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

OFFICE OF PREVENTION,
PESTICIDES, AND TOXIC SUBSTANCES

DATE: June 21, 2006

ACTION MEMORANDUM

SUBJECT: Inert Reassessment—n-Octyl Alcohol (CAS Reg. No. 111-87-5) and n-Decyl Alcohol (CAS Reg. No. 112-30-1)

FROM: Pauline Wagner, Chief Pauline Wagner 6/21/06
Inert Ingredient Assessment Branch
Registration Division (7505P)

TO: Lois A. Rossi, Director
Registration Division (7505P)

I. FQPA REASSESSMENT ACTION

Action: Reassessment of one exemption from the requirement of a tolerance for n-octyl alcohol and one exemption from the requirement of a tolerance for n-decyl alcohol. The exemptions are being reassessed as-is. Both chemicals are used as solvents/cosolvents in pesticide products. Please note the Code of Federal Regulations (40 CFR 180.920) lists n-decyl alcohol as a dye when in fact it is used as a solvent or cosolvent. This error will be corrected through a future rulemaking and both chemicals will be described as "solvent or cosolvent."

Chemicals: n-Octyl Alcohol and n-Decyl Alcohol

CFR: 40 CFR 180.920 (n-octyl alcohol); 40 CFR 180.920 (n-decyl alcohol)

CAS #: 111-87-5 (n-octyl alcohol) and 112-30-1 (n-decyl alcohol)

Use Summary: Industrially, both alcohols are used as ingredients in perfumes, flavoring agents, and industrial solvents. In addition, the U.S. Food and Drug Administration (FDA) has approved the use of both chemicals as direct food additives. As pesticide inert ingredients, n-octyl and n-decyl alcohol are used as solvents or cosolvents in products applied to agricultural crops under 40 CFR 180.920. n-Octyl and n-decyl alcohol are also pesticide active ingredients; both are used as tobacco sucker control agents.

List Reclassification Determination: The current List Classification for n-octyl alcohol is 3. Because EPA has determined that there is a reasonable certainty that no harm to any population subgroup will result from aggregate exposure to n-octyl alcohol used as an inert ingredient in pesticide formulations, the List Classification will change from List 3 to List 4B. The current List Classification for n-decyl alcohol is 4B; it will retain its current Classification.

II. MANAGEMENT CONCURRENCE

I concur with the reassessment of the two exemptions from the requirement of a tolerance for the inert ingredient n-octyl Alcohol (CAS Reg. No. 111-87-5) and with the List reclassification determination, as described above. I also concur with the reassessment of the one exemption from the requirement of a tolerance for the inert ingredient n-decyl alcohol (CAS Reg. No. 112-30-1) and with the List reclassification determination, as described above. I consider the two exemptions established in 40 CFR 180.920 to be reassessed for purposes of FFDCA's section 408(q) 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

June 26, 2006
Date:

cc: Debbie Edwards, SRRD
Joe Nevola, SRRD

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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OFFICE OF PREVENTION,
PESTICIDES, AND TOXIC SUBSTANCES

June 21, 2006

MEMORANDUM

SUBJECT: Reassessment of One Exemption from the Requirement of a Tolerance for n-Octyl Alcohol (CAS Reg. No. 111-87-5) and One Exemption from the Requirement of a Tolerance for n-Decyl Alcohol (CAS Reg. No. 112-30-1)

FROM: Kathleen Martin, Chemist Kathleen Martin 6/21/06
Inert Ingredient Assessment Branch
Registration Division (7505P)

TO: Pauline Wagner, Chief
Inert Ingredient Assessment Branch
Registration Division (7505P)

BACKGROUND

Attached is the science assessment for n-octyl and n-decyl alcohol. The purpose of this document is to reassess the existing exemptions from the requirement of tolerance for residues of n-octyl alcohol and n-decyl alcohol as required under the Food Quality Protection Act (FQPA). These two chemicals are being assessed in one document because they have similar use patterns and toxicity profiles. This assessment summarizes available information on the use, physical/chemical properties, toxicological effects, exposure profile, environmental fate, and ecotoxicity of n-octyl and n-decyl alcohol.

EXECUTIVE SUMMARY

The alcohols n-octyl and n-decyl are being assessed in this document. Both are straight chain alcohols with n-octyl having eight carbons and n-decyl having ten carbons. They are being assessed together because they have similar use patterns and toxicity. Industrially, both alcohols are used as ingredients in perfumes, flavoring agents, industrial solvents, and as U.S. Food and Drug Administration (FDA) direct food additives. As with other linear saturated aliphatic alcohols, n-octyl and n-decyl alcohol are ubiquitous in nature. n-Octyl alcohol is a natural constituent of plants and microbes and n-decyl alcohol has been found as a natural component in apples and oranges. As pesticide inert ingredients, n-octyl and n-decyl alcohol are used as solvents or cosolvents in products applied to agricultural crops under 40 CFR 180.920.

Based on how n-octyl and n-decyl alcohol are used as inert ingredients in pesticide products, EPA expects that exposure will be limited to the oral route, via consumption of crops to which these alcohols have been applied, and exposure through the drinking water. Exposure is expected to be low.

Overall, n-octyl and n-decyl alcohol are of low acute toxicity. Acute oral toxicity for n-octyl alcohol is in Toxicity Category III (see 40 CFR 156.62) and n-decyl alcohol is in Toxicity Category IV. Acute dermal toxicity for both alcohols is in Toxicity Category III. n-Octyl alcohol is slightly irritating to the skin while n-decyl alcohol is irritating to the skin. Both alcohols are irritating to the eye. In an oral subchronic toxicity study for n-octyl alcohol, no effects were seen. An oral developmental study conducted using a blend of n-octyl and n-decyl alcohol showed maternal effects at a high dose of 1,000 mg/kg/day; no developmental effects were seen. Finally, in testing mutagenicity using a blend of n-octyl and n-decyl alcohol, all results were negative.

Taking into consideration all available information on n-octyl and n-decyl alcohol, EPA has determined that there is a reasonable certainty that no harm to any population subgroup will result from aggregate exposure to n-octyl and n-decyl alcohol when used as inert ingredients in pesticide products when considering dietary (i.e., food and water) exposure and all other nonoccupational sources of pesticide exposure for which there is reliable information. Overall exposure due to the inert use of n-octyl and n-decyl alcohol is expected to result in human exposure below any dose level that would produce any adverse effect. This is based on available animal toxicity studies and the use pattern of n-octyl and n-decyl alcohol. Therefore, it is recommended that the two exemptions from the requirement of a tolerance established for residues of n-octyl and n-decyl alcohol (one tolerance for each alcohol) can be considered reassessed as safe under section 408(q) of FFDCA.

I. INTRODUCTION

This report provides a qualitative assessment for n-octyl and n-decyl alcohol, inert ingredients in pesticide formulations that are exempted from the requirement of a tolerance when applied to growing crops (40 CFR 180.920). Because of their similar use patterns and toxicity, n-octyl and decyl alcohol are being assessed together, in this reassessment document.

Both alcohols have a number of industrial uses such as ingredients in perfumes, flavoring agents, industrial solvents (Lewis 2002), and U.S. Food and Drug Administration (FDA) direct food additives (21 CFR 172). As with other linear saturated aliphatic alcohols, n-octyl and n-decyl alcohol are ubiquitous in nature (IPCS 1998). n-Octyl alcohol is a natural constituent of plants and microbes and n-decyl alcohol has been found as a natural component in apples and oranges (NIH 2005).

n-Decyl alcohol and n-octyl alcohol have been identified as chemicals meeting the criteria of EPA's High Production Volume (HPV) Challenge Program[1]. They are being sponsored under the purview of the Organization for Economic Cooperation and Development's (OECD) SIDS (Screening Information Data Set) Program;[2] the United Kingdom is the sponsoring country. The SIAR (SIDS Initial Assessment Report) is under preparation.

II. USE INFORMATION

A. Pesticides

As active ingredients in pesticide products, both n-octyl and n-decyl alcohol are used as tobacco sucker control agents. Note that this document only addresses the use of n-octyl and n-decyl alcohol as inert ingredients. The active ingredient uses will be addressed in a future Reregistration Eligibility Decision (RED) document.

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[1]HPV chemicals are those that are manufactured or imported into the United States in volumes greater than one million pounds/year. The HPV Challenge Program is a voluntary partnership among industry, environmental groups, and EPA which invites chemical manufacturers and importers to provide basic hazard data on the HPV chemicals they produce/import. The goal of this program is to facilitate the public's right-to-know about the potential hazards of chemicals found in their environment, their homes, their workplace, and in consumer products. http://www.epa.gov/opptintr/chemrtk/hpvchmlt.htm

[2]The SIDS Program is a voluntary cooperative international testing program that began in 1989. It is focused on developing base level test information on approximately 600 poorly characterized international HPV chemicals. The SIDS data are used to "screen" the chemicals and set priorities for further testing or risk assessment/management activities. http://cs3-hq.oecd.org/scripts/hpv/

As inert ingredients, n-octyl and n-decyl alcohol are used as solvents or cosolvents in products applied to agricultural crops. The exemptions from the requirement of a tolerance for n-octyl and n-decyl alcohol are provided in Table 1 below. Please note that the use listed for n-decyl alcohol is as a dye. EPA recognizes that the use of n-decyl alcohol as an inert ingredient in pesticide products is actually as a solvent or cosolvent. This error under section 180.920 of part 40 of the Code of Federal Regulations will be corrected through future rulemaking.

Table 1. Tolerance Exemptions Being Reassessed in this Document

40 CFR 180	CFR Citation			CAS Registry Number and 9CI Name
	Inert Ingredient	*Limits*	*Uses*	
n-Octyl Alcohol				
.920[a]	n- Octyl alcohol	(none)	solvent, cosolvent	111-87-5 1-Octanol
n-Decyl Alcohol				
.920[a]	n-Decyl alcohol	(none)	dye[3]	112-30-1 1-Decanol

[a]Residues listed in 40 CFR 180.920 are exempted from the requirement of a tolerance when used in accordance with good agricultural practice as inert (or occasionally active) ingredients in pesticide formulations applied to growing crops only.

B. Other Uses

n-Octyl and decyl alcohol have a number of industrial uses. For example, n-octyl alcohol is used in perfumery, cosmetics, organic synthesis, solvent manufacture of high-boiling esters, and as an antifoaming agent (Lewis 2002). On the other hand, n-decyl alcohol is used in plasticizers, detergents, synthetic lubricants, solvents, perfumes, and as an antifoaming agent (Lewis 2002). In addition to their industrial uses, these two alcohols are used as flavoring agents[4] (IPCS 1998). Their FDA-approved direct food additive uses are listed in Table 2 below.

[3]NOTE: According to 40 CFR 180.920, n-decyl alcohol is used as a dye; however, this is an error. n-Decyl alcohol is actually used as a solvent or cosolvent. This error will be corrected through a future rulemaking.

[4]IPCS, or International Programme on Chemical Safety, is an entity under the auspices of the Joint WHO/FAO Expert Committee on Food Additives (JECFA). The main role of IPCS is to establish the scientific basis for safe use of chemicals, and to strengthen national capabilities and capacities for chemical safety.

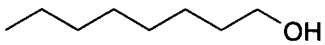
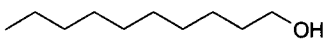
Table 2. Food Additives Permitted for Direct Addition to Food for Human Consumption

Name	21 CFR	Use
n-Octyl alcohol	172.230	In microcapsules for flavoring substances.
1-Octanol; octyl alcohol	172.515	Synthetic flavoring substances and adjuvants provided they are used in the minimum quantity required to produce their intended effect.
1-Decanol	172.515	Synthetic flavoring substances and adjuvants provided they are used in the minimum quantity required to produce their intended effect.

III. PHYSICAL AND CHEMICAL PROPERTIES

Some of the physical and chemical characteristics of n-octyl and n-decyl alcohol, along with their structures and nomenclature, are found in Table 3.

Table 3. Physical and Chemical Properties of n-Octyl and n-Decyl Alcohol

Parameter	n-Octyl Alcohol	n-Decyl Alcohol
Structure		
CAS Reg. No. and 9CI Name	111-87-5 1-Octanol	112-30-1 1-Decanol
Empirical Formula	$C_8H_{18}O$	$C_{10}H_{22}O$
Molecular Weight	130.23	158.29
Common Names	Caprylic alcohol, n-Octanol, Octanol (all isomers), Octyl alcohol NIH 2004	1-Decanol, Decyl alcohol, n-Decanol, Alcohol C-10, Capric alcohol, Caprinic alcohol NIH 2004
Physical State	liquid Merck 2005	Moderately viscous Merck 2005
Melting Point	-17 to -16°C Merck 2005	6.4°C Merck 2005
Boiling Point	194-195°C Merck 2005	232.9°C Merck 2005
Water Solubility	insoluble Merck 2005	insoluble Merck 2005
Other Solubility	miscible with alcohol, ether, chloroform Merck 2005	alcohol, ether Merck 2005
Relative Density (water=1)	0.827 @ 20°C Merck 2005	0.8297 @ 20°C Merck 2005
Relative Vapor Density (air = 1)	4.5 NIOSH 2002	5.5 NIOSH 2005
Vapor Pressure	0.0794 mm Hg @ 25°C US EPA 2002	0.00851 mm Hg @ 25°C US EPA 2002
Log P_{ow}	3.0 NIOSH 2002	4.57 US EPA 2002
Henry's Law Constant	2.45×10^{-5} atm m^3/mole US EPA 2002	3.2×10^{-5} atm m^3/mole US EPA 2002

IV. HAZARD ASSESSMENT

A. Hazard Profile

To assess the hazard of n-octyl and n-decyl alcohol used as inert ingredients in pesticide formulations, EPA considered several publicly-available sources including: published literature, peer-reviewed international documents (e.g., IUCLID[5], JEFCA[6]) and other standard available references (e.g., Patty's Industrial Hygiene and Toxicology). Agency data evaluation records (DER's) were available for: subchronic dermal toxicity (US EPA 1996), developmental toxicity (US EPA 1993b), and mutagenicity (US EPA 1993a). Note that the Agency's DER data were conducted using a "fatty alcohol blend," which is a mixture of approximately 40% n-octyl alcohol and 55% n-decyl alcohol.

B. Toxicological Data

Acute Toxicity

A summary of the acute toxicity data, along with the corresponding 40 CFR 156.62 Acute Toxicity Categories, is provided in Table 4. Except for eye and skin irritation, n-octyl and n-decyl alcohol are not acutely toxic.

Subchronic Toxicity

Oral. No effects were observed in a study in which n-octyl alcohol was administered orally to mice for one month at a dose of 180 mg/kg bw/day (IPCS 1998, citing Voskoboinikova 1966).

[5]IUCLID, the International Uniform Chemical Information Database, is a database of existing chemicals that is being compiled by the European Chemicals Bureau (ECB). IUCLID is the basic tool for data collection and evaluation within the European Union-Risk Assessment Programme; it has been accepted by the OECD as the data exchange tool under the OECD Existing Chemicals Programme. (European Commission 2000a,b)

[6]JECFA is the Joint WHO/FAO Expert Committee on Food Additives. It conducts toxicological evaluations of food additives and contaminants in food. The resulting monographs are used by the Codex Alimentarius Commission and national governments to set international food standards and safe levels for protection of the consumer. (IPCS 1998, 2001a, 2001b)

Table 4. Summary of Acute Toxicity Data for n-Octyl and n-Decyl Alcohol

Parameter	Toxicity Value *Toxicity Category*[a]	Reference
n-Octyl Alcohol		
Oral LD_{50} rat	4,135 mg/kg *Toxicity Category III*	IPCS 1998, citing Levenstein & Wolven 1972
Dermal LD_{50} rabbit	>5,000 mg/kg *Toxicity Category III*	Lington and Bevan 1991
Skin Irritation rabbit	slightly	Lington and Bevan 1991
Eye Irritation rabbit	irritating	European Commission 2000a
n-Decyl Alcohol		
Oral LD_{50} rat	9,800 mg/kg *Toxicity Category IV*	IPCS 1998, citing Smyth et al. 1951
Dermal LD_{50} rabbit	3,560 mg/kg *Toxicity Category III*	European Commission 2000b
Skin Irritation rabbit	irritating	European Commission 2000b
Eye Irritation rabbit	irritating	European Commission 2000b

[a]40 CFR 156.62

Dermal. In a subchronic toxicity study, a fatty alcohol blend containing 43% n-octyl alcohol and 57% n-decyl alcohol was applied to the skin of rats, 5 days/week for 13 weeks at dose levels of 0; 100; 300; or 1,000 mg/kg. The primary adverse clinical sign was severe irritation at the application site. Body weight was reduced in the mid- and high-dose groups. Gross necropsy findings were primarily related to the severe irritation of the skin. Adrenal gland weights were statistically-increased in the mid- and high-dose animals, but there was no histopathology accompanying the organ weight increases. Reduced red blood cell counts and hematocrit, increased white blood cell and platelet counts, and decreased lymphocyte counts were seen in treated animals compared to controls. Increased albumin and albumin/globulin ratios, and decreased glucose were seen in treated animals. There is no NOEL for dermal irritation. The LOEL for dermal irritation is 100 mg/kg based on severe irritation. The NOEL for systemic toxicity is 100 mg/kg. The LOEL for systemic toxicity is 300 mg/kg based on hematological, clinical chemistry, and organ weight changes. (US EPA 1996)

Neurotoxicity

No neurotoxicity data were identified for n-octyl alcohol or n-decyl alcohol.

Mutagenicity for a Blend of n-Octyl and Decyl Alcohol

Studies conducted using a fatty alcohol blend containing 41% n-octyl alcohol and 55% n-decyl alcohol showed no evidence of mutagenicity. An *in vivo* mammalian cytogenetics micronucleus assay was negative for micronucleus induction in bone marrow cells of male and female mice harvested 24 or 48 hours post-administration of three daily oral gavage doses of 500; 1,000; or 2,000 mg/kg/day. In addition, a microsomal mutagenicity assay was negative for

reverse gene mutation in *Salmonella typhimurium* TA1535, TA1537, TA1538, TA98, and TA100 exposed in the presence or absence of S9 activation to six doses ranging from 1.5 µg/plate to 500 µg/plate. Finally, under the conditions of the mouse lymphoma forward mutation assay, the fatty alcohol blend was tested in two independent assays with and without activation and found not to be mutagenic. (US EPA 1993a)

Carcinogenicity

No adequate carcinogenicity data were identified for n-octyl alcohol or n-decyl alcohol.

Developmental and Reproductive Toxicity

Oral. A blend of fatty alcohol (41% n-octyl alcohol and 55% n-decyl alcohol) was administered to pregnant rats via gavage at doses of 0; 125; 375; or 1,000 mg/kg/day on gestation days (GD) six through 16, inclusively. Compound-related maternal toxicity was observed at 1,000 mg/kg/day and was manifested as an increased incidence of salivation in dams. No compound-related effects on body weight and weight gain were observed in any dose group. Also, no compound-related necropsy findings were observed. Consequently, the maternal NOEL was established at 375 mg/kg/day and the maternal LOEL 1,000 mg/kg/day. Developmental toxicity was not observed; therefore, the developmental NOEL is 1,000 mg/kg/day. (US EPA 1993b)

Inhalation. To examine the validity of Richardson's Law[7], Nelson (Nelson et al 1990) reported a summary of his findings from a series of studies investigating the developmental toxicology of aliphatic alcohols administered by inhalation to rats. Pregnant rats were exposed to the maximally attainable vapor concentration of n-octyl alcohol (65 ppm or 350 mg/m^3) or n-decyl alcohol (15 ppm or 100 mg/m^3) for 7 hours/day during GD one to 19. For developmental toxicology evaluations, dams were sacrificed on GD 20. Fetuses were removed, weighed, sexed, and examined for external malformations. Nelson observed that in alcohols with carbon chains longer than four (which is the case for n-octyl and n-decyl alcohols), vapors could not be generated at concentrations that produced maternal toxicity. Developmental toxicity was also not seen.

C. Metabolism and Pharmacokinetics

Linear aliphatic acyclic alcohols such as n-octyl and n-decyl alcohol are absorbed through the gastrointestinal tract (IPCS 1998). Like other alcohols, n-octyl alcohol and n-decyl alcohol are oxidized to their corresponding aldehydes, which are then rapidly oxidized to their acids. This metabolism occurs via the fatty acid and tricarboxylic acid pathways. (IPCS 1998)

[7]In the late 1800's Richardson observed that the toxicity of the alcohols to adult animals generally increased with chain length, up to about six carbons, after which the toxicity decreased.

D. Special Considerations for Infants and Children

Linear aliphatic alcohols, which would include n-octyl and n-decyl alcohol, exhibit low acute toxicity (IPCS 1998). At exposure levels expected for the use of n-octyl and n-decyl alcohol as inert ingredient in pesticide products, developmental and reproductive toxicity is not expected and the young are not expected to be more sensitive to its effects than adults. In a developmental toxicity study conducted by the oral route (the route by which exposure is expected) maternal toxicity was observed only at the highest dose tested which was 1,000 mg/kg/day; no maternal toxicity was observed at the next lower dose which is 375 mg/kg/day. Developmental toxicity was not observed at any dose level.

Based on this information, there is no concern, at this time, for increased sensitivity to infants and children to n-octyl and n-decyl alcohol when used as inert ingredients in pesticide formulations. For the same reasons, a safety factor analysis has not been used to assess the risks resulting from the use of n-octyl and n-decyl alcohol; therefore, an additional tenfold safety factor for the protection of infants and children is unnecessary.

V. ENVIRONMENTAL FATE CHARACTERIZATION AND DRINKING WATER CONSIDERATIONS

The Office of Pesticide Programs Environmental Fate and Effects Division (EFED) has reviewed (US EPA 2002) the fate and environmental effects of the aliphatic alcohols by reviewing the available data and considering structure activity relationships (SAR). In summary, n-octyl and n-decyl alcohol are not expected to be persistent in the environment.

As a group, the C6 through C8 alcohols, which includes n-octyl alcohol, are water soluble and mobile in terrestrial and aquatic environments, moving mainly with the water phase to surface and ground water receptors. Volatility from soil (vapor pressure 0.0794 mm Hg @ 25°C), and water (Henry's law constant of 2.45×10^{-5} atm m^3/mole) and microbially-mediated degradation are expected to limit transport to surface and ground water from applications or releases to land, with biodegradation being the major route of environmental dissipation. Predicted dissipation half-lives range from 1.0 to 1.5 days in rivers and 15 to 20 days in lakes. These data suggest that n-octyl alcohol is not persistent in the environment.

The C10 through C12 compounds, which includes n-decyl alcohol, are slightly water soluble, mobile in terrestrial and aquatic environments, moving mainly with the sediment/soil phase to surface water receptors. Volatility from soil (vapor pressure 0.00851 mm Hg @ 25°C) and water (Henry's law constant of 3.2×10^{-5} atm m^3/mole) and microbially-mediated degradation are expected to limit transport to surface and

ground water from applications or releases to land, with biodegradation being the major route of environmental dissipation. Predicted dissipation half-lives range from 1.0 to 1.5 days in rivers and 15 to 20 days in lakes. These data suggest that n-decyl alcohol is not persistent in the environment.

VI. EXPOSURE ASSESSMENT

Based on a review of the information available in EPA's Office of Pesticide Programs Information Network (OPPIN) and due to the use pattern of both n-octyl and n-decyl alcohol, it is likely that exposure will be limited to the oral route, via consumption of crops to which these alcohols have been applied, and exposure through the drinking water. And, because of the use pattern of these two alcohols, residential exposure is not expected.

Food

Application of n-octyl and decyl alcohol as an inert ingredient in pesticide formulations is expected to result in low residues in food. Both alcohols are applied to growing crops only and any residues are expected to dissipate or degrade before harvest.

n-Octyl and n-decyl alcohol are naturally-occurring in food, but not necessarily at significant levels. n-Octyl alcohol has been reported in the essential oils of: green tea, grapefruit, California orange, violet leaves, dill, and bitter orange. As a food volatile, it has been identified in fried bacon, roasted filberts, nectarines, apple juice, beaufort cheese, and cassava products. In addition, it has been quantified in nonalcoholic beverages (2.9 ppm); ice cream (0.91 ppm); candy (2.8 ppm); baked goods (3.0 ppm); gelatins and puddings (1.5 ppm); and chewing gum (16 to 57 ppm). n-Decyl alcohol has been reported in the essential oils of: ambrette seeds, almond flowers, citrus oils, and fermented beverages. As a food volatile, it has been identified in the juice of Kogyoku apples. Additionally, it as been quantified has a flavor ingredient in nonalcoholic beverages (2.1 ppm); ice cream (4.6 ppm); candy (5.2 ppm); baked goods (5.2 ppm); and chewing gum (3.0 ppm). (NIH 2005, citing numerous sources)

Drinking Water

Because of their environmental fate properties, EPA expects that drinking water exposures would be low as n-octyl and n-decyl alcohol readily biodegrade in soil and water and are not persistent in the environment, thus making them not readily available in drinking water.

VII. AGGREGATE EXPOSURES

In examining aggregate exposure, the Federal Food, Drug, And Cosmetic Act (FFDCA) section 408 directs EPA to consider available information concerning exposures from the pesticide residue in food and all other nonoccupational 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 n-octyl and n-decyl alcohol, 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 n-octyl and n-decyl alcohol as inert ingredients in pesticide formulations.

VIII. 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 n-octyl and n-decyl alcohol and any other substances and, n-octyl and n-decyl alcohol 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 n-octyl and n-decyl alcohol 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/pesticides/cumulative/.

IX. HUMAN HEALTH RISK CHARACTERIZATION

Taking into consideration all available information on n-octyl and n-decyl alcohol, EPA has determined that there is a reasonable certainty that no harm to any population subgroup will result from aggregate exposure to n-octyl and n-decyl alcohol when used as inert ingredients in pesticide products when considering dietary (i.e., food and water) exposure and all other nonoccupational sources of pesticide exposure for which there is reliable information. Overall exposure due to the inert use of n-octyl and n-decyl alcohol is expected to result in human exposure below any dose level that would produce any adverse effect. This is based on available animal toxicity studies and the use pattern of n-octyl and n-decyl alcohol. Therefore, it is recommended that the two exemptions from the requirement of a tolerance established for residues of n-octyl and n-decyl alcohol (one tolerance for each alcohol) can be considered reassessed as safe under section 408(q) of FFDCA.

The overall toxicity of n-octyl and n-decyl alcohol is low. Oral and dermal acute toxicity of n-octyl alcohol are in Toxicity Category III (according to the 40 CFR 156.62 classification); oral toxicity of n-decyl alcohol is Toxicity Category IV and the dermal is Toxicity Category III. In an oral subchronic toxicity study for n-octyl alcohol, no effects were seen. An oral developmental study conducted using a blend of n-octyl and n-decyl alcohol showed maternal effects at a high dose of 1,000 mg/kg/day; no developmental effects were seen. Finally, in testing mutagenicity using a blend of n-octyl and n-decyl alcohol, all results were negative.

Any exposure to n-octyl and n-decyl alcohol is expected to occur at levels much lower than the levels where any effects were seen in animal studies. Individuals are exposed to n-octyl and n-decyl alcohol naturally—they have been detected as flavor volatiles in a number of foods. The World Health Organization (WHO) has approved n-octyl and n-decyl alcohol's use as a flavoring agent (IPCS 2001a, b). FDA allows it as a direct food additive, "the minimum quantity required to produce their intended effect" (21 CFR 172.515). Finally, because of the environmental fate properties of n-octyl and n-decyl alcohols, EPA does not expect concentrations of concern to occur in drinking water.

X. ECOTOXICITY AND ECOLOGICAL RISK CHARACTERIZATION

EFED finds, based on their ecotoxicity estimates, n-octyl and n-decyl alcohol to be moderately to slightly toxic on an acute basis. For freshwater fish, n-octyl alcohol has a predicted LC_{50} of 17 mg/L (US EPA 2002). By contrast, measured data in EPA's Ecotox database (US EPA 2006) indicated an LC_{50} on the same order of magnitude (Rainbow trout 17 mg/L; Medaka 16 to 24 mg/L; Killifish 12 to 23 mg/L; and carp 16 to 20 mg/L). Saltwater fish LC_{50} is estimated to be about 5.7 mg/L. Predicted freshwater invertebrate LC_{50} is 19 mg/L, by contrast, measured toxicity was 47 mg/L in a 24-hour study. A reproduction study using *Daphnia magna* produced a seven-day NOEC (no observed ecological concentration) of 1 mg/L. Saltwater invertebrate predicted that the

LC_{50} is 2.7 mg/L and measured data using the brine shrimp produced an LC_{50} of 58 mg/L. Algae LC_{50} was estimated to be 12.4 mg/L. Measured data was variable, but was within the same order of magnitude. Based on mammal data alone, n-octyl alcohol is considered practically nontoxic.

N-decyl alcohol's predicted freshwater fish LC_{50} is 2.4 mg/L and measured data located in EPA's Ecotox database (U.S. EPA 2006) indicated LC_{50}'s on the same order of magnitude (Rainbow trout 5.6 to 6.5 mg/L; Fathead minnow 2.4 mg/L; bluegill sunfish 5 to 10 mg/L; and carp 0.6 mg/L). The predicted saltwater fish LC_{50} is 1.3 mg/L. The predicted freshwater invertebrate LC_{50} is 2.9 mg/L with a measured effects concentration of 16 mg/L in a single study on *Daphnia magna*. Behavior changes were observed in *Daphnia magna* at an EC_{50} of 11 mg/L. The saltwater invertebrate LC_{50} was estimated at 1.3 mg/L. The algae LC_{50} were estimated to be 2.0 mg/L.

Mallard and Bobwhite quail were exposed to n-decyl alcohol over eight days. The mallard eight-day LD_{50} was >4,640 mg/kg and the LC_{50} was >10,000 ppm. The Bobwhite quail LC_{50} was likewise >10,000 ppm. N-decyl alcohol is classified as practically nontoxic to birds and based on the available mammal data, is likewise practically nontoxic.

Given the available fate and ecotoxicity information and using a simplified Tier I exposure assessment, application rates of n-octyl alcohol would need to exceed 6 lbs/A to exceed the endangered species LOC (level of concern) for the most sensitive species (saltwater fish). The most sensitive freshwater species endangered LOC would be exceeded if applications exceeded 12 lbs/A. N-decyl alcohol would exceed the most sensitive species endangered species LOC if applications exceed 1 lb/A (carp) based on available fate information and a simplified Tier I exposure assessment. However, it is important to note the exposure model does not take into account degradation in aquatic systems, volatilization and assumes a half-life of seven days on the field. Both alcohols are known to degrade much faster than the seven-day value (some data indicate half-lives of as little as one to two days) used in the model.

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