Reregistration Eligibility Decision (RED) for 4-t-Amylphenol

September 30, 2005

United States
Environmental Protection
Agency

Prevention, Pesticides
and Toxic Substances
(7508C)

EPA738-R-05-001
January 2005

Reregistration Eligibility Decision for Para-Tertiary-Amylphenol, Potassium Sodium Salt (Case 3016)

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

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

CERTIFIED MAIL

Dear Registrant:

This is to inform you that the Environmental Protection Agency (hereafter referred to as EPA or the Agency) has completed its review of the available data and public comments received related to the preliminary risk assessments for the antimicrobial, Para-Tertiary-amylphenol (4-t-amylphenol). The enclosed Reregistration Eligibility Decision (RED) document was approved on September 30, 2005. Public comments and additional data received were considered in this decision.

Based on its review, EPA is now publishing its Reregistration Eligibility Decision (RED) and risk management decision for 4-t-amylphenol and its associated human health and environmental risks. A Notice of Availability will be published in the *Federal Register* announcing the publication of the RED.

The RED and supporting risk assessments for 4-t-amylphenol are available to the public in EPA's Pesticide Docket **OPP-2005-0181** at: http://www.epa.gov/edockets.

The 4-t-amylphenol RED was developed through EPA's public participation process, published in the Federal Register on July 20, 2005, which provides opportunities for public involvement in the Agency's pesticide tolerance reassessment and reregistration programs. Developed in partnership with USDA and with input from EPA's advisory committees and others, the public participation process encourages robust public involvement starting early and continuing throughout the pesticide risk assessment and risk mitigation decision making process. The public participation process encompasses full, modified, and streamlined versions that enable the Agency to tailor the level of review to the level of refinement of the risk assessments, as well as to the amount of use, risk, public concern, and complexity associated with each pesticide. Using the public participation process, EPA is attaining its strong commitment to both involve the public and meet statutory deadlines.

Please note that the 4-t-amylphenol risk assessment and the attached RED document concern only this particular pesticide. This RED presents the Agency's conclusions on the dietary, drinking water, occupational and ecological risks posed by exposure to 4-t-amylphenol alone. This document also contains both generic and product-specific data that the Agency intends to require in Data Call-Ins (DCIs). Note that DCIs, with all pertinent instructions, will be

sent to registrants at a later date. Additionally, for product-specific DCIs, the first set of required responses will be due 90 days from the receipt of the DCI letter. The second set of required responses will be due eight months from the receipt of the DCI letter.

As part of the RED, the Agency has determined that 4-t-amylphenol will be eligible for reregistration provided that all the conditions identified in this document are satisfied, including implementation of the risk mitigation measures outlined in Section IV of the document. Sections IV and V of this RED document describe labeling amendments for end-use products and data requirements necessary to implement these mitigation measures. Instructions for registrants on submitting the revised labeling can be found in the set of instructions for product-specific data that accompanies this document.

Should a registrant fail to implement any of the risk mitigation measures outlined in this document, the Agency will continue to have concerns about the risks posed by 4-t-amylphenol. Where the Agency has identified any unreasonable adverse effect to human health and the environment, the Agency may at any time initiate appropriate regulatory action to address this concern. At that time, any affected person(s) may challenge the Agency's action.

If you have questions on this document or the label changes necessary for reregistration, please contact the Chemical Review Manager, Killian Swift, at (703) 308-6346. For questions about product reregistration and/or the Product DCI that accompanies this document, please contact Adam Heyward at (703) 308-6422.

Sincerely,

Frank Sanders, Director
Antimicrobials Division (7510C)

REREGISTRATION ELIGIBILITY DECISION
for
Para-tertiary-amylphenol
List C
CASE 3016

Approved By:

Frank Sanders
Director, Antimicrobials Division
Date: September 30, 2005

Attachment

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Glossary of Terms and Abbreviations

a.i.	Active Ingredient
aPAD	Acute Population Adjusted Dose
APHIS	Animal and Plant Health Inspection Service
ARTF	Agricultural Re-entry Task Force
BCF	Bioconcentration Factor
CDC	Centers for Disease Control
CDPR	California Department of Pesticide Regulation
CFR	Code of Federal Regulations
ChEI	Cholinesterase Inhibition
CMBS	Carbamate Market Basket Survey
cPAD	Chronic Population Adjusted Dose
CSFII	USDA Continuing Surveys for Food Intake by Individuals
CWS	Community Water System
DCI	Data Call-In
DEEM	Dietary Exposure Evaluation Model
DL	Double layer clothing {i.e., coveralls over SL}
DWLOC	Drinking Water Level of Comparison
EC	Emulsifiable Concentrate Formulation
EDSP	Endocrine Disruptor Screening Program
EDSTAC	Endocrine Disruptor Screening and Testing Advisory Committee
EEC	Estimated Environmental Concentration. The estimated pesticide concentration in an environment, such as a terrestrial ecosystem.
EP	End-Use Product
EPA	U.S. Environmental Protection Agency
EXAMS	Tier II Surface Water Computer Model
FDA	Food and Drug Administration
FFDCA	Federal Food, Drug, and Cosmetic Act
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FOB	Functional Observation Battery
FQPA	Food Quality Protection Act
FR	Federal Register
GL	With gloves
GPS	Global Positioning System
HIARC	Hazard Identification Assessment Review Committee
IDFS	Incident Data System
IGR	Insect Growth Regulator
IPM	Integrated Pest Management
RED	Reregistration Eligibility Decision
LADD	Lifetime Average Daily Dose
LC_{50}	Median Lethal Concentration. Statistically derived concentration of a substance expected to cause death in 50% of test animals, usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm.
LCO	Lawn Care Operator
LD_{50}	Median Lethal Dose. Statistically derived single dose causing death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation), expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LOAEC	Lowest Observed Adverse Effect Concentration
LOAEL	Lowest Observed Adverse Effect Level
LOC	Level of Concern
LOEC	Lowest Observed Effect Concentration
mg/kg/day	Milligram Per Kilogram Per Day
MOE	Margin of Exposure
MP	Manufacturing-Use Product

MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
MRL	Maximum Residue Level
N/A	Not Applicable
NASS	National Agricultural Statistical Service
NAWQA	USGS National Water Quality Assessment
NG	No Gloves
NMFS	National Marine Fisheries Service
NOAEC	No Observed Adverse Effect Concentration
NOAEL	No Observed Adverse Effect Level
NPIC	National Pesticide Information Center
NR	No respirator
OP	Organophosphorus
OPP	EPA Office of Pesticide Programs
ORETF	Outdoor Residential Exposure Task Force
PAD	Population Adjusted Dose
PCA	Percent Crop Area
PDCI	Product Specific Data Call-In
PDP	USDA Pesticide Data Program
PF10	Protections factor 10 respirator
PF5	Protection factor 5 respirator
PHED	Pesticide Handler's Exposure Data
PHI	Pre-harvest Interval
Ppb	Parts per Billion
PCCs	Poison Control Centers
PPE	Personal Protective Equipment
PRZM	Pesticide Root Zone Model
RBC	Red Blood Cell
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RPA	Reasonable and Prudent Alternatives
RPM	Reasonable and Prudent Measures
RQ	Risk Quotient
RTU	(Ready-to-use)
RUP	Restricted Use Pesticide
SCI-GROW	Tier I Ground Water Computer Model
SF	Safety Factor
SL	Single layer clothing
SLN	Special Local Need (Registrations Under Section 24C of FIFRA)
STORET	Storage and Retrieval
TEP	Typical End-Use Product
TGAI	Technical Grade Active Ingredient
TRAC	Tolerance Reassessment Advisory Committee
TTRS	Transferable Turf Residues
UF	Uncertainty Factor
USDA	United States Department of Agriculture
USFWS	United States Fish and Wildlife Service
USGS	United States Geological Survey
WPS	Worker Protection Standard

4Para-Tertiary-Amylphenol Reregistration Team

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Executive Summary

The Environmental Protection Agency (hereafter referred to as EPA or the Agency) has completed its review of public comments on the human health and environmental risk assessments for para-tertiary-amylphenol (4-t-amylphenol) and its potassium and sodium salt and is issuing its risk management decision. The Agency has determined 4-t-amylphenol and its potassium and sodium salts are eligible for reregistration provided all measures outlined in this document are implemented. 4-t-Amylphenol is a member of the phenolic class of antimicrobials. 4-t-Amylphenol is an active ingredient in disinfectant, food-contact sanitizer and deodorizer products used in agricultural, food handling, commercial, institutional, industrial, residential, public access, and medical settings, primarily on hard, non-porous surfaces. The majority of the products are virucidal, fungicidal, tuberculocidal or bactericidal. Examples of registered uses for 4-t-amylphenol include application to hard surfaces (e.g., walls, floors, tables, fixtures), textiles (e.g., clothing, diapers, mattresses, bedding), carpets, medical instruments, and agricultural equipment. Additionally, there are registered uses for fogging in occupational settings and air deodorization in both occupational and residential settings.

Overall Risk Summary

The Agency's human heath risk assessment indicates no risks of concern for dietary or drinking water exposures. An acute dietary risk estimate was completed for females 13-49 years old, the only population subgroup with an acute toxicity endpoint, and is below the Agency's level of concern. Chronic dietary risk estimates were provided for the general U.S. population and all population subgroups. All chronic dietary risk estimates are below the Agency's level of concern.

4-t-Amylphenol and its salts are not likely to contaminate surface and ground waters based on its use patterns and fate characteristics. Thus, a drinking water assessment was not conducted. Therefore, no risk mitigation measures are required to address 4-t-amylphenol exposure from drinking water.

Residential risks from handler and post-application exposure were calculated for short- and intermediate-term dermal, inhalation and incidental oral exposures. All exposure and risk estimates for residential handler scenarios are below the Agency's level of concern. Risks of concern have been identified for several post-application exposure scenarios including children's dermal exposure to treated clothing and treated diapers and children's incidental oral exposure to treated clothing. The Agency believes that adding clear instructions for washing and rinsing textile items will result in the adequate removal of residues from the treated items and address the Agency's concerns for this scenario. The MOE for dermal exposure to children to treated surfaces in daycare centers slightly exceeds the Agency's level of concern (MOE = 940 with a target MOE of 1,000). However, the Agency believes actual exposure from this pathway to not exceed its level of concern when taking into account the conservative nature of the risk estimate which is likely to overestimate potential exposures.

Aggregate short and intermediate term risk assessments were conducted for this chemical that includes incidental oral and inhalation risks only. Dermal risks are not included in the aggregate risk estimates because they have a different toxicity endpoint. The aggregate oral and inhalation risks are not of concern for adults, as the total aggregate MOE is greater than the target of 3,000. For children, the aggregate risk estimates are also above the target MOE of 3,000 and thus are not of concern. However, incidental oral exposures to treated textiles are not included in the aggregate assessment because the oral MOE is already of concern.

For the occupational handler dermal and inhalation risk assessment, the short- and intermediate- term risks calculated at baseline exposure (no gloves and no respirators) were above target MOEs for all scenarios. For most of the occupational scenarios, postapplication dermal exposure is not expected to occur or is expected to be negligible based on the application rates and chemical properties of the chemical. Postapplication/bystander inhalation exposures, however, were assessed for entry into a building after a fogging application. The representative building selected was a poultry barn. The calculated inhalation MOEs were above the target MOE of 300 for all fogging postapplication scenarios with the exception of the scenario for 8-hr exposure to the product with a 2-hr reentry interval (MOE = 86).

There is a concern about the possibility of endocrine disruption in fish, since 4-t-amylphenol is considered an ecoestrogen. However, since this chemical is restricted to indoor uses only, the possibility for exposure to fish to 4-t-amylphenol would be limited. The limited exposure resulting from indoor uses of 4-t-amylphenol and its salts is not anticipated to cause adverse effects to terrestrial or aquatic organisms.

Dietary Exposure Risk

An acute dietary risk assessment was conducted for 4-t-amylphenol indirect food uses. Dietary risk estimates are provided for females 13-49 years old, the only population subgroup for which an endpoint was selected. The result of this assessment showed the risk estimate to be 2.7% of the aPAD and therefore is not of concern

A chronic dietary risk assessment was conducted for 4-t-amylphenol food uses. The risk analysis assumes daily exposure from the hard surface disinfection of counter tops. The result of this assessment showed the risk estimates to be <42% of the cPAD and therefore are not of concern.

Drinking Water Risk

4-t-Amylphenol and its salts are not likely to contaminate surface and ground waters based on its use patterns and fate characteristics. There are no currently registered outdoor uses of 4-t-amylphenol and its salts. Further, the estimated value for biodegradation indicates it may biodegrade linearly within days in the aquatic environment, although ultimate biodegradation (mineralization) may take months. It also is volatile based on its vapor pressure of 0.00116 mmHg, and has a moderate to slight mobility in soils based on its estimated Koc value of 3799. The sodium and potassium salts of 4-t-amylphenol also are slightly to moderately mobile in

soils, and are estimated to biodegrade within days to weeks. Because of the possibility of biodegradation in water and soils and the lack of outdoor uses, 4-t-amylphenol and its salts are not likely to contaminate surface and ground waters. Thus, a drinking water assessment was not conducted.

Residential Handler Risk

For residential handlers that handle products containing 4-t-amylphenol and its salts, short-term, and intermediate-term MOEs were above the target MOEs (i.e., >1,000 for dermal and >3,000 for inhalation) for all scenarios evaluated and thus, do not exceed the Agency's level of concern.

Residential Post-Application Risk

Risks of concern have been identified for several post-application exposure scenarios including children's dermal exposure to treated clothing and treated diapers and children's incidental oral exposure to treated clothing. The Agency believes that adding clear instructions for washing and rinsing textile items will result in the adequate removal of residues from the treated items and address the Agency's concerns for this scenario. The MOE for dermal exposure to children to treated surfaces in daycare centers slightly exceeds the Agency's level of concern (MOE = 940 with a target MOE of 1,000). However, the Agency believes actual exposure from this pathway to not exceed its level of concern when taking into account the conservative nature of the risk estimate which is likely to overestimate potential exposures.

Aggregate Risk

Short- and intermediate-term aggregate risks are considered together because the exposure and toxicity endpoints are identical for incidental oral and inhalation residential exposures for both durations. For children, the short- and intermediate-term aggregate assessment includes average dietary exposure (food) and estimated incidental oral exposures to children from residential uses such as hard surface disinfection. In addition, inhalation exposure from post-application of an air deodorizer use was aggregated with the oral exposures since the toxicity endpoint is the same. For adults, the aggregate assessment includes dietary (oral) and residential inhalation exposures from wiping a hard surface disinfectant, in addition to post application inhalation exposure from the air deodorizer.

Aggregate oral and inhalation risks are not of concern for adults, as the total aggregate MOE is greater than the target of 3,000. For children, the aggregate risk estimates are also above the target MOE of 3,000 and thus are not of concern. As noted previously, incidental oral exposures to treated textiles are not included in the aggregate assessment because the oral MOE is already of concern.

A dermal aggregate assessment was not conducted because the toxicity effects for the dermal exposure route are not the same as the oral/inhalation exposure route. However, short-

and intermediate dermal risks are already of concern for residents for the treated textile and diaper use.

Occupational Risk

To assess the handler risks, the Agency used surrogate unit exposure data from both the proprietary Chemical Manufacturers (CMA) antimicrobial exposure study and the Pesticide Handlers Exposure Database (PHED). For the occupational handler dermal and inhalation risk assessment, the short- and intermediate-term risks calculated at baseline exposure (no gloves and no respirators) were above target MOEs for all scenarios (i.e., dermal MOEs > 100 and inhalation MOEs were >300). Note, however, that high pressure spray application method in the agricultural use site category was assessed using gloved data.

For most of the occupational scenarios, post-application dermal exposure is not expected to occur and it is expected to be negligible based on the application rates and chemical properties of the chemical. However, post-application/bystander inhalation exposures were assessed for entry into a building after fogging application. The representative building selected was a poultry barn. The Agency used MCCEM (Multi-Chamber Concentration and Exposure Model) to estimate post-application/bystander exposures. The calculated inhalation MOEs were above the target MOE of 300 for all fogging post-application scenarios with the exception of the scenario for 8-hour exposure to the product with a 2-hour re-entry interval (MOE = 86).

The Agency does not believe that any mitigation is necessary to address the post-application scenario with a 2-hr reentry interval at this time. The risk estimate was calculated using the Agency's standard assumptions for air exchange rates. The Agency believes that in the case of animal barns and facilities this assumption in very conservative given the relatively high air exchange rates for such facilities.

Ecological Risk

There is a concern about the possibility of endocrine disruption in fish, since 4-t-amylphenol is considered an ecoestrogen. This was documented in several studies on carp (*Cyprimus carpio)*. However, since this chemical is restricted to indoor uses only, the possibility for exposure to fish to 4-t-amylphenol would be limited. The limited exposure resulting from indoor uses of 4-t-amylphenol and its salts is not anticipated to cause adverse effects to terrestrial or aquatic organisms.

Regulatory Decision

The Agency has completed its review and has determined that the data are sufficient to support reregistration of all supported products containing 4-t-amylphenol. The Agency is issuing this RED for 4-t-amylphenol, as announced in a Notice of Availability published in the *Federal Register*. This RED document includes guidance and time frames for making any necessary label changes for products containing 4-t-amylphenol.

Summary of Mitigation Measures

The Agency has determined that 4-t-amylphenol and its salts (potassium and sodium) are eligible for reregistration provided the mitigation measures described in this document and the label changes included in Table 13 in Section V of the RED are implemented.

Residential Risk Mitigation

To reduce residential exposure, the Agency has determined that the following mitigation and label changes for specific scenarios are appropriate and required for reregistration eligibility:

- Delete all diaper uses
- Delete all use on non-laundered textiles\items including mattresses, helmets, headgear, headphones, facegear, and mouthpieces.
- All labels with laundered textile uses must have directions that indicate that items must be treated prior to washing and rinsing.

I. Introduction

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was amended in 1988 to accelerate the reregistration of products with active ingredients registered prior to November 1, 1984 and amended again by the Pesticide Registration Improvement Act of 2003 to set time frames for the issuance of Reregistration Eligibility Decisions. The amended Act calls for the development and submission of data to support the reregistration of an active ingredient, as well as a review of all submitted data by the U.S. Environmental Protection Agency (EPA or the Agency). Reregistration involves a thorough review of the scientific database underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential hazards arising from the currently registered uses of the pesticide; to determine the need for additional data on health and environmental effects; and to determine whether or not the pesticide meets the "no unreasonable adverse effects" criteria of FIFRA.

On August 3, 1996, the Food Quality Protection Act of 1996 (FQPA) was signed into law. This Act amends FIFRA to require tolerance reassessment. The Agency has decided that, for those chemicals that have tolerances and are undergoing reregistration, the tolerance reassessment will be initiated through this reregistration process. The Act also requires that by 2006, EPA must review all tolerances in effect on the day before the date of the enactment of the FQPA. FQPA also amends the Federal Food, Drug, and Cosmetic Act (FFDCA) to require a safety finding in tolerance reassessment based on factors including consideration of cumulative effects of chemicals with a common mechanism of toxicity. This document presents the Agency's revised human health and ecological risk assessments; and the Reregistration Eligibility Decision (RED) for 4-tertiary-amylphenol (4-t-amylphenol), and salts (potassium and sodium).

4-t-Amylphenol and salts are active ingredients in disinfectant and food-contact sanitizer products used in agricultural, food handling, commercial/institutional/industrial, residential, public access, and medical settings – primarily on hard, non-porous surfaces. The majority of the products are virucidal, fungicidal, bactericidal, pseudomonacidal, or staphylocidal. Examples of registered uses for 4-t-amylphenol and salts include application to hard surfaces (e.g., walls, floors, tables, and fixtures), textiles (e.g., clothing, diapers, mattresses, and bedding), carpets, medical instruments, and agricultural equipment. Additionally, there are registered uses for fogging in occupational settings and air deodorization in both occupational and residential settings. Concentrations of 4-t-amylphenol and salts in products range from 0.0027% to 10%. The products are formulated as soluble concentrates, ready-to-use liquid solutions, pressurized sprays, and impregnated wipes.

The Agency has concluded that the hazard based FQPA safety factor should be retained at 10X**.** The toxicology data base is not complete with respect to assessing the increased susceptibility to infants and children as required by FQPA for 4-t-amylphenol. The rat prenatal developmental study showed no quantitative evidence of increased susceptibility (i.e., developmental NOAELs /LOAELs were higher than those for maternal effects). However, there was qualitative evidence of increased susceptibility as the fetal effects (i.e., skeletal abnormalities, decreased body weight gain) were considered to be more severe than maternal toxicity (reversible clinical signs). In addition, there is an absence of developmental toxicity data in the rabbit, and an absence of reproductive toxicity data. Furthermore, studies in the open

literature suggest that 4-t-amylphenol may be an endocrine disruptor. It increased non-pregnant uterine weight in rats and was associated with elevated blood levels of billirubin in children exposed to 4-t-amylphenol and other phenols in disinfectants. These studies, while not indicative, are suggestive of a basis for increased concern for reproductive and/or developmental effects due to exposure to 4-t-amylphenol.

Risks summarized in this document are those that result only from the use of the active ingredients 4-t-amyphenol and its salts (potassium and sodium). The Food Quality Protection Act (FQPA) requires that 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. The reason for consideration of other substances is due to the possibility that low-level exposures to multiple chemical substances that cause a common toxic effect by a common toxic mechanism could lead to the same adverse health effect that would occur at a higher level of exposure to any of the substances individually. 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 for 4-t-amyphenol and its salts (potassium and sodium) and any other substances. 4-t-Amyphenol and it salts (potassium and sodium) do not appear to produce a toxic metabolite produced by other substances. For the purposes of this action, therefore, EPA has not assumed that 4-t-amyphenol and it salts (potassium and sodium) has 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 .

This document presents the Agency's decision regarding the reregistration eligibility of the registered uses of 4-t-amyphenol and its salts (potassium and sodium). In an effort to simplify the RED, the information presented herein is summarized from more detailed information which can be found in the technical supporting documents for 4-t-amylphenol and salts referenced in this RED. The revised risk assessments and related addenda are not included in this document, but are available in the Public Docket at http://www.epa.gov/edocket (OPP-2005-0181)

This document consists of six sections. Section I is the introduction. Section II provides a chemical overview, a profile of the use and usage of 4-t-amylphenol and its salt (potassium and sodium), and its regulatory history. Section III, Summary of 4-t-amylphenol and salts Risk Assessment, gives an overview of the human health and environmental assessments, based on the data available to the Agency. Section IV, Risk Management, Reregistration, and Tolerance Reassessment Decision, presents the reregistration eligibility and risk management decisions. Section V, What Registrants Need to Do, summarizes the necessary label changes based on the risk mitigation measures outlined in Section IV. Finally, the Appendices list all use patterns eligible for reregistration, bibliographic information, related documents and how to access them, and Data Call-In (DCI) information.

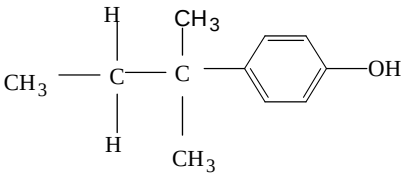
II. Chemical Overview

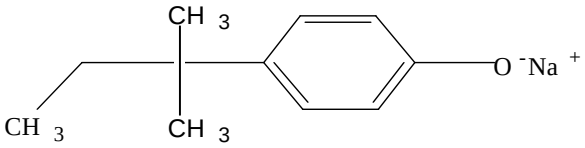
A. Regulatory History

4-t-Amyphenol and its salts (potassium and sodium) have been registered for use since 1962. Currently, there are 35 products containing 4-t-amyphenol (one technical product and 34 end-use-products) registered under Section 3 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

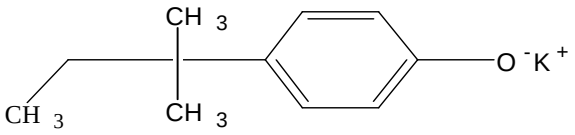
B. Chemical Identification

1. Para-Tertiary-Amylphenol & its Potassium and Sodium Salts





Paratertiaryamyl Phenol, Sodium Salt



Paratertiaryamyl Phneol, Potassium Salt

Common name: Para-Tertiary amylphenol

Chemical name: 4-tertiary-amylphenol, and salts

Chemical Family: Antimicrobial Disinfectant

Empirical formula: $C_5H_{11}C_6H_4OH$ (064101) $C_5H_{11}C_6H_4Na^+$ (064111) $C_5H_{11}C_6H_4K^+$ (064112)

CAS Registry No.: 064101: 80-46-6 (4-t-amylphenol)
064111: 53404-18-5 (sodium salt)
064112: 31366-95-7 (potassium salt)

Case number: 3016

OPP Chemical Code: 064101, 064111, 064112

Molecular weight: 164.25 (064111)

Trade name: Nipacide PTAP

Basic manufacturer: Clariant Corporation

Technical 4-t-amylphenol is a white solid. 4-t-Amylphenol has a melting point of 95 C. The water solubility of 4-t-amylphenol is 113.4 ppm. 4-t-Amylphenol has a vapor pressure of 1.16×10^{-3} mm Hg at 25° C.

Sodium 4-tert-amylphenate is also a solid with an estimated melting point of 205 C, water solubility of 4,595 ppm and an estimated vapor pressure of 7.7×10^{-10} at 25°C. Potassium 4-tert-amylphenate is also a sold with an estimated melting point of 206 C, water solubility of 3,811 ppm and an estimated vapor pressure of 7.7×10^{-10} at 25°C.

C. Use Profile

The following is information on the currently registered uses of 4-t-amylphenol and salts products and an overview of use sites and application methods. A detailed table of the uses of eligible for reregistration is contained in Occupational and Residential Exposure Assessment for this RED.

Type of Pesticide: Antimicrobial

Summary of Use:

Food: 4-tert-amylphenol and its salts are applied to the following use sites, which may result in indirect food contact: commercial egg washing, handling, hatchery, and processing facilities; milking equipment; and mushroom houses.

Non-Food: Farm and agricultural equipment and structures/premises; beverage processing plants; eating establishment surfaces, equipment, and utensils;

food storage and distribution equipment and utensils; and food dispensing equipment.

Residential: Air deodorizer in residential premises, hard surface disinfection, textiles, and carpets.

Target Pests: Viruses, fungi, tuberculocidal microbes, bacteria, pseudomonacidal microbes, and staphylocidal microbes.

Formulation Types: Soluble concentrates, ready-to-use liquid solutions, pressurized sprays, and impregnated wipes

Method and Rates of Application:

Equipment: Mops, wipes, trigger-pump sprayer, aerosol.

Application Rates: Concentrations of 4-t-amylphenol and salts products range from 0.0027% to 10%.

Timing: Most labeling indicates product needs to remain on surface for at least a 10 second contact time before it is removed using a potable water rinse.

III. Summary of 4-Tert-Amylphenol Risk Assessments

The purpose of this summary is to assist the reader by identifying the key features and findings of these risk assessments, and to help the reader better understand the conclusions reached in the assessments. The human health and ecological risk assessment documents and supporting information listed in Appendix C were used to formulate the safety finding and regulatory decision for 4-t-amylphenol. While the risk assessments and related addenda are not included in this document, they are available from the OPP Public Docket and may also be accessed on the Agency's website at http://epa.gov/dockets. Hard copies of these documents may be found in the OPP public docket under docket number OPP-2004-0220. The OPP public docket is located in Room 119, Crystal Mall II, 1801 Bell Street, Arlington, VA, and is open Monday through Friday, excluding Federal holidays, from 8:30 a.m. to 4:00 p.m.

A. Human Health Risk Assessment

1. Toxicity of 4-tertiary-amylphenol

A brief overview of the toxicity studies used for determining the dietary endpoints in the risk assessments are outlined in Table 2. Further details on the toxicity of 4-t-amylphenol can be found in the "Toxicology Science Chapter for Reregistration Eligibility Decision Document", September 2005; and "4-t-amylphenol Report of the Antimicrobial Division's Toxicology Endpoint Selection Committee (ADTC)", July 2005. These documents are available on Agency's website in the EPA Docket at http://www/epa.gov/edockets. (OPP-2005-0181)

The Agency has reviewed all toxicity studies submitted for 4-t-amylphenol and has determined that the toxicological database is sufficient for reregistration. Major features of the toxicology profile are presented below. The toxicology database for 4-t-amylphenol, in terms of guideline studies, is largely incomplete. 4-t-amylphenol appears to be a primary dermal and eye irritant (Category I), and it may be in Category III for acute oral dermal studies, according to data from the open literature, and two registrant submitted studies. However, four acceptable guideline acute studies are not available, and the literature data protocols were inadequate.

Table 1. Acute Toxicity of 4-t-amylphenol Technical

Guideline No./ Study Type	MRID Number	Results	Toxicity Category
870.1100 Acute Oral Toxicity	46616601	LD_{50} >2000 mg/kg	III
870.1200 Acute Dermal Toxicity	Not available; required		
870.1300 Acute Inhalation Toxicity	Not available; required		
870.2400 Acute Eye Irritation	Not available; required		
870.2500 Acute Dermal Irritation	46616602	Corrosive	I
870.2600 Skin Sensitization	Not available; required		

The doses and toxicological endpoints selected for the dietary exposure scenarios are summarized in Table 2 below.

Table 2. Toxicological Endpoints for 4-t-amylphenol and salts (Dietary)

Exposure Scenario	Dose for Risk Assessment and Uncertainty Factor	Special FQPA Safety Factor and Population Adjusted Dose	Study and Toxicological Effects
Acute Dietary (Females 13-50 years of age)	NOAEL = 200 mg/kg/day *UF = 100* **Acute RfD** = 0.67 mg/kg/day	FQPA SF = 10x **aPAD** = acute RfD / FQPA SF = 0.6 mg/kg/day	Developmental Toxicity Study in Rats LOAEL = 500 mg/kg/day based on skeletal effects and decreased fetal body weight.
Chronic Dietary (All populations)	NOAEL=50 mg/kg/day *UF = 100* **Chronic RfD = 0.17** mg/kg/day	FQPA SF = 10x **cPAD** = chronic RfD / FQPA SF = 0.17 mg/kg/day	Developmental toxicity study in the rat. LOAEL = 200 mg/kg/day based on clinical signs of toxicity, decreased body weight and body weight gain, and decreased food consumption.

UF = uncertainty factor, FQPA SF = Special FQPA safety factor, NOAEL = no observed adverse effect level, LOAEL = lowest observed adverse effect level, PAD = population adjusted dose, (a = acute, c = chronic) RfD = reference dose, MOE = margin of exposure, N/A = Not Applicable

In short-term studies, 4-t-amylphenol produced clinical signs along with decreased food consumption and body weight in a developmental toxicity study, but not systemic effects in a 13-week dermal study. The structural abnormalities and developmental delays that occurred in the developmental study occurred at higher dose levels than the maternal effects, suggesting that increased quantitative susceptibility concerns are not warranted. However, the minimal maternal effects (reversible clinical signs) seen in the presence of developmental effects increases concern for qualitative susceptibility.

Available data suggest that 4-t-amylphenol has endocrine disrupter capabilities (uterotrophic and estrogenic effects) and increased billirubin production in babies. When taken with the lack of available developmental and reproductive toxicity data, concerns for FQPA issues are heightened.

General Toxicity Observations

Dietary

The acute RfD is 0.67 mg/kg/day for females (13-50 years), based on adverse developmental effects (skeletal effects and decreased fetal body weight) at 500 mg/kg/day in a rat developmental study. The chronic RfD is 0.17 mg/kg/day based on clinical signs of toxicity and decreased body weight and food consumption at 200 mg/kg/day in a rat developmental study. An uncertainty factor of 300 (10X for interspecies extrapolation, 10X for intraspecies variability, and 3X for database uncertainties) was applied to the NOAEL to obtain the acute and chronic RfDs. A database uncertainty factor of 3x is applied to non-occupational risk assessments for 4-t-amylphenol, due to the number and significance of the data gaps including lack of repeated oral toxicity studies. An additional Food Quality Protection Factor (FQPA) safety factor is applied, which is discussed below.

Incidental Oral

The short- and intermediate-term incidental oral NOAEL is 50 mg/kg/day from a rat oral developmental toxicity study that noted clinical signs, decreases in body weight and body weight gain, coupled with decreased food consumption at 200 mg/kg/day. The target margin of exposure (MOE) is 3,000 (includes 10X FQPA factor).

Short- and Intermediate-term Dermal

The short- and intermediate-term dermal NOAEL is 25 mg/kg/day, which is based on the lack of systemic effects identified up to and including a dose of 25 mg/kg/day in a rat subchronic dermal toxicity study. Uncertainty factors or "target" margins of exposure (MOE) for 4-t-amylphenol dermal exposures are 100 for occupational scenarios and 1,000 for residential scenario (includes 10X FQPA factor).

Short-, Intermediate- and Long-term Inhalation

The short-, intermediate- and long-term inhalation NOAEL is 50 mg/kg/day from a rat oral developmental toxicity study that noted clinical signs, decreases in body weight and body weight gain, coupled with decreased food consumption at 200 mg/kg/day. In the absence of data, it was conservatively assumed that inhalation absorption is equivalent to oral absorption (i.e., 100%). For inhalation exposures, the uncertainty factors are 300 for occupational scenarios and 3,000 for residential scenarios (includes 10X FQPA factor). An additional 3X database uncertainty factor was applied due to the absence of inhalation toxicity data, and studies that address the sensitivity of infants and children. The 3,000 MOE represents the maximum uncertainty that can be applied under Agency guidelines and applies to residential exposures.

Carcinogenicity Classification

There are no lifetime carcinogenicity studies available for 4-t-amylphenol.

Mutagenicity Potential

The data base for mutagenicity is considered adequate based on EPA's 1991 mutagenic guidelines and indicates that 4-t-amylphenol is not mutagenic or genotoxic.

Endocrine Disruption Potential

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." 4-t-Amylphenol has properties that could indicate Endocrine Disrupting Chemical (EDC) properties given that available data suggest that 4-t-Amylphenol has endocrine disruptor capabilities (uterotrophic and estrogenic effects) and increased billirubin production in babies.

2. FQPA Safety Factor

The FQPA Safety Factor (as required by the Food Quality Protection Act of 1996) is intended to provide an additional 10-fold safety factor (10X), to protect for special sensitivity in infants and children to specific pesticide residues in food, drinking water, or residential exposures, or to compensate for an incomplete database. The FQPA Safety Factor has been

retained (i.e., remains 10X) for 4-t-amylphenol based on the limited database, qualitative evidence of sensitivity in the developmental toxicity study, and the suggestive evidence in the open literature of possible endocrine effects.

The toxicology data base is not complete with respect to assessing that increased susceptibility to infants and children as required by FQPA for 4-t-Amylphenol. The rat prenatal developmental study showed no quantitative evidence of increased susceptibility (i.e., developmental NOAELs/LOAELs were higher than those for maternal effects). However, there was qualitative evidence of increased susceptibility [i.e., fetal effects (skeletal abnormalities, decreased body weight gain) were considered to be more severe than the maternal toxicity (reversible clinical signs) observed at the same dose level]. In addition, there is an absence of developmental toxicity data in the rabbit and an absence of reproductive toxicity data.

3. Population Adjusted Dose (PAD)

Dietary risk is characterized in terms of the Population Adjusted Dose (PAD), which reflects the reference dose (RfD), either acute or chronic, that has been adjusted to account for the FQPA Safety Factor (SF). This calculation is performed for each population subgroup. A risk estimate that is less than 100% of the acute or chronic PAD is not of concern.

a. Acute PAD

Acute dietary risk for 4-t-amylphenol is assessed by comparing acute dietary exposure estimates (in mg/kg/day) to the acute Population Adjusted Dose (aPAD). Acute dietary risk is expressed as a percent of the aPAD. The aPAD is the acute reference dose (0.67 mg/kg/day) modified by the FQPA safety factor. The acute reference dose was derived from a developmental toxicity study in rats in which both the NOAEL (200 mg/kg/day) and the LOAEL (500 mg/kg/day) were determined. Acute dietary exposure was estimated only for females ages 13-49 because available studies did not show a toxicity endpoint attributable to a single exposure for the general population. The 4-t-amylphenol aPAD is 0.067 mg/kg/day based on a reference dose of 0.6 mg/kg/day, and incorporating the FQPA safety factor of 10X.

b. Chronic PAD

Chronic dietary risk for 4-t-Amylphenol is assessed by comparing chronic dietary exposure estimates (in mg/kg/day) to the chronic Population Adjusted Dose (cPAD). Chronic dietary risk is expressed as a percent of the cPAD. The cPAD is the chronic reference dose (0.17 mg/kg/day) modified by the FQPA safety factor. The cPAD was derived from a developmental toxicity study in rats in which both the NOAEL (50 mg/kg/day) and the LOAEL (200 mg/kg/day) were determined. The 4-t-amylphenol cPAD is 0.017 mg/kg/day based on a reference dose of 0.17 mg/kg/day, which includes the incorporation of the FQPA safety factor (10X) for the overall U.S. population or any population subgroups**.**

4. Exposure Assumptions

The use of antimicrobial chemicals on food or feed contact surfaces, agricultural commodities, in animal premises and poultry premises including hatcheries and application to food-grade eggs may result in pesticide residues in human food. The Agency must determine the risk to human health that may occur from exposure to these chemicals.

Refrigerators, counter tops, sinks and stoves are use sites on registered labels. These surfaces that have been treated with the 4-t-amylphenol products may bear small residues of the 4-t-amylphenol products after rinsing with potable water; i.e., rinsing with potable water may not remove all residues deposited on the treated surfaces from the proposed uses. Residues from treated surfaces can migrate to food coming into contact with the treated and rinsed surfaces and can be ingested by humans.

In the absence of residue data for 4-t-amylphenol on treated food contact surfaces, the Agency estimated residue levels that may occur in food using the highest application rate for food contact surfaces. To estimate the Estimated Daily Intake (EDI), the Agency has used an FDA model. The maximum ingredient percentage for 4-t-amylphenol in food handling establishments from the various labeled ready-to-use products is 0.054 % a.i (540 ppm). The Agency assumed that food can contact 2000 cm^2 of treated surfaces, and that 10% of the pesticide migrates to food based on the Agency Residential SOPs. The use of the 10% transfer rate instead of the use of a 100% transfer rate that is used in the FDA Sanitizer Solution Guidelines requires the submission of confirmatory data to establish the reliability of the use of the10% transfer rate. These daily estimates were conservatively used to assess both acute and chronic dietary.

5. Dietary (Food) Risk Assessment

Generally, a dietary risk estimate that is less than 100% of the acute or chronic PAD does not exceed the Agency's risk concerns. A summary of acute and chronic risk estimates are shown in Table 3.

a. Acute Dietary Risk

An acute dietary risk assessment was conducted for 4-t-amylphenol food uses. Dietary risk estimates are provided for females 13-49 years old, the only population subgroup for which an endpoint was selected. The result of this assessment showed the risk estimate to be 2.7% of the aPAD and therefore is not of concern

b. Chronic (Non-cancer) Dietary Risk

A chronic dietary risk assessment was conducted for 4-t-amylphenol food uses. The risk analysis assumes daily exposure from the hard surface disinfection of counter tops. The result of this assessment showed the risk estimates to be <42% of the cPAD and therefore are not of

concern. However, since the Agency assumed 10% of the residues are transferred to foods it is requiring confirmatory data for this transfer rate because 100% residue transfer indicates risks of concern.

Table 3: Acute and Chronic Dietary Exposure and Risk

Population Subgroup	Acute Dietary		Chronic Dietary	
	Dietary Exposure (mg/kg/day) [a]	% aPAD b	Dietary Exposure (mg/kg/day) a	% cPAD b
adult male	0.0015	NA	0.0015	9
females (13-50 years)	0.0018	2.7	0.0018	10.6
infants/children	0.0072	NA	0.0072	42

NA=not applicable

b. Dietary Risk from Drinking Water

4-t-Amylphenol and its salts are not likely to contaminate surface and ground waters based on its use patterns and fate characteristics. There are no currently registered outdoor uses of 4-t-amylphenol and its salts. Further, the estimated value for biodegradation indicates it may biodegrade linearly within days in the aquatic environment, although ultimate biodegradation (mineralization) may take months. It also is volatile based on its vapor pressure of 0.00116 mmHg, and has a moderate to slight mobility in soils based on its estimated Koc value of 3799. The sodium and potassium salts of 4-t-amylphenol also are slightly to moderately mobile in soils, and are estimated to biodegrade within days to weeks. Because of the possibility of biodegradation in water and soils and the lack of outdoor uses, 4-t-amylphenol and its salts are not likely to contaminate surface and ground waters. Thus, a drinking water assessment was not conducted.

6. Residential Exposure

Residential exposure assessment considers all potential pesticide exposure, other than exposure due to residues in food or in drinking water. Exposure may occur during and after application as a hard surface disinfectant (e.g., walls, floors, tables, fixtures), to textiles (e.g., clothing, diapers, mattresses, bedding) and to carpets. Each route of exposure (oral, dermal, inhalation) is assessed, where appropriate, and risk is expressed as a Margin of Exposure (MOE), which is the ratio of estimated exposure to an appropriate NOAEL. Based on its use patterns, 4-t-amylphenol has been assessed for the residential mixing/loading/applicator (or "handler") exposure for applications by homeowners mopping, wiping and spraying hard surfaces. For post-application exposure, 4-t-amylphenol has been assessed for adults and children contacting treated hard surfaces/floors, wearing treated clothing, wearing treated diapers (children), mouthing treated textiles (children) and bystander inhalation exposure.

a. Toxicity

The toxicological endpoints and associated uncertainty factors used for assessing the non-dietary risks for 4-t-amylphenol are listed in Table 4.

A MOE greater than or equal to 3,000 is considered adequately protective for the residential exposure assessment for the incidental oral and inhalation routes of exposure. The MOE of 3,000 includes 10x for interspecies extrapolation, 10x for intraspecies variation, 3x for database uncertainty and the 10x FQPA factor. For the dermal route of exposure, a MOE greater than or equal to 1,000 is considered adequately protective for the residential exposure assessment. The MOE of 1,000 includes 10x for interspecies extrapolation, 10x for intraspecies variation and the 10x FQPA factor.

Table 4: Toxicity Endpoints Selected for Assessing Occupational and Residential Risk for 4-t-Amylphenol

Exposure Scenario	Dose Used in Risk Assessment	Level of Concern for Risk Assessment	Study and Toxicological Effects
Incidental Oral, Short- and Intermediate-Term	Maternal Oral NOAEL = 50 mg/kg/day	**Residential LOC for MOE** = 3000 **Occupational** = NA	Developmental toxicity study in the rat LOAEL = 200 mg/kg/day based on clinical signs of toxicity, decreased body weight and body weight gain, and decreased food consumption
Short-, and Intermediate -Term Dermal	Dermal NOAEL = 25 mg/kg/day for systemic effects	**Residential LOC for MOE** = 1000 **Occupational** = 100	Subchronic dermal toxicity study in Rats Systemic LOAEL = not identified. No systemic effects identified up to and including 25 mg/kg/day (HDT). Dermal LOAEL= 10 mg/kg/day for dermal effects and irritation. Dermal NOAEL=2.5 mg/kg/day
Short-, Intermediate-, and Long-Term Inhalation	Oral NOAEL = 50 mg/kg/day	**Residential LOC for MOE** = 3000 **Occupational** = 300	Developmental toxicity study in the rat LOAEL = 200 mg/kg/day based on clinical signs of toxicity, decreased body weight and body weight gain, and decreased food consumption.
Cancer	No cancer data available for 4-t-amylphenol		

HDT= Highest dose tested

b. Residential Handler

i. Exposure Scenarios, Data and Assumptions

Residential exposure may occur during application of 4-t-amylphenol as a hard surface disinfectant (e.g., walls, floors, tables, fixtures), to textiles (e.g., clothing, diapers, mattresses, bedding) and to carpets. A number of assumptions, or estimates, such as adult body weight and area treated per application, are made by the Agency for residential risk assessment. Also, note that residential handlers are sometimes addressed somewhat differently than occupational handlers in that homeowners are assumed to complete all elements of an application (mix/load/apply) without the use of personal protective equipment.

The quantitative exposure/risk assessment developed for residential handlers is based on these scenarios:

(1) mopping hard surfaces,
(2) wiping hard surfaces,
(3) using trigger pump equipment to treat hard surfaces and/or textiles, and
(4) application to air using an aerosol spray can

4-t-Amylphenol products are widely used disinfectants and have a large number of use patterns that are difficult to completely capture in this assessment. As such, the Agency has selected representative scenarios for each use site that are believed to be representative of the vast majority of 4-t-amylphenol uses, based on end-use product application methods and use amounts.

Surrogate data are available for mopping, wiping, trigger pump spray and aerosol can application methods. Dermal and inhalation exposures were assessed for mopping and wiping using proprietary Chemical Manufacturers Association (CMA) data (CMA 1992, USEPA 1999). These data are based on individuals mopping floors and receiving exposure via contact with the mop or with the bucket, or using a finger pump sprayer to apply the product and then wipe the surfaces with a paper towel. Dermal and inhalation exposures were assessed for trigger pump spray and aerosol application methods using *PHED Version 1.1* values found in the *Residential Exposure SOPs* (U.S. EPA, 1997a, 2001). The surrogate exposure data in PHED are based on test subjects applying an aerosol insecticide to baseboards in kitchens. The dermal and inhalation exposures from these techniques have been normalized by the amount of active ingredient handled and reported as unit exposures (UE) expressed as mg/lb ai handled.

In addition, product label maximum application rates, related use information, and Agency standard values were used to assess residential handler exposures. For example, it was assumed that one gallon of diluted solution is used for mopping floors, while 0.5 liters (0.13 gallons) are used in the wiping and trigger pump spray scenario. For aerosol can spray, it was assumed that one 16 oz can of product is used in a day. The residential handler scenarios are assumed to be of short- and intermediate-term duration (1-30 days and 1-6 months)

ii. Residential Handler Risk Estimates

Based on toxicological criteria and potential for exposure, the Agency has conducted dermal and inhalation exposure assessments. As noted previously, MOEs greater than or equal to 3,000 for the inhalation route of exposure and 1,000 for dermal exposure are considered adequately protective for the residential exposure assessment.

A summary of the residential handler exposures and risk are presented on Table 5. For residential handlers that handle products containing 4-t-amylphenol and its salts, short-term, and intermediate-term MOEs were above the target MOEs (i.e., >1000 for dermal and >3000 for inhalation) for all scenarios evaluated and thus, do not exceed the Agency's level of concern.

Table 5: Estimates of Exposures and Risks to Residential Handlers of 4-t-Amylphenol (Short- and Intermediate-Duration)

Scenario	Dermal Dose (mg/kg/day)	Inhalation Dose (mg/kg/day)	Dermal MOE (Target MOE>1000)	Inhalation MOE (Target MOE>3000)
(1) Mopping	0.00128	4.25×10^{-5}	20,000	1,200,000
(2) Wiping	0.00666	1.56×10^{-4}	3,800	320,000
(3) Trigger Pump Spray	0.00198	2.16×10^{-5}	13,000	2,300,000
(4) Aerosol Spray	0.00233	2.54×10^{-5}	11,000	2,000,000

c. Residential Post-Application

i. Exposure Scenarios, Data and Assumptions

Residential postapplication exposures result when bystanders (adults and children) come in contact with 4-t-amylphenol in areas where pesticide end-use products have recently been applied (e.g., treated hard surfaces/floors), or when children incidentally ingest the pesticide residues through mouthing the treated end products/treated articles (i.e., hand-to-mouth or object-to-mouth contact).

For the purposes of this screening level assessment, postapplication scenarios have been developed that encompass multiple products, but still represent a high end exposure scenario for all products represented. Representative postapplication scenarios assessed include:

- contacting treated hard surfaces/floors (dermal and incidental oral exposure to children),
- wearing treated clothing (dermal exposure to adults and children),
- wearing diapers treated with a trigger-pump spray (dermal exposure to children),
- mouthing treated textiles such as clothing and blankets (incidental oral exposure to children), and

- postapplication/bystander inhalation exposures from use of disinfecting/deodorizing products (vapor exposure to adults and children).

Typically, most products used in a residential setting result in exposures occurring over a short-term time duration (1 – 30 days). If the products are used on a routine basis (i.e., once a week) and the active ingredient has a long indoor half-life, exposures may occur over an intermediate-term time duration (30 days – 6 months). At this time, the Agency does not have residue dissipation data or reliable use pattern data, including the frequency and duration of use of antimicrobial products in the residential setting. Even though the Agency does not believe that the use patterns of many residential products result in intermediate-term exposure, they are assessed to provide an upper bound estimate of exposure. The Agency does believe, however, that intermediate-term exposure to children may occur in day care centers where disinfecting products are used more frequently.

A number of conservative assumptions were used in assessing postapplication risks including maximum application rate from the label. In addition quantities handled/treated were estimated based on information from various sources, including the Draft Standard Operating Procedures (SOPs) for Residential Exposure Assessments (USEPA 2000, 2001) and the AD Draft Residential SOP use table. In certain cases, no standard values were available for some scenarios. Assumptions for these scenarios were based on AD estimates and could be further refined from input from affected sectors. In the absence of data, for both the textile and diaper scenarios, it was assumed that either 100% or 5% of 4-t-amylphenol could transfer and be available for dermal contact. The Agency will require data to confirm the actual transfer factor of 4-t-amylphenol.

No postapplication air concentration data have been submitted for 4-t-amylphenol to determine potential vapor inhalation risk. Therefore, the Multi-Chamber Concentration and Exposure Model (MCCEM v1.2) was used to present a screening-level estimate of the potential inhalation risk to adults and children for the air deodorizer use. MCCEM estimates average and peak indoor air concentrations of chemicals released from products or materials in houses, apartments, townhouses, or other residences. The data libraries in MCCEM contain information about residential settings. MCCEM estimates inhalation exposures to chemicals, calculated as single day doses, chronic average daily doses, or lifetime average daily doses. All dose estimates are potential doses; they do not account for actual absorption into the body.

ii. Residential Post-Application Risk Estimates

Based on toxicological criteria and potential for exposure, the Agency has conducted dermal, incidental oral and inhalation exposure assessments. As noted previously, MOEs greater than or equal to 3,000 for incidental oral and inhalation exposure and 1,000 for dermal exposure are considered adequately protective for the residential exposure assessment. A summary of the residential post-application exposures and risk are presented on Table 6.

The child short- and intermediate-term dermal MOEs for contact following hard surface disinfection is above the target MOE of 1,000 for residential settings and slightly below the MOE for daycare centers. The short- and intermediate-term MOEs for dermal contact with

treated clothing is of concern for young children (MOEs are <1 assuming a 100% transfer factor; MOE=17 assuming a 5% transfer factor). For adults, the dermal MOE is below the target MOE of 1,000 using a 100% transfer factor (MOE = 140) and above the MOE using the 5% transfer factor. The dermal MOE for children wearing treated diapers is only of concern (MOE=59) using a transfer factor of 100%, but it not of concern when using a transfer factor of 5%. In addition, it should be noted that 4-t-amylphenol caused dermal irritant effects following repeated dermal exposure, and may also be a potential dermal sensitizer.

The short- and intermediate-term incidental oral MOEs following hard surface disinfection are above the target MOE of 3,000 for residential settings and daycare centers, and thus are not of concern. However, the oral MOE for children mouthing treated textiles exceeds the Agency's level of concern (MOE=650 compared to target MOE>3,000).

For both adults and children, the calculated inhalation MOEs are greater than the target MOE of 3,000 for inhalation exposures following use of an air deodorizer, and thus are not of concern.

Table 6: Summary of Short- and Intermediate-Term Residential Post-Application Exposures and Risks

Scenario		Dose (mg/kg/day)	MOE (Target MOE>1000 dermal; >3000 oral and inhalation)
Dermal Exposure			
Hard surface Disinfection	Residential Setting	0.0067	3,700
	Daycare center	0.0267	940
Treated clothing	Adults	0.0092 (5% transfer) 0.185 (100% transfer)	2,700 **140**
	Children	1.45 (5% transfer) 28.9 (100% transfer)	**17** **<1**
Treated Diapers	Children	0.0212 (5% transfer) 0.424 (100% transfer)	1,200 **59**
Incidental Oral Exposure			
Hard surface Disinfection	Residential Setting	0.000817	61,000
	Daycare center	0.00155	32,000
Treated clothing	Children		**650**
Inhalation Exposure			
Air Deodorizer	Adults	0.00186	27,000
	Children	0.00666	7,500

7. Aggregate Risk

The Food Quality Protection Act amendments to the Federal Food, Drug, and Cosmetic Act (FFDCA, Section 408(b)(2)(A)(ii)) require "that there is a reasonable certainty that no harm will result from aggregate exposure to pesticide chemical residue, including all anticipated dietary exposures and other exposures for which there are reliable information." Aggregate exposure will typically include exposures from food, drinking water, residential uses of a pesticide, and other non-occupational sources of exposure. Since no drinking water estimates

were developed for 4-t-amylphenol, aggregate assessments include exposure to food and as a result of residential uses only.

Typically, aggregate risk assessments are conducted for acute (1 day), short-term (1-30 days), intermediate-term (1-6 months) and chronic (6 months to lifetime) exposures. However, acute and chronic aggregate assessments were not conducted because there are no significant impacts to drinking water sources, nor are there long-term residential uses. Thus, only short- and intermediate-term aggregate assessments were conducted. Oral and inhalation exposure and risk estimates were combined for the aggregate risk assessment because these endpoints are based on the same toxicity study (oral developmental study) and effects of concern (clinical signs and changes in body weight and food consumption). Dermal exposures were not aggregated with the oral or inhalation exposures due to different toxicological endpoints for oral (clinical signs and body weight changes), and dermal (no systemic effects at the highest dose tested).

a. Short- and Intermediate-Term Aggregate Risk

Aggregate short- and intermediate-term risk assessments are designed to provide estimates of risk likely to result from exposures to the pesticide or pesticide residues in food, water, and from residential (or other non-occupation) pesticide uses. Short- and intermediate-term aggregate risks are considered together because the exposure and toxicity endpoints are identical for incidental oral and inhalation residential exposures for both durations. For children, the short- and intermediate-term aggregate assessment includes average dietary exposure (food) and estimated incidental oral exposures to children from residential uses such as hard surface disinfection. In addition, inhalation exposure from postapplication of an air deodorizer use was aggregated with the oral exposures since the toxicity endpoint is the same. For adults, the aggregate assessment includes dietary (oral) and residential inhalation exposures from wiping a hard surface disinfectant, in addition to post application inhalation exposure from the air deodorizer.

The results of the aggregate short- and intermediate-term risk assessments are presented in Table 7. The aggregate oral and inhalation risks are not of concern for adults, as the total aggregate MOE is greater than the target of 3,000. For children, the aggregate risk estimates are also above the target MOE of 3,000 and thus are not of concern. As noted previously, incidental oral exposures to treated textiles are not included in the aggregate assessment because the oral MOE is already of concern.

A dermal aggregate assessment was not conducted because the toxicity effects for the dermal exposure route are not the same as the oral/inhalation exposure route. However, as shown previously on Table 6, short- and intermediate dermal risks are already of concern for residents for the treated textile and diaper use.

Table 7. Summary of Short- and Intermediate-Term Aggregate Risk Estimates

Exposure Scenario	Dose (mg/kg/day)		Total MOE (b) (Target MOE>3000	
	Child	Adult	Child	Adult
Oral Exposure	0.0072	0.0018(a)	6940 (c)	28,000 (c)
Dietary Exposure	0.00155	NA	32,000	NA
Hard Surface Disinfection – Daycare Center				
Inhalation Exposure Handler of hard surface Disinfectant – wiping	NA	0.000156	NA	320,000
Air Deodorizer	0.00666	0.00186	7,500	27,000
Total Aggregate Dose & MOE	0.0154	0.00316	3,240	13,000

NA: Not Applicable.
(a): Chronic Dietary Exposure for Females (13-50 years).
(b): MOE = NOAEL (mg/kg/day) / potential dose rate (mg/kg/day) [Where short- & intermediate-term oral NOAEL = 50.
(c): Risk estimates are equivalent to percent of the PAD of 42% for child and 10.6% for adults.

b. Long-Term Aggregate Risk

A long-term (or chronic) aggregate assessment was not undertaken because the only long-term residential use (diaper use) results in dermal exposure, which has a different toxicological effect than the chronic dietary oral exposure.

8. Occupational Exposure and Risk

Workers can be exposed to a pesticide through mixing, loading, and/or applying a pesticide, or re-entering treated sites. Occupational handlers of 4-t-amylphenol include workers in a variety of occupational settings. Additionally, postapplication exposures are likely to occur in these settings. The representative scenarios selected for assessment were evaluated using maximum application rates as recommended on the product labels for 4-t-amylphenol.

Occupational risk is assessed for exposure at the time of application (termed “handler” exposure) and is assessed for exposure following application, or post-application exposure. Application parameters are generally defined by the physical nature of the formulation (e.g., formula and packaging), by the equipment required to deliver the chemical to the use site, and by the application rate required to achieve an efficacious dose.

Occupational risk for all of these potentially exposed populations is measured by a Margin of Exposure (MOE) which determines how close the occupational exposure comes to a No Observed Adverse Effect Level (NOAEL) from toxicological studies. In the case of 4-t-amylphenol, MOEs greater than 100 for dermal exposures and 300 for inhalation exposures are not of concern to the Agency. For workers entering a treated site, MOEs are calculated for each day after application to determine the minimum length of time required before workers can safely re-enter.

For more information on the assumptions and calculations of 4-t-amylphenol 's potential risk to workers, see the Occupational Exposure Assessment (Section 8.0) in the "AD Risk Assessment for the Reregistration Eligibility Decision (RED) Document"(Revised)," dated September, 2005. 3

a. Occupational Toxicity

Table 4 provides a listing of the toxicological endpoints used in the occupational risk assessment for 4-t-amylphenol.

b. Occupational Handler Exposure

Potential occupational handler exposure can occur at various use sites, including agricultural premises, food handling, commercial/institutional/industrial premises, and medical premises. MOEs are: >100 for dermal exposure and; >300 for inhalation exposure. Only the high pressure spray in the agricultural use scenario was evaluated using gloved data.

The Agency has determined that there is potential for dermal and inhalation worker exposure to 4-t-amylphenol at various use sites including agricultural premises, food handling, commercial/institutional/industrial premises, and medical premises. To assess handler risks, the Agency used surrogate unit exposure data from both proprietary Chemical Manufacturers (CMA) antimicrobial exposure study and the Pesticide Handlers Exposure Database (PHED).

c. Occupational Handler Risk Summary

For the occupational handler dermal and inhalation risk assessment, the short- and intermediate- term risks calculated at baseline exposure (no gloves and no respirators) were above target MOEs for all scenarios (i.e., dermal MOEs were >100 and inhalation MOEs were >300). Note, however, that the high pressure spray application method in the agricultural use site category was assessed using gloved data. A summary of the results of the occupational handler assessment is provided in Table 8.

Table 8: Short-, Intermediate-Term Risks for Occupational Handlers

Exposure Scenario	Method of Application	Application Rate (lb ai/ gallon)	Quantity Handled/ Treated per day (gallons)	MOE		
				Baseline Dermal (a) (Target MOE>100)	PPE Gloves Dermal (b) (Target MOE>100)	Baseline Inhalation (Target MOE>300)
Agricultural Premises and Equipment						
Application to hard surfaces	Low Pressure Handwand	0.0034	10	270	No Data	150,000
	High Pressure Handwand		40	No Data	5,100	210,000
	Mopping		2	3,600	No Data	220,000
	Wiping		0.26	690	No Data	59,000
	Trigger Pump Spray		0.26	10,000	24,000	3,000,000
Fogger	Liquid Pour of soluble concentrate	0.163 lb ai/gal/ 6,000 ft2	15,000 ft2	120	No Data	4,500
Food Handling						
Application to indoor hard surfaces	Low Pressure Handwand	0.0025	2	1,800	No Data	1,000,000
	Mopping		2	4,900	No Data	290,000
	Wiping		0.26	940	No Data	80,000
	Trigger Pump Spray		0.26	7,300	17,000	2,100,000
Commercial/Institutional Premises						
Application to indoor hard surfaces	Low Pressure Handwand	0.005	2	920	No Data	510,000
	Mopping		2	2,400	No Data	150,000
	Wiping		0.26	470	No Data	40,000
	Trigger Pump Spray		0.26	7,100	17,000	2,100,000
Air Deodorization	Aerosol Spray	0.074% ai by weight	3 16 oz cans	4,100	9,700	1.200,000
Medical Premises and Equipment						
Application to indoor hard surfaces	Low Pressure Handwand	0.005	2	920	No Data	510,000
	Mopping		45	110	No Data	6,500
	Wiping		0.26	470	No Data	40,000
	Trigger Pump Spray		0.26	7,100	17,000	2,100,000
Air Deodorization	Aerosol Spray	0.074% ai by weight	3 16 oz cans	4,100	9,700	1,200,000

(a) Baseline Dermal: Long-sleeve shirt, long pants, no gloves.
(b) PPE Dermal with gloves: baseline dermal plus chemical-resistant gloves.

d. Occupational Post-application Risk Summary

For most of the occupational scenarios, postapplication dermal exposure is not expected to occur or is expected to be negligible based on the application rates and chemical properties of the chemical. Postapplication/bystander inhalation exposures, however, were assessed for entry into a building after a fogging application. The representative building selected was a poultry barn. The Agency used the MCCEM (Multi- Chamber Concentration and Exposure Model) to estimate postapplication/bystander exposures. The calculated inhalation MOEs were above the target MOE of 300 for all fogging postapplication scenarios with the exception of the scenario for 8-hr exposure to the product with a 2-hr reentry interval (MOE = 86).

The Agency does not believe that any mitigation is necessary to address the post-application scenario with a 2-hr reentry interval at this time. The risk estimate was calculated using the Agency's standard assumptions for air exchange rates. The Agency believes that in the case of animal barns and facilities this assumption in very conservative given the relatively high air exchange rates for such facilities.

e. Human Incident Data

There are some reported incidents associated with exposure to end-use products containing 4-t-amylphenol. Dermal, ocular and inhalation are the primary routes of exposure. Most of the incidents are related to irritation reaction. The most common symptoms reported for cases of inhalation exposure were respiratory irritation/burning, irritation to mouth/throat/nose, coughing/choking, shortness of breath, dizziness, flu-like symptoms, and headache. Eye pains, burning of eyes, conjunctivivitis, blurring vision, and acute inflammation have been reported in ocular incidents. Neurological effects, such as dizziness, headache and blurred vision also have been reported.

B. Environmental Risk Assessment

A summary of the Agency's environmental risk assessment is presented below. The following risk characterization is intended to describe the magnitude of the estimated environmental risks for 4-t-amylphenol use sites and any associated uncertainties. A detailed ecological hazard and environmental risk assessment for 4-t-amylphenol and its salts is presented in "Ecological Hazard and Environmental Risk Assessment for 4-tert-amylphenol and salts to be included in the RED", September 2005. A brief summary is presented below.

1. Environmental Fate and Transport

The environmental fate assessment for 4-t-amylphenol and its potassium and sodium salts is based on US EPA s Estimation Programs Interface (EPI) Suite. EPI Suite provides estimations of physical/chemical properties and environmental fate properties.

4-t-Amylphenol may be bioaccumlative (log K_{OW} 3.91) and is likely to pose a concern for aquatic organisms. It is expected to have moderate to slight mobility in soils based upon the estimated Koc value of 3799. Estimated value for biodegradation probability indicates that it

may biodegrade linearly within days in aquatic medium. However, ultimate biodegradation (mineralization) may take months. It is volatile and may vaporize into the atmosphere. The estimated half life in the air for 4-t-amylphenol is about three hours which indicates that it is not persistent in air. Because of the possibility of biodegradation in water and soils, it is not likely to contaminate surface and ground waters.

4-t-Amylphenol, potassium salt, is not likely to be bioaccumlative (log K_{OW} 1.23) and may not pose a concern for bioconcentration in aquatic organisms. It may be expected to have moderate to slight mobility in soils as its estimated Koc value is 3799. Estimated probability of biodegradation of 4-t-amylphenol, potassium salt, in soils and water indicates that it is likely to biodegrade within days to weeks. Therefore, it may be unlikely that soil and water contamination would take place. It has low volatility and its estimated half life in air is about 4.68 hours and is not likely to be persistent in air.

4-t-Amylphenol, sodium salt, is not likely to be bioaccumlative (log K_{OW} is 1.23) and may not pose a concern for bioconcentration in aquatic organisms. It may be expected to have moderate to slight mobility in soils as its estimated Koc value is the same as the parent molecule, 4-t-amylphenol. Probability for sodium 4-t-amylphenate biodegradation is the same as the parent molecule, 4-t-amylphenol. Hence, it is not likely to persist in soils and water, and surface and ground water contamination is not likely to occur. It has low volatility and its estimated half life in air is about 4.68 hours and is not likely to be persistent in air.

2. Ecological Risk

Guideline ecological effects data has not submitted for 4-t-amylphenol. The only data that was available was found in the peer-reviewed literature. None of these studies met current guideline requirements and therefore, could not be used in a risk assessment. There is a concern about the possibility of endocrine disruption in fish, since 4-t-amylphenol is considered an ecoestrogen. This was documented in several studies on carp (*Cyprimus carpio)*. However, since this chemical is restricted to indoor uses only, the possibility for exposure to fish to 4-t-amylphenol would be limited. The limited exposure resulting from indoor uses of 4-t-amylphenol and its salts is not anticipated to cause adverse effects to terrestrial or aquatic organisms.

The acute toxicity data for 4-t-amylphenol are summarized on Table 9. As shown in Table 9, acute toxicity for freshwater fish ranged from 2.50 mg/L to 16 mg/L in the fathead minnow. The first study was conducted using criteria similar to OPP/OPPTS guidelines and would have more weight than the second study which did not provide any information on how the study was conducted. Therefore, the data indicates that 4-t-amylphenol is moderately toxic to coldwater species, such as the fathead minnow. The fathead minnow is considered to be less sensitive than the bluegill. Also shown in Table 9, acute toxicity to shrimp was LC50 = 1.7 mg/L. This indicated that 4-t-amylphenol was moderately toxic to shrimp. The study does not meet current guideline requirements.

Table 9. Acute Toxicity of 4-t-amylphenol and salts

Organism	Results - LC50 (mg/L) (95% Confidence Limit)	Toxicity Category	Comments	Reference
Freshwater Fish				
Fathead minnow (*Pimephales promelas*)	2.50 (1.87 - 3.34)	moderately toxic	- 96h test duration; - flow-through bioassay -caused necrosis in fish	Holcombe, G W et al. 1984 Environ Pollut ser A Ecol Biol 35:367-81
Fathead minnow *(Pimephales promelas*)	16	Slightly toxic	- No information available on the test parameters	Russon, C L et al. 1997 Environ. Toxicol. Chem 16:948
Marine/Estuarine Invertebrates				
Shrimp (*Crangon septemspinosa*)	96h LC50 = 1.7 mg/L	Moderately toxic	- 96h test duration; - aerated gently and changed at 49 hours	McLeese, D W 1981 Chemosphere 10(7):723

3. Endocrine Effects in Fish

As mentioned above, potential endocrine effects for 4-t-amylphenol have been identified. Examples of the impacts of 4-t-amylphenol affecting the reproductive processes of carp have been reported in the peer-reported literature. Since the use pattern for this chemical is restricted to indoor uses, exposure to fish, such as carp, should be limited. Therefore, no additional testing for endocrine disruption effects on fish is necessary.

Table 10: Examples of 4-t-amylphenol Affecting the Endocrine System in Fish

Organism	Results	Toxicity Category	Comments	Reference
Male common carp (*Cyprinus carpio*)	caused formation of oviducts in male fish and reduced the number of primordial germ cells in gonads	identified as an ecoestrogen	- test concentration 0.14 mg/L - exposed embryos and fingerlings at various ages	Gimeno et al. 1997 Environ Sci Technol 31(10): 2884-2890.
Male common carp (*Cyprinus carpio*)	30-day EC50 for oviduct formation = 63 ug/L NOEC for oviduct formation = <36 ug/L primordial germ cells lower in treated fish NOEC for vitellogenin induction =90-256 ug/L	identified as causing endocrine disruption effects	- 120 male carp tested - nominal concentrations of 100, 320, & 1000 ug/L were tested - 160 day test duration - intermittent flow through system	Gimeno, S. et al. 1998a Aquatic Toxicology (Amsterdam) 43:77-92.
Cultured hepatocytes from genetically-uniform, all male, F1-hybrid progenies of common carp (*Cyprinus capio*)	vitellogenin induction in carp hepatocytes with LOEC ranging from 5-50 uM, cytotoxic at 100uM	identified as causing endocrine disruption effects	-six month old hepatocytes with fully mature testes containing mature sperm	Smeets, J. M. et al. 1999. Toxicol. Sci. 50(2): 206-213.
Male common carp (*Cyprinus carpio*)	elevated levels of vitellogenin, inhibition of spermatogenesis, disappearance of spermatozoa and spermatogenic cysts, reduced diameter of seminiferous lobules, reduced spermatocrit values and early appearance of ovo-testes LOAEL= 0.032 mg/L	identified as causing endocrine disruption effects and no mortality or growth effects	- 3 month test duration - nominal concentrations of 32, 100, 320 and 1000 ug/L were tested	Gimeno et al. 1998b Aquatic Toxicology (Amsterdam) 43:93-109.

4. Listed Species Consideration

a. The Endangered Species Act

Section 7 of the Endangered Species Act, 16 U.S.C. Section 1536(a)(2), requires all federal agencies to consult with the National Marine Fisheries Service (NMFS) for marine and anadromous listed species, or the United States Fish and Wildlife Services (FWS) for listed wildlife and freshwater organisms, if they are proposing an "action" that may affect listed species or their designated habitat. Each federal agency is required under the Act to insure that any action they authorize, fund, or carry out is not likely to jeopardize the continued existence of a

listed species or result in the destruction or adverse modification of designated critical habitat. To jeopardize the continued existence of a listed species means "to engage in an action that reasonably would be expected, directly or indirectly, to reduce appreciably the likelihood of both the survival and recovery of a listed species in the wild by reducing the reproduction, numbers, or distribution of the species." 50 C.F.R. § 402.02.

To facilitate compliance with the requirements of the Endangered Species Act subsection (a)(2) the Environmental Protection Agency, Office of Pesticide Programs has established procedures to evaluate whether a proposed registration action may directly or indirectly reduce appreciably the likelihood of both the survival and recovery of a listed species in the wild by reducing the reproduction, numbers, or distribution of any listed species (U.S. EPA 2004). After the Agency's screening-level risk assessment is performed, if any of the Agency's Listed Species LOC Criteria are exceeded for either direct or indirect effects, a determination is made to identify if any listed or candidate species may co-occur in the area of the proposed pesticide use. If determined that listed or candidate species may be present in the proposed use areas, further biological assessment is undertaken. The extent to which listed species may be at risk then determines the need for the development of a more comprehensive consultation package as required by the Endangered Species Act.

For certain use categories, the Agency assumes there will be minimal environmental exposure, and only a minimal toxicity data set is required (Overview of the Ecological Risk Assessment Process in the Office of Pesticide Programs U.S. Environmental Protection Agency - Endangered and Threatened Species Effects Determinations, 1/23/04, Appendix A, Section IIB, pg.81). Chemicals in these categories therefore do not undergo a full screening-level risk assessment, and are considered to fall under a "no effect" determination. Due to the low likelihood of exposure form the indoor uses of 4-t-amylphenol , the Agency expects no effects to listed species or critical habitat and therefore makes a "No Effect" determination for this chemical.

b. General Risk Mitigation

4-t-Amylphenol end-use products (EPs) may also contain other registered pesticides. Although the Agency is not proposing any mitigation measures for products containing 4-t-amylphenol specific to federally listed species, the Agency needs to address potential risks from other end-use products. Therefore, the Agency requires that users adopt all listed species risk mitigation measures for all active ingredients in the product. If a product contains multiple active ingredients with conflicting listed species risk mitigation measures, the more stringent measure(s) should be adopted.

IV. Risk Management, Reregistration, and Tolerance Reassessment Decision

A. Determination of Reregistration Eligibility

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether or not products containing the active ingredient are eligible for reregistration. The Agency has previously identified and required the submission of the generic (i.e., active ingredient-specific) data required to support reregistration of products containing 4-t-amylphenol and its salts (potassium and sodium) as active ingredients. The Agency has completed its review of these generic data, and has determined that the data are sufficient to support reregistration of all supported products containing 4-t-amylphenol and salts,

The Agency has completed its assessment of the dietary, occupational, drinking water and ecological risks associated with the use of pesticide products containing the active ingredients 4-t-amylphenol. Based on a review of these data and on public comments on the Agency's assessments for the active ingredients 4-t-amylphenol and its salts (potassium and sodium), the Agency has sufficient information on the human health and ecological effects of to make decisions as part of the tolerance reassessment process under FFDCA and reregistration process under FIFRA, as amended by FQPA. The Agency has determined that products containing 4-t-amylphenol and its salts are eligible for reregistration provided that: (i) current data gaps and confirmatory data needs are addressed; (ii) the risk mitigation measures outlined in this document are adopted; and (iii) label amendments are made to reflect these measures. Label changes are described in Section V. Appendix A summarizes the uses of 4-t-amylphenol and salts that are eligible for reregistration. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of 4-t-amylphenol and salts, and lists the submitted studies that the Agency found acceptable. Data gaps are identified as generic data requirements that have not been satisfied with acceptable data.

Based on its evaluation of 4-t-amylphenol and salts, the Agency has determined that 4-t-amylphenol and salts products, unless labeled and used as specified in this document, would present risks inconsistent with FIFRA. Accordingly, should a registrant fail to implement any of the risk mitigation measures identified in this document, the Agency may take regulatory action to address the risk concerns from the use of 4-t-amylphenol and salts. If all changes outlined in this document are incorporated into the product labels, then all current risks for 4-t-amylphenol and salts (potassium and sodium) will be substantially mitigated for the purposes of this determination.

B. Public Comments and Responses

Through the Agency's public participation process, EPA worked with stakeholders and the public to reach the regulatory decisions for 4-t-amylphenol. During the public comment period on the risk assessments, which closed on September 19, 2005, the Agency received comments from the Clariant Corporation regarding risk assessment assumptions and endocrine disruption potential and from a private citizen concerned about the diaper use of this chemical. These comments in their entirety are available in the public docket, http://docket.epa.gov/edkpub/index.jsp, (OPP-2005-0181).

C. Regulatory Position

1. Food Quality Protection Act (FQPA) Considerations

a. "Risk Cup" Determination

As part of the FQPA tolerance reassessment process, EPA assessed the risks associated with 4-t-amylphenol. The Agency has concluded that the tolerance exemption for 4-t-amylphenol meets the FQPA safety standards and that the risk from dietary (food sources only) exposure is within the "risk cup." An aggregate assessment was conducted for exposures through food, drinking water and residential exposure. The Agency has determined that the human health risks from these combined exposures are within acceptable levels provided that the mitigation contained in this document is implemented. In reaching this determination, EPA has considered the available information on the special sensitivity of infants and children, as well as aggregate exposure from food, water and residential exposures.

b. Determination of Safety to U.S. Population

As part of the FQPA tolerance reassessment process, EPA assessed the risks associated with 4-t-amylphenol and its salts (potassium and salts). The Agency has determined that the established tolerance exemption for 4-t-amylphenol and its salts with amendments and changes as specified in this document, meet the safety standards under the FQPA amendments to section 408(b) (2) (D) of the FFDCA, and that there is a reasonable certainty no harm will result to the general population or any subgroup from the reregistered, labeled uses of 4-t-amylphenol and salts. In reaching this conclusion, the Agency has considered all available information on the toxicity, use practices and exposure scenarios, and the environmental behavior of 4-t-amylphenol and its salts. Both the acute dietary (food alone) and chronic dietary risks from 4-t-amylphenol are not of concern. 4-t-Amylphenol and its salts are not likely to contaminate surface and ground waters based on its use patterns and fate characteristics. Thus, a drinking water assessment was not conducted.

Short- and intermediate-term aggregate risk assessments were conducted for 4-t-amylphenol. The aggregate oral and inhalation risks are not of concern for adults, as the total aggregate MOE is greater than the target of 3,000. For children, the aggregate risk estimates are also above the target MOE of 3,000 and thus are not of concern. As noted previously, incidental oral exposures to treated textiles are not included in the aggregate assessment because the oral MOE is already of concern.

A dermal aggregate assessment was not conducted because the toxicity effects for the dermal exposure route are not the same as the oral/inhalation exposure route. However, as shown previously on Table 6, short- and intermediate dermal risks are already of concern for the treated textile and diaper uses.

c. Determination of Safety to Infants and Children

EPA has determined that the established tolerance exemption for 4-t-amylphenol, with amendments and changes as specified in this document, meets the safety standards under the FQPA amendments to section 408(b)(2)(C) of the FFDCA, that there is a reasonable certainty of no harm for infants and children. The safety determination for infants and children considers factors of the toxicity, use practices, and environmental behavior noted above for the general population, but also takes into account the possibility of increased dietary exposure due to the specific consumption patterns of infants and children, as well as the possibility of increased susceptibility to the toxic effects of 4-t-amylphenol residues in this population subgroup.

A Special FQPA Safety Factor is necessary to protect the safety of infants and children. In determining whether or not infants and children are particularly susceptible to toxic effects from 4-t-amylphenol residues, the Agency considered the completeness of the database for developmental and reproductive effects, the nature of the effects observed, and other information. The FQPA Safety Factor has been retained (i.e., remains 10X) for 4-t-amylphenol based on a lack of guideline studies, qualitative evidence of sensitivity in the developmental toxicity study, and the suggestive evidence in the open literature of possible endocrine effects.

The toxicology data base is not complete with respect to assessing that increased susceptibility to infants and children as required by FQPA for 4-t-amylphenol. The rat prenatal developmental study showed no quantitative evidence of increased susceptibility (i.e., developmental NOAELs/LOAELs were higher than those for maternal effects). However, there was qualitative evidence of increased susceptibility (i.e., fetal effects (skeletal abnormalities, decreased body weight gain) were considered to be more severe than the maternal toxicity (reversible clinical signs) observed at the same dose level). In addition, there is an absence of developmental toxicity data in the rabbit and an absence of reproductive toxicity data.

d. Endocrine Disruptor Effects

EPA is required under the 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 endocrine effects as the Administrator may designate." Following recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there was a scientific basis 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 EPA include evaluations of potential effects in wildlife. For pesticides, 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 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 EDSP have been developed, 4-t-amylphenol may be subject to additional screening and/or testing to better characterize effects related to endocrine disruption.

e. Cumulative Risks

Risks summarized in this document are those that result only from the use of 4-t-amylphenol and salts. The Food Quality Protection Act (FQPA) requires that 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." The reason for consideration of other substances is due to the possibility that low-level exposures to multiple chemical substances that cause a common toxic effect by a common toxic mechanism could lead to the same adverse health effect as would a higher level of exposure to any of the substances individually. 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 for 4-t-amylphenol. 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/.

2. Tolerance Summary

4-t-amylphenol (also known as phenol, 4-1,1-dimethylpropyl) (CAS No. 80-46-6) has a tolerance exception in 40CFR 180.940 (c) as a food-contact sanitizer for use in food-processing equipment and utensils with a not to exceed limit of 80 ppm.

a. Tolerances Currently Listed Under 40 CFR §180.940(c) and Tolerance Reassessment

Table 11. Tolerance Reassessment Summary for 4-t-amylphenol

Tolerance Exemption Listed Under 40 CFR § 180.940 (c)			
Use Site	**Current Limit (ppm)**	**Tolerance Reassessment (ppm)**	**Correct Definition/Comment**
Food processing equipment and utensils	80	540	When ready for use, the end-use concentration is not to exceed 540 ppm.

b. Codex Harmonization

Currently there are no Codex MRLs established for 4-t-amylphenol.

D. Regulatory Rationale

The Agency has determined that 4-t-amylphenol is eligible for reregistration provided that additional required data confirm this decision and that the risk mitigation measures outlined in this document are adopted, and label amendments are made to reflect these measures.

The following is a summary of the rationale for managing risks associated with the use of 4-t-amylphenol. Where labeling revisions are warranted, specific language is set forth in the summary tables of Section V of this document.

1. Human Health Risk Management

a. Dietary (Food) Risk Mitigation

For all supported uses, the acute and chronic dietary exposure estimates are below the Agency's level of concern. Therefore, no risk mitigation measures are required to address exposure to 4-t-amylphenol residues in food. Residue data are required to confirm the 10% transfer assumption used in the risk assessment.

b. Drinking Water Risk Mitigation

4-t-Amylphenol and its salts are not likely to contaminate surface and ground waters based on its use patterns and fate characteristics. Thus, a drinking water assessment was not conducted. Therefore, no risk mitigation measures are required to address 4-t-amylphenol exposure from drinking water.

c. Residential Risk Mitigation

Residential risks from handler and post-application exposure were calculated for short- and intermediate-term dermal, inhalation and incidental oral exposures. All exposure and risk estimates for residential handler scenarios are below the Agency's level of concern. Therefore, no risk mitigation measures are required for these handler scenarios.

Risks of concern have been identified for several post-application exposure scenarios including children's dermal exposure to treated clothing and treated diapers and children's incidental oral exposure to treated clothing. The Agency believes that adding clear instructions for washing and rinsing textile items will result in the adequate removal of residues from the treated items and address the Agency's concerns for this scenario. The MOE for dermal exposure to children to treated surfaces in daycare centers slightly exceeds the Agency's level of concern (MOE = 940 with a target MOE of 1,000). However, the Agency believes actual exposure from this pathway to not exceed its level of concern when taking into account the conservative nature of the risk estimate which is likely to overestimate potential exposures.

In summary, to reduce residential exposure, the Agency has determined that the following mitigation and label changes for specific scenarios are appropriate and required for reregistration eligibility:

- Delete all diaper uses
- Delete all use on non-laundered textiles\items including mattresses, helmets, headgear, headphones, face gear, and mouthpieces.
- All labels with laundered textile uses must have directions that indicate that items must be treated prior to washing and rinsing.

d. Occupational Risk Mitigation

i. Handler Exposure

Occupational risks from handler and applicator exposures were calculated for short-term and intermediate-term dermal and inhalation exposures. All exposure and risk estimates for occupational handler scenarios are below the Agency's level of concern. Therefore, no risk mitigation measures are required for these handler scenarios.

ii. Post-Application Risk Mitigation

Post-application exposure to re-entry workers is possible because 4-t-amylphenol can be applied as a fogging application to animal buildings. The Agency used the MCCEM (Multi-Chamber Concentration and Exposure Model) to estimate postapplication/bystander exposures. The calculated inhalation MOEs were above the target MOE of 300 for all fogging postapplication scenarios with the exception of the scenario for 8-hr exposure to the product with a 2-hr reentry interval (MOE = 86).

The Agency does not believe that any mitigation is necessary to address the post-application scenario with a 2-hr reentry interval at this time. The risk estimate was calculated using the Agency's standard assumptions for air exchange rates. The Agency believes that in the case of animal barns and facilities this assumption is very conservative given the relatively high air exchange rates for such facilities.

2. Environmental Risk Management

As the uses of 4-t-amylphenol considered in this RED make it unlikely that any appreciable exposure to terrestrial or aquatic organisms would occur, no risk mitigation measures are required to address environmental exposure to 4-t-amylphenol.

3. Other Labeling Requirements

In order to be eligible for reregistration, various use and safety information will be included in the labeling of all end-use products containing 4-t-amylphenol. For the specific labeling statements and a list of outstanding data, refer to Section V of this RED document.

4. Listed Species Considerations

a. The Endangered Species Act

Section 7 of the Endangered Species Act, 16 U.S.C. Section 1536(a)(2), requires all federal agencies to consult with the National Marine Fisheries Service (NMFS) for marine and anadromous listed species, or the United States Fish and Wildlife Services (FWS) for listed wildlife and freshwater organisms, if they are proposing an "action" that may affect listed species or their designated habitat. Each federal agency is required under the Act to insure that any action they authorize, fund, or carry out is not likely to jeopardize the continued existence of a listed species or result in the destruction or adverse modification of designated critical habitat. To jeopardize the continued existence of a listed species means "to engage in an action that reasonably would be expected, directly or indirectly, to reduce appreciably the likelihood of both the survival and recovery of a listed species in the wild by reducing the reproduction, numbers, or distribution of the species." 50 C.F.R. § 402.02.

To facilitate compliance with the requirements of the Endangered Species Act subsection (a)(2) the Environmental Protection Agency, Office of Pesticide Programs has established procedures to evaluate whether a proposed registration action may directly or indirectly reduce appreciably the likelihood of both the survival and recovery of a listed species in the wild by reducing the reproduction, numbers, or distribution of any listed species (U.S. EPA 2004). After the Agency's screening-level risk assessment is performed, if any of the Agency's Listed Species LOC Criteria are exceeded for either direct or indirect effects, a determination is made to identify if any listed or candidate species may co-occur in the area of the proposed pesticide use. If determined that listed or candidate species may be present in the proposed use areas, further biological assessment is undertaken. The extent to which listed species may be at risk then determines the need for the development of a more comprehensive consultation package as required by the Endangered Species Act.

For certain use categories, the Agency assumes there will be minimal environmental exposure, and only a minimal toxicity data set is required (Overview of the Ecological Risk Assessment Process in the Office of Pesticide Programs U.S. Environmental Protection Agency - Endangered and Threatened Species Effects Determinations, 1/23/04, Appendix A, Section IIB, pg.81). Chemicals in these categories therefore do not undergo a full screening-level risk assessment, and are considered to fall under a "no effect" determination. Due to the low likelihood of exposure of 4-t-amylphenol, the Agency expects no effects to listed species or critical habitat and therefore makes a "No Effect" determination for this chemical.

b. General Risk Mitigation

4-t-Amylphenol end use products (EPs) may also contain other registered pesticides. Although the Agency is not proposing any mitigation measures for products containing 4-t-amylphenol specific to federally listed threatened and endangered species, the Agency needs to address potential risks from other end-use products. Therefore, the Agency requires that users adopt all threatened and endangered species risk mitigation measures for all active ingredients in

the product. If a product contains multiple active ingredients with conflicting threatened and endangered species risk mitigation measures, the more stringent measure(s) should be adopted.

V. What Registrants Need to Do

The Agency has determined that 4-t-amylphenol is eligible for reregistration provided that: (i) additional data that the Agency intends to require confirm this decision; and (ii) the risk mitigation measures outlined in this document are adopted, and (iii) label amendments are made to reflect these measures. To implement the risk mitigation measures, the registrants must amend their product labeling to incorporate the label statements set forth in the Label Changes Summary Table in Section B below (Table 13). The additional data requirements that the Agency intends to obtain will include, among other things, submission of the following:

For 4-t-amylphenol technical grade active ingredient products, the registrant needs to submit the following items:

Within 90 days from receipt of the generic data call in (DCI):

1. completed response forms to the generic DCI (i.e., DCI response form and requirements status and registrant's response form); and

2. submit any time extension and/or waiver requests with a full written justification.

Within the time limit specified in the generic DCI:

1. cite any existing generic data which address data requirements or submit new generic data responding to the DCI.

Please contact Killian Swift at (703) 308-6346 with questions regarding generic reregistration.

By US mail:
Document Processing Desk (DCI/SRRD)
Killian Swift
US EPA (7510C)
1200 Pennsylvania Ave., NW
Washington, DC 20460

By express or courier service:
Document Processing Desk (DCI/SRRD)
Killian Swift
Office of Pesticide Programs (7510C)
Room 266A, Crystal Mall 2
1801 S. Bell Street
Arlington, VA 22202

For end use products containing the active ingredient 4-t-amylphenol, the registrant needs to submit the following items for each product.

Within 90 days from the receipt of the product-specific data call-in (PDCI):

1. completed response forms to the PDCI (i.e., PDCI response form and requirements status and registrant's response form); and

2. submit any time extension or waiver requests with a full written justification.

Within eight months from the receipt of the PDCI:

1. two copies of the confidential statement of formula (EPA Form 8570-4);

2. a completed original application for reregistration (EPA Form 8570-1). Indicate on the form that it is an "application for reregistration";

3. five copies of the draft label incorporating all label amendments outlined in Table 13 of this document;

4. a completed form certifying compliance with data compensation requirements (EPA Form 8570-34); and

5. if applicable, a completed form certifying compliance with cost share offer requirements (EPA Form 8570-32); and

6. the product-specific data responding to the PDCI.

Please contact Adam Heyward at (703) 308-6422 with questions regarding product reregistration and/or the PDCI. All materials submitted in response to the PDCI should be addressed as follows:

By US mail:
Document Processing Desk (PDCI/PRB)
Adam Heyward
US EPA (7510C)
1200 Pennsylvania Ave., NW
Washington, DC 20460

By express or courier service:
Document Processing Desk (PDCI/PRB)
Adam Heyward
Office of Pesticide Programs (7510C)
Room 266A, Crystal Mall 2
1801 South Bell Street
Arlington, VA 22202

A. Manufacturing Use Products

1. Additional Generic Data Requirements

The generic database supporting the reregistration of 4-t-amylphenol has been reviewed and determined to be substantially complete. However, the following additional data requirements have been identified by the Agency as confirmatory and included in the generic DCI for this RED.

The Agency has established an interim two-tiered system for toxicology testing requirements. Tier I toxicology data requirements would apply to all indirect food additives that result in residue concentrations ranging from 0-200ppb which applies to 4-t amylphenol. The requirements would consist of an acute toxicity testing battery, subchronic toxicity studies in the rodent, a developmental toxicity study in the rat, and a mutagenicity testing battery. The developmental toxicity study in the rat, mutagenicity testing battery, the acute oral toxicity and the acute dermal irritation data requirements has been fulfilled for 4-t amylphenol. The Agency also conducts a literature search and can also conduct a Structural Activity Relationship analysis (SAR) if appropriate. The Agency also will hold in reserve a two-generation reproduction toxicity study in the rat and a subchronic toxicity studies in a non-rodent which would become data requirements if warranted by the Agency's evaluation of the Tier 1 data. A 2-generation reproduction study and a subchronic toxicity study in a non-rodent are being held in reserve for 4-t amylphenol.

Tier II studies would be triggered by the presence of significant (i.e. >200ppb) residues in food or evidence of significant toxicity from the Tier I data set, which may include developmental / reproductive, or other systemic toxicity such as presence of neoplastic growth or significant target organ toxicity. In such cases, chronic toxicity and carcinogenicity testing would be required.

As mentioned earlier, the Agency assumed that food can contact 2000 cm^2 of treated surfaces, and that 10% of the pesticide migrates to food based on the Agency Residential SOPs in its dietary risk assessment. The use of the 10% transfer rate instead of the use of a 100% transfer rate that is used in the FDA Sanitizer Solution Guidelines requires the submission of confirmatory data to establish the reliability of the use of the10% transfer rate.

The Agency is also holding in reserve a developmental toxicity study in rabbits based on the potential endocrine disruption effects of this chemical. The need for this study will be determined following the Agency's review of the 90-day oral study in rodents.

The risk assessment noted deficiencies in the surrogate dermal and inhalation exposure data available from the Chemical Manufacturers Association (CMA) data base. Therefore, the Agency is requiring confirmatory data to support the uses assessed with the CMA exposure data within this risk assessment. The risk assessment also noted that many of the use parameters

(e.g., amount handled and duration of use) were based on professional judgments. Therefore, descriptions of human activities associated with the uses assessed are required as confirmatory.

A 28-day rat inhalation study for hazard considerations because 4-t-amylphenol is an air deodorizer was considered, however, the Agency does not believe this study is necessary because the MOEs are sufficiently high for this use, and thus not of concern. In addition, the Agency believes the repeat dermal toxicity study with end use formulation product, and confirmatory residue migration data are not necessary because the diaper and textile use are no longer eligible for registration.

Table 12. Confirmatory Data Requirements for Reregistration

Guideline Study Name	New OPPTS Guideline No.	Old Guideline No.
90-day Oral Subchronic in Rats (including neurotoxicity and endocrine endpoints)	870-3100	82-1
Acute Dermal Toxicity	870.1200	81-2
Acute Inhalation Toxicity	870.1300	81-3
Acute Eye Irritation	870.2400	81-4
Skin Sensitization	870.2600	81-6
Dermal Indoor Exposure	875.1200, 875.1600	233 and 236
Inhalation Indoor Exposure	875.1400, 875.1600	234 and 236
Descriptions of Human Activity	875.2800	133-1
Avian acute oral toxicity	850.2100	71-1
Freshwater fish acute toxicity	850.1075	72-1
Freshwater invertebrate acute toxicity	850.1010	72-2
Dietary-Residues in Food from Treating Countertops with 4-t amylphenol (FDA Wipe Study Methodology) (FDA, 2003a and 2003b)	Non-Guideline	Non-Guideline
Studies Held in Reserve		
2-Generation Reproduction	870.3800	83-4
90-day Oral Subchronic in Non-Rodents	870-3150	82-1
Developmental Toxicity in Rabbits	870.3700b	83-3b

2. Labeling for Technical and Manufacturing Use Products

To ensure compliance with FIFRA, technical and manufacturing use product (MP) labeling should be revised to comply with all current EPA regulations, PR Notices and applicable policies. The Technical and MP labeling should bear the labeling contained in Table 13 , Label Changes Summary Table.

B. End-Use Products

1. Additional Product-Specific Data Requirements

Section 4(g)(2)(B) of FIFRA calls for the Agency to obtain any needed product-specific data regarding the pesticide after a determination of eligibility has been made. The Registrant must review previous data submissions to ensure that they meet current EPA acceptance criteria and if not, commit to conduct new studies. If a registrant believes that previously submitted data meet current testing standards, then the study MRID numbers should be cited according to the instructions in the Requirement Status and Registrants Response Form provided for each product.

A product-specific data call-in, outlining specific data requirements, will follow this RED.

2. Labeling for End-Use Products

Labeling changes are necessary to implement measures outlined in Section IV above. Specific language to incorporate these changes is specified in Table 13.

Registrants may generally distribute and sell products bearing old labels/labeling for 26 months from the date of the issuance of this Reregistration Eligibility Decision document. Persons other than the registrant may generally distribute or sell such products for 52 months from the approval of labels reflecting the mitigation described in this RED. However, existing stocks time frames will be established case-by-case, depending on the number of products involved, the number of label changes, and other factors. Refer to "Existing Stocks of Pesticide Products; Statement of Policy," *Federal Register*, Volume 56, No. 123, June 26, 1991.

a. Label Changes Summary Table

In order to be eligible for reregistration, amend all product labels to incorporate the risk mitigation measures outlined in Section IV. The following table describes how language on the labels should be amended.

Table 13. Labeling Changes Summary Table

Summary of Labeling Changes for 4-t-Amylphenol and its Salts		
Description	Amended Labeling Language	Placement on Label
Delete use on diapers		Use Directions
Delete all use on non-laundered textiles\items including mattresses, helmets, headgear, headphones, facegear, and mouthpieces.		Use Directions
Laundry Use	Clarify language to ensure use requires washing and rinsing prior to wearing clothing	Use Directions

VI. APPENDICES

Appendix A: Use Patterns Eligible for Reregistration
4-T-Amylphenol

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
(1) **Agricultural premises and equipment**				
Mushroom houses-empty premises/equipment	Soluble concentrate: Reg.211-36	Mop, cloth, sponge or hand trigger sprayer	1 oz per gallon of water 1:128 dilution Thoroughly wet for 10 minutes allow to air dry	**Use as a premises spray, do not apply to the crop, compost, or casing.** Following application as a spray, do not enter or allow others to enter the treated area until sprays have dries. Do not apply in a way that will contact workers or any other persons, either directly or through drift. Only protected handlers may be in the area during the application. Do not contaminate other materials (including foods/drinks/feeds/ water)
	Soluble concentrate: Reg. 1043-26 Reg.211-25 Reg.65020-7	Mop, cloth, sponge or hand trigger sprayer	1/2 oz per gallon of water 1:256 dilution Thoroughly wet for 10 minutes allow to air dry	Following application as a spray, do not enter or allow others to enter the treated area until sprays have dries. Do not apply in a way that will contact workers or any other persons, either directly or through drift. Only protected handlers may be in the area during the application. Do not contaminate other materials (including foods/drinks/feeds/ water)
Hard, non porous, non food contact surfaces	Soluble concentrate: Reg.211-36 Reg.49403-6 Reg. 1043-118 Reg.11725-9	Mop, cloth, sponge or hand trigger sprayer	1 oz per gallon of water 1:128 dilution Thoroughly wet for 10	Following application as a spray, do not enter or allow others to enter the treated area until sprays have dries. Do not apply in a way that will contact workers or any other persons, either directly or through drift. Only protected

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
			minutes allow to air dry	handlers may be in the area during the application. Do not contaminate other materials (including foods/drinks/feeds/ water)
Agricultural/farm equipment/shoe baths Agricultural/farm equipment/shoe baths *(continued)*	Soluble concentrate: Reg.211-36 Reg.49403-6 Reg. 1043-118 Reg. 66171-1 Reg.11725-9	Mop, cloth, sponge or hand trigger sprayer	1 oz per gallon of water 1:128 dilution Thoroughly wet for 10 minutes allow to air dry **Shoe bath sanitizer containing one inch of freshly made disinfectant should be placed at all entrances	**Do not use in milking stalls. Milking parlors, or milk houses. Do not apply to crop, soil or growing media in which a crop grows or will be growing** Following application as a spray, do not enter or allow others to enter the treated area until sprays have dries. Do not apply in a way that will contact workers or any other persons, either directly or through drift. Only protected handlers may be in the area during the application. Do not contaminate other materials (including foods/drinks/feeds/ water)
	Soluble concentrate: Reg. 11725-8 Reg.1043-91 Reg.11725-7 Reg.1043-26 Reg.211-25	Fogger (wet misting)	½ oz per gallon of water 1:256 dilution Set the automatic timer on the fogger for 6 minutes for 1000cu.ft and leave the room. Allow at least 2 hours before entering a room that has been fogged	**Treated food contact surfaces must be thoroughly rinsed with potable water prior to use.** Do not apply in a way that will contact workers or any other persons, either directly or through drift. Only protected handlers may be in the area during the application. Do not contaminate other materials (including foods/drinks/feeds/ water)

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
	Soluble concentrate: Reg.66171-1 Reg. 11725-7 Reg.1043-26 Reg.211-25 Reg.65020-7 Reg.3862-180	Mop, cloth, sponge or hand trigger sprayer	1/2 oz per gallon of water 1:256 dilution Thoroughly wet for 10 minutes allow to air dry **Shoe bath sanitizer containing one inch of freshly made disinfectant should be placed at all entrances	Following application as a spray, do not enter or allow others to enter the treated area until sprays have dries. Do not apply in a way that will contact workers or any other persons, either directly or through drift. Only protected handlers may be in the area during the application. Do not contaminate other materials (including foods/drinks/feeds/ water)
(2) **Food handling/storage establishments premises and equipment**				
Hard, non porous, non food contact surfaces Hard, non porous, non food contact surfaces *(continued*)	Ready to use solution: Reg.1270-237 Reg. 1008-105	Spray	To disinfect: Thoroughly wet (saturate) all surfaces for 10 minutes.	Following application as a spray, do not enter or allow others to enter the treated area until sprays have dries. Do not apply in a way that will contact workers or any other persons, either directly or through drift. Only protected handlers may be in the area during the application. Do not contaminate other materials (including foods/drinks/feeds/ water)

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
	Soluble concentrate: Reg.1043-92 Reg.1043-91 Reg.11725-7	Mop, cloth, sponge or hand trigger sprayer	1/2 oz per gallon of water 1:256 dilution Thoroughly wet for 10 minutes allow to air dry	Following application as a spray, do not enter or allow others to enter the treated area until sprays have dries. Do not apply in a way that will contact workers or any other persons, either directly or through drift. Only protected handlers may be in the area during the application. Do not contaminate other materials (including foods/drinks/feeds/ water)
Meat processing plant premises (nonfood)	Ready to use solution: Reg.10088-105 Reg.1270-237	Spray	To disinfect: Thoroughly wet (saturate) all surfaces for 10 minutes.	Following application as a spray, do not enter or allow others to enter the treated area until sprays have dries. Do not apply in a way that will contact workers or any other persons, either directly or through drift. Only protected handlers may be in the area during the application. Do not contaminate other materials (including foods/drinks/feeds/ water)
	Soluble concentrate: Reg.11725-7	Mop, cloth, sponge or hand trigger sprayer	1/2 oz per gallon of water 1:256 dilution Thoroughly wet for 10 minutes allow to air dry	Following application as a spray, do not enter or allow others to enter the treated area until sprays have dries. Do not apply in a way that will contact workers or any other persons, either directly or through drift. Only protected handlers may be in the area during the application. Do not contaminate other materials (including foods/drinks/feeds/ water)

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
Poultry processing plant premises (nonfood)	Ready to use solution: Reg.10088-105 Reg. 1270-237	Spray	To disinfect: Thoroughly wet (saturate) all surfaces for 10 minutes.	Following application as a spray, do not enter or allow others to enter the treated area until sprays have dries. Do not apply in a way that will contact workers or any other persons, either directly or through drift. Only protected handlers may be in the area during the application. Do not contaminate other materials (including foods/drinks/feeds/ water)
Poultry processing plant premises (nonfood) *(continued)*	Soluble concentrate: Reg.49403-23 Reg.211-25	Mop, cloth, sponge or hand trigger sprayer	1/2 oz per gallon of water 1:256 dilution Thoroughly wet for 10 minutes allow to air dry	Following application as a spray, do not enter or allow others to enter the treated area until sprays have dries. Do not apply in a way that will contact workers or any other persons, either directly or through drift. Only protected handlers may be in the area during the application. Do not contaminate other materials (including foods/drinks/feeds/ water)
Processing/handling equipment (nonfood)	Ready to use solution: Reg.10088-105 Reg. 1270-237	Spray	To disinfect: Thoroughly wet (saturate) all surfaces for 10 minutes.	Following application as a spray, do not enter or allow others to enter the treated area until sprays have dries. Do not apply in a way that will contact workers or any other persons, either directly or through drift. Only protected handlers may be in the area during the application. Do not contaminate other materials (including foods/drinks/feeds/ water)

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
	Soluble concentrate: Reg.11725-7	Mop, cloth, sponge or hand trigger sprayer	1/2 oz per gallon of water 1:256 dilution Thoroughly wet for 10 minutes allow to air dry	Following application as a spray, do not enter or allow others to enter the treated area until sprays have dries. Do not apply in a way that will contact workers or any other persons, either directly or through drift. Only protected handlers may be in the area during the application. Do not contaminate other materials (including foods/drinks/feeds/ water)
(3) **Commercial, institutional and industrial premises and equipment**				
Institutional premises	Ready-to-use-solution: Reg.104319, Reg.44446-67 Reg.10088-105 Reg. 1270-237 Reg.7405-51	Spray	To disinfect: Thoroughly wet (saturate) all surfaces for 10 minutes.	Following application as a spray, do not enter or allow others to enter the treated area until sprays have dries. Do not apply in a way that will contact workers or any other persons, either directly or through drift. Only protected handlers may be in the area during the application. Do not contaminate other materials (including foods/drinks/feeds/ water)

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
Institutional premises *(continued)*	Soluble concentrate: Reg. 11725-8 Reg.1043-91	Fogger (wet misting)	½ oz per gallon of water 1:256 dilution Set the automatic timer on the fogger for 6 minutes for 1000cu.ft and leave the room. Allow at least 2 hours before entering a room that has been fogged	**Treated food contact surfaces must be thoroughly rinsed with potable water prior to use.** Do not apply in a way that will contact workers or any other persons, either directly or through drift. Only protected handlers may be in the area during the application. Do not contaminate other materials (including foods/drinks/feeds/ water)
Hard, non porous, non food contact surfaces	Soluble concentrate: Reg.66171-1 Reg.117258 Reg.1043-91 Reg,1043-92 Reg.66171-2 Reg. 211-25 Reg.3862-180	Mop, cloth, sponge or hand trigger sprayer	1/2 oz per gallon of water 1:256 dilution Thoroughly wet for 10 minutes allow to air dry	Following application as a spray, do not enter or allow others to enter the treated area until sprays have dries. Do not apply in a way that will contact workers or any other persons, either directly or through drift. Only protected handlers may be in the area during the application. Do not contaminate other materials (including foods/drinks/feeds/ water)

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
	Soluble concentrate: Reg.211-36, Reg.1043-115 Reg.1043-87 Reg.2212-5 Reg.49403-6 Reg. 1043-118 Reg.11725-9	Mop, cloth, sponge or hand trigger sprayer	1 oz per gallon of water 1:128 dilution Thoroughly wet for 10 minutes allow to air dry	Following application as a spray, do not enter or allow others to enter the treated area until sprays have dries. Do not apply in a way that will contact workers or any other persons, either directly or through drift. Only protected handlers may be in the area during the application. Do not contaminate other materials (including foods/drinks/feeds/ water)
	Ready-to-use-solution Reg. 1043-19 Reg.44446-67 Reg.10088-105 Reg.1270-237 Reg.7405-51 Reg.55195-3 Reg.3862-104	Spray	To disinfect: Thoroughly wet (saturate) all surfaces for 10 minutes.	Following application as a spray, do not enter or allow others to enter the treated area until sprays have dries. Do not apply in a way that will contact workers or any other persons, either directly or through drift. Only protected handlers may be in the area during the application. Do not contaminate other materials (including foods/drinks/feeds/ water)

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
Hard, non porous, non food contact surfaces *(continued)*	Soluble concentrate: Reg. 11725-8 Reg.1043-91	Fogger (wet misting)	½ oz per gallon of water 1:256 dilution Set the automatic timer on the fogger for 6 minutes for 1000cu.ft and leave the room. Allow at least 2 hours before entering a room that has been fogged	**Treated food contact surfaces must be thoroughly rinsed with potable water prior to use.** Do not apply in a way that will contact workers or any other persons, either directly or through drift. Only protected handlers may be in the area during the application. Do not contaminate other materials (including foods/drinks/feeds/ water)
Bedside and office furniture	Soluble concentrate: Reg.66171-1, Reg.11725-8, Reg. 1043-92 Reg.1043-91, Reg.66171-2, Reg.211-25	Mop, cloth, sponge or hand trigger sprayer	1/2 oz per gallon of water 1:256 dilution Thoroughly wet for 10 minutes allow to air dry	Following application as a spray, do not enter or allow others to enter the treated area until sprays have dries. Do not apply in a way that will contact workers or any other persons, either directly or through drift. Only protected handlers may be in the area during the application. Do not contaminate other materials (including foods/drinks/feeds/ water)

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
Bedside and office furniture *(continued)*	Soluble concentrate: Reg.211-36 Reg.1043-115 Reg.1043-87 Reg.2212-5 Reg.49403-6 Reg. 1043-118	Mop, cloth, sponge or hand trigger sprayer	1 oz per gallon of water 1:128 dilution Thoroughly wet for 10 minutes allow to air dry	Following application as a spray, do not enter or allow others to enter the treated area until sprays have dries. Do not apply in a way that will contact workers or any other persons, either directly or through drift. Only protected handlers may be in the area during the application. Do not contaminate other materials (including foods/drinks/feeds/ water)
	Impregnated material.: Reg.55195-4	Wipe	Thoroughly wet pre-cleaned surface with a wipe and allow to air dry	Do not reuse wipes
	Ready-to-use-solution: Reg. 1043-19 Reg.44446-67, Reg.10088-105	Spray	To disinfect: Thoroughly wet (saturate) all surfaces for 10 minutes.	Following application as a spray, do not enter or allow others to enter the treated area until sprays have dries. Do not apply in a way that will contact workers or any other persons, either directly or through drift. Only protected handlers may be in the area during the application. Do not contaminate other materials (including foods/drinks/feeds/ water)
Trash carts	Ready-to-use-solution: Reg. 1043-19 Reg.44446-67	Spray	To disinfect: Thoroughly wet (saturate) all surfaces for 10 minutes.	Following application as a spray, do not enter or allow others to enter the treated area until sprays have dries. Do not apply in a way that will contact workers or any other persons,

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
	Reg.10088-105			either directly or through drift. Only protected handlers may be in the area during the application. Do not contaminate other materials (including foods/drinks/feeds/ water)
Telephones	Ready-to-use-solution: Reg. 1043-19 Reg.44446-67 Reg.10088-105	Spray	To disinfect: Thoroughly wet (saturate) all surfaces for 10 minutes.	Following application as a spray, do not enter or allow others to enter the treated area until sprays have dries. Do not apply in a way that will contact workers or any other persons, either directly or through drift. Only protected handlers may be in the area during the application. Do not contaminate other materials (including foods/drinks/feeds/ water)
Waste cans and laundry hampers	Ready-to-use-solution: Reg. 1043-19 Reg.44446-67 Reg.10088-105	Spray	To disinfect: Thoroughly wet (saturate) all surfaces for 10 minutes.	Following application as a spray, do not enter or allow others to enter the treated area until sprays have dries. Do not apply in a way that will contact workers or any other persons, either directly or through drift. Only protected handlers may be in the area during the application. Do not contaminate other materials (including foods/drinks/feeds/ water)
Sinks	Ready-to-use-solution: Reg. 1043-19 Reg.44446-67	Spray	To disinfect: Thoroughly wet (saturate) all surfaces for 10 minutes.	Following application as a spray, do not enter or allow others to enter the treated area until sprays have dries. Do not apply in a way that will contact workers or any other persons,

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
	Reg.10088-105			either directly or through drift. Only protected handlers may be in the area during the application. Do not contaminate other materials (including foods/drinks/feeds/ water)
Carpet cleaning	Soluble concentrate: Reg.70263-7	Hot water extraction	1 oz per gallon of water Inject and extract as you would with other extraction cleaners	Test fibers for colorfastness before use. Apply diluted cleaner to inconspicuous area, and rub with a white cloth. If color transfers to cloth or changes, a water based cleaning system should not be used.
	Soluble concentrate: Reg.70263-7	Spin bonnet cleaning (spray)	4 oz per gallon of water Spray on at a rate of 200-300 square feet per gallon, scrub with rotary floor machine equipped with bonnet or pad	Test fibers for colorfastness before use. Apply diluted cleaner to inconspicuous area, and rub with a white cloth. If color transfers to cloth or changes, a water based cleaning system should not be used.
	Soluble concentrate: Reg.70263-7	Immersion	Mix 2 oz per gallon of water in a cleaning tank. Immerse rug in cleaning solution.	Test fibers for colorfastness before use. Apply diluted cleaner to inconspicuous area, and rub with a white cloth. If color transfers to cloth or changes, a water based cleaning system should not be used.
(4)Residential and public access premises				
Household/domestic dwelling	Ready-to-use-solution: Reg. 1043-19 Reg.4444667	Spray	To disinfect: Thoroughly wet (saturate) all surfaces for 10 minutes.	Following application as a spray, do not enter or allow others to enter the treated area until sprays have dries. Do not apply in a way that will contact workers or any other persons,

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
	Reg.10088-105 Reg.1008-104 Reg.1270-237			either directly or through drift. Only protected handlers may be in the area during the application. Do not contaminate other materials (including foods/drinks/feeds/ water)
Carpet cleaning	Soluble concentrate: Reg.70263-7	Hot water extraction	1 oz per gallon of water Inject and extract as you would with other extraction cleaners	Test fibers for colorfastness before use. Apply diluted cleaner to inconspicuous area, and rub with a white cloth. If color transfers to cloth or changes, a water based cleaning system should not be used.
	Soluble concentrate: Reg.70263-7	Spin bonnet cleaning (spray)	4 oz per gallon of water Spray on at a rate of 200-300 square feet per gallon, scrub with rotary floor machine equipped with bonnet or pad	Test fibers for colorfastness before use. Apply diluted cleaner to inconspicuous area, and rub with a white cloth. If color transfers to cloth or changes, a water based cleaning system should not be used.
Carpet cleaning *(continued)*	Soluble concentrate: Reg.70263-7	Immersion	Mix 2 oz per gallon of water in a cleaning tank. Immerse rug in cleaning solution.	Test fibers for colorfastness before use. Apply diluted cleaner to inconspicuous area, and rub with a white cloth. If color transfers to cloth or changes, a water based cleaning system should not be used.
Hard, non porous, non food contact surfaces	Ready-to-use-solution: Reg. 1043-19, Reg.44446-67 Reg.10088-105	Spray	To disinfect: Thoroughly wet (saturate) all surfaces for 10 minutes.	Following application as a spray, do not enter or allow others to enter the treated area until sprays have dries. Do not apply in a way that will contact workers or any other persons, either directly or through drift. Only protected

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
	Reg.1008-104 Reg.1270-237 Reg.3862-104			handlers may be in the area during the application. Do not contaminate other materials (including foods/drinks/feeds/ water)
Animals kennels/sleeping quarters (commercial)	Soluble concentrate: Reg.303-225	Mop, cloth, sponge or hand trigger sprayer	1/2 oz per gallon of water 1:256 dilution Thoroughly wet for 10 minutes allow to air dry	Following application as a spray, do not enter or allow others to enter the treated area until sprays have dries. Do not apply in a way that will contact workers or any other persons, either directly or through drift. Only protected handlers may be in the area during the application. Do not contaminate other materials (including foods/drinks/feeds/ water)
	Soluble concentrate: Reg. 66171-2	Mop, cloth, sponge or hand trigger sprayer	1 oz per gallon of water 1:128 dilution Thoroughly wet for 10 minutes allow to air dry	Following application as a spray, do not enter or allow others to enter the treated area until sprays have dries. Do not apply in a way that will contact workers or any other persons, either directly or through drift. Only protected handlers may be in the area during the application. Do not contaminate other materials (including foods/drinks/feeds/ water)
(5) Medical premises and equipment				

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
Hospital non critical items(bedpans/furniture	Ready-to-use-solution: Reg. 1043-19 Reg.44446-67 Reg.10088-105 Reg.1270237 Reg.10807-177 Reg.10807-178 Reg.3862-104 Reg.706-69	Spray	To disinfect: Thoroughly wet (saturate) all surfaces for 10 minutes.	Following application as a spray, do not enter or allow others to enter the treated area until sprays have dries. Do not apply in a way that will contact workers or any other persons, either directly or through drift. Only protected handlers may be in the area during the application. Do not contaminate other materials (including foods/drinks/feeds/ water)
	Soluble concentrate: Reg.211-25	Mop, cloth, sponge or hand trigger sprayer	1/2 oz per gallon of water 1:256 dilution Thoroughly wet for 10 minutes allow to air dry	Following application as a spray, do not enter or allow others to enter the treated area until sprays have dries. Do not apply in a way that will contact workers or any other persons, either directly or through drift. Only protected handlers may be in the area during the application. Do not contaminate other materials (including foods/drinks/feeds/ water)
	Soluble concentrate: Reg.675-21	Mop, cloth, sponge or hand trigger sprayer	40cc per 2 gallons of water 1:200 dilution Thoroughly wet for 10 minutes allow to air dry	Following application as a spray, do not enter or allow others to enter the treated area until sprays have dries. Do not apply in a way that will contact workers or any other persons, either directly or through drift. Only protected handlers may be in the area during the application. Do not contaminate other materials (including foods/drinks/feeds/ water)

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
Hospital non critical items(bedpans/furniture *(continued)*	Soluble concentrate: Reg.211-36 Reg.49403-6	Mop, cloth, sponge or hand trigger sprayer	1 oz per gallon of water 1:128 dilution Thoroughly wet for 10 minutes allow to air dry	Following application as a spray, do not enter or allow others to enter the treated area until sprays have dries. Do not apply in a way that will contact workers or any other persons, either directly or through drift. Only protected handlers may be in the area during the application. Do not contaminate other materials (including foods/drinks/feeds/ water)
Hospital semi critical items	Soluble concentrate: Reg.211-36 Reg.49403-6	Mop, cloth, sponge or hand trigger sprayer	1 oz per gallon of water 1:128 dilution Thoroughly wet for 10 minutes allow to air dry **Prior to sterilization or high level decontamination	Following application as a spray, do not enter or allow others to enter the treated area until sprays have dries. Do not apply in a way that will contact workers or any other persons, either directly or through drift. Only protected handlers may be in the area during the application. Do not contaminate other materials (including foods/drinks/feeds/ water)

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
Hospital critical items (surgical instruments/pacemakers)	Soluble concentrate: Reg.1043-114	Immersion	2 oz per gallon of water 1:64 dilution Soak for a minimum of 20 minutes to achieve interim instrument decontamination **Prior to sterilization or high level decontamination	Do not apply in a way that will contact workers or any other persons, either directly or through drift. Only protected handlers may be in the area during the application. Do not contaminate other materials (including foods/drinks/feeds/ water)
	Soluble concentrate: Reg.675-21	Immersion	5oz per 2 gallons of water 2:100 dilution Soak for 15 minutes to achieve interim instrument decontamination, then immerse in 70% alcohol for one minute	Do not apply in a way that will contact workers or any other persons, either directly or through drift. Only protected handlers may be in the area during the application. Do not contaminate other materials (including foods/drinks/feeds/ water)

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
Hospital critical items (surgical instruments/pacemakers) *(continued)*	Soluble concentrate: Reg. 2212-170	Ultra sonic cleaning system	1 oz per gallon of water 1:128 dilution Fill the basket with pre cleaned instruments, place cover on machine and run cycle for 10 minutes **Prior to sterilization or high level decontamination	Do not apply in a way that will contact workers or any other persons, either directly or through drift. Do not contaminate other materials (including foods/drinks/feeds/ water)
Hospital/medical institutions premises (human/veterinary)	Ready to use solution: Reg.7405-51, Reg.3862-104 Reg.706-69	Spray	To disinfect: Thoroughly wet (saturate) all surfaces for 10 minutes.	Following application as a spray, do not enter or allow others to enter the treated area until sprays have dries. Do not apply in a way that will contact workers or any other persons, either directly or through drift. Only protected handlers may be in the area during the application. Do not contaminate other materials (including foods/drinks/feeds/ water)

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
Hospital/medical institutions premises (human/veterinary) *(continued)*	Soluble concentrate: Reg. 11725-8	Fogger (wet misting)	½ oz per gallon of water 1:256 dilution Set the automatic timer on the fogger for 6 minutes for 1000cu.ft and leave the room. Allow at least 2 hours before entering a room that has been fogged	**Treated food contact surfaces must be thoroughly rinsed with potable water prior to use.** Do not apply in a way that will contact workers or any other persons, either directly or through drift. Only protected handlers may be in the area during the application. Do not contaminate other materials (including foods/drinks/feeds/ water)
	Soluble concentrate: Reg.66171-1 Reg.1043-92 Reg.11725-8 Reg.66171-2 Reg. 49403-23 Reg.211-25	Mop, cloth, sponge or hand trigger sprayer	1/2 oz per gallon of water 1:256 dilution Thoroughly wet for 10 minutes allow to air dry	Following application as a spray, do not enter or allow others to enter the treated area until sprays have dries. Do not apply in a way that will contact workers or any other persons, either directly or through drift. Only protected handlers may be in the area during the application. Do not contaminate other materials (including foods/drinks/feeds/ water)
	Soluble concentrate: Reg.211-36 Reg.1043-87 Reg.1043-115 Reg.49403-6 Reg. 1043-118 Reg.11725-9	Mop, cloth, sponge or hand trigger sprayer	1 oz per gallon of water 1:128 dilution Thoroughly wet for 10 minutes allow to air dry	Following application as a spray, do not enter or allow others to enter the treated area until sprays have dries. Do not apply in a way that will contact workers or any other persons, either directly or through drift. Only protected handlers may be in the area during the application. Do not contaminate other materials (including foods/drinks/feeds/ water)

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
	Impregnated material:. Reg.55195-4	Wipe	Thoroughly wet pre-cleaned surface with a wipe and allow to air dry	Do not reuse wipes
Hard, non porous, non food contact surfaces	Ready-to-use-solution: Reg. 1043-19 Reg.44446-67 Reg.1008-105 Reg.12702-37 Reg.10807-177 Reg.10807-178 Reg.7405-51 Reg.55195-3 Reg.3862-104	Spray	To disinfect: Thoroughly wet (saturate) all surfaces for 10 minutes.	Following application as a spray, do not enter or allow others to enter the treated area until sprays have dries. Do not apply in a way that will contact workers or any other persons, either directly or through drift. Only protected handlers may be in the area during the application. Do not contaminate other materials (including foods/drinks/feeds/ water)
	Soluble concentrate: Reg.11725-8 Reg.66171-2 Reg. 211-25	Mop, cloth, sponge or hand trigger sprayer	1/2 oz per gallon of water 1:256 dilution Thoroughly wet for 10 minutes allow to air dry	Following application as a spray, do not enter or allow others to enter the treated area until sprays have dries. Do not apply in a way that will contact workers or any other persons, either directly or through drift. Only protected handlers may be in the area during the application. Do not contaminate other materials (including foods/drinks/feeds/ water)

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
	Soluble concentrate: Reg. 11725-8	Fogger (wet misting)	½ oz per gallon of water 1:256 dilution Set the automatic timer on the fogger for 6 minutes for 1000cu.ft and leave the room. Allow at least 2 hours before entering a room that has been fogged	**Treated food contact surfaces must be thoroughly rinsed with potable water prior to use.** Do not apply in a way that will contact workers or any other persons, either directly or through drift. Only protected handlers may be in the area during the application. Do not contaminate other materials (including foods/drinks/feeds/ water)
	Impregnated material: Reg.55195-4	Wipe	Thoroughly wet pre-cleaned surface with a wipe and allow to air dry	Do not reuse wipes
	Soluble concentrate: Reg.211-36 Reg.1043-87 Reg.1043-115 Reg.49403-6 Reg. 1043-118 Reg.11725-9	Mop, cloth, sponge or hand trigger sprayer	1 oz per gallon of water 1:128 dilution Thoroughly wet for 10 minutes allow to air dry	Following application as a spray, do not enter or allow others to enter the treated area until sprays have dries. Do not apply in a way that will contact workers or any other persons, either directly or through drift. Only protected handlers may be in the area during the application. Do not contaminate other materials (including foods/drinks/feeds/ water)
Household sickrooms premises/contents/utensils	Ready-to-use-solution: Reg. 1043-19 Reg.44446-67 Reg.10088-105	Spray	To disinfect: Thoroughly wet (saturate) all surfaces for 10 minutes.	Following application as a spray, do not enter or allow others to enter the treated area until sprays have dries. Do not apply in a way that will contact workers or any other persons, either directly or through drift. Only protected

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
	Reg.3862-104			handlers may be in the area during the application. Do not contaminate other materials (including foods/drinks/feeds/ water)
Morgues/mortuaries/autopsy/embalming equipment	Ready to use solution: Reg.10088-105	Spray	To disinfect: Thoroughly wet (saturate) all surfaces for 10 minutes.	Following application as a spray, do not enter or allow others to enter the treated area until sprays have dries. Do not apply in a way that will contact workers or any other persons, either directly or through drift. Only protected handlers may be in the area during the application. Do not contaminate other materials (including foods/drinks/feeds/ water)
Morgues/mortuaries/autopsy/embalming room premises	Ready to use solution : Reg.10088-105	Spray	To disinfect: Thoroughly wet (saturate) all surfaces for 10 minutes.	Following application as a spray, do not enter or allow others to enter the treated area until sprays have dries. Do not apply in a way that will contact workers or any other persons, either directly or through drift. Only protected handlers may be in the area during the application. Do not contaminate other materials (including foods/drinks/feeds/ water)

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
Barber/beauty shop instruments and equipment	Ready to use solution: Reg.10088-105	Spray	To disinfect: Thoroughly wet (saturate) all surfaces for 10 minutes.	Following application as a spray, do not enter or allow others to enter the treated area until sprays have dries. Do not apply in a way that will contact workers or any other persons, either directly or through drift. Only protected handlers may be in the area during the application. Do not contaminate other materials (including foods/drinks/feeds/ water)
	Soluble concentrate: Reg.66171-1	Immersion	1/2 oz per gallon of water 1:256 dilution Thoroughly wet for 10 minutes allow to air dry	Following application as a spray, do not enter or allow others to enter the treated area until sprays have dries. Do not apply in a way that will contact workers or any other persons, either directly or through drift. Only protected handlers may be in the area during the application. Do not contaminate other materials (including foods/drinks/feeds/ water)
Carpet cleaning	Soluble concentrate: Reg.70263-7	Hot water extraction	1 oz per gallon of water Inject and extract as you would with other extraction cleaners	Test fibers for colorfastness before use. Apply diluted cleaner to inconspicuous area, and rub with a white cloth. If color transfers to cloth or changes, a water based cleaning system should not be used.

Use Site	Formulation	Method of Application	Application Rate/ No. of applications	Use Limitations
Carpet cleaning *(continued)*	Soluble concentrate: Reg.70263-7	Spin bonnet cleaning (spray)	4 oz per gallon of water Spray on at a rate of 200-300 square feet per gallon, scrub with rotary floor machine equipped with bonnet or pad	Test fibers for colorfastness before use. Apply diluted cleaner to inconspicuous area, and rub with a white cloth. If color transfers to cloth or changes, a water based cleaning system should not be used.
	Soluble concentrate: Reg.70263-7	Immersion	Mix 2 oz per gallon of water in a cleaning tank. Immerse rug in cleaning solution.	Test fibers for colorfastness before use. Apply diluted cleaner to inconspicuous area, and rub with a white cloth. If color transfers to cloth or changes, a water based cleaning system should not be used.

APPENDIX B: Para-Tertiary Amylphenol Case 3016

Appendix B lists the **generic** (not product specific) data requirements which support the re-registration of Para-tertiary Amylphenol. These requirements apply to Para-Tertiary Amylphenol in all products, including data requirements for which a technical grade active ingredient is the test substance. The data table is organized in the following formats:

1. **Data Requirement** (Columns 1 and 2). The data requirements are listed by Guideline Number. The first column lists the new Part 158 Guideline numbers, and the second column lists the old Part 158 Guideline numbers. Each Guideline Number has an associated test protocol set forth in the Pesticide Assessment Guidance, which are available on the EPA website.

2. **Guideline Description** (Column 3). Identifies the guideline type.

3. **Use Pattern** (Column 4). This column indicates the standard Antimicrobial Division use patterns categories for which the generic (not product specific) data requirements apply. The number designations are used in Appendix B.

   (1) Agricultural premises and equipment
   (2) Food handling/ storage establishments premises and equipment
   (3) Commercial, institutional and industrial premises and equipment
   (4) Residential and public access premises
   (5) Medical premises and equipment
   (6) Human water systems
   (7) Materials preservatives
   (8) Industrial processes and water systems
   (9) Antifouling coatings
   (10) Wood preservatives
   (11) Swimming pools
   (12) Aquatic areas

3. **Bibliographic Citation** (Column 5). If the Agency has data in its files to support a specific generic Guideline requirement, this column will identity each study by a "Master Record Identification (MRID) number. The listed studies are considered "valid" and acceptable for satisfying the Guideline requirement. Refer to the Bibliography appendix for a complete citation of each study.

DATA REQUIREMENT				CITATION(S)
New Guideline Number	**Old Guideline Number**	**Study Title**	**Use Pattern**	**MRID Number**
PRODUCT CHEMISTRY				
830.1550	61-1	Product Identity and Composition	All	Data Gap
830.1600 830.1620 830.1650	61-2a	Starting Materials and Manufacturing Process	All	Data Gap
830.1670	61-2b	Formation of Impurities	All	Data Gap
830.1700	62-1	Preliminary Analysis	All	Data Gap
830.1750	62-2	Certification of Limits	All	Data Gap
830.1800	62-3	Analytical Method	All	Data Gap
830.6302	63-2	Color	All	Data Gap
830.6303	63-3	Physical State	All	Data Gap
830.6304	63-4	Odor	All	Not Applicable
830.7050	None	UV/Visible Absorption	All	Data Gap
830.7200	63-5	Melting Point	All	Data Gap
830.7220	63-6	Boiling Point	All	Not Applicable
830.7300	63-7	Density	All	Data Gap
830.7840 830.7860	63-8	Solubility	All	Data Gap
830.7950	63-9	Vapor Pressure	All	Data Gap
830.7370	63-10	Dissociation Constant in Water	All	Not Applicable

DATA REQUIREMENT				CITATION(S)
New Guideline Number	**Old Guideline Number**	**Study Title**	**Use Pattern**	**MRID Number**
830.7550 830.7560 830.7570	63-11	Partition Coefficient (Octanol/Water)	All	Data Gap
830.7000	63-12	pH	All	Data Gap
830.6313	63-13	Stability	All	Data Gap
830.6314	63-14	Oxidizing/Reducing Action	All	Not Applicable
830.6315	63-15	Flammability	All	Data Gap
830.6316	63-16	Explodability	All	Not Applicable
830.6317	63-17	Storage Stability	All	Data Gap
830.7100	63-18	Viscosity	All	Not Applicable
830.6319	63-19	Miscibility	All	Data Gap
830.6320	63-20	Corrosion Characteristics	All	Not Applicable
830.6321	63-21	Dielectric breakdown voltage	All	Not Applicable
ECOLOGICAL EFFECTS				
850.2100	71-1	Avian Acute Oral Toxicity Test (Quail/Duck)	All	Data Gap
850.1075	72-1	Fish Acute Toxicity – Freshwater (Rainbow Trout)	All	Data Gap
850.1010	72-2	Acute Aquatic Invertebrate Toxicity	All	Data Gap
TOXICOLOGY				
870.1100	81-1	Acute Oral - Rat	All	46616601
870.1200	81-2	Acute Dermal - Rabbit	All	Data Gap
870.1300	81-3	Acute Inhalation - Rat	All	Data Gap
870.2400	81-4	Primary Eye Irritation - Rabbit	All	Data Gap
870.2500	81-5	Primary Dermal Irritation - Rabbit	All	46616602

DATA REQUIREMENT				CITATION(S)
New Guideline Number	**Old Guideline Number**	**Study Title**	**Use Pattern**	**MRID Number**
870.2600	81-6	Dermal Sensitization	All	Data Gap
870.3100	82-1a	90-Day Feeding-Rodent, with modifications (See RED)	All	Data Gap
870.3200	82-2	21/28-Day Dermal Toxicity - Rat	All	Not Applicable
870.3250	82-3	90-day Dermal Toxicity - Rodent	All	42470301
870.3465	82-4	28/90-Day Inhalation - Rat	All	waived
870.3700	83-3	Developmental Toxicity -Rat	All	Data Gap
870.3700a	83-3a	Prenatal Developmental in Rodents	All	41920002, 41920001, 42026801
870.5265	84-2	Bacterial Reverse Mutation Assay	All	41438401, 41572701, 41728801
870.5300	84-2	Detection of gene mutations in somatic cells (CHO)	All	41572701
870.5385	84-2	Micronucleus Assay	All	41710801
		Reserved Studies		
870.3150	82-1b	90-Day Oral Subchronic in Non-Rodent		Data Gap, Reserved Study
870.3700b	83-3b	Developmental Toxicity -Rabbit		Data Gap, Reserved Study
870.3800	83-4	Reproduction and Fertility Effects - 2 Generation Repro		Data Gap, Reserved Study
OCCUPATIONAL/RESIDENTIAL EXPOSURE				
875.2800	133-1	Descriptions of Human Activity	All	Data Gap
875.1200 875.1600	233/236	Dermal Indoor Exposure	All	Data Gap
875.1400 875.1600	234/236	Inhalation Indoor Exposure	All	Data Gap

DATA REQUIREMENT				CITATION(S)
New Guideline Number	**Old Guideline Number**	**Study Title**	**Use Pattern**	**MRID Number**
ENVIRONMENTAL FATE				
835.2120	161-1	Hydrolysis	All	Required
OTHER DATA REQUIREMENTS				
FDA Guideline identified here	FDA Guideline identified here	Dietary-Residues in Food from Treating hard non-porous surfaces with 4-t-Amylphenol (conducted according to FDA guideline entitled “Recommendations for Chemistry Data for Indirect Food Additive Petitions.”)	All	Required

Appendix C. Technical Support Documents

Additional documentation in support of this RED is maintained in the OPP docket, located in room 119, Crystal Mall #2, 1801 Bell St., Arlington, VA 22202. It is open Monday through Friday, excluding legal holidays, from 8:30 AM to 4:00 PM.

The docket initially contained preliminary risk assessments and related documents as of April 28, 2004. Sixty days later the first public comment period closed. The EPA then considered comments and revised the risk assessments.

All documents, in hard copy form, may be viewed in the OPP docket room or downloaded or viewed via the Internet at the following site: http://www.epa.gov/edockets

These documents include:

1. 4-t-Amylphenol: Report of the Antimicrobials Divisions's Toxicology Endpoint Selection Committee (ADTC), July 2005

2. Toxicology Science Chapter for the Reregistration Eligibility Decision Document, From M. Ottley to K. Swift, July 2005 D316279

3. Occupational and Residential Exposure Assessment for t-Tert-Amylphenol and Salts. S. Mostaghimi . May 2005. D316290

4 Product Chemistry of Para-Tertiary-Amylphenol, para-tertiary-amylphenol, sodium salt and para-tertiary-amylphenol, potassium salt. From A. N. Shamim to T. McMahon. D316275

5 Environmental Fate Assessment of 4-tert-Amylphenol and its Potassium and Sodium salts for the Reregistration Eligibility Decision (RED) Document. From S. Gowda, Microbiologist to M. Hartman. May 2005, D316277

6 Ecological Hazard and Environmental Risk Assessment for 4-tert-amylphenol and salts to be included in the RED. D. Bays to A. Heyward and K. Swift. July 2005, D316278

7 Incident Reports Associated with 4-tert-amylphenol. J. Chen. May 2005, D3162

8 Dietary Exposure Assessments for the Reregistration Eligibility Decision. R. Quick. July 2005. D316295.

Appendix D. Citations Considered to be Part of the Data Base Supporting the 4-t-amylphenol Reregistration Decision (Bibliography)

GUIDE TO APPENDIX D

1. CONTENTS OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the 4-t-amylphenol Reregistration Eligibility Document. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, are included.

2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study." In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review and can be described with a conventional bibliographic citation. The Agency has also attempted to unite basic documents and commentaries upon them, treating them as a single study.

3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by Master Record Identifier, or "MRID" number. This number is unique to the citation, and should be used whenever a specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies (see paragraph 4(d)(4) below for further explanation). In a few cases, entries added to the bibliography late in the review may be preceded by a nine character temporary identifier. These entries are listed after all MRID entries. This temporary identifying number is also to be used whenever specific reference is needed.

4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standard of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

a. Author. Whenever the author could confidently be identified, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an

identifiable laboratory or testing facility as the author. When no author or laboratory could be identified, the Agency has shown the first submitter as the author.

b. Document date. The date of the study is taken directly from the document. When the date is followed by a question mark, the bibliographer has deduced the date from the evidence contained in the document. When the date appears as (1999), the Agency was unable to determine or estimate the date of the document.

c. Title. In some cases, it has been necessary for the Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

(1) Submission date. The date of the earliest known submission appears immediately following the word "received."

(2) Administrative number. The next element immediately following the word "under" is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.

(3) Submitter. The third element is the submitter. When authorship is defaulted to the submitter, this element is omitted.

(4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," which stands for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume.

BIBRA, Working Group (1990): Para-tertiary-Amylphenol. Toxicity Profile BIBRA Toxicology International. 3pp.

MRID No. 41710801
Edwards, C. N. 1990. Assessment of Clastogenic Action on Bone Marrow Erthrocytes in the Micronucleus Test. Prepared by Life Science Research Ltd., Suffolk, UK. Study No. 90/ NLL033.0533. Submitted by Nipa Laboratories, Inc. Wilmington, DE.

MRID No. 41438401
May, K. 1990. Nipacide PTAP (para-tertiary amylphenol): Assessment of Mutagenic Potential in Histidine Auxotrophs of *Salmonella typhimurium*. Prepared by Life Science Research Ltd., Suffolk, UK. Study No. 90/0109. Submitted by Nipa Laboratories, Inc. Wilmington, DE.

MRID No. 41572701
Lloyd, J. M. 1990. Investigation of Mutagenic Activity in the TK+/ - Mouse Lymphoma Cell Mutation System. Prepared by Life Science Research Ltd., Suffolk, UK. Study No. 90/NLL034/0395. Submitted by Nipa Laboratories, Inc., Wilmington, DE.

MRID No. 41920002
Siglin, J. C. 1991. Nipacide PTAP, Teratology Study in Rats. Prepared by Springborn Laboratories, Inc. Spencerville, OH. Study No. 3227.3. Submitted by Nipa Laboratories, Inc., Wilmington, DE.

MRID No. 46616601
Tufnell, P. P. 1992. Phenol, 4-(1,1-dimethylpropyl): Acute Oral Toxicity Test in the Rat. Prepared by Safepharm Laboratories Ltd., Derby U.K., Laboratory Test No. 47/2097. Submitted by Sandoz Chemicals Ltd.

MRID No. 46616602
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Appendix E. Generic Data Call-In

The Agency intends to issue a Generic Data Call-In at a later date. See Chapter V of the RED for a list of studies that the Agency plans to require for 4-t-amylphenol.

Appendix F. Product Specific Data Call-In

The Agency intends to issue a Product Specific Data Call-In at a later date.

Appendix G. Batching of Products for Meeting Acute Toxicity Data Requirements for Reregistration

In an effort to reduce the time, resources and number of animals needed to fulfill the acute toxicity data requirements for reregistration of products containing 4-t-amylphenol as the active ingredient, the Agency has batched products which can be considered similar for purposes of acute toxicity. Factors considered in the sorting process include each product's active and inert ingredients (identity, percent composition and biological activity), type of formulation (e.g., emulsifiable concentrate, aerosol, wettable powder, granular, etc.), and labeling (e.g., signal word, use classification, precautionary labeling, etc.). Note that the Agency is not describing batched products as "substantially similar" since some products within a batch may not be considered chemically similar or have identical use patterns.

Using available information, batching has been accomplished by the process described in the preceding paragraph. Not with-standing the batching process, the Agency reserves the right to require, at any time, acute toxicity data for an individual product should the need arise.

Registrants of products within a batch may choose to cooperatively generate, submit or cite a single battery of six acute toxicological studies to represent all the products within that batch. It is the registrants' option to participate in the process with all other registrants, only some of the other registrants, or only their own products within a batch, or to generate all the required acute toxicological studies for each of their own products. If a registrant chooses to generate the data for a batch, he/she must use one of the products within the batch as the test material. If a registrant chooses to rely upon previously submitted acute toxicity data, he/she may do so provided that the data base is complete and valid by today's standards (see acceptance criteria attached), the formulation tested is considered by EPA to be similar for acute toxicity, and the formulation has not been significantly altered since submission and acceptance of the acute toxicity data. Regardless of whether new data is generated or existing data is referenced, registrants must clearly identify the test material by EPA Registration Number. If more than one confidential statement of formula (CSF) exists for a product, the registrant must indicate the formulation actually tested by identifying the corresponding CSF.

In deciding how to meet the product specific data requirements, registrants must follow the directions given in the Data Call-In Notice and its attachments appended to the RED. The DCI Notice contains two response forms which are to be completed and submitted to the Agency within 90 days of receipt. The first form, "Data Call-In Response," asks whether the registrant will meet the data requirements for each product. The second form, "Requirements Status and Registrant's Response," lists the product specific data required for each product, including the standard six acute toxicity tests. A registrant who wishes to participate in a batch must decide whether he/she will provide the data or depend on someone else to do so. If a registrant supplies the data to support a batch of products, he/she must select one of the following options: Developing Data (Option 1), Submitting an Existing Study (Option 4), Upgrading an Existing Study (Option 5) or Citing an Existing Study (Option 6). If a registrant depends on another's

data, he/she must choose among: Cost Sharing (Option 2), Offers to Cost Share (Option 3) or Citing an Existing Study (Option 6). If a registrant does not want to participate in a batch, the choices are Options 1, 4, 5 or 6. However, a registrant should know that choosing not to participate in a batch does not preclude other registrants in the batch from citing his/her studies and offering to cost share (Option 3) those studies.

The batching information will be provided with the product-specific DCI

Appendix H. List of All Registrants To Be Sent the Generic Data Call-In

Clariant Corporation

Appendix I. List of Available Related Documents and Electronically Available Forms

Pesticide Registration Forms are available at the following EPA internet site:
http://www.epa.gov/opprd001/forms/ .

Pesticide Registration Forms (These forms are in PDF format and require the Acrobat reader)

Instructions

1. Print out and complete the forms. (Note: Form numbers that are bolded can be filled out on your computer then printed.)

2. The completed form(s) should be submitted in hardcopy in accord with the existing policy.

3. Mail the forms, along with any additional documents necessary to comply with EPA regulations covering your request, to the address below for the Document Processing Desk.

DO NOT fax or e-mail any form containing 'Confidential Business Information' or 'Sensitive Information.'

If you have any problems accessing these forms, please contact Nicole Williams at (703) 308-5551 or by e-mail at williams.nicole@epamail.epa.gov.

The following Agency Pesticide Registration Forms are currently available via the internet at the following locations:

8570-1	Application for Pesticide Registration/Amendment	http://www.epa.gov/opprd001/forms/8570-1.pdf
8570-4	Confidential Statement of Formula	http://www.epa.gov/opprd001/forms/8570-4.pdf
8570-5	Notice of Supplemental Registration of Distribution of a Registered Pesticide Product	http://www.epa.gov/opprd001/forms/8570-5.pdf
8570-17	Application for an Experimental Use Permit	http://www.epa.gov/opprd001/forms/8570-17.pdf
8570-25	Application for/Notification of State Registration of a Pesticide To Meet a Special Local Need	http://www.epa.gov/opprd001/forms/8570-25.pdf
8570-27	Formulator's Exemption Statement	http://www.epa.gov/opprd001/forms/8570-27.pdf
8570-28	Certification of Compliance with Data Gap Procedures	http://www.epa.gov/opprd001/forms/8570-28.pdf
8570-30	Pesticide Registration Maintenance Fee Filing	http://www.epa.gov/opprd001/forms/8570-30.pdf
8570-32	Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data	http://www.epa.gov/opprd001/forms/8570-32.pdf
8570-34	Certification with Respect to Citations of Data (in PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf
8570-35	Data Matrix (in PR Notice 98-5)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-5.pdf
8570-36	Summary of the Physical/Chemical Properties (in PR Notice 98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf
8570-37	Self-Certification Statement for the Physical/Chemical Properties (in PR Notice 98-1)	http://www.epa.gov/opppmsd1/PR_Notices/pr98-1.pdf

Pesticide Registration Kit
www.epa.gov/pesticides/registrationkit/.

Dear Registrant:

For your convenience, we have assembled an online registration kit that contains the following pertinent forms and information needed to register a pesticide product with the U.S. Environmental Protection Agency's Office of Pesticide Programs (OPP):

1. The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug and Cosmetic Act (FFDCA) as Amended by the Food Quality Protection Act (FQPA) of 1996.

2. Pesticide Registration (PR) Notices

    a. 83-3 Label Improvement Program—Storage and Disposal Statements

    b. 84-1 Clarification of Label Improvement Program

    c. 86-5 Standard Format for Data Submitted under FIFRA

    d. 87-1 Label Improvement Program for Pesticides Applied through Irrigation Systems (Chemigation)

    e. 87-6 Inert Ingredients in Pesticide Products Policy Statement

    f. 90-1 Inert Ingredients in Pesticide Products; Revised Policy Statement

    g. 95-2 Notifications, Non-notifications, and Minor Formulation Amendments

    h. 98-1 Self Certification of Product Chemistry Data with Attachments (This document is in PDF format and requires the Acrobat reader.)

    Other PR Notices can be found at http://www.epa.gov/opppmsd1/PR_Notices.

3. Pesticide Product Registration Application Forms (These forms are in PDF format and will require the Acrobat reader.)

    a. EPA Form No. 8570-1, Application for Pesticide Registration/Amendment

    b. EPA Form No. 8570-4, Confidential Statement of Formula

    c. EPA Form No. 8570-27, Formulator's Exemption Statement

    d. EPA Form No. 8570-34, Certification with Respect to Citations of Data

    e. EPA Form No. 8570-35, Data Matrix

4. General Pesticide Information (Some of these forms are in PDF format and will require the Acrobat reader.)

   a. Registration Division Personnel Contact List

   b. Biopesticides and Pollution Prevention Division (BPPD) Contacts

   c. Antimicrobials Division Organizational Structure/Contact List

   d. 53 F.R. 15952, Pesticide Registration Procedures; Pesticide Data Requirements (PDF format)

   e. 40 CFR Part 156, Labeling Requirements for Pesticides and Devices (PDF format)

   f. 40 CFR Part 158, Data Requirements for Registration (PDF format)

   g. 50 F.R. 48833, Disclosure of Reviews of Pesticide Data (November 27, 1985)

Before submitting your application for registration, you may wish to consult some additional sources of information. These include:

1. The Office of Pesticide Programs' Web Site

2. The booklet "General Information on Applying for Registration of Pesticides in the United States", PB92-221811, available through the National Technical Information Service (NTIS) at the following address:

   National Technical Information Service (NTIS)
   5285 Port Royal Road
   Springfield, VA 22161

The telephone number for NTIS is (703) 605-6000. Please note that EPA is currently in the process of updating this booklet to reflect the changes in the registration program resulting from the passage of the FQPA and the reorganization of the Office of Pesticide Programs. We anticipate that this publication will become available during the Fall of 1998.

3. The National Pesticide Information Retrieval System (NPIRS) of Purdue University's Center for Environmental and Regulatory Information Systems. This service does charge a fee for subscriptions and custom searches. You can contact NPIRS by telephone at (765) 494-6614 or through their Web site.

4. The National Pesticide Telecommunications Network (NPTN) can provide information on active ingredients, uses, toxicology, and chemistry of pesticides. You can contact NPTN by telephone at (800) 858-7378 or through their Web site: http://npic.orst.edu .

The Agency will return a notice of receipt of an application for registration or amended registration, experimental use permit, or amendment to a petition if the applicant or petitioner encloses with his submission a stamped, self-addressed postcard. The postcard must contain the following entries to be completed by OPP:

Date of receipt
EPA identifying number
Product Manager assignment

Other identifying information may be included by the applicant to link the acknowledgment of receipt to the specific application submitted. EPA will stamp the date of receipt and provide the EPA identifying File Symbol or petition number for the new submission. The identifying number should be used whenever you contact the Agency concerning an application for registration, experimental use permit, or tolerance petition.

To assist us in ensuring that all data you have submitted for the chemical are properly coded and assigned to your company, please include a list of all synonyms, common and trade names, company experimental codes, and other names which identify the chemical (including "blind" codes used when a sample was submitted for testing by commercial or academic facilities). Please provide a CAS number if one has been assigned.