g/L @ 25° C (M)	BASF, 2003
Melting Point:	>300° C (M)	UAkron, 2003
Vapor Pressure	7.43 x 10^{-22} mm Hg @ 25° C (E)	MPBPVPWIN EPI Suite, 2000 as cited IACM, 2004
Henry's Law Constant	1 x 10^{-15} atm-m^3/mole @ 25° C (E)	MPBPVPWIN EPI Suite, 2000 as cited IACM, 2004
Octanol-Water Partition Coefficient (K_{OW})	log K_{OW}= -10.17 (E)	SRC, 2004
Structure		ChemIDplus 2004

APPENDIX B

Dietary Exposure Model for Inert Ingredients

A screening level model for predicting dietary exposure to inert ingredients was developed and is based on the following assumptions and inputs:

Model Assumptions

Actual crop-specific residue data for active ingredients can be utilized as surrogate data for inert ingredient residue levels (including secondary residues in meat, milk, poultry and eggs).

Inert ingredients are used on all crops and 100% of all crops are "treated" with inert ingredients

No adjustment made for % of inert in formulation, application rate, or multiple applications of different active ingredient formulations

Considers only preharvest applications

Model Inputs

A group of 57 of the most "significant" active ingredients were considered. These active ingredients included substances in the insecticide (20) , fungicide (17), and herbicide class (20) and were selected based on a overall ranking scheme that included the following components:

Overall Use–Based on 1999 data for active ingredient use (in lbs/yr). *(All herbicides at >5 million lbs/yr and all fungicides and insecticides at > 1 million lbs/yr were included)*

Use on crops that are significant contributors to diet *(All a.i.s which had substantial use on crops that make up the "Top 25" kids diet were included).*

Use on specific crops (*crop-by-crop pesticide use information was evaluated to identify the most frequently used active ingredients*)

3. Actual residue monitoring studies (*active ingredients with the highest frequency of detection)*

Model Construct

A DEEM™-type analysis was performed utilizing the highest established tolerance level residue for each commodity. In those cases where DEEM listed a commodity for which a published tolerance did not exist, the input value was selected based on representative crops or other "default" values (e.g, use of standard processing factors). A DEEM-FCID™, Version 1.3 analyses were performed for both acute and chronic dietary exposure scenarios and the results for each are given in Table 1 and 2.

DEEM-FCID™ Program and Consumption Information

Generic inert ingredient acute and chronic dietary exposure assessments were conducted using the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID™, Version 1.3), which incorporates consumption data from USDA's Continuing Surveys of Food Intakes by Individuals (CSFII), 1994-1996 and 1998. The 1994-96, 98 data are based on the reported consumption of more than 20,000 individuals over two non-consecutive survey days. Foods "as consumed" (e.g., apple pie) are linked to EPA-defined food commodities (e.g. apples, peeled fruit - cooked; fresh or N/S; baked; or wheat flour - cooked; fresh or N/S, baked) using publicly available recipe translation files developed jointly by USDA/ARS and EPA. Consumption data are averaged for the entire U.S. population and within population subgroups for chronic exposure assessment, but are retained as individual consumption events for acute exposure assessment.

For chronic exposure and risk assessment, an estimate of the residue level in each food or food-form (e.g., orange or orange juice) on the food commodity residue list is multiplied by the average daily consumption estimate for that food/food form. The resulting residue consumption estimate for each food/food form is summed with the residue consumption estimates for all other food/food forms on the commodity residue list to arrive at the total average estimated exposure. Exposure is expressed in mg/kg body weight/day. This procedure is performed for each population subgroup.

For acute exposure assessments, individual one-day food consumption data are used on an individual-by-individual basis. The reported consumption amounts of each food item can be multiplied by a residue point estimate and summed to obtain a total daily pesticide exposure for a deterministic (Tier 1 or Tier 2) exposure assessment, or "matched" in multiple random pairings with residue values and then summed in a probabilistic (Tier 3/4) assessment. For this screening-level assessment, only a Tier 1 analysis was performed.

Use of Model in Inert Risk Assessment

The results of this model would likely represent an upper-bound estimate of likely potential dietary exposure to an inert ingredient resulting from preharvest use. These values could be compared to the expected toxicity in a qualitative (Tier 1 substance) assessment, or, in those cases where a bounding level risk assessment is necessary, these exposure values could be compared to the selected toxicity endpoints in a %PAD or MOE type approach (see Figure 1). In cases where this model would yield dietary risk values below the level of concern, no further refinements would be necessary, and the potential dietary exposure and risk could be considered adequately characterized. If this model results in dietary risk, above the level of concern, then additional data, use limitations, and/or /further refinements would be necessary. Additionally, the use of this model could allow apportionment of the amount of remaining 'acceptable' risk to other routes of exposure.

Figure 1.

Fictional Example of Use of Dietary Exposure Model in %PAD Approach
Dose selected= 500 mg/kg-bw/day

Uncertainty factor=1000
cPAD=0.5 mg/kg-bw/day
Dietary exposure=0.12 mg/kg/day
%cPAD=0.12 mg/kg/day/0.5 mg/kg-bw/day x100 =24

Model Limitations and Areas for Further Consideration

Actual inert ingredient residue levels--While the selected group of active ingredients possesses some chemical structural diversity, could inert ingredients (by virtue of their uptake into plants and environmental persistence) differ greatly from active ingredients in terms of the nature and magnitude of their plant and animal residues? What about degradates–would they be of concern or need to be separately assessed?

Concentration of inert in formulation--Initial analysis of "benchmark" products for many of the 57 most "significant" active ingredients indicates that the concentration of the a.i ≥ any single inert ingredient. If this can be further confirmed, it may allow for a "maximum % inert" adjustment to be used in the model.

Differences in product use rate and impacts on residue level.--While there are a few outliers, most of these a.i.'s are used in the 1-5 lb (AI basis) per season use rate.

"Generic" inert–The model makes no distinction as to formulation type or timing of application. It may be possible to develop other models for more specific inert use (e.g., preemergent use only, soil incorporation only).

Residues in meat, milk, poultry and eggs–This model used the highest tolerance level residues for input into DEEM™, but it may be possible to utilize residues in livestock feed items and chemical specific information related to uptake or accumulation of secondary residues develop a different set of values on a per inert basis for meat, milk, poultry and eggs.

Table 1. Estimated Chronic Dietary Exposure[1] for a Generic Inert.

Population Subgroup[2]	Estimated Exposure, mg/kg/day
U.S. Population (total)	0.120
All infants (< 1 year)	0.245
Children (1-2 years)	0.422
Children (3-5 years)	0.310
Children (6-12 years)	0.174
Youth (13-19 years)	0.100
Adults (20-49 years)	0.087
Adults (50+ years)	0.086
Females (13-49 years)	0.087

[1]Exposure estimates are based on highest-tolerance-level residues of high-use active ingredients for all food forms, including meat, milk, poultry, and eggs.
[2]Only representative population subgroups are shown.

Table 2. Estimated Acute Dietary Exposure[1] for a Generic Inert.			
Population Subgroup[2]	Estimated Exposure, mg/kg/day		
	95th Percentile	99th Percentile	99.9th Percentile
U.S. Population (total)	0.336	0.643	1.164
All infants (< 1 year)	0.701	1.060	2.056
Children (1-2 years)	0.939	1.382	2.106
Children (3-5 years)	0.683	1.010	1.476
Children (6-12 years)	0.395	0.563	0.827
Youth (13-19 years)	0.239	0.357	0.815
Adults (20-49 years)	0.199	0.295	0.468
Adults (50+ years)	0.191	0.263	0.357
Females (13-49 years)	0.198	0.287	0.415

[1]Exposure estimates are based on highest-tolerance-level residues of high-use active ingredients for all food forms, including meat, milk, poultry, and eggs.
[2]Only representative population subgroups are shown.

In the case of the FD&C Dyes an adjustment was made to the inputs whereby an effective application rate "factor" of 0.02 was utilized (which accounts for the maximum actual % of dye in formulation and product use rate).

Utilizing this adjustment, the estimated upper bound dietary exposures to the FD&C dyes resulting from their use as inert ingredients is given in Table 3.

Table 3. Estimated Chronic Dietary Exposure[1] for FD&C Blue No. 1, FD&C Red No. 40 and FD&C Yellow No. 5	
Population Subgroup[2]	Estimated Exposure, mg/kg/day
U.S. Population (total)	0.002
All infants (< 1 year)	0.005
Children (1-2 years)	0.008
Children (3-5 years)	0.006
Children (6-12 years)	0.003
Youth (13-19 years)	0.002

Adults (20-49 years)	<0.0001
Adults (50+ years)	<0.0001
Females (13-49 years)	<0.0001

APPENDIX C

Estimated Environmental Concentration (EEC) of FD&C Blue No. 1, FD&C Red. No 40 and FD&C Yellow No. 5 in Untreated Drinking Water and Surface Water

I. Drinking Water

Monitoring data were not available for surface or ground water, therefore modeling was performed. In the absence of measured chemical properties, known fate and transformation half-lives, and use and usage information, Tier I models provide a conservative assessment of exposures in which, under almost all conditions, are unlikely to be exceeded. In addition, proper parameterization of higher tier models necessitates measured fate and known usage data. Drinking water exposures were estimated using the Tier I surface water exposure model FQPA Index Reservoir Screening Tool (FIRST, Version 1.0, dated August 1, 2001). The Tier I ground water exposure model, Screening Concentrations in Ground Water, was not used in this assessment because these compounds are unlikely to result in exposures exceeding surface waster concentrations when measured chemical property and fate data are used. Modeling inputs for fate and transport of the FD&C dyes were assumed to be stable because; 1) the behavior of each dye in the environment is somewhat different, and 2) available data were either qualitative in nature (e.g., microbial degradation is days to weeks) or were estimated to likely fall in a range. This approach is expected to be conservative, resulting in exposures that are unlikely to actually occur in the environment based on physical-chemical inputs and environmental fate and the application rate used. Compounds modeled as stable and very mobile, result in exposures that will be linear with increases in application rate or in numbers of applications. For example, the exposures from a 2 pound application rate will be twice as high from a 1 pound application rate, whether applied at once or separated by time within a year. Environmental fate data and default application rate information are presented in Table 1. The results of the model were then scaled to adjust for an effective application rate of 0.02 lbs/acre (based upon a color additive weight fraction of 0.1%, a product application rate of 5 lbs/product acre and four applications per year).

Table 1. FD&C Dyes Modeling Input Parameters for FIRST and GENEEC

Parameter	Value	Source
Maximum single application rate (lb/acre)	1	Assumed.
Application Method	Aerial Spray	No limits on application method; method yielding most conservative results used
Max No. application per year	1	Assumed
PCA factor (decimal)	0.87 (default)	Effland et al[17] (2000)
Kd (mL/g)	0.01	Assumed

Aerobic soil met. $t_{1/2}$ (d)	**Stable[1]**	**Assumed**
Solubility (mg/L)	**100000**	**assumed**
Aerobic aquatic met. $t_{1/2}$ (d)	**Stable[1]**	**assumed**
Hydrolysis (pH 7) $t_{1/2}$ (d)	**Stable[1]**	**assumed**
Aqueous photolysis $t_{1/2}$ (d)	**Stable[1]**	**assumed**

[1]For the purpose of estimating a high-end surface water concentration, FD&C dyes are assumed to be stable to these degradation pathways on the field and in surface water.

Drinking Water EEC Using FIRST:

RUN No. 1 FOR Generic ON Generic * INPUT VALUES *

RATE (#/AC) ONE(MULT)	No.APPS & INTERVAL	SOIL Kd	SOLUBIL (PPM)	APPL TYPE (%DRIFT)	%CROPPED AREA	INCORP (IN)
1.000(1.000)	1 1	.0*******		AERIAL(16.0)	87.0	.0

FIELD AND RESERVOIR HALFLIFE VALUES (DAYS)

METABOLIC (FIELD)	DAYS UNTIL RAIN/RUNOFF	HYDROLYSIS (RESERVOIR)	PHOTOLYSIS (RES.-EFF)	METABOLIC (RESER.)	COMBINED (RESER.)
1000.00	2	N/A	.00- .00	.00	.00

UNTREATED WATER CONC (MICROGRAMS/LITER (PPB)) Ver 1.0 AUG 1, 2001

PEAK DAY (ACUTE) CONCENTRATION	ANNUAL AVERAGE (CHRONIC) CONCENTRATION
92.170	66.089

ADJUSTED UNTREATED WATER CONC (MICROGRAMS/LITER (PPB))

PEAK DAY (ACUTE) CONCENTRATION	ANNUAL AVERAGE (CHRONIC) CONCENTRATION
1.834	1.322

II. Surface Water Ecological Exposure

To determine ecological exposures from the FD&C dyes, estimated environmental concentrations (EECs) were modeled using the Tier I model Generic Estimated Environmental Concentrations (GENEEC, Version 2.0, dated August 1, 2001) and based on input parameter data presented in Table 1. An additional input variable in GENEEC, spray drift application method, permitted the use of a define spray droplet spectrum. The same approach used for fate and use rate inputs was applied to estimating exposures for ecological receptors. Table X provides the results from the model.

Surface Water EEC Using GENEEC:

RUN No. 1 FOR Generic ON Generic * INPUT VALUES *

RATE (#/AC) ONE(MULT)	No.APPS & INTERVAL	SOIL Kd (PPM)	SOLUBIL (%DRIFT)	APPL TYPE ZONE(FT)	NO-SPRAY (IN)	INCORP
1.000(1.000)	1 1	.0*******	AERL_B(13.0)	.0	.0	

FIELD AND STANDARD POND HALF-LIFE VALUES (DAYS)

METABOLIC (FIELD)	DAYS UNTIL RAIN/RUNOFF	HYDROLYSIS (POND)	PHOTOLYSIS (POND-EFF)	METABOLIC (POND)	COMBINED (POND)
1000.00	2	N/A	.00- .00	.00	.00

GENERIC EECs (IN MICROGRAMS/LITER (PPB)) Version 2.0 Aug 1, 2001

PEAK GEEC	MAX 4 DAY AVG GEEC	MAX 21 DAY AVG GEEC	MAX 60 DAY AVG GEEC	MAX 90 DAY AVG GEEC
60.6	60.6	60.5	60.5	60.5

ADJUSTED EECs (IN MICROGRAMS/LITER (PPB)) Version 2.0 Aug 1, 2001

PEAK GEEC	MAX 4 DAY AVG GEEC	MAX 21 DAY AVG GEEC	MAX 60 DAY AVG GEEC	MAX 90 DAY AVG GEEC
1.21	1.21	1.21	1.21	1.21

III. Uncertainties

The FIRST model is designed to yield concentration values which exceed those predicted by the linked EPA PRZM and EXAMS models for all but the most vulnerable sites, application patterns and environmental fate properties. PRZM/EXAMS predictions may exceed FIRST predictions under the following circumstances:

Applications to crops in managed environments known to produce excessive runoff (e.g., crops grown over plastic mulch).

Applications at sites with hydrologic group D soils which also receive excessively high rainfall (e.g., EFED sweet potato scenario in southern Louisiana).

Multiple applications over a window of 30 days or longer in exceptionally high rainfall areas (e.g., far southeastern US).

FD&C dyes were assumed to be stable in surface water environments which may overestimate actual concentrations.

APPENDIX D

RESULTS OF ECOSAR ECOLOGICAL EFFECTS MODELING

I. FD&C Blue No. 1

SMILES : OS(=O)(=O)c1ccccc1C(=C2C=CC(=N(CC)Cc3cccc(S(=O)(=O)O[Na])c3)C=C2)c4cc
c(N(CC)Cc5cccc(S(=O)(=O)O[Na])c5)cc4
CHEM : Benzenemethanaminium, N-ethyl-N-[4-[[4-[ethyl[(3-sulfophenyl)methyl]a
mino]phenyl](2-sulfophenyl)methylene]-2,5-cyclohexa
CAS Num: 003844-45-9
ChemID1:
ChemID2:
ChemID3:
MOL FOR: C37 H35 N2 O9 S3 Na2
MOL WT : 793.86
Log Kow: -4.94 (KowWin estimate)
Melt Pt:
Wat Sol: 4.232E+010 mg/L (calculated)

ECOSAR v0.99h Class(es) Found

Neutral Organics-acid

ECOSAR Class	Organism	Duration	End Pt	Predicted mg/L (ppm)
Neutral Organic SAR (Baseline Toxicity)	: Fish	14-day	LC50	1.18e+009

--> Acid moeity found: Predicted values multiplied by 10

Neutral Organics-acid	: Fish	96-hr	LC50	1.96e+010
Neutral Organics-acid	: Fish	14-day	LC50	1.18e+010
Neutral Organics-acid	: Daphnid	48-hr	LC50	1.3e+010
Neutral Organics-acid	: Green Algae	96-hr	EC50	5.47e+009
Neutral Organics-acid	: Fish	30-day	ChV	8.27e+008
Neutral Organics-acid	: Daphnid	16-day	EC50	3.21e+007
Neutral Organics-acid	: Green Algae	96-hr	ChV	9.9e+006
Neutral Organics-acid	: Fish (SW)	96-hr	LC50	1.57e+008
Neutral Organics-acid	: Mysid Shrimp	96-hr	LC50	8.03e+011 *
Neutral Organics-acid	: Earthworm	14-day	LC50	6.7e+006

Note: * = asterisk designates: Chemical may not be soluble
enough to measure this predicted effect.
Fish and daphnid acute toxicity log Kow cutoff: 5.0
Green algal EC50 toxicity log Kow cutoff: 6.4
Chronic toxicity log Kow cutoff: 8.0
MW cutoff: 1000

II. FD&C Red No. 40

SMILES : COc1cc(c(C)cc1N=Nc2c(O)ccc3cc(ccc23)S(O[Na])(=O)=O)S(O[Na])(=O)=O
CHEM : C.I. Food Red 17
CAS Num: 025956-17-6
ChemID1:
ChemID2:
ChemID3:
MOL FOR: C18 H14 N2 O8 S2 Na2
MOL WT : 496.42
Log Kow: -0.55 (KowWin estimate)
Melt Pt:
Wat Sol: 8.807E+005 mg/L (calculated)

ECOSAR v0.99h Class(es) Found

Phenols

ECOSAR Class	Organism	Duration	End Pt	Predicted mg/L (ppm)
Neutral Organic SAR (Baseline Toxicity)	: Fish	14-day	LC50	1.11e+005
Phenols	: Fish	96-hr	LC50	2714.246
Phenols	: Daphnid	48-hr	LC50	294.985
Phenols	: Green Algae	96-hr	EC50	44524.520
Phenols	: Fish	30-day	ChV	435.110
Phenols	: Fish	90-day	ChV	8.179
Phenols	: Daphnid	21-day	ChV	288.768
Phenols	: Green Algae	96-hr	ChV	1019.880

Note: * = asterisk designates: Chemical may not be soluble

enough to measure this predicted effect.
Fish and daphnid acute toxicity log Kow cutoff: 7.0
Green algal EC50 toxicity log Kow cutoff: 7.0
Chronic toxicity log Kow cutoff: 9.0
MW cutoff: 1000

III. FD&C Yellow No. 5

SMILES : [Na]Oc2c(N=Nc1ccc(cc1)S(O[Na])(=O)=O)c(nn2c3ccc(cc3)S(O[Na])(=O)=O)C(=O)(O[Na])
CHEM : Tarttrazine
CAS Num: 001934-21-0
ChemID1:
ChemID2:
ChemID3:
MOL FOR: C16 H8 N4 O9 S2 Na4
MOL WT : 556.34
Log Kow: -10.17 (KowWin estimate)
Melt Pt:
Wat Sol: 6.408E+015 mg/L (calculated)

ECOSAR v0.99h Class(es) Found

Neutral Organics

ECOSAR Class	Organism	Duration	End Pt	Predicted mg/L (ppm)
Neutral Organic SAR (Baseline Toxicity)	: Fish	14-day	LC50	2.97e+013
Neutral Organics	: Fish	96-hr	LC50	1.14e+014
Neutral Organics	: Fish	14-day	LC50	2.97e+013
Neutral Organics	: Daphnid	48-hr	LC50	5.25e+013
Neutral Organics	: Green Algae	96-hr	EC50	1.63e+013
Neutral Organics	: Fish	30-day	ChV	2.06e+012
Neutral Organics	: Daphnid	16-day	EC50	1.31e+010
Neutral Organics	: Green Algae	96-hr	ChV	1.44e+009
Neutral Organics	: Fish (SW)	96-hr	LC50	7.24e+010
Neutral Organics	: Mysid Shrimp	96-hr	LC50	1.94e+017 *

Neutral Organics : Earthworm 14-day LC50 1.92e+007

Note: * = asterisk designates: Chemical may not be soluble enough to measure this predicted effect.
Fish and daphnid acute toxicity log Kow cutoff: 5.0
Green algal EC50 toxicity log Kow cutoff: 6.4
Chronic toxicity log Kow cutoff: 8.0
MW cutoff: 1000
