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

OFFICE OF PREVENTION,
PESTICIDES, AND TOXIC SUBSTANCES

July 28, 2006

ACTION MEMORANDUM

SUBJECT: Reassessment of Three Exemptions from the Requirement of a Tolerance for Tristyrylphenol Ethoxylates (as defined in Table 1)

FROM: Pauline Wagner, Chief Pauline Wagner 7/28/06
Inert Ingredient Assessment Branch
Registration Division (7505P)

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

I. FQPA REASSESSMENT ACTION

Action: Reassessment of three inert ingredient exemptions from the requirement of a tolerance as listed in Table 1 below.

Table 1.

CFR Citation				CAS Reg. No. Chemical Name
40 CFR §	**Inert Ingredients**	**Limits**	**Uses**	
180.920[a]	α-[2,4,6-Tris[1-(phenyl)ethyl]phenyl]-ω-hydroxypoly(oxyethylene), the poly(oxyethylene) content averages 4-150 moles	Not more than 15% of the formulation.	Surfactant.	70559-25-0 Poly(oxy-1,2-ethanediyl), α-[2,4,6-tris(1-phenylethyl)phenyl]-ω-hydroxy- 99734-09-5 Poly)oxy-1,2-ethanediyl, α-[tris(1-phenylethyl)phenyl]-ω-hydroxy-, ammonium salt
180.920	α-[2,4,6-Tris[1-(phenyl)ethyl]phenyl]-ω-hydroxypoly(oxyethylene); mixture of monohydrogen and dihydrogen phosphate esters and the corresponding ammonium, calcium, magnesium, potassium, sodium, and zinc salts, the poly(oxyethylene) content averages 4-150 moles	Not more than 15% of the formulation.	Surfactant.	163436-84-8 Poly(oxy-1,2-ethanediyl), α-[2,4,6-tris(1-phenylethyl)phenyl)]-ω-hydroxy-, phosphate, potassium salt 90093-37-1

CFR Citation				CAS Reg. No. Chemical Name
40 CFR §	Inert Ingredients	Limits	Uses	
180.920	α-[2,4,6-Tris[1-(phenyl)ethyl]phenyl]-ω-hydroxypoly(oxyethylene) sulfate, and the corresponding ammonium, calcium, magnesium, potassium, sodium, and zinc salts, the poly(oxyethylene) content averages 4-150 moles.	Not more than 15% of the formulation.	Surfactant.	396089-99-9 Poly(oxy-1,2-ethanediyl), α-[2,4,6-tris(1-phenylethyl)phenyl)]-ω-hydroxy-,sulfate 119432-41-6 Poly(oxy-1,2-ethanediyl), α-sulfo-ω-[2,4,6-tris(1-phenylethyl)phenoxy]-, ammonium salt

[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.

Use Summary: Tristyrylphenol ethoxylates (as defined in Table 1) are used as surfactants at not more than 15% in pesticide formulations applied to growing crops only.

List Classification Determination: Because EPA has determined that there is a reasonable certainty that no harm to any population subgroup will result from aggregate exposure to these chemicals when used as inert ingredients at not more than 15% in pesticide formulations, the List Classification for tristyrylphenol ethoxylates (as defined in Table 1) will be List 4B.

II. MANAGEMENT CONCURRENCE

I concur with the reassessment of the three exemptions from the requirement of a tolerance for the tristyrylphenol ethoxylates (as defined in Table 1), as well as the List Classification Determination described above. I consider the three 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

Lois A. Rossi, Director
Registration Division

July 31, 2006

Date:

cc: Debbie Edwards, SRRD
Joe Nevola, SRRD

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July 28, 2006

MEMORANDUM

SUBJECT: Reassessment of Three Exemptions from the Requirement of a Tolerance for the Tristyrylphenol Ethoxylates (as defined in Table 1)

FROM: Keri Grinstead
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 the tristyrylphenol ethoxylates (as defined in Table 1). This assessment summarizes available information on the use, physical/chemical properties, toxicological effects, exposure profile, environmental fate, and ecotoxicity of these chemicals. The purpose of this document is to reassess the three existing exemptions from the requirement of a tolerance for residues of these chemicals when used as inert ingredients as required under the Food Quality Protection Act (FQPA).

Executive Summary

This document evaluates the three exemptions from the requirement of a tolerance for the tristyrylphenol ethoxylates (as defined in Table 1). These substances are exempted from the requirement of a tolerance under 40 CFR 180.920 when used as inert ingredients at not more than 15% of the pesticide formulations applied to growing crops only. When used as inert ingredients in pesticide products, the tristyrylphenol ethoxylates (as defined in Table 1) have similar use patterns, restrictions/limitations, and potential exposures.

The available toxicity database for the tristyrylphenol ethoxylates (as defined in Table 1) consists of studies on subject chemicals and guideline studies on an analog chemical [CAS Reg. No. 105362-40-1]. Additionally, a Structure Activity Relationship (SAR) assessment for specific subject chemicals and an analog chemical [CAS Reg. No.

105362-40-1] was performed by the Agency's Office of Pollution Prevention and Toxics (OPPT) Structure Activity Team (SAT). The SAT has determined that, based on structural similarities, the data presented in this assessment on various subject chemicals as well as a suitable analog chemical are adequate to characterize the expected behavior of the entire group of tristyrylphenol ethoxylates (as defined in Table 1).

Data from animal studies conducted on subject chemicals and/or a suitable analog chemical resulted in low acute and low-moderate subchronic oral toxicity, negative results for mutagenicity, and no increased sensitivity to offspring in a developmental toxicity study.

The primary route of exposure to these chemicals from their use as inert ingredients in pesticide products would most likely be through consumption of food to which pesticide products containing them have been applied, and possibly through drinking water (from runoff). Dermal and inhalation exposures are also possible from residential use of pesticide products containing these inert ingredients.

Due to their physical/chemical properties (very strong sorption to soils/sediments) and the effects of biodegradation, these chemicals are expected to exhibit negligible migration to ground water sources and are, therefore, not likely to be present in ground water drinking water sources at levels of concern from their use as inert ingredients in pesticide products.

Based on available animal data, the tristyrylphenol ethoxylates are expected to exhibit low acute oral toxicity and moderate subchronic oral toxicity to terrestrial species. Additionally, according to measured and estimated data, these chemicals are expected to have moderate to high toxicity to aquatic species.

Based on the information provided in this assessment, the use of tristyrylphenol ethoxylates (as defined in Table 1) as inert ingredients at not more than 15% of the pesticide formulations is not expected to result in dietary (from food and drinking water) exposures of concern. The use/application limitations and physical/chemical properties of these chemicals are expected to limit exposures of concern from residues of these chemicals (from food and drinking water) when used as inert ingredients in pesticide products. The Agency's OPPT SAT has performed a Structure Activity Relationship assessment on specific members and/or analogs of the tristyrylphenol ethoxylates (as defined in Table 1) and determined that they are of low-moderate concern for human health, and, by analogy, the tristyrylphenol ethoxylates (as defined in Table 1.) are expected to exhibit similar toxicity.

Taking into consideration all available information on the tristyrylphenol ethoxylates, the Agency has determined that there is a reasonable certainty that no harm to any population subgroup will result from aggregate exposure to these chemicals (as defined in Table 1) when used at not more than 15% of the pesticide formulations applied to growing crops only when considering dietary exposure and all other nonoccupational sources of exposure for which there is reliable information. Therefore, it is

recommended that the three exemptions from the requirement of a tolerance for the tristyrylphenol ethoxylates (as defined in Table 1) under 40 CFR 180.920 be considered reassessed as safe under section 408(q) of the Federal Food, Drug, and Cosmetic Act.

I. Introduction

This report provides a qualitative assessment for the tristyrylphenol ethoxylates (as defined in Table 1), surfactants used as inert ingredients at not more than 15% of the pesticide formulations applied to growing crops only under 40 CFR 180.920.

II. Pesticide Uses

The exemptions from the requirement of a tolerance are provided in Table 1 below.

Table 1. Pesticide Uses

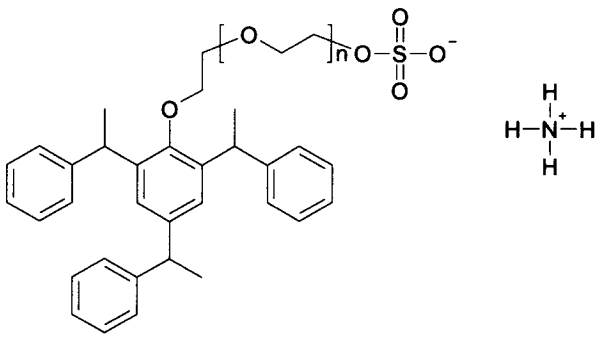
CFR Citation				CAS Reg. No. Chemical Name
40 CFR §	**Inert Ingredients**	**Limits**	**Uses**	
180.920[a]	α-[2,4,6-Tris[1-(phenyl)ethyl]phenyl]-ω-hydroxypoly(oxyethylene), the poly(oxyethylene) content averages 4-150 moles	Not more than 15% of the formulation.	Surfactant.	70559-25-0 Poly(oxy-1,2-ethanediyl), α-[2,4,6-tris(1-phenylethyl)phenyl]-ω-hydroxy- 99734-09-5 Poly(oxy-1,2-ethanediyl), α-[tris(1-phenylethyl)phenyl]-ω-hydroxy-,
180.920	α-[2,4,6-Tris[1-(phenyl)ethyl]phenyl]-ω-hydroxypoly(oxyethylene); mixture of monohydrogen and dihydrogen phosphate esters and the corresponding ammonium, calcium, magnesium, potassium, sodium, and zinc salts, the poly(oxyethylene) content averages 4-150 moles	Not more than 15% of the formulation.	Surfactant.	163436-84-8 Poly(oxy-1,2-ethanediyl), α-[2,4,6-tris(1-phenylethyl)phenyl)]-ω-hydroxy-, phosphate, potassium salt 90093-37-1
180.920	α-[2,4,6-Tris[1-(phenyl)ethyl]phenyl]-ω-hydroxypoly(oxyethylene) sulfate, and the corresponding ammonium, calcium, magnesium, potassium, sodium, and zinc salts, the poly(oxyethylene) content averages 4-150 moles.	Not more than 15% of the formulation.	Surfactant.	396089-99-9 Poly(oxy-1,2-ethanediyl), α-[2,4,6-tris(1-phenylethyl)phenyl)]-ω-hydroxy-,sulfate 119432-41-6 Poly(oxy-1,2-ethanediyl), α-sulfo-ω-[2,4,6-tris(1-phenylethyl)phenoxy]-, ammonium salt

[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.

III. Physical and Chemical Properties

The physical and chemical properties of a representative chemical from the tristyrylphenol ethoxylates are provided in the table below.

Table 2. Physical/Chemical Properties

Parameter	Value	Source
Chemical	CAS Reg. No. 119432-41-6	National Industrial Chemicals Notification and Assessment Scheme, Full Public Report, [CAS Reg. No. 119432-41-6], Commonwealth of Australia, 2005[1]
9CI Name	Poly(oxy-1,2-ethanediyl), α-sulfo-ω-[2,4,6-tris(1-phenylethyl)phenoxy]-, ammonium salt	
Molecular formula	$C_{62}H_{104}O_{20}NS$	
Molecular weight	1230	
Color and form	Brown viscous paste	
Melting point	30°C	
Boiling point	> 100°C	
Density	1140 kg/m^3	
Vapor pressure	9.12 x 10^{-11} kPa at 25°C or 6.84x10^{-10} mmHg	
Water solubility	Highly soluble	
Octanol water partition coefficient	5.6 (0.01M) 58.1 (0.001M)	
Structure		

[1] http://www.nicnas.gov.au/PUBLICATIONS/CAR/NEW/NA/NASUMMR/NA0100SR/na167.asp

IV. Hazard Assessment

The tristyrylphenol ethoxylates (as defined in Table 1) are being evaluated as part of the US EPA's tolerance reassessment process of inert ingredients.

A. Hazard Profile

The available toxicity database for the tristyrylphenol ethoxylates (as defined in Table 1) consists of studies on subject chemicals and guideline studies on an analog

chemical [CAS Reg. No. 105362-40-1] (analog chemical), and a public report on [CAS Reg. No. 119432-41-6] (subject chemical) from the National Industrial Chemicals Notification and Assessment Scheme (Australia). Additionally, a Structure Activity Relationship assessment was performed by the Agency's OPPT SAT for specific subject chemicals and an analog chemical [CAS Reg. No. 105362-40-1]. The SAT determined that, based on structural similarities, [CAS Reg. No. 105362-40-1] is a suitable analog chemical, and that the available data on the chemicals presented in this assessment, as well as their SAR assessment are adequate to characterize the expected toxicity of the entire group of tristyrylphenol ethoxylates (as defined in Table 1).

B. Toxicological Data

Acute Toxicity

Study	Results	
	[CAS Reg. No. 105362-40-1](analog) (USEPA MRID 465877-04)	[CAS Reg. No. 90093-37-1] (USEPA MRID 465877-05)
Oral (rat)	Not toxic at 4750 mg/kg. No a[b]normal symptom was noted in the treated animals, autopsy showed no lesion, weight gain was similar to controls.	Not toxic at 7150 mg/kg. No a[b]normal symptom was noted in the treated animals, autopsy showed no lesion, weight gain was similar to controls
Eye (rabbit) Draize	Slightly irritant	Fairly irritant, slightly irritant with distilled water rinse 30 seconds post-application
Skin (rabbit) Draize, patch-test	Slightly irritant	Slightly irritant

Subchronic Toxicity

In a 90-day study of beagle dogs orally administered [CAS Reg. No. 105362-40-1] (analog chemical) by gelatin capsule at 0, 50, 500, or 1000 (reduced to 750 mg/kg/day on day 43 due to six deaths) mg/kg/day, the predominant pathological effects noted were: hyperemia of the stomach and intestines and hepatic degenerative changes. Clinical observations of loose feces, mucoid feces, other fecal signs, vomitus, and salivation were considered test material-related effects. Hepatic pathological changes, significantly increased mean liver weights/ratios were noted in the mid- and high-dose groups and food consumption was significantly decreased in the high-dose group (USEPA MRID 465877-06).

In a 90-day study of Sprague-Dawley rats administered [CAS Reg. No. 105362-40-1] (analog chemical) by gavage at 0, 500, 1500, or 4000 mg/kg/day, "mean liver weights were increased in high-dose males and all dose levels in females and mean kidney weights were increased in high-dose females. There are no apparent morphological changes to explain these organ weight differences. Mean liver and kidney to final body weight ratios were increased in all dose levels except low-dose males (liver only)" Additionally, effects in thyroid and pituitary glands were observed (USEPA MRID 465877-07). The supplemental pathology report (USEPA MRID 465877-08)

concluded that gavage administration of this chemical "resulted in increased thyroid activity characterized by increased follicular epithelial height, decreased follicle size, and altered colloid. These alterations are typical of a physiological hypertrophy due to hormonal stimulations. Also, in male rats at the highest dose, and increase in the number of vacuolated pituitary (severity) was noted. These cells appear to represent hypertrophic cells and may be indicative of a compound-induced interference with the feedback control of hormone synthesis between the pituitary and thyroid."

In a 90-day subchronic oral gavage study, Albino rats were administered [CAS Reg. No. 119432-41-6] (subject chemical) at concentrations of 0, 100, 500, or 2500 mg/kg/day five days per week. Dose-related renal intratubular mineralization was observed in all treated male rats; however, no supporting histologic or clinical evidence of renal alterations were observed and, therefore, the increased mineralization was not suggestive of a direct nephrotoxic effect of the test material. Increases in thyroid weight were evident in the animals (particularly females) from the mid- and high-dose groups; thyroid function was not affected in the low-dose animals. Other than the renal findings in males, there were no effects that were clearly treatment-related in male or female rats at a dose of 100 mg/kg bw/day (USEPA MRID 464052-11).

In a study to further evaluate kidney toxicity, male Albino rats were administered [CAS Reg. No. 119432-41-6] (subject chemical) by gavage at 1, 10, 30, or 100 mg/kg/day for 5 days/week for 13 weeks. "No clinical signs of toxicity, altered food consumption, body weight changes, urinalysis alterations, kidney weights, or necropsy [kidney] findings were observed. The animals in the high-dose group lost more weight during the fasting period prior to sacrifice than did the controls or animals in the other dose groups thus resulting in slightly higher kidney to body weight ratio. This finding was not considered to be treatment related. Microscopic examination of the kidneys revealed an incidence of intratubular mineralization in the high-dose group which was similar to that observed in the comparable dose group from the previous study. However, this lesion was also noted to a minimal degree in the control and two of the lower dose groups. This minimal to mild degree of intratubular mineralization was not considered to be biologically significant at any dose level. Intratubular mineralization was not observed in the 30 mg/kg/day group. The no observable effect level (NOEL) for renal intratubular mineralization in this strain of rats under the conditions of this study is considered to be at least 30 mg/kg/day" (USEPA MRID 464052-10).

Neurotoxicity

No neurotoxicity information is currently available; however, no neurotoxic symptoms were observed in any of the available studies.

Mutagenicity/Genotoxicity

In an Ames genetic toxicity study, [CAS Reg. No. 105362-40-1] (analog chemical) showed no mutagenic activity to *Salmonella typhimurium* strains TA 1535, 1537, 1538, 98, or 100, both with and without activation (USEPA MRID 465877-03).

Results of acceptable mutagenicity studies, including a chromosomal aberration assay in Chinese hamster ovary cells (CHO) and a test for unscheduled DNA synthesis in rat primary hepatocyte cultures were negative (Federal Register 1993).

Developmental and Reproductive Toxicity

In a developmental study, [CAS Reg. No. 119432-41-6] (subject chemical) was administered by gavage to pregnant Sprague-Dawley rats at 0, 100, 300, or 1000 mg/kg/day. Slight maternal toxicity was observed at 300 and 1000 mg/kg/day (expressed as reduced weight gain, reduced food consumption and clinical signs of toxicity) and slight fetotoxicity (expressed as reduced skeletal ossification in the foot phalanges in the absence of reduced fetal weight) at 1000 mg/kg/day were observed. There was no treatment-related increased incidence of malformations at any dose level. The NOEL was 100 mg/kg/day for maternal toxicity and a NOEL of 300 mg/kg/day for developmental toxicity (USEPA MRID 464052-13).

There were no available reproductive toxicity data for this group of chemicals.

C. Metabolism and Pharmacokinetics

In the SAT assessment report of subject/analog chemicals, the SAT made the judgment that absorption is poor through the skin and moderate through the gastrointestinal tract. Based on their similar structures, uses, and potential exposures, it is expected that the tristyrylphenol ethoxylates (as defined in Table 1) would exhibit similar absorption characteristics.

D. Special Considerations for Infants and Children

The developmental toxicity study in which rats were administered [CAS Reg. No. 119432-41-6] (subject chemical) at 0, 100, 300, or 1000 mg/kg/day by gavage, resulted in a NOEL of 100 mg/kg/day for maternal toxicity and a NOEL of 300 mg/kg/day for developmental toxicity. Fetal effects were seen only at a dosage that was maternally toxic. Based on this toxicity information, and the determination by the SAT that the toxicity results for [CAS Reg. No. 119432-41-6] (subject chemical) are suitable to characterize the expected developmental toxicity for this group of tristyrylphenol ethoxylates (as defined in Table 1), there is no concern, at this time, for increased sensitivity to infants and children to the tristyrylphenol ethoxylates (as defined in Table 1) when used as inert ingredients at not more than 15% in pesticide formulations applied to growing crops only. For the same reasons, a safety factor analysis has not been used to assess risk and, therefore, the additional tenfold safety factor for the protection of infants and children is also unnecessary.

V. Environmental Fate Characterization and Drinking Water Considerations

Three low molecular weight representative chemicals of the tristyrylphenol ethoxylates are estimated to exhibit low solubility (range 0.001 to 0.776 mg/L), low volatility (vapor pressure $<1.0x10^{-6}$ mmHg; Henry's Law Constant $<1.0x10^{-8}$ - $2.58x10^{-8}$ atm-m^3/mole), very strong sorption to soils (K_{OC} range 759,000 to 47,900,000 Kg/L), and ultimate biodegradation in the range of months. POTW (Publicly Owned Treatment Works) removal is expected to be 50-90% via sorption and biodegradation and migration to groundwater is estimated to be negligible because of the high level of sorption. Even though the octanol water partition coefficients appeared to indicate the potential to bioaccumulate in fish (K_{OW} range 43 to 251,000), the estimated bioconcentration factors ranged from low to moderate and inversely with the K_{OW} (BCF range 5.62 to 851). Considering the high sorption capabilities of these compounds, the BCFs are considered relatively low. From their low vapor pressure and Henry's Law Constant estimates, these compounds are unlikely to volatilize from dry surfaces or moist surfaces or moist soils or sediments.

Due to their physical/chemical properties (very strong sorption to soils/sediments and organic carbon) and the effects of biodegradation, these chemicals and, by analogy, the tristyrylphenol ethoxylates (as defined in Table 1), are expected to exhibit negligible migration to ground water sources; therefore, they are not likely to reach drinking waters (from groundwater sources) at levels of concern from their use as inert ingredients in pesticide products. They would only reach adjacent bodies of surface waters in runoff events accompanied by erosion that occur shortly after the application (weeks). They would also reach surface waters via spray drift. Once there, the chemicals are likely to partition with the sediment, where biodegradation may take place at an unknown rate.

In summary, the tristyrylphenol ethoxylates do not appear to be very persistent in the environment. The major route of dissipation of these compounds in the environment seems to be metabolism. There is no information about abiotic processes, such as hydrolysis or photolysis. They are unlikely to leach to subsurfaces, but can reach adjacent bodies of water via spray drift or runoff accompanied by erosion in event that occur shortly after application (weeks). In bodies of water, they will partition with the sediment, where their fate is an uncertainty.

VI. Exposure Assessment

These tristyrylphenol ethoxylates (as defined in Table 1) are approved for use as surfactants at not more than 15% in pesticide formulations applied to growing crops only.

For the general population, the primary route of exposure to these chemicals from their use as inert ingredients in pesticide products would most likely be through consumption of food to which pesticide products containing them have been applied, and possibly through drinking water (from runoff). Dermal and inhalation exposures are also possible from residential use of pesticide products containing these inert ingredients.

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 the tristyrylphenol ethoxylates (as defined in Table 1), a qualitative assessment for all pathways of human exposure (food, drinking water, and residential) is appropriate given the use limitations and lack of human health concerns associated with exposure to these substances when used as inert ingredients in pesticide formulations.

VIII. Cumulative Exposure

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."

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 the tristyrylphenol ethoxylates (as defined in Table 1) and any other substances, and these chemicals do not appear to produce toxic metabolites produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that these chemicals 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

When used as inert ingredients in pesticide products, the tristyrylphenol ethoxylates (as defined in Table 1) have similar use patterns and restrictions/limitations, and potential exposures. Additionally, the Agency has determined that, based on their structural similarities, the data on various members and suitable analogs of this group of chemicals are adequate to characterize the expected toxicity of the entire group (as defined in Table 1).

Animal studies conducted on subject chemicals or on a suitable analog, resulted in low acute and subchronic oral toxicity, slight skin irritation, slight-fair eye irritation, no mutagenicity, and no increased offspring sensitivity in a developmental study.

Due to their physical/chemical properties (very strong sorption to soils/sediments) and the effects of biodegradation, these chemicals are expected to exhibit negligible migration to ground water sources and are, therefore, not likely to be present in drinking water (from groundwater sources) at levels of concern from their use as inert ingredients in pesticide products.

Based on the information provided in this assessment and the determination that this information is suitable to characterize the expected toxicity of the entire group of tristyrylphenol ethoxylates (as defined in Table 1), the use of these chemicals as inert ingredients at not more than 15% in pesticide formulations is not expected to result in dietary (from food and drinking water) or residential exposures of concern.

Taking into consideration all available information, the Agency has determined that there is a reasonable certainty that no harm to any population subgroup will result from aggregate exposure to the tristyrylphenol ethoxylates (as defined in Table 1) used as inert ingredients at not more than 15% in pesticide formulations applied to growing crops when considering dietary exposure and all other nonoccupational sources of exposure for which there is reliable information. Therefore, it is recommended that the three exemptions from the requirement of a tolerance for the tristyrylphenol ethoxylates (as defined in Table 1) under 40 CFR 180.920 be considered reassessed as safe under section 408(q) of the Federal Food, Drug, and Cosmetic Act.

X. Ecotoxicity and Ecological Risk Characterization

Measured ecotoxicity data on [CAS Reg. No. 105362-40-1] (analog chemical) include an acute daphnid 24 hour EC_{50}=550 mg/L (USEPA MRID 465877-01) and an acute fish 24 hour LC_{50}=3100 mg/L and 48 hour LC_{50}=3000 mg/L (USEPA MRID 465877-02). These measured results indicate this chemical is practically non-toxic to aquatic species.

Based on available animal studies conducted on subject chemicals or a suitable analog, the tristyrylphenol ethoxylates exhibit low acute oral toxicity and low to moderate subchronic oral toxicity to terrestrial species. When used as inert ingredients in pesticide products applied to growing crops, the exposure to these chemicals by non-target aquatic and terrestrial species is expected to be mitigated by their limitation of not more than 15% in pesticide formulations, their very strong sorption to soils resulting in negligible migration to groundwater sources, and the effects of biodegradation.

REFERENCES:

Federal Register, Vol. 58 No.30, OPP-300271, FRL 4178-9, Ethoxylated Polyarylalkylphenols; Tolerance Exemptions, Environmental Protection Agency, Proposed Rule, February 17, 1993.

National Industrial Chemicals Notification and Assessment Scheme, Full Public Report, [CAS Reg. No. 119432-41-6], Commonwealth of Australia, 2005, http://www.nicnas.gov.au/PUBLICATIONS/CAR/NEW/NA/NASUMMR/NA0100SR/na167.asp.

USEPA MRID 464052-10, Bushy Run Research Center, Ninety-Day Gavage Kidney Toxicity Study with [CAS Reg. No. 119432-41-6] in Albino Rats, November 20, 1989.

USEPA MRID 464052-11, Bushy Run Research Center, Ninety-Day (Subchronic) Gavage Toxicity Study with [CAS Reg. No. 119432-41-6] in Albino Rats, February 10, 1988.

USEPA MRID 464052-13, Developmental Toxicity Evaluation of [CAS Reg. No. 119432-41-6] Administered by Gavage to CD (Sprague-Dawley) Rats, November 23, 1987.

USEPA MRID 464052-14, Analytical Biochemistry Laboratories, Inc., Determination of the Photolysis Rate of [CAS Reg. No. 119432-41-6] on the Surface of Soil, February 29, 1988.

USEPA MRID 464052-15, Analytical Biochemistry Laboratories, Inc., Soil/Sediment Adsorption/Desorption with ^{14}C[CAS Reg. No. 119432-41-6], December 18, 1987.

USEPA MRID 465877-01, M. Dion and J. Mocotte, Acute Lethal Toxicity of [CAS Reg. No. 105362-40-1] to *Daphnia magna* straus (Cladocera, Crustacea), Project Number 614-8110, Rhone-Poulenc Recherche, France, March 3, 1982.

USEPA MRID 465877-02, M. Dion and J. Mocotte, Acute Lethal Toxicity of [CAS Reg. No. 105362-40-1] to a Freshwater Fish, *Brachydanio rerio* (Hamilton Buchanan), Project Number 614-8109, Rhone-Poulenc Recherche, France, March 2, 1980.

USEPA MRID 465877-03, D. Marzin, Investigation on *Salmonella typhimurium* According to the Technique of B.N. Ames on [CAS Reg. No. 105362-40-1], Prpject Number R 0 08 012, Departement Recerche et Essais Biologiques Stallergenes, France, August 26, 1980.

USEPA MRID 465877-04, D. Marzin, [CAS Reg. No. 105362-40-1]: Acute Toxicity in the Rat by the Oral Route, Local Tolerance in the Rabbit, Project Number R 9 07 024, Departement Recerche et Essais Biologiques Stallergenes, France, July 31, 1979.

USEPA MRID 465877-05, D. Marzin, [CAS Reg. No. 90093-37-1]: Acute Toxicity in the Rat by the Oral Route, Local Tolerance in the Rabbit, Project Number R 9 07 025, Departement Recerche et Essais Biologiques Stallergenes France, July 31, 1979.

USEPA MRID 465877-06, WIL Research Laboratories, 90-day Oral Dosing Study in Dogs with [CAS Reg. No. 105362-40-1], July 21, 1982.

USEPA MRID 465877-07, WIL Research Laboratories, 90-day Oral Gavage Dosing Study in Rats with [CAS Reg. No. 105362-40-1], August 30, 1982.

USEPA MRID 465877-08, Experimental Pathology Laboratories, Inc., Pathology Report: 90-Day Oral Gavage Dosing Study in Rats with [CAS Reg. No. 105362-40-1] (Supplement to WIL Research Laboratories Study WIL-81143), September 22, 1986.