UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

MEMORANDUM **Date: September 30, 2019**

SUBJECT: Registration Review Draft Risk Assessment for *Ortho*-Phenylphenol (O-PP) and Salts

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This document provides the draft human health and ecological risk assessment conducted in support of the antimicrobial and conventional pesticide active ingredient *ortho*-phenylphenol and salts, also known as 2-phenylphenol and salts.

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EXECUTIVE SUMMARY

The 2-phenylphenol case (2575), commonly called *ortho*-phenylphenol (PC codes 064103, 064104, 064108), contains chemicals 2-phenylphenol and its sodium (Na O-PP), and potassium (K O-PP) salts. The compound will be referred to as O-PP for the purpose of this assessment. These compounds contain biphenyl groups that are substituted by a hydroxy group or a sodium or potassium salt. O-PP products are intended for use as a sanitizer, disinfectant, or cleaner on hard surfaces in a variety of use patterns: agricultural, food handling, commercial, institutional, industrial, residential and public access, and medical settings, as well as a material preservative. The Agency has established tolerance exemptions for O-PP when used in specific commercial and agricultural areas. O-PP as an inert ingredient, which should not exceed 0.1% of the formulation, is incorporated into pesticide formulations that are applied to growing crops only. Currently, there are 65 antimicrobial products and 5 conventional products containing O-PP as an active ingredient (a.i.), and 57 products containing O-PP as an inert ingredient.

Human Health

The available toxicity data submitted for O-PP are adequate for evaluation of human health hazard and risk assessment. Data available include acute toxicity studies, subchronic oral and dermal toxicity studies in rats, prenatal developmental studies in rats and rabbits, 2-generation reproduction toxicity in rats, oral carcinogenicity studies in rats and mice, mutagenicity studies, and metabolism/pharmacokinetics studies in rats. The toxicity endpoints and points of departure for O-PP have been revised for registration review by the Office of Pesticide Programs since the publication of the Reregistration Eligibility Decision (RED) document. This risk assessment includes the updated toxicity endpoints.

Dietary Risk Summary

Chronic dietary risk from exposure to O-PP is not of concern as all dietary risks were found to be below 100% of the chronic Population Adjusted Dose (cPAD). This includes exposure from indirect dietary antimicrobial, direct conventional, and inert pesticidal uses within commercial, residential and agricultural use patterns associated with O-PP.

Residential Handler Risk Summary (Antimicrobials Uses Only)

There is the potential for residential handler dermal and inhalation exposure when using treated articles such as paints that are preserved with O-PP or when using surface disinfectants that contain O-PP as an a.i. Inhalation exposures can be to O-PP as an aerosol from spray applications of disinfectants and paints or to O-PP as a vapor from brush/roller applications of paints. The margins of exposure (MOEs) for residential handler inhalation exposures to O-PP aerosols ranged from 400 to 7100. The inhalation MOE of 400, which is for the airless spray

application of paint, is of concern because it is less than the target MOE of 1000. The inhalation MOE of 9 from exposure to O-PP vapors from paint is of concern because it is less than the target MOE of 1000. The MOEs for residential handler dermal exposures to O-PP range from 1.6 to 530. The MOE of 1.6, which is for the airless spray application of paint, is of concern because it is less than the target MOE of 10.

Residential Post Application Risk Summary (Antimicrobial Uses Only)

The incidental oral MOE from O-PP in preserved floor cleaning products is 450 and is not of concern because it is greater than the target MOE of 100. The dermal MOE is 12 and is not of concern because it is greater than the target MOE of 10. The incidental oral MOE from O-PP in carpet treatment products is 320 and is not of concern. The dermal MOE is 4.4 and is of concern. The MOE for incidental oral exposure to plastic toys is 2,800 and is not of concern.

The MOE for incidental oral exposure to O-PP is 430 for textiles treated at the low rate of 2,600 ppm and 71 for textiles treated at the high rate of 17,000 ppm. The MOE is not of concern because it is greater than the target MOE of 100.The dermal MOEs are less than 10 for both application rates and are of concern.

There is the potential for residential post application inhalation exposures from two products (EPA Reg Nos. 44446-67 and 70385-3) that are applied by fogging to residential areas. The inhalation MOE is 430 for EPA Reg No. 44446-67 and 11 for EPA Reg No. 79385-3. These MOEs are of concern because they are less than the target MOE of 1000.

Aggregate Risk Summary

Short- and intermediate-term aggregate oral exposures and risks were assessed for children that could be exposed to O-PP residues from the use of products in non-occupational environments. These exposures include average dietary exposures to O-PP and incidental oral exposures from application of O-PP products to floors and carpets as well as incidental oral exposure from O-PP incorporation into plastic toys and textiles. The risk cup is filled with the dietary uses which are expected to co-occur, so the aggregate MOE based on these exposures is of concern because it is less than the target MOE of 100.

Occupational Handler Risk Summary (Antimicrobial Uses)

There is the potential for occupational handler exposure when O-PP is used to treat processes such as paper mill water systems, preserve materials such as paints, disinfectant surfaces or treat lumber for sapstain control. There is also the potential for occupational handler exposure when using treated articles, such as paints and metal working fluids, that are preserved with O-PP.

Inhalation exposures can be to O-PP as an aerosol from spray applications of disinfectants and paints or to O-PP as a vapor from brush/roller applications of paints. The MOEs for occupational handler inhalation exposures to O-PP aerosols range from 1.5 to 16,000. Several MOEs are of concern because they are less than 1000. The MOE of 2 for inhalation exposures to O-PP paint vapors is also of concern because it is less than the target MOE of 1000.

The MOEs for occupational handler dermal exposures to O-PP range from <1 to 4300. Several MOEs are of concern because they are less than 10. The MOEs for sapstain control worker inhalation exposures to O-PP aerosols range from 48 to 1700. The MOE of 48, which is for the cleanup crew, is of concern because it is less than 1000. The dermal MOEs for sapstain control worker range from 1 to 13. The MOEs of 1 for the cleanup crew and 3 for the chemical attendants are of concern because they are less than 10.

There is the potential for dermal and inhalation exposure to machinists using metal working fluids (MWFs) treated with O-PP. The application rates range from 500 to 15,000 ppm depending upon the product. The inhalation MOE is 1,600 for MWFs treated with 15,000 ppm O-PP and is not of concern because it is greater than the LOC of 1000. The dermal MOEs are 1.3 for MWF treated with 15,000 ppm O-PP and 39 for MWF treated with 500 ppm O-PP. The dermal MOE of 1.3 is of concern because it is less than the LOC of 10.

Occupational Post Application Risk Summary (Antimicrobial Uses)

There is one product that has use directions for fogging as an adjunct to regular cleaning and disinfection in animal and poultry facilities. There is potential for post application exposure to workers who work in these areas after the fogging application and two-hour reentry period. The inhalation MOE is 1,100 and is not of concern because it is greater than the LOC of 1000.

Occupational Handler Risk Summary (Conventional Uses)

Most of the estimated conventional occupational handler inhalation exposure scenarios assessed result in potential risks of concern (*i.e.*, MOEs are < the LOC of 1,000). The exposure scenarios, mixing/loading liquid solutions for automated closed system brushing, dipping, foaming, and spraying, and mixing/loading liquid solutions for automated open system brushing, dipping, foaming, and spraying, result in an estimated risk of concern assuming a closed system or no respirator, respectively. The inhalation risk of concern for the open system exposure scenario is no longer of concern considering the addition of a protection factor 10 (PF10) respirator; the MOE = 2,000 which is > the LOC of 1,000. However, the closed system scenario assumes the use of engineering controls which is the maximum respiratory protection available and remains of concern (*i.e.*, the MOE of 510 is < the LOC of 1,000). The exposure scenario, loading/applying RTU for thermo-fogging of pears, is not of concern assuming no respirator.

Occupational Post Application Risk Summary (Conventional Uses)

Risks of concern have been identified for the post-harvest packing and sorting activities associated with O-PP usage assuming baseline attire (*i.e.*, no respirator), as well as with maximum available personal protective equipment (PPE) (*i.e.*, the MOEs are < the LOC of 1,000 with the addition of a PF10 respirator).

Indirect inhalation exposures from the automated treatment process are also of concern assuming baseline attire (*i.e.*, no respirator; the MOE is 300 which is < the LOC of 1,000). With the maximum available PPE (*i.e.*, a PF10 respirator), indirect inhalation exposures are not of concern; the MOE = 3,000 which is > the LOC of 1,000.

Occupational post-application dermal exposures are anticipated for the registered conventional post-harvest uses of O-PP; however, a quantitative dermal assessment was not conducted as no toxicological hazard was identified.

The Worker Protection Standard (WPS) does not apply to the post-harvest treatments of O-PP; therefore, restricted entry intervals (REIs) are not required for those uses. However, for the thermal fogging uses of O-PP, there are re-entry restrictions on the registered labels based on ventilation requirements.

Environmental Effects

The Agency reviewed the available ecotoxicity data for O-PP and its salts. No chronic data was available for review. No toxicity was found with terrestrial non-target organisms, with the exception of the honey bee, which was found to be highly toxic to this chemical. Exposure data from the wood preservative uses was lacking, but due to only having a sapstain use pattern, exposure to honey bees should be limited and therefore the potential risk of O-PP to the honey bee should be negligible. O-PP is moderately toxic to most of the nontarget aquatic organisms tested. Freshwater fish, freshwater invertebrate and aquatic plant endpoints were compared to exposure model output to determine risk from the cooling tower uses of this chemical. Screening level estimates, discussed as exceedances of Concentrations of Concern (COCs), were used to assess exposure from cooling tower discharges. These screening level estimates indicate risk, however, it would be assumed that O-PP would be diluted rapidly once it entered the streams and since the chemical is only moderately toxic to aquatic organisms, the potential risk to nontarget aquatic organisms would be considered minimal. Ecological risks from conventional uses were separately assessed with the conclusion that the current outdoor uses as a crack and crevice treatment would not result in risk of concern (U.S. EPA, 2019).

INTRODUCTION

1.1 Case Overview

The docket for the O-PP and its salts case (Case 2575) has been established at https://www.regulations.gov/ in docket number EPA-HQ-OPP-2013-0524.

1.2 Ingredient Profile

In solution, the sodium (Na) and potassium (K) salts of O-PP rapidly dissociate, releasing sodium and potassium cations (Na^+ and K^+, respectively) and the *ortho*-phenyl phenate anion ($O\text{-}PP^-$). Because of this rapid dissociation, all three ingredients are considered the same as it relates to this risk assessment. The equilibrium in solution between the $O\text{-}PP^-$ anion and the protonated or unionized O-PP depends on the pH of the solution though the protonated form will dominate at environmentally relevant pH.

Table 1 presents the active ingredients to be assessed in Case 2575: *ortho*-phenyl phenol (O-PP) (PC Code 064103); sodium *ortho*-phenyl phenate a sodium salt of O-PP (Na O-PP; PC Code 064104); and potassium *ortho*-phenyl phenate a potassium salt of O-PP (K O-PP; PC Code 064108).

Table 1. Chemical Identification of O-PP and its Salts

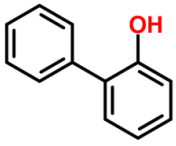
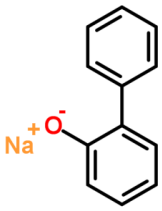
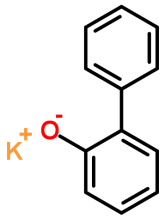
Chemical Name	O-PP	Na-O-PP	K-O-PP
Common Name	*ortho*-phenyl phenol; 2-phenyl phenol	Sodium *ortho*-phenyl phenate; *OPP* sodium salt	Potassium *ortho*-phenyl phenate; *OPP* potassium salt
Chemical Classification	Phenol	Phenol	Phenol
PC Code	064103	064104	064108
CAS Number	90-43-7	132-27-4	13707-65-8
Molecular Formula	$C_{12}H_{10}O$	$C_{12}H_9NaO$	$C_{12}H_9KO$
Molecular Weight	170.2 g/mole	192.19 g/mole	208.30 g/mole
Molecular Structure			

Table 2. Physical and Chemical Properties of O-PP

Guideline No.	Parameter	O-PP	Na-O-PP
830.7000	pH at 22.7ºC	6.1	12-13.5
830.7050	UV/visible Absorption (nm)	243-283	--

Guideline No.	Parameter	O-PP	Na-O-PP
830.7300	Density (g/cm^3 at 25 °C)	1.2	0.61-0.69
830.7370	Dissociation constant (pKa)	9.9 (25°C)	10 (20°C)
830.7550	Octanol-water partition coefficient at 25 °C (Log K_{ow})	3.3	0.59
830.7840	Solubility in water at 25°C (mg/L)	700	60.6
830.7950	Vapor pressure at 25°C (mmHg)	0.002	$1.8x10^{-9}$

Source: MRID 00101697 and 41605001C

1.3 Use Pattern

O-PP is a pesticide with both conventional and antimicrobial uses. It is used as an antimicrobial pesticide on hard surfaces (walls, floors, barns), on agricultural premises and equipment, on commercial and institution premises, on medical premises, in residential and public access premises (carpet, hard surfaces, and in cracks and crevices); as an air deodorizer; as a material preservative (stains and paints, metal working fluids, textiles, paper slurries and cement mixtures, glues, and adhesives, and consumer, household and institutional cleaning products); and a dip and spray application for sapstain treatment. As a conventional pesticide, O-PP is used as a post-harvest fungicide fruit wash on citrus and pears for the control of blue, gray, green molds, stem-end rot, mucor rot and citrus canker. The conventional use products are formulated as soluble concentrates (SC), emulsifiable concentrates (EC), and ready to use (RTU) formulations. O-PP is also formulated as an inert ingredient (not to exceed 0.1% of the formulation) in agricultural pesticide products.

There are also "dual use" products that contain O-PP as an antimicrobial component in insecticidal products. The product Ant & Roach Killer Pump Spray B (EPA Reg no. 92564-37) contains beta-cyfluthrin which "Kills most common household insect pests" and O-PP which "reduces 99.9% of the germs they may leave behind". This product can be used to spray inside around baseboards and into cracks and crevices and other places where insects might hide. This product can also be sprayed outside as a band 3 to 4 feet wide around and alongside the foundation and porches of the house. The product X-580 Spray Plus (EPA Reg No. 70385-3) contains O-PP and the insecticides pyrethrins, piperonyl butoxide and n-octyl bicycloheptane dicarboximide. This product is a "Limited Disinfectant against Gram-negative Bacteria and is also effective in controlling insects and bacterial and organic odors". It can be used inside residential areas, farm premises and animal quarters.

The antimicrobial uses of O-PP are summarized in Table 3 and the conventional uses are summarized in Table 4.

Table 3. Antimicrobial Uses of O-PP

Use Site	Application Method	Application Rate (ppm ai)
Agricultural Premises and Equipment		
Greenhouse premises and equipment	Sponge, Mop, Spray	233 to 268 ppm

Use Site	Application Method	Application Rate (ppm ai)
Cattle, Swine and Poultry Farms Hatching facilities and incubators Trucks and other vehicles	Sponge, Mop, Spray RTU (Ready To Use) Spray	194 to 782 ppm 2,200 ppm
	Fogger	26.2 mg/m^3 (initial air concentration)
Shoe sanitizer	Shoe Bath Tray	233 to 476 ppm
Aquatic Areas		
Sewage Disposal Lagoons[1]	Spray	4 lb ai/acre
Commercial/Institutional/Industrial (CII) Premises and Equipment		
Nonporous, nonfood contact surfaces including Transportation facilities and vehicles, Storage facilities, and General indoor premises.	Sponge/Mop/Spray RTU Spray	233 to 782 ppm 140 to 4,000 ppm
	Fogger	2.0 mg/m^3 (initial air concentration)
Food Handling Premises and Equipment		
Food processing plants; Non-food handling areas	Spray (RTU) Sponge, Mop	500 to 2,200 ppm 258 to 2,200 ppm
Eating establishment food handling areas	Spray (RTU) Sponge, Mop	500 to 2,200 ppm 158 to 410 ppm
Industrial Processes		
Air Washer, Cooling Tower and Paper Mill Water Systems	Open Pour	5.3 to 10.6 ppm
Oil Drilling Muds, Packer Fluids, Oil field water systems, Oil Recovery Water, Secondary	Open Pour	86 to 4,300 ppm 5.3 to 10.6 ppm
Material Preservative		
Adhesives, Glues, Caulks and Sealants	Open Pour	500 to 11,400 ppm
Ceramic glazes	Open Pour	375 to 5,600 ppm
Cleaning Solutions	Open Pour	375 to 4,100 ppm
Vehicle polishes and waxes	Open Pour	625 to 5040 ppm
Concrete and Concrete Additives	Open Pour	875 to 7,170 ppm
Leather	Dip and Spray	690 to 15,000 ppm
Metal Working Fluids	Open Pour	500 to 15,000 ppm
Paints, Stains and Coatings (In Can)	Open Pour	500 to 5,700 ppm
Paper Auxillaries and Additives	Open Pour	400 to 4,300 ppm
Plastics	Open Pour	5000 ppm
Polymer Dispersions and Emulsions (i.e. rubber)	Open Pour	500 to 3,800 ppm
Textile Auxillaries	Open Pour	500 to 4,300 ppm

[1] The Sewage Disposal Lagoons use is included on EPA Reg # 39967-116.

Use Site	Application Method	Application Rate (ppm ai)
Textiles (Awnings and Tarps) Textiles (Carpet and Upholstery) Textiles (Cotton)	Open Pour	8,700 to 56,600 ppm 3,500 to 22,600 ppm 2,600 to 17,000 ppm
Medical Premises and Equipment		
Critical Items (Surgical Equipment)	Immersion	84 to 536 ppm
Hair Care Shavers and Scissors	Immersion	22 to 782 ppm
Dental Lines	Circulate in Place	268 to 537 ppm
Hard Surfaces (Noncritical Areas) Hard Surfaces (Critical Areas)	Mop, Wipe, Spray	196 to 1,550 ppm 196 to 520 ppm
Residential and Public Access Premises		
Hard surfaces including floors and bathrooms	Sponge, Mop or Spray RTU Spray	194 to 1,550 ppm 500 to 3,700 ppm
Exterior roof, Siding, Trim, Decks, Fences	Spray	118 ppm[1] (as O-PP)
Carpets and Upholstery	RTU Spray	2,200 ppm
Bedding and Mattresses	RTU Spray	1,800 to 2,200 ppm
Laundry and Footwear	RTU Spray	1,000 to 2,200 ppm
Portable Toilets	Open Pour	409 to 288,000 ppm
Garbage Cans	Spray RTU Spray	258 to 520 ppm 140 to 4,000 ppm
Lawn, turf, outdoor soil and plant beds and vegetation adjacent to building foundations and structures including decks, porches, and fences; sidewalks, driveways, patios, and porches; ant hills [2]	Spray including spot treatments and crack and crevice treatments	Up to 0.133 lb a.i./Acre[3]
Wood Preservative including Sapstain Control		
Fresh Cut Lumber, Construction Woods Fruit and Vegetable Containers, Pallets	Dip or Spray	6,870 to 45,200 ppm 32,000 to 34,000 ppm

[1]The product (EPA Reg. No. 69587-1) contains Na O-PP but the application rate is expressed as O-PP only. The spray volume is 20 gallons per 2,000 ft^2 roof and 20 gallons per 4000 ft^2 for other structures.

[2] EPA Reg No. 92564-37 contains 0.05% beta-cyfluthrin to kill insects and 0.3% percent sodium o-phenylphenate to reduce the germs they leave behind. This product can be applied to a band 3 to 4 feet wide alongside the foundation and porches of the house, to soil, turf or walkways adjacent to foundation and porches, and to 1 to 2 feet up along the side of the building.

[3] This application rate assumes 4 houses per acre (quarter-acre lot per house) and that each homeowner applies the entire contents of one container of spray (=170 ounces). Therefore, the application rate in pounds a.i. per acre (lb a.i./A) is 0.133 (4 houses per acre x 1 container per house x 170 ounces per container x 1 gallon per 128 ounces (unit conversion) x 8.33 lb/gallon (density for water) x 0.003 (% a.i./100)).

Table 4 below lists the conventional uses of O-PP.

Table 4. Conventional Uses of O-PP

Use	Application Method	Application Rate
Post-Harvest Fruit Treatment and Wash		
Citrus	Wash	0.046 lb ai/gallon solution

Use	Application Method	Application Rate
[EPA Reg. No. 2792-28]		(0.35% solution)
	Drench	0.066 lb ai/gallon solution (0.05% solution)
Pears [EPA Reg. No. 2792-28]	Wash, Drench	0.002 lb ai/gallon solution (0.05% solution)
Citrus, Pears [EPA Reg. No. 64864-45]	Spray, Flood, Dip	0.17 lb ai/gallon solution (2% solution)
Citrus [EPA Reg. No. 8764-1]	Spray, Wash	0.041 lb ai/gallon solution (0.5% solution)
	Wax	0.081 lb ai/gallon solution (1% solution)
Pears [EPA Reg. No. 8764-1]	Dip	0.041 lb ai/gallon solution (0.5% solution)
Citrus, Pears [EPA Reg. No. 8764-16]	Foaming	0.17 lb ai/gallon solution (2% solution)
Pears [EPA Reg. No. 57227-7]	Thermo-fog	0.000029 lb ai/lb fruit

HUMAN HEALTH RISK ASSESSMENT

2.1 Data Deficiencies

Residue Chemistry: The analytical reference standard for ortho-phenylphenol (O-PP) is currently not available in the EPA National Pesticide Standards Repository (NPSR; e-mail communication between T. Cole and S. Keel, 7/2/2019). The registrant, Lanxess Corporation, is required to maintain reasonable amounts of the reference standards in the NPSR as long as tolerances remain published in 40 CFR §180.475. For the submission of analytical standards, please see Appendix F.

The toxicology database for O-PP and salts is considered adequate for registration review. A 90-day inhalation toxicity study was requested in the Generic Data Call-In (GDCI) for O-PP and salts (GDCI-064103-1427, GDCI-064104-1460, and GDCI-064108-1461) issued in September of 2014. This study was not conducted in time for registration review risk assessment. In the absence of a repeated dose inhalation toxicity study, a search of acute inhalation toxicity studies with O-PP was conducted. Three acute inhalation toxicity studies were found with O-PP as the sole active ingredient and were used in a weight of evidence approach to assess inhalation risk. The acute and subchronic neurotoxicity studies were recommended to be waived by the Office of Pesticide Programs' Hazard and Science Policy Council (HASPOC) in July of 2019 (TXR 0057902). An immunotoxicity study that is normally required was recommended to be waived by HASPOC in August of 2016 (TXR 0057473).

2.2 Tolerance Considerations

There are several tolerances for direct food uses and tolerance exemptions for the antimicrobial and inert uses listed in 40 CFR. The tolerances are discussed in this section and the tolerance exemptions are discussed in Section 1.11.

Enforcement Analytical Methods

Acceptable enforcement analytical methods are available for ortho-phenylphenol residues in/on plant commodities. The photometric method for determination of O-PP residues in/on fruits and vegetables was published in the Pesticide Analytical Manual (PAM) Volume II, Method I. The sensitivity of the method was 3 ppm.

Another adequate method developed for determining free and conjugated O-PP in citrus fruit and pear commodities as well as metabolite, phenylhydroquinone (PHQ), found in citrus fruit involves a one-step hydrolysis/steam distillation/extraction, trimethylsilylation, and analysis with GC/MSD (a gas chromatography with mass spectrometry detection). For citrus oil, the analysis of O-PP is by direct injection of the oil onto GC/MSD without hydrolysis and derivatization. Ions monitored for pear are m/z 211 and 217; for citrus commodities except oil, m/z 227 and 242; for citrus oil, m/z 170 and 141. For the determination of metabolite PHQ (found in citrus fruit, not in pear), the ions monitored are m/z 330 and 299. The validated LOQ for O-PP in pear was 0.15 ppm. The LOQs for O-PP and PHQ in all citrus metrices except oil were 0.05 and 0.2 ppm, respectively; the LOQ for O-PP and PHQ in citrus oil was 1 ppm.

Recommended & Established Tolerances

There are several tolerances listed in 40 CFR 180.129 for O-PP, including lemon, lime, orange, tangerine, tomato, bell pepper, cucumber, pineapple, grapefruit, kumquat, cantaloupe pulp and citron citrus fruit crops. A 20 ppm tolerance exists for plums, prunes, carrots and peaches. There is also a 25 ppm tolerance for apples and pears in addition to a 125 ppm tolerance for whole cantaloupe. In the 2006 RED, all the O-PP post-harvest uses and tolerances were revoked except for citrus fruit and pear. However, the 12 commodities (apple, cantaloupe, carrot roots, cherry, cucumber, nectarine, bell pepper, peach, pineapple, plum/prune, sweet potato roots and tomato) that should have been revoked after the publication of RED are still listed in 40 CFR §180.129(a).

Permanent tolerances for food commodities are established under 40 CFR §180.129(a) for combined residues of the fungicide O-PP and Na O-PP, each expressed as O-PP, from postharvest application of either in or on the following food commodities. Per the Health Effects Division's (HED's) Interim Guidance on Tolerance Expressions (USEPA 2009), HED

recommends that the current tolerance definition for plant commodities in 40CFR §180.129(a) be revised as follows:

"Tolerances are established for residues of *o*-phenylphenol and sodium *o*-phenylphenate, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only free and conjugated *o*-phenylphenol in or on the commodity."

The tolerances of O-PP and its salts were reassessed when conducting the human health risk assessments for the Reregistration Eligibility Decision (RED). The only food/feed uses of Na O-PP (064104) are postharvest fruit treatment and wash. In the 2006 RED (see pages 53-54 and Table 23 of *RED for OPP and its Salts*, July 2006), all the Na O-PP food uses and tolerances, except for citrus fruit and pear, were revoked due to the cancellation of registration (US EPA 2006). For registration review HED is currently revising the 40 CFR §180.129(a). A summary of tolerance revisions for O-PP and Na O-PP is provided in the Table below.

Table 5. Summary of Tolerance Revisions for O-PP and Na O-PP (40 CFR §180.129(a))[1].

Commodity/ **Correct Commodity Definition**	Established Tolerance (ppm)	Recommended Tolerance (ppm)	Comments
Fruit, citrus, group 10-10	-	10	Commodity definition revision.
Citrus fruits	10	remove	
Lemon	10	remove	
Orange	10	remove	
Pear	-	**20**	Harmonization with Codex.
Pear	25.0	remove	
Apple	25	revoke	Tolerances revoked (see Tolerance Reassessment Summary section in page 54 of *RED for OPP and its Salts*, July 2006)
Cantaloupe (NMT 10 ppm in edible portion)	125	revoke	
Carrot, roots	20	revoke	
Cherry	5	revoke	
Cucumber	10	revoke	
Nectarine	5	revoke	
Pepper, bell	10	revoke	
Peach	20	revoke	
Pineapple	10	revoke	
Plum, prune, fresh	20	revoke	
Sweet potato, roots	15	revoke	
Tomato	10	revoke	

1 For complete list of established/recommended tolerances see the International Residue Limits Sheet in Appendix G.

International Harmonization

Codex has established maximum residue limits (MRL) for residues of 2-phenylphenol in/on citrus fruits, citrus dry pulp, orange juice and pear. The MRL of citrus fruits (10 mg/kg) is harmonized with the established U.S. tolerance (10 ppm). The US tolerance for orange juice was not established separately, because the orange processing data indicate that residues of O-PP do not concentrate in juice. Thus, the tolerance of citrus fruit is adequate to cover orange juice. For citrus dry pulp, the US did not establish a tolerance because the postharvest use is for preservation of citrus fruit, no citrus dry pulp for animal feed will be produced.

The US tolerance for pear (25 ppm) is not harmonized with Codex MRL (20 mg/kg). The Codex Committee proposed in 2003 an MRL of 20 mg/kg for O-PP in/on pears based on field trial data provided by the Pear Bureau Northwest, USA, and revoked the previous MRL of 25 mg/kg, which was based on US data reported in the 1969 JMPR (Report of the Thirty-fifth Session of the Codex Committee on Pesticide Residues, 31 March ~ 5 April 2003, ALINORM 03/24A). HED will adopt the updated Codex MRL and set the tolerance for pear commodities at 20 ppm to harmonize with Codex.

Mexico adopts U.S. tolerances and/or Codex MRLs for its export purposes. Canada has established numerous MRLs in/on crop commodities listed in the 40CFR 180.129(a)—apples, bell peppers, cantaloupe, carrot roots, cherries, citrus fruits, cucumbers, nectarines, peaches, pears, pineapples, plums, sweet potato roots and tomatoes. In the 2006 *Reregistraion Eligibility Decision (RED) for 2-phenylphenol and Salt*s, all the O-PP food uses and tolerances with the exception of citrus fruit and pear were revoked. HED is updating the 40CFR §180.129(a) during the current O-PP Registration Review. The updated O-PP postharvest uses should include only citrus fruit and pear. The tolerance of citrus fruit has been harmonized with the established Canadian MRLs (10 ppm). See Appendix G for more details.

2.3 Label Recommendations

EPA continues to make the following recommendations originally published in the Final Work Plan (FWP) associated with this case:

- "Some labels permit the use of handheld fogging. If the labels were amended to require that fogging be done only by automatic equipment, then EPA would likely no longer need the anticipated requirement for the indoor exposure study for handheld fogging."

- "All of the labels permit open pour addition of liquids and soluble powders for material preservation and industrial process treatment. If the labels were amended to require that liquids be handled using closed loading and delivery systems and that powders be

packaged in water soluble packaging, then EPA would likely no longer need the anticipated requirement for the indoor exposure study for open pouring of liquids and soluble powders."

The use directions for fogging need to be clarified on two product labels:

- EPA Reg no. 44446-67. One paragraph of the label indicates that the product should not be used in a room 5 x 5 ft or smaller while the next paragraph has an application rate information of one unit for each 6000 cubic feet of unobstructed area, do not use in an area less than 100 cubic feet, and do not use more than one unit in an average size room. In addition, the label indicates that the product is packaged in 16.5 ounce, 6 ounce and 5ounce containers; however, the size of the container (i.e. unit) to be used for fogging is not defined.

- EPA Reg No. 70385-3. This label does not include an application rate for fogging applications but instead indicates that *adequate amounts of product should be applied so that the treated surfaces remain wet for 10 minutes*. The label also has conflicting information regarding ventilation prior to re-occupancy. The statement that *Three air exchanges of ventilation or air scrubbing must be completed prior to re-occupancy*, conflicts with the statement that *Sufficient mechanical ventilation should be used to achieve 4 air changes prior to allowing reentry*.

The Agency also recommends that the registrants of EPA Registration Nos. 8764-1, 39967-3, and 39967-20 remove the unsupported commodities—vegetables, apple, cantaloupe *etc*. from the labels, because all the O-PP/Na O-PP food uses and tolerances except for citrus fruit and pear have been revoked.

For the conventional uses of O-PP, no specific label recommendations are being made; however, there are several risk estimates of concern for occupational handlers and occupational post-application workers. Some of these risk estimates are not of concern with the addition of PPE beyond what is currently on labels. Product label changes regarding PPE may be required based on the occupational risks of concern identified in this memorandum.

It is recommended that the label for the dual use product Ant & Roach Killer Pump Spray B (EPA Reg. No. 92564-37) be reviewed to determine if the antimicrobial claims are valid. Antimicrobial products are not typically applied to interior baseboards, cracks and crevices or to exterior building foundations for the purposes of controlling *Staphylococcus aureus* and *Enterbacter aerogenes*.

2.4 Anticipated Exposure Pathways

Dietary exposure to O-PP can occur from its antimicrobial use as a disinfectant or sanitizer on hard food-contact surfaces and conveyor belts in food processing plants, on hard surfaces and equipment in farm premises, hatcheries, and animal/poultry housing facilities, on hatching eggs, in adhesives, mineral slurries, pigments and fillers for food-contact paper, in process water systems of paper mills as a slimicide, and in process water systems of sugar beet mills. Dietary exposure is also expected from the conventional post-harvest use of O-PP on citrus and pears, applied inside production facilities.

Drinking water exposure is not expected from O-PP since the conventional uses are post-harvest and spot treatments and the antimicrobial uses with down the drain exposure are expected to dissipate before reaching drinking water intakes and facilities.

Residential handler (dermal and inhalation) exposure is expected from the antimicrobial uses of O-PP, including use on indoor and outdoor hard surfaces, air deodorization, fogging, treated plastics, and treated paint. Residential post-application exposure to O-PP is expected from contacting treated hard surfaces/floors (dermal and incidental oral exposure to children), wearing treated clothing (dermal exposure to adults and children), mouthing treated textiles such as clothing and blankets (incidental oral exposure to children), and mouthing treated plastic toys (incidental oral exposure to infants). Additionally, post-application/bystander inhalation exposures were assessed for use of the disinfecting/deodorizing products (vapor exposure to adults and children) and paints (vapor exposure to adults and children). No residential exposures are expected from the conventional uses of O-PP since it is only registered for post-harvest and is only applied inside a treatment facility.

Occupational handler (dermal and inhalation) exposures from the antimicrobial uses of O-PP may occur in numerous scenarios under the Use Site Categories of agricultural premises, food handling premises, commercial/institutional/industrial premises, and medical premises. Additionally, occupational exposure can occur during the preservation of materials that are used for household, institutional, and industrial uses, along with the preservation of wood. Further, occupational handler and post-application dermal and inhalation exposures are expected from the post-harvest treatment of citrus fruit and pears.

2.5 Human Health Incident Report

A search of the Agency's Incident Data System (IDS) on September 9, 2019, did not identify any severe incidents (*i.e.*, deaths or incidents classified as 'major') in the last five years that involved only an O-PP chemical and no other chemicals.

2.6 Hazard Characterization and Dose-Response Assessment

2.6.1 Toxicology Studies Available for Analysis

The following toxicology studies are available and considered adequate for characterizing toxicity and conducting human health risk assessments for O-PP:

- Acute toxicity test battery
- Subchronic oral toxicity test in the rat
- 21-day dermal toxicity study in the rat
- Developmental toxicity studies in the rat and rabbit
- 2-generation reproduction toxicity study in the rat
- Chronic toxicity study in the dog
- Chronic toxicity and carcinogenicity studies in the rat and mouse
- Mutagenicity test battery
- Metabolism study in the rat
- EDSP Tier I assays

2.6.2 Absorption, Distribution, Metabolism, and Excretion (ADME)

The disposition, metabolism and pharmacokinetics of O-PP have been examined in studies from the peer reviewed scientific literature (Reitz *et al*., 1983 [MRID 92154002]; Bartels *et al*., 1998). Excretion of O-PP is primarily in urine, where > 80% of an administered dose is excreted. Fecal excretion is a minor route (1-5%), and biliary excretion is approximately 20% of the administered dose. Biotransformation of O-PP initially involves formation of phenolic metabolites (such as 2,4'-dihydroxyphenyl and phenylhydroquinone) in the liver through the action of cytochrome P-450 by rat CYP2C11 and possibly CYP2E1, and human CYP1A2. O-PP, phenylhydroquinone, and 2,4'-dihydroxybiphenyl can themselves undergo conjugation reactions through the action of either sulfotransferase or glucuronidation phase II reactions. At oral doses below approximately 200 mg/kg/day, O-PP is found primarily in urine as the glucuronide and sulfate conjugates in both rats and mice. With increasing doses above 200 mg/kg/day, however, the metabolic profile changes. High doses of O-PP lead to saturation of phase II detoxification enzyme pathways, resulting in increased oxidative metabolites phenylhydroquinone (PHQ) and/or phenylbenzoquinone (PBQ). PHQ can also be converted to phenyl-1,4-benzoquinone by a secondary peroxidase-mediated activation in the kidney and/or bladder involving the prostaglandin endoperoxide synthase (PHS) complex. The involvement of PHS has been suggested on the basis of data submitted to the Office of Pesticide Programs (D203250). The increase in oxidative metabolites forms the basis for the mammalian toxic mode of action of O-PP on the kidney and urinary bladder.

2.6.3 Summary of Toxicological Effects

The mammalian mode of action for O-PP toxicity to the kidney and bladder has been reviewed and accepted by the Office of Pesticide Program's Carcinogenicity Assessment Review Committee (CARC). The MOA for these effects is related to the alteration in biotransformation of the chemical with increasing dose. At doses below approximately 200 mg/kg/day, O-PP is transformed primarily to the glucuronide and sulfate conjugates in both rats and mice. With increasing dose, (> 200 mg/kg/day), the metabolic profile changes. Saturation of phase II detoxification enzyme pathways occurs, and the oxidative metabolites phenylhydroquinone (PHQ) and 2-phenyl-1,4-benzoquinone (PBQ) are formed in increased amounts. The shift to these biotransformation products with increased dose has been postulated to be associated with the non-linear response observed in tumorigenicity of the urinary bladder and liver, involving oxidative damage to cells and subsequent regenerative hyperplasia. With continued exposure, this process leads to development of tumors. Tumor response is observed in male rats but not female rats for urinary bladder tumors.

In a repeated subchronic oral toxicity study in rats, O-PP produced decreases in body weight, food consumption, and water consumption. Increased urinary bladder weight and proliferative lesions of the bladder were also observed. Urinary histopathology was also observed in chronic oral toxicity studies with O-PP in rats (kidney and urinary bladder hyperplasia, inflammation, and necrosis). Adverse effects in the subchronic toxicity study occurred at doses (2798 mg/kg/day) exceeding the limit dose. In a 21-day dermal toxicity study, no systemic effects were observed at doses up to 1000 mg/kg/day, but irritation effects were observed at a dose of 500 mg/kg/day consisting of erythema, edema, acanthosis, and hyperkeratosis.

In developmental toxicity studies with O-PP, increased mortality and renal inflammation/tubular degeneration were observed in maternal rabbits. In rats, no significant maternal effects were observed up to and including the high dose used in the study. There were no significant effects observed on the developing fetus in the rat or rabbit. In reproduction toxicity studies, decreased body weight was observed in parental animals and in offspring at the same dose; parental animals were also observed with urinary bladder calculi and transitional cell hyperplasia/ nodular papillary transitional cell hyperplasia/inflammation of the urinary bladder. There were no adverse reproductive effects observed in this study at any dose tested.

The chronic toxicity of O-PP has been examined in rats, mice, and dogs. In dogs, there was no specific target organ toxicity of O-PP observed; no adverse effects were observed up to and including the high dose of 300 mg/kg/day. In rats, administration of O-PP in the diet over the lifespan resulted in an increase in incidence of non-neoplastic lesions of the kidney (cysts, hyperplasia, infarct) and urinary bladder (hyperplasia, mineralization, necrosis) and neoplastic lesions of the urinary bladder. In mice, O-PP administered in the diet for 78 weeks resulted in an

increase in absolute and relative liver weights at 12 and 24 months in all treated males and females; also, treated males had increased adrenal absolute and relative weights at 24 months. Spleen weights (absolute and relative) in the males and females were reduced in all treated groups. Accentuated lobular pattern of the liver was reported in mice at 12 and 24 months.

The carcinogenicity of O-PP has been examined in rats and mice in experimental studies. In male rats, statistically significant increases in urinary bladder papillomas, transitional cell carcinomas, and papillomas and/or transitional cell carcinomas combined were observed. No increase in tumors was observed in female rats. In mice, significant increasing trends, and significant differences in the pair-wise comparisons were observed for liver adenomas and adenomas and/or carcinomas combined.

The acute oral toxicity of O-PP is assigned a Toxicity Category III (MRID 43334201) with an oral LD_{50} value of 2733 mg/kg /day(combined). By the dermal route, an LD_{50} value of > 5000 mg/kg/day (Toxicity Category IV) was obtained in a submitted study (MRID 00078779). The available acute inhalation toxicity data (MRID 42333101) is inadequate to assign a category; only one concentration was tested (0.036 mg/L) that showed no mortality or clinical signs. A primary eye irritation study was conducted (MRID 00139884) but the study was considered unacceptable because the observation period employed in the study (7 days) was not long enough to assign a Toxicity Category. O-PP is a severe (Toxicity Category I) dermal irritant. O-PP is not a dermal sensitizer.

The Office of Pesticide Programs' Carcinogenicity Assessment Review Committee (OPP/CARC) identified two cancer classifications for O-PP and sodium O-PP, based on dose (TXR 0053796): (i) "Likely to be Carcinogenic to Humans," based on the presence of urinary bladder tumors in rats and the presence of liver tumors in mice at doses above 200 mg/kg/day. High doses (> 200 mg/kg/day) of O-PP lead to saturation of phase II detoxification enzyme pathways, resulting in increased amounts of the oxidative metabolites PHQ and/or PBQ. The generation of PBQ is considered dose-dependent, appearing in increased quantity only at higher doses of O-PP (>200 mg/kg/day). (ii) "Not Likely to be Carcinogenic to Humans" based on evidence that carcinogenic effects are not likely below a defined dose range (*i.e*, below 200 mg/kg/day).

2.6.4 Safety Factor for Infants and Children (FQPA Safety Factor)

The FQPA Safety Factor (SF) for O-PP can be reduced to 1x for residential exposure scenarios with the exception of the inhalation scenario where the FQPA SF is retained at 10X in the form of a database uncertainty factor (UF_{DB}) for lack of a subchronic inhalation study. The existing toxicity database for O-PP is adequate to evaluate the potential for susceptibility in infants and young children resulting from exposure to O-PP, and the dietary and residential assessments are

based on reliable data and will not underestimate exposure. There is no evidence of developmental toxicity or susceptibility to offspring in the rat and rabbit developmental toxicity studies; the NOAELs and LOAELs are also well-defined. There is no evidence of reproductive toxicity in the 2-generation reproduction toxicity study in rats; NOAELs and LOAELs in this study are also well-defined. Although there are no studies specifically examining neurotoxicity of O-PP in the database, there is no evidence of neurotoxicity in the available data for O-PP database[2].

2.6.4.1 Completeness of the Toxicology Database

The toxicology database for O-PP is complete with the exception of a subchronic inhalation toxicity study. Acceptable studies are available for developmental, reproduction, chronic, and subchronic toxicity. The immunotoxicity and neurotoxicity studies were recommended to be waived by HASPOC (TXR 0057473 and 0057902). The inhalation toxicity study was recommended to not be waived by HASPOC (TXR 0057902). In the absence of a repeated dose inhalation toxicity study, a search of acute inhalation toxicity studies with O-PP was conducted. Three acute inhalation toxicity studies were found with O-PP as the sole active ingredient. Considering the three acute studies together, and the fact that the studies with formulations containing O-PP as the sole active may contain inert ingredients that may or may not be irritants themselves or have other toxicities, the weight of the evidence indicated that a LOAEC of 0.2 mg/L is an appropriate POD for risk assessment based on clinical signs in the 10.48% ai formulation VitaSan 10.

2.6.4.2 Evidence of Sensitivity/Susceptibility in the Developing or Young Animal

The data submitted to the Agency, including developmental toxicity studies in the rat, rabbit, and mouse, as well as reproduction toxicity studies in the rat demonstrated no increased qualitative or quantitative susceptibility in the rat and rabbit developmental toxicity studies and in the rat reproduction toxicity study.

2.6.4.3 Residual Uncertainty in the Exposure Database

There are no residual uncertainties in the exposure database.

2.7 Toxicity Endpoint and Point of Departure Selections

Toxicity endpoints and PODs for dietary, residential, and occupational exposure scenarios for antimicrobial uses of O-PP are summarized below. Table 6 summarizes dietary PODs and endpoints. Table 7 summarizes non-dietary PODs and endpoints for antimicrobial uses of O-PP.

[2] HED's standard toxicological, exposure, and risk assessment approaches are consistent with the requirements of EPA's children's environmental health policy (https://www.epa.gov/children/epas-policy-evaluating-risk-children).

Table 8 summarizes occupational PODs and endpoints for conventional uses of O-PP. Only the Data Evaluation Records (DERs) for those toxicology studies with O-PP that were relevant for endpoint selection and risk assessment were updated to current practice.

Acute Dietary [Females 13-49] And [General Population]: No appropriate endpoints were identified in the O-PP database that represent a single dose effect.

Chronic Dietary: The two-generation reproduction toxicity study in rats (MRID 43928801) was selected for the chronic dietary assessment. The study is appropriate for the route and duration of exposure and has a robust endpoint consistent with the effects of O-PP observed in the database. The chronic dietary assessment was previously based on the chronic toxicity/carcinogenicity study in the rat (MRID 43954301) with a NOEL of 39 mg/kg/day and LOEL of 200 mg/kg/day. This chronic toxicity/carcinogenicity study was re-evaluated, and the NOAEL was revised to 200 mg/kg/day and LOAEL revised to 402 mg/kg/day, based on decreased (>10%) absolute body weight, and increased incidence of non-neoplastic and neoplastic lesions of the urinary bladder. The effects noted in the original review at 200 mg/kg/day (decreased body weight gains, decreased food consumption and reduced food efficiency, and increased clinical and pathological signs of toxicity) were not considered adverse at this dose. At the high dose, non-neoplastic and neoplastic effects in the urinary bladder were observed in increased incidence (hyperplasia, papillary/nodular hyperplasia, papilloma, and carcinoma) that were not observed at 200 mg/kg/day. In addition, significant decreases (> 10%) in absolute body weight in male rats was observed over the duration of the study, as well as blood in the urine of high dose males, and increased non -neoplastic lesion incidence in kidneys of high dose males. The selection of the 100 mg/kg/day NOAEL from the reproduction toxicity study for the chronic dietary endpoint is protective of non-cancer effects occurring in other toxicity studies for O-PP. The LOAEL of 500 mg/kg/day is based on decreased body weights, body weight gains, increased incidence of bladder hyperplasia in F0 and F1 males, dilatation and hyperplasia of the ureters, and chronic active inflammation in the kidneys**.** Uncertainty factors include 10X for interspecies extrapolation and 10X for intraspecies variation. The cPAD is 1.00 mg/kg/day.

Short-/Intermediate-term Inhalation: While there are several inhalation exposure scenarios for O-PP, there are no guideline repeat exposure inhalation studies for the O-PP technical active, and no new data are expected before the date scheduled for Registration Review. An oral endpoint is not suitable for use in the inhalation risk assessment because systemic effects would not be protective of irritation-driven effects.

In the absence of repeat exposure studies, a search of acute inhalation toxicity studies with O-PP was conducted. Three acute inhalation toxicity studies were found with O-PP as the sole active ingredient:

- An acute inhalation study with 99.92% - 99.88% O-PP technical (MRID 42333101) was able to test only one dose due to technical difficulties, and that dose is a NOAEC of 0.036 mg/L because no significant effects were detected in rats.

- In an acute inhalation study using the 10.48% a.i. formulation VitaSan 10 (MRID 42620006), the LOAEC is the lowest dose tested of 1.93 mg VitaSan 10 formulation/L (0.20 mg a.i./L), based on increased incidence of irregular respiration lasting for 3 or more days after exposure, and hunched posture lasting 6 days or more after exposure following a single whole-body exposure of 4.5 hours.

- An acute inhalation study using the 3.9% a.i. formulation VitaSan 33 (MRID 42620009) tested only one dose of 4.92 mg VitaSan 33 formulation/L (0.19 mg a.i./L), which resulted in mortality of all animals in the study (5 males and 5 females) within 48 hours after a single whole-body exposure of 4.5 hours.

Considering the three acute studies together, and the fact that these formulations may contain inert ingredients that may or may not be irritants themselves or have other toxicities, the weight of the evidence indicates that a LOAEC of 0.2 mg/L is an appropriate POD for risk assessment based on clinical signs in the 10.48% a.i. formulation VitaSan 10. Because it is known that O-PP is an irritant, the observed effects are likely the result of portal of entry irritation, even though the study did not include a pathology analysis. A 10x UF_L is warranted to account for the lack of a NOAEC in the selected study. This results in an extrapolated NOAEC of 0.02 mg/L, which is similar to the NOAEC observed in the study with technical O-PP (0.036 mg/L) where no adverse effects were detected. Therefore, the selected LOAEC is considered protective of effects observed in both formulation studies. In addition, since an acute endpoint is used to extrapolate to repeated exposure scenarios, a 10x uncertainty factor (UF_{DB}) is also warranted.

The POD is further refined by calculating a Human Equivalent Concentration (HEC) from the LOAEC of 0.2 mg/L (200 mg/m^3) and particle size information in the 10.48% ai formulation VitaSan 10 study (mass median diameter = 2.4 microns; geometric standard deviation = 1.82). Since the study does not have enough data to determine which respiratory region was affected, the most conservative RDDR is used, which is the extrathoracic RDDR of 0.215. Based on this RDDR, and given the animal exposure time of 4.5 hours in the VitaSan 10 Study, the HEC for an 8 hour daily exposure is 24 mg/m^3 and the HEC for a 24 hour daily exposure is 8.1 mg/m^3.
As indicated previously, because an acute endpoint is used to extrapolate to repeated exposure scenarios, a 10x UF_{DB} is warranted. A 10x UF_L is also applied for the lack of a NOAEC in the selected study. However, the interspecies uncertainty factor (UF_A) is reduced to 3x for two reasons: (1) due to the calculation of HECs accounting for the pharmacokinetic component (not pharmacodynamic) of interspecies differences, and (2) for a direct irritant like O-PP, pharmacokinetic characteristics are not likely to have a significant effect on the irritant responses between species. The intraspecies uncertainty factor (UF_H) can be reduced to 3x because pharmacokinetic characteristics are not likely to have a significant effect on responses among the

human population for direct acting irritants, such as O-PP, with toxicity occurring at the point of contact. Therefore, the level of concern (LOC) for the short-term, intermediate, and long-term inhalation risk assessments is 1000X.

Dermal (all durations): For antimicrobial uses of O-PP**,** the route-specific 21-day dermal toxicity study in rats (MRID 42881901) was selected for the dermal assessment. The study is appropriate for the route and duration of exposure. The POD selected (100 mg/kg/day) is protective of the dermal effects observed at the LOAEL of 500 mg/kg/day (erythema, scaling, acanthosis, and hyperkeratosis) at the site of test substance application. The use of the irritation endpoint is consistent with the policy developed in the Antimicrobials Division for use of irritation as an endpoint for materials preservative uses of antimicrobial pesticides that do not bear pesticide labels. Under this policy, reduced uncertainty factors of 3x for interspecies extrapolation and 3x for intraspecies variation are also applied to the dermal irritation POD. The LOC is therefore 10 for this endpoint. For the conventional uses of O-PP, a dermal assessment is not needed as there are no systemic effects from dermal exposure up to a limit dose of 1000 mg/kg/day.

Short/Intermediate-term Incidental Oral: The 2-generation reproduction toxicity study in the rat (MRID 43928801) was selected for incidental oral assessment. The study is appropriate for the duration of exposure, and the POD (100 mg/kg/day) is protective of other short-term effects observed at the same or higher doses in the database. The LOAEL is 500 mg/kg/day based on decreased body weights, body weight gains, increased incidence of bladder hyperplasia in F0 and F1 males, dilatation and hyperplasia of the ureters, and chronic active inflammation in the kidneys**.** The LOC is 100 which includes uncertainty factors of 10X for interspecies extrapolation and 10X for intraspecies variation.

2.7.1 Recommendation for Combining Routes of Exposures for Risk Assessment

Chronic dietary and incidental oral (short- and intermediate-term) can be combined since the same study (two-generation reproduction toxicity study) was the basis for the selected endpoints for these risk assessments.

2.7.2 Cancer Classification and Risk Assessment Recommendation

The Office of Pesticide Programs' Carcinogenicity Assessment Review Committee (OPP/CARC) identified two cancer classifications for O-PP and sodium O-PP, based on dose (TXR 0053796): (i) "Likely to be Carcinogenic to Humans," based on the presence of urinary bladder tumors in rats and the presence of liver tumors in mice at doses above 200 mg/kg/day. High doses (> 200 mg/kg/day) of O-PP lead to saturation of phase II detoxification enzyme pathways, resulting in increased amounts of the oxidative metabolites PHQ and/or PBQ. The generation of PBQ is considered dose-dependent, appearing in increased quantity only at higher

doses of O-PP (>200 mg/kg/day). (ii) "Not Likely to be Carcinogenic to Humans" based on evidence that carcinogenic effects are not likely below a defined dose range (*i.e*, below 200 mg/kg/day).

Based on the available data regarding the mutagenicity of O-PP, there is no clear evidence of mutagenicity. Positive results generally seen in cytogenetic assays were associated with excessive cytotoxicity and not related to direct damage to DNA. The proposed mechanism for severe cytotoxicity in cytogenetic assays is oxidative damage. In 2005, the O-PP CARC determined that non-linear quantification of cancer risk was appropriate for O-PP.

Table 6: Summary Points of Departure for Dietary Exposures to O-PP

Exposure Scenario	Point of Departure	Uncertainty Factor (UF), FQPA Safety Factor (SF)	Study and Toxicological Effects
Acute Dietary (all populations)	No appropriate endpoints were identified in the O-PP database to represent a single dose effect. Therefore, this risk assessment is not required.		
Chronic Dietary (all populations)	**NOAEL** = 100 mg/kg/day	**UF_A =** 10 **UF_H =** 10 **FQPA SF** = 1 **LOC** = 100 **RfD** = 1.0 mg/kg/day **PAD** = 1.0 mg/kg/day	Reproduction and Fertility Effects Rat (MRID 43928801) Parental LOAEL of 500 mg/kg/day based on decreased body weights, body weight gains, increased incidence of bladder hyperplasia in F0 and F1 males, dilatation and hyperplasia of the ureters, and chronic active inflammation in the kidneys**.**
Cancer (oral)	**Classification:** In 2005, the OPP CARC classified O-PP as "Not Likely to be Carcinogenic to Humans" based on evidence that carcinogenic effects are not likely below a defined dose range (i.e, below 200 mg/kg/day). Quantification of cancer risk is performed using the chronic Reference Dose (1.0 mg/kg/day). This point of departure is protective for precursor events leading to development of bladder and liver tumors. (TXR 0053796)		

Point of Departure (POD) = A data point or an estimated point that is derived from observed dose-response data and used to mark the beginning of extrapolation to determine risk associated with lower environmentally relevant human exposures. NOAEL = no observed adverse effect level. LOAEL = lowest observed adverse effect level. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). FQPA SF = FQPA Safety Factor. PAD = population adjusted dose. RfD = reference dose. LOC = level of concern. N/A = not applicable.

Table 7: PODs for Non-Dietary Risk Assessment of the Antimicrobial Uses of O-PP

Exposure Scenario	Point of Departure (POD)	Target MOE, Uncertainty Factor (UF), FQPA Safety Factor (SF)	Study and Toxicological Effects
Incidental Oral Short- and Intermediate-Term (1 - 30 days, 1-6 months)	**NOAEL (parental)** = 100 mg/kg/day	**UF_A =** 10 **UF_H =** 10 **LOC** = 100 (Target MOE)	Reproduction and Fertility Effects Rat (MRID 43928801) Parental LOAEL of 500 mg/kg/day based on decreased body weights, body weight gains, increased incidence of bladder hyperplasia in F0 and F1 males, dilatation and hyperplasia of the ureters, and chronic active inflammation in the kidneys**.**
Dermal Short-, Intermediate, and long-term Term	**NOAEL (dermal)** = 100 mg/kg/day (200 µg/cm^2)[A]	**UF_A = 3** **UF_H = 3** **LOC** = 10 (Target MOE)	21-Day Dermal toxicity study in rats (MRID 42881901) LOAEL (dermal) of 500 mg/kg/day based upon dermal irritation (erythema, scaling, acanthosis, and hyperkeratosis) at the site of test substance application.
Inhalation Short-, Intermediate, and Long-Term	**LOAEC** = 0.2 mg/L (200 mg/m^3) 8 Hour HEC[B] = 24 mg/m^3 24 Hour HEC[B] = 8.1 mg/m^3	**UF_A = 3** **UF_H = 3** **UF_{DB} = 10** **UF_L = 10** **LOC** = 1000 (Target MOE)	Acute inhalation toxicity study with VitaSan 10 (MRID 42620006) LOAEC = 0.2 mg/L (200 mg/m^3), based on increased incidence of irregular respiration lasting for 3 or more days after exposure, and hunched posture lasting 6 days or more after exposure following a single whole-body exposure of 4.5 hours
Cancer (oral, dermal, inhalation)	**Classification:** In 2005, the OPP CARC classified O-PP as "Not Likely to be Carcinogenic to Humans" based on evidence that carcinogenic effects are not likely below a defined dose range (i.e, below 200 mg/kg/day). Quantification of cancer risk is performed using the chronic Reference Dose (1.0 mg/kg/day). This point of departure is protective for precursor events leading to development of bladder and liver tumors. (TXR 0053796)		

Point of Departure (POD) = A data point or an estimated point that is derived from observed dose-response data and used to mark the beginning of extrapolation to determine risk associated with lower environmentally relevant human exposures. NOAEL = no observed adverse effect level. LOAEL = lowest observed adverse effect level. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). UF_{DB} = use of an acute study for longer term exposure duration (i.e., lack of a repeat dose study). UF_L = lack of a NOAEC. FQPA SF = FQPA Safety Factor. MOE = margin of exposure. LOC = level of concern. N/A = not applicable.

[A] 200 ug/cm^2 = [Dose (100 mg/kg/day) x Rat BW (0.200 kg) x 1000 µg/mg)] / Rat Dose Area (100 cm^2)

[B] HEC =LOAEC (200 mg/m^3) * Exposure Time Correction (4.5 hours /8.0 or 24 hours) * RDDR (0.215)

Table 8. PODs for Occupational Handler Risk Assessment of the O-PP Conventional Uses

Exposure/ Scenario	POD	Uncertainty/ FQPA Safety Factors	Study and Toxicological Effects
Dermal (All Durations)	No systemic hazard identified at the limit dose. No quantification required of dermal irritation due to the use of PPE.		
Inhalation Short-, Intermediate, and Long-Term (1 - 30 days, 1-6 months, > 6 months) (occupational)	**LOAEC** = 0.2 mg/L (200 mg/m^3) 8 Hour HEC[A] = 24 mg/m^3 8 Hour HED[B] = 2.3 mg/kg/day	**UF_A = 3** **UF_H = 3** **UF_{DB} = 10** **UF_L = 10** **LOC** = 1000 **(Target MOE)** **Note:** The UF_{DB} of 10x is for duration extrapolation.	Acute inhalation toxicity study with VitaSan 10 (MRID 42620006) LOAEC = 0.2 mg/L, based on increased incidence of irregular respiration lasting for 3 or more days after exposure, and hunched posture lasting 6 days or more after exposure following a single whole-body exposure of 4.5 hours
Cancer (dermal, inhalation)	In 2005, the OPP CARC classified O-PP as "Not Likely to be Carcinogenic to Humans" based on evidence that carcinogenic effects are not likely below a defined dose range (i.e, below 200 mg/kg/day). Quantification of cancer risk is performed using the Reference Dose (1.0 mg/kg/day). This dose is protective of the precursor events leading to development of bladder and liver tumors (TXR 0053796)		

Point of Departure (POD) = A data point or an estimated point that is derived from observed dose-response data and used to mark the beginning of extrapolation to determine risk associated with lower environmentally relevant human exposures. NOAEL = no observed adverse effect level. LOAEL = lowest observed adverse effect level. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). UF_{DB} = use of an acute study for longer term exposure duration (i.e., lack of a repeat dose study). UF_L = for lack of a NOAEC in the study. FQPA SF = FQPA Safety Factor. MOE = margin of exposure.

[A]HEC =LOAEC (200 mg/m^3) * Exposure Time Correction (4.5 hours /8.0) * RDDR (0.215)

[B]HED = HEC (24 mg/m^3) * Breathing Rate (13.8 l/min or 0.828 m^3/hr) * Exposure Duration (8 hours) * (1/70 kg)

2.7.3 Endocrine Disruptor Screening Program

As required by FIFRA and FFDCA, EPA reviews numerous studies to assess potential adverse outcomes from exposure to chemicals. Collectively, these studies include acute, subchronic and chronic toxicity, including assessments of carcinogenicity, neurotoxicity, developmental, reproductive, and general or systemic toxicity. These studies include endpoints which may be susceptible to endocrine influence, including effects on endocrine target organ histopathology, organ weights, estrus cyclicity, sexual maturation, fertility, pregnancy rates, reproductive loss, and sex ratios in offspring. For ecological hazard assessments, EPA evaluates acute tests and chronic studies that assess growth, developmental and reproductive effects in different taxonomic groups. As part of the reregistration decision for O-PP, EPA reviewed the data for O-PP and selected the most sensitive endpoints for relevant risk assessment scenarios from the existing hazard database. O-PP is subject to the endocrine screening part of the Endocrine Disruptor Screening Program (EDSP).

EPA has developed the EDSP to determine whether certain substances (including pesticide active and other ingredients) may have an effect in humans or wildlife similar to an effect produced by a "naturally occurring estrogen, or other such endocrine effects as the Administrator may designate." The EDSP employs a two-tiered approach to making the statutorily required determinations. Tier 1 consists of a battery of 11 screening assays to identify the potential of a chemical substance to interact with the estrogen, androgen, or thyroid (E, A, or T) hormonal systems. Chemicals that go through Tier 1 screening and are found to have the potential to interact with E, A, or T hormonal systems will proceed to the next stage of the EDSP where EPA will determine which, if any, of the Tier 2 tests are necessary based on the available data. Tier 2 testing is designed to identify any adverse endocrine-related effects caused by the substance and establish a dose-response relationship between the dose and the E, A, or T effect.

Under FFDCA section 408(p), the Agency must screen all pesticide chemicals. Between October 2009 and February 2010, EPA issued test orders/data call-ins for the first group of 67 chemicals, which contains 58 pesticide active ingredients and 9 inert ingredients. A second list of chemicals identified for EDSP screening was published on June 14, 2013[1] and includes some pesticides scheduled for registration review and chemicals found in water. Neither of these lists should be construed as a list of known or likely endocrine disruptors.

O-PP was tested in several guideline EDSP Tier I assays, including:

890.1150 Androgen receptor binding in rat prostate
890.1200 Aromatase assay
890.1250 Estrogen receptor binding
890.1400 Hershberger assay
890.1450 Female pubertal assay
890.1500 Male pubertal assay
890.1550 Steroidogenesis assay
890.1600 Uterotrophic assay

In addition, several non-guideline studies were performed, including:

Estrogen-sensitive cell proliferation in rat pituitary tumor cells
Estrogen-sensitive gene expression assays in yeast, MCF-7 human breast cancer cells, and human BG1 ovarian carcinoma cells.

The findings and conclusions of these assays were presented in the document "EDSP Weight of Evidence Conclusions on the Tier 1 Screening Assays for the List 1 Chemicals," available in docket ID EPA-HQ-OPP-2013-0524-0009. In summary, for those assays examining interaction with estrogen receptors and/or pathways, the evidence was insufficient for a potential interaction

in *in vivo* mammalian studies. For the androgen pathway, there was evidence of a potential interaction in the *in vitro* androgen receptor (AR) binding assay and conflicting evidence in the steroidogenesis assay where a 30% increase in testosterone production at 10 µM O-PP and a 30% decrease at 100 µM O-PP was observed. However, there were no androgen-related effects observed in *in vivo* mammalian toxicity studies. Therefore, there is no convincing evidence for a potential interaction with the androgen pathway.

With regard to interaction with thyroid hormones, there was no evidence of potential interaction. In the female pubertal assay, there were no treatment-related effects on thyroid hormones [T_4 and thyroid stimulating hormone (TSH)], thyroid weights or thyroid histopathology from O-PP. In the male pubertal assays the only thyroid-related effect observed was a decrease in serum T_4 levels at all doses tested.

2.8 Dietary Exposure and Risk Assessment of Antimicrobial and Conventional Uses

2.8.1 FFDCA Clearances

The US EPA has established exemptions from the requirement of a tolerance for O-PP under the Federal Food, Drug, and Cosmetic Act (FFDCA) Section 408. Table 9 provides a summary of the exemptions and corresponding use information.

Table 9. Summary of EPA Tolerances Exemptions for O-PP

40 CFR Section	Exemption	Chemical CAS	Maximum Residue Level
180.129[1,2]	Combined residues of the fungicide o-phenylphenol and sodium o-phenylphenate, each expressed as o-phenylphenol, from postharvest application of either in or on the following food commodities: lemon, lime, orange, tangerine, tomato, bell pepper, cucumber, pineapple, grapefruit, kumquat, cantaloupe pulp and citron citrus fruit crops.	o-phenylphenol CAS No. 90-43-7	Various residue levels
180.920	Inert ingredient used pre-harvest: exemption from a requirement of a tolerance	Sodium *ortho*-phenyl phenate CAS No. 132-27-4	No limit; preservative for formulation
180.940 (c)	Active and inert ingredients for use in antimicrobial formulations (Food-contact surface sanitizing solutions) for food-processing equipment and utensils	o-phenylphenol CAS No. 90-43-7	When ready for use, the end-use concentration is not to exceed 400 ppm.

[1] In the 2006 RED, all O-PP post-harvest uses and tolerances were revoked except for citrus fruit and pear. HED currently is revising the 40 CFR §180.129 for registration review.

[2]Refer to Table 5 and Appendix G for tolerance exemption levels of each crop commodity.

The Food and Drug Administration (FDA) has established several food additive regulations for indirect food uses of O-PP and Na O-PP under FFDCA's section 409. Table 10 list regulation summaries.

Table 10. FDA's Clearances for indirect Food Additives for *ortho*-phenylphenol and Sodium *ortho*-phenyl phenate

21 CFR Section	FDA Clearances for Indirect Food Additives	Chemical CAS	Maximum Residue Level
175.105	**Adhesives and components of coating**: May be safely used as a preservative in the manufacturing of food contact adhesives	o-phenylphenol (O-PP) CAS No. 90-43-7	No limit specified
176.170	Preservative of coatings only as a component of paper and paperboard in contact with aqueous and fatty foods	Sodium *ortho*-phenyl phenate (Na-O-PP) CAS No. 132-27-4	No limit specified
176.210	**Paper and paperboard:** May be used as defoaming agents used in the manufacture of paper and paperboard	o-phenylphenol (O-PP) CAS No. 90-43-7 Sodium *ortho*-phenyl phenate CAS No. 132-27-4	No limit specified
177.1632	**Polymers:** For use as a fungicide for finish coating materials (resin fibers and yarns).	o-phenylphenol (O-PP) CAS No. 90-43-7	Not to exceed 0.01 percent by weight of base polymer poly (phenylene terephthalamide)
177.2600	**Polymers:** Rubber articles intended for repeated use for food contact	o-phenylphenol (O-PP) CAS No. 90-43-7	No limit specified
178.1010 (b)	Food contact sanitizer used on food-processing equipment and utensils, and on other food-contact articles	o-phenylphenol (O-PP) CAS No. 90-43-7	≤400 ppm mixed with two other phenols
178.3120	Preservative in animal glue in articles for food contact	Sodium *ortho*-phenyl phenate (Na-O-PP) CAS No. 132-27-4	No limit specified
177.1210	Component of closures by when used with sealing gaskets for food containers	Sodium *ortho*-phenyl phenate (Na-O-PP) CAS No. 132-27-4	≤0.05 % by weight

2.8.2 Food Exposure Profile

2.8.2.1 Antimicrobial Food Exposure

Indirect dietary exposure to O-PP is expected to occur as the chemicals are labeled for use as a sanitizer, cleaner, and disinfectant in residential, commercial, industrial and agricultural environments. In residential areas, O-PP and O-PP salt derived compounds typically are applied

to kitchen use sites at rates are as high as 2200 ppm but some labels instruct users to scrub surfaces with detergents and wash with water prior to the placement of food. In commercial premises and other areas such as schools, nursing homes, restaurants industrial sites, eating establishments as well as various food processing equipment, O-PP can be used at 6000 ppm or below, but some labels contain language that instructs users to scrub surfaces with detergent and rinse with water prior to placement of food or feed. Additional indirect dietary exposure can result from material preservative uses of O-PP as an adhesive, incorporated with antimicrobial uses in paper slurries.Additional indirect dietary exposure can result from material preservative uses of O-PP as an adhesive, plastics and paper coating along with antimicrobial uses in paper slurries.

2.8.2.2 Conventional Food Exposure

Ortho-phenylphenol is formulated into and applied as a sodium salt of *ortho*-phenylphenol. Sodium *ortho*-phenylphenate (Na- O-PP) is a pesticide with both agricultural and antimicrobial uses. As an agricultural pesticide, (Na- O-PP) is used as a postharvest fungicide on citrus fruit and pears. Dietary exposure is expected from the postharvest use.

The existing residue chemistry database for O-PP is adequate for Registration Review. Adequate plant metabolism data, magnitude of the residue data (*i.e.*, field trials and processing studies), and storage stability data are available to support the food uses of Na- O-PP and the established tolerances.

Residues of O-PP from field trials conducted with grapefruits, lemons, oranges ranged from 1.32 to 8.02 ppm (not exceeding the established tolerance of 10 ppm) following a postharvest treatment with foam wash solution and wax emulsion and collected at post-treatment intervals of 0, 28, 56 days. Residues of PHQ in these samples ranged from <0.2 – 0.519 ppm (D226172, L. Cheng, 4/2/1997). The orange processing data indicate that residues of O-PP do not concentrate in juice following exaggerated postharvest treatment. However, residues of O-PP may concentrate in dried pulp (3.7x) and oil (82x). The expected O-PP residues in citrus dried pulp and citrus oil would be 25.8 ppm and 572 ppm, respectively. A concentration factor for PHQ in citrus oil has not been determined because residue levels in the RAC (raw agricultural commodity) and the processed commodity are less than the LOQ (0.2 ppm).

Data from the Pear Bureau Northwest, USA show that residues of O-PP from ten field trials conducted with pear ranged from 5.9-13 ppm following a postharvest dip treatment, water rinse and collected after 20-27 days of frozen storage.

Since the Na- O-PP use on citrus fruit is only for postharvest preservation of fruit, no citrus dry pulp for livestock feed will be produced. Nor are there any poultry feed items associated with the

postharvest uses of Na- O-PP on citrus fruits and pears. Thus, no secondary residue in livestock is expected.

2.8.3 Water Exposure Profile

Drinking water exposure is not expected for O-PP or O-PP salts since the conventional uses are post-harvest fruit treatments which are restricted to indoor applications. The spot treatments and the antimicrobial uses with down the drain exposure are expected to dissipate before reaching drinking water intakes and facilities. Furthermore, as of September 23, 2019, according Agency's drinking water contaminate register, O-PP has not been identified as a known or anticipated candidate for drinking water contamination[3].

2.8.4 Commercial Use Patterns

In commercial areas, there is potential for indirect dietary exposure to O-PP products when used as a sanitizer and applied to food contact surfaces such as countertops and stovetops in schools and other institutions, restaurants, and other public access premises, treated plastic surfaces and polymers, agricultural farm premises and equipment, hatcheries, poultry houses, food processing equipment and utensils. There is also likelihood for indirect exposure when O-PP is used as a materials preservative in paper slurries, paper coating, glues and adhesives.

2.8.5 Residential Dietary Use Patterns

In households, there is potential for indirect dietary exposure to O-PP residues from products intended for disinfection and cleaning of residential hard non-porous food-contact surfaces. Such use sites include kitchen countertops, plastic surfaces (cutting boards) stovetops, sinks, and exterior surfaces of refrigerators.

2.8.6 Description of Residue Data Used

For this assessment, no acceptable residue data was available for O-PP products formulated as surface sanitizers, disinfectants, material preservatives, or foam agents. Thus, no additional residue refinements were considered while evaluating dietary exposures.

2.8.7 Dietary Risk Assessment for Antimicrobials and Conventional Use Patterns

2.8.7.1 Acute Dietary Risk Assessments for Antimicrobials

No appropriate endpoints were identified to represent a single dose effect for O-PP. Therefore, an acute dietary risk assessment was not conducted.

2.8.7.2 Chronic Dietary Risk Assessment for Antimicrobials and Conventionals

[3] https://www.epa.gov/ground-water-and-drinking-water/national-primary-drinking-water-regulations

To evaluate potential exposure to O-PP throughout various food use patterns, several dietary models were utilized within this assessment. To provide clarity of dietary models, each dietary assessment table will include informative footnotes and default assumptions to explain how exposure results were obtained. Dietary model summaries are listed with the corresponding dietary sections below.

2.8.7.3 Dietary Assessment for Commercial Use Patterns

To assess indirect dietary commercial exposures in food handling establishments, public eating areas, food processing or similar settings, the Commercial Tier1A model is used.
This unrefined model is intended for antimicrobial products applied to hard non-porous surfaces and estimates the exposure of all subpopulations to chemical residues that will remain on surfaces and are available to transfer on food. Further, this conservative screening-level model is based on food consumption data from the US Department of Agriculture's (USDA's) National Health and Nutrition Examination Survey and What We Eat in America (NHANES/WWEIA). It accounts for the average daily food consumption rates from the surveying data, assumes all food contacts a 4000 cm^2 treated surface, and 100% of the chemical is available for transfer.

O-PP is exempt from the requirement of a tolerance when used on food-processing equipment and utensils (40 CFR §180.940 (b) regulation) but because some labels contain uses for public eating areas, the commercial model is most appropriate for evaluating commercial use sites.

In commercial applications, there are O-PP labels with use rate exceedances at 2,200 ppm which is well above the tolerance exemption. However, those labels instruct the applicator to scrub surfaces with detergent and rinse with water after O-PP is applied. Because O-PP compounds are slightly to readily soluble in water (according to solubility properties for O-PP and Salts of O-PP listed in Table 2), it is assumed that a scrub with detergent accompanied by a potable water rinse will greatly reduce residues of O-PP. Based on this solubility assumption, the next highest rate (1,000 ppm) without scrubbing with detergent followed by potable water rinse instructions is being assessed for dietary risk. The next maximum rate (1,000 ppm) without potable water scrub instructions is being assessed for dietary risk. Commercial treatments of 2,200 ppm O-PP concentrations would result in a cPAD of 32% for Children 1-2 years old. However, based on the solubility assumptions of O-PP when applying a potable water rinse, it is determined that a rate of 1,000 ppm (without potable water rinse instructions) be assessed and incorporated into the total dietary and aggregate calculations.

For commercial food areas with label rate of 1,000 ppm (EPA Reg. No.498-134), dietary exposure and risk estimates are below the Agency's level of concern (<100% cPAD) for all population subgroups. The most highly exposed population subgroup is Children 1-2 years old at 14% cPAD.

Table 11. Commercial Use Patterns with O-PP applications of 1,000 ppm

Population Group	Residue Value (mg ai)[1]	Dose prior to consumption adjustment	Consumption Ratio[2]	Exposure (Dose) (mg/kg/day)[3]	Risk Estimates % cPAD (Food Only)[4]
General U.S. Population	4.0	0.057	1.000	0.0570	6
All Infants (<1 year old)		0.519	0.196	0.102	10
Children 1-2 years old		0.317	**0.453**	**0.144**	**14**
Children 3-5 years old		0.214	0.496	0.106	11
Children 6-12 years old		0.108	0.629	0.0678	7
Youth 13-19 years old		0.059	0.780	0.0464	5
Adults 20-49 years old		0.049	1.051	0.0516	5
Adults 50-99 years old		0.049	0.967	0.0476	5
Females 13-49 years old		0.055	0.941	0.0516	5

[1] Residue Value (mg ai) = [Active Ingredient Concentration from the label (ppm) ÷ 1,000,000] x Residual Solution (1 mg product /cm^2) x surface area (4000 cm^2) x [fraction transferred (%)/100]
[2] The FDA assumption that a typical American's diet contacts 4000 cm^2 of treated surface per day is based on habits of the general U.S. population. Because different subpopulations consume various quantities of food, a consumption ratio (CR) is used in the commercial hard surface sanitizer scenarios to account for this difference. CR (unitless) = Total food consumed by population subgroup (kg) ÷ Total food consumed by the general US Population (kg). For example, Children 1-2 years old's total food consumed is 1.77kg, while the general US population consumes 3.91kg. Therefore, the CR for Children 1-2 = 1.77kg / 3.91kg= 0.45269
[3] Exposure Dose (mg/kg/day) = Residue Value (mg ai) x Consumption Ratio ÷ BW (kg)
[4] The most highly exposed subpopulation is in bold.

In indirect dietary commercial settings where hard surfaces are used to prepare, serve, transport and store food, the Food Contact Sanitizing Solution Model (FCSSM) was used. This model is designed to assess exposures to food contact sanitizing products used on food processing equipment and utensils, which is categorized under 40 CFR §180.940 (b) and (c). The model's estimates are based on the worst-case scenario of Clean-In-Place (CIP) uses of food contact sanitizing solutions. The FCSSM does not evaluate indirect exposures resulting from product use in public eating establishments which is categorized as 40 CFR 180.940 (a). Identical to other dietary models, this model also incorporates various food consumption data from (NHANES/WWEIA), and assumes all residues transfer to processed food.

O-PP is exempt from the requirement of a tolerance when used on more specific sites such as food-processing equipment and utensils (40 CFR §180.940 (c) regulation). For this reason, a dietary assessment was performed using the Food Contact Sanitizing Solution Model (FCSSM) to evaluate exposures at the tolerance exemption level (400 ppm) and specific food use sites listed above. More information about this model can be found on the webpage https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/food-contact-sanitizing-solutions-model-fcssm.

FCSSM assumptions for specific commercial use sites

- A food weight factor (FWF) is used to represent the weight of food per unit surface area of the equipment, with the surface area of typical clean- in- place (CIP) systems.
- FDA guidance, that 1 mg/cm² of product residue is present on the surfaces and that all residue (100%) transfers to the food being processed.
- A daily intake of each of the relevant individual food items was determined for each population subgroup.
- Assumes that an individual consumes every single item in the food category. Summary consumption statistics were developed for each available category within each subpopulation.

For commercial use sites covered by the current tolerance exemption (use as sanitizing solution on food processing equipment and utensils), dietary exposure and risk estimates are below the Agency's level of concern (<100% cPAD) for all population subgroups.

Table 12. Chronic Dietary Exposure Assessment for O-PP in specific Commercial areas covered by tolerance exemption 180.940(c) at 400 ppm

Population Group	Mean (AM) Concentration (µg conc/cm²)	Exposure (Dose)[1] (µg/kg/day)	Risk Estimates % cPAD (Food Only)
General U.S. Population	0.4	0.896	0.1
All Infants (<1 year old)		1.13	0.1
Children 1-2 years old[4]		**1.04**	**0.1**
Children 3-5 years old		0.709	0.07
Children 6-12 years old		0.527	0.05
Youth 13-19 years old		0.456	0.05
Adults 20-49 years old		0.497	0.05
Adults 50-99 years old		0.410	0.04
Females 13-49 years old		0.594	0.06

[1] Exposure is determined by the mean and 95% consumption data for each food category and population subgroup where a clean in place scenario is relevant.

[4] The most highly exposed subpopulation is in bold.

The model information can be found at https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/food-contact-sanitizing-solutions-model-fcssm.

2.8.7.4 Dietary Assessment for Residential Use Patterns

The residential indirect dietary assessment utilizes an unrefined (Residential Tier 1A) model which considers antimicrobial disinfection products applied to hard surfaces in the home. This model is intended to estimate the dietary exposure of subpopulations from antimicrobial residues applied to residential hard non-porous food-contact surfaces. The model also uses WWEIA surveying data but integrates parameters specific residential food consumption and residential use patterns. In contrast to the commercial model, this model assumes food contact with a 2000 cm² treated surface, and 100% of the chemical is available for transfer.

The highest application rate of O-PP applied in household food contact areas without potable water rinse instructions is 1,000 ppm (EPA Reg. No. 498-134).
For residential areas, dietary exposure and risk estimates are below the Agency's level of concern (<100% cPAD) for all population subgroups. The most highly exposed population subgroup is Children 1-2 years old at 7 % cPAD.

Table 13. Residential Use Patterns with application of O-PP at 1,000 ppm

Population Group	Residue Value (mg ai)[1]	Dose prior to consumption adjustment	Consumption Ratio[2]	Exposure (Dose) (mg/kg/day)[3]	Risk Estimates % cPAD (Food Only)[4]
General U.S. Population	2.0	0.028	1.000	0.0285	3
All Infants (<1 year old)		0.260	0.196	0.0509	5
Children 1-2 years old		0.159	**0.453**	**0.0719**	**7**
Children 3-5 years old		0.107	0.496	0.0531	5
Children 6-12 years old		0.054	0.629	0.0339	3
Youth 13-19 years old		0.030	0.780	0.0232	2
Adults 20-49 years old		0.025	1.051	0.0258	3
Adults 50-99 years old		0.025	0.967	0.0238	2
Females 13-49 years old		0.027	0.941	0.0258	3

[1] Residue Value (mg ai) = [Active Ingredient Concentration from the label (ppm) ÷ 1,000,000] x Residual Solution (1 mg product /cm^2) x surface area (2000 cm^2) x [fraction transferred (%)/100]
[2] The FDA assumption that a typical American's diet contacts 2000 cm^2 of treated surface per day is based on habits of the general U.S. population. Because different subpopulations consume various quantities of food, a consumption ratio (CR) is used in the residential hard surface sanitizer scenarios to account for this difference. CR (unitless) = Total food consumed by population subgroup (kg) ÷ Total food consumed by the general US Population (kg). For example, Children 1-2 years old's total food consumed is 1.77kg, while the general US population consumes 3.91kg. Therefore, the CR for Children 1-2 = 1.77kg / 3.91kg= 0.4526 or 0.453
[3] Exposure Dose (mg/kg/day) = Residue Value (mg ai) x Consumption Ratio ÷ BW (kg)
[4] The most highly exposed subpopulation is in bold.

2.8.7.5 Dietary Assessment for Pulp and Paper Use Patterns

To evaluate indirect dietary exposure via the food contact papermaking process where pesticide residues may migrate into food, a Slimicide Model is utilized. The screening level exposure is based on the used pattern (i.e. slimicide added to the slurry, coating for finished paper) such that different inputs used in the calculator depends on where the pesticide is added in during paper production. The assumptions and methodology are based on an FDA guidance for food contact surfaces[4].

Dietary risk and exposure for O-PP in pulp and paperboard (slurries and paper coatings) are highly conservative in that the model assumes the following:

<u>Assumptions based on FDA guidance for papermaking</u>

[4] (*Guidance for Industry: Preparation of Premarket Submissions for Food Contact Substances: Chemistry Recommendations*, 2007).

- Slurry contain approximately 33% pulp and 67% slurry water.
- 100% of chemical migrates to from treated paper to food
- Finished paper contains approximately 92% pulp and 8% water
- Body weights (kg) and total food consumed are derived from the NHANES/WWEIA 2003-2008 data.

For slimicide uses in the paper slurry, dietary exposure and risk estimates are below the Agency's level of concern (<100% cPAD) for all population subgroups. The most highly exposed population subgroup is Children 1-2 years old at 5% cPAD.

Table 14. Paper Slurry Use Patterns at 4300 ppm

Population Group	DDD= Daily dietary dose (mg/kg/day)	Risk Estimates % cPAD
General U.S. Population	0.0200	2
All Infants (<1 year old)	0.0357	4
Children 1-2 years old	**0.0504**	**5**
Children 3-5 years old	0.0372	4
Children 6-12 years old	0.0238	2
Youth 13-19 years old	0.0163	2
Adults 20-49 years old	0.0181	2
Adults 50-99 years old	0.0167	2
Females 13-49 years old	0.0181	2

[1]Assumes a food mass to surface area ratio of 10 g food/in^2 paper (equivalent to 1.55 g food/cm^2) and a surface area of 2000 cm^2. The Dietary Concentration (µg ai/g food) is calculated using the Slimicides Spreadsheet. Residue Value= Dietary concentration (µg ai/g food)* 1.55 g food/cm^2*2000cm^2.

[2] The most highly exposed population subgroup is in bold

When used as a preservative for coated paper and paperboard, dietary exposure and risk estimates are below the Agency's level of concern (<100% cPAD) for all population subgroups. The most highly exposed population subgroup is Children 1-2 years old at 41% cPAD.

Table 15. Paper and Paperboard Coating Preservative Use Patterns at 6300 ppm

Population Group	DDD= Daily dietary dose (mg/kg/day)	Risk Estimates % cPAD
General U.S. Population	0.164	16
All Infants (<1 year old)	0.293	29
Children 1-2 years old	**0.414**	**41**
Children 3-5 years old	0.305	31
Children 6-12 years old	0.195	20
Youth 13-19 years old	0.133	13
Adults 20-49 years old	0.148	15
Adults 50-99 years old	0.137	14
Females 13-49 years old	0.149	15

[1]Assumes a food mass to surface area ratio of 10 g food/in^2 paper (equivalent to 1.55 g food/cm^2) and a surface area of 2000 cm^2. The Dietary Concentration (µg ai/g food) is calculated using the Slimicides Spreadsheet. Residue Value= Dietary concentration (µg ai/g food)* 1.55 g food/cm^2*2000cm^2.
[2] The most highly exposed population subgroup is in bold

2.8.7.6 Dietary Assessment for Adhesives and Detergents

Antimicrobials used to preserve adhesive or detergents formulations may result in the migration of the pesticide into the food that results in indirect dietary exposure.

Assumptions for adhesives:

- Surface area contacting food (RC) = 10 g food/in^2 or 1.55 g food/cm^2 (amount of food that can contact 1 square inch of paper)
- Treated surface area = 1000 cm^2
- Dietary concentration (DC) = 7 ppb (0.007 µg ai/g food). Assumes a maximum 7 ppb level of residues are likely to migrate from food packaging materials into food (based off of FDA guidance[3]).

Risk and exposure estimates for material preservatives as an adhesive are negligible at the highest label rate (4300 ppm).

When used as a dish detergent at 8,000 ppm, dietary exposure and risk estimates are below the Agency's level of concern (<100% cPAD) for all population subgroups (exposure to food is negligible in this scenario).

2.8.7.7 Dietary Assessment for Polymers and plastics

Due to lack of acceptable migration residue data and migration models, plastics and polymers risk are not included in the assessment. Exposures via this route are not expected to be greater than the assessed material preservative uses and should have limited impacts on the dietary exposure assessment.

2.8.7.8 Dietary Assessment for Direct Food Use

Dietary Exposure Evaluation Model - Food Commodity Intake Database (DEEM-FCID) software, version 3.16 is utilized to conduct risk assessments involving the direct food use of O-PP as a post-harvest treatment on citrus or pear. The version of DEEM uses 2003-2008 food consumption data from the USDA's NHANES/WWEIA.

The DEEM-FCID analyses estimate the dietary exposure of the US population and various population subgroups. All chronic dietary risk estimates are below the level of concern (<100% of the cPAD) for the US population and all population subgroups. The most highly exposed

subgroup is "Children 1-2 years old" with a risk estimate at 37% of the cPAD, whereas the risk estimate for the general US population is at 6.2% of the cPAD (D453216, S. Keel, 9/18/2019).

Table 16. Summary of Chronic Dietary (Food Only) Exposure and Risk Estimates for O-PP Residues of Concern

Population Subgroup[1] [Years of Age]	DEEM Chronic Dietary Analysis		
	Residue Value (mg ai)	Exposure Estimate (mg/kg/day)	% cPAD
General US Population	1.0	0.0623	6.2
All Infants [<1]		0.230	23
Children [1-2]		**0.371**	**37**
Children [3-5]		0.226	23
Children [6-12]		0.0956	**9.6**
Youth [13-19]		0.0428	4.3
Adults [20-49]		0.0349	3.5
Adults [50-99]		0.0374	3.7
Females [13-49]		0.0362	3.6

[1] Highest subpopulation and risk are bolded.

The chronic dietary (food only) exposure and risk assessment for O-PP and Na O-PP is conservative. Tolerance-level residues for citrus fruit (10 ppm) and pear (20 ppm) have been used in the analyses. The product label of EPA Registration No. 8764-1 (2/6/2013) lists all the commodities that were revoked in the 2006 RED. Since the label dates back to 2013, the product has been in use for many years. Although recommended to be revoked in the RED, tolerances for apple, bell pepper, cantaloupe, carrot roots, cherry, cucumber, nectarine, peach, pineapple, plum/prune, sweet potato roots and tomato are still listed in 40 CFR §180.129(a). HED has therefore included tolerance-level residues for these commodities in the dietary exposure assessment so that the dietary risk will not be underestimated. The empirical processing factor of 82x for citrus oil and HED's 2018 default processing factors for dried apple, carrot juice, cherry juice, lemon peel, orange peel, dried peach, peach juice, dried pear, pear juice, dried bell pepper, dried pineapple, plum/prune juice and dried tomato were incorporated in the assessment.

The chronic dietary (food only) risk assessment for O-PP and Na O-PP was conducted with the DEEM-FCID (ver. 3.16) model with tolerance-level residues, 100% crop treated, empirical processing factor and HED's 2018 default processing factors. The resulting chronic dietary risk estimates for the general U.S. population and all population subgroups are not of concern. Further refinement is unnecessary as all exposure estimates were less than the level of concern.

The Agency is confident that this risk assessment does not underestimate exposure or risk for the general U.S. population or any population subgroup.

2.8.7.9 Dietary Assessments for Inert Ingredients in Agricultural Products

Dietary Exposure Evaluation Model - Food Commodity Intake Database (DEEM-FCID™) software, version 3.16 is utilized to conduct risk assessments involving for antimicrobials used as inert ingredients. The version of DEEM uses 2003-2008 food consumption data from the USDA's NHANES/WWEIA.

O-PP, specifically Sodium *ortho*-phenylphenate (Na O-PP), is formulated as an inert ingredient (not to exceed 0.1% of the formulation) in agricultural pesticide products. See Table 9 for information about this tolerance exemption regulation.

For the inert chronic dietary assessment, the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID™, Version 3.16), and food consumption data from the U.S. Department of Agriculture's (USDA's) 2003-2008 National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA) were used.

The resulting chronic dietary risk estimates for the general U.S. population and all population subgroups for O-PP used as an inert are not of concern (As shown in Table 17).

Table 17. Inert use at tolerance exemption (0.1% of formulation)[1]

Population Group	Exposure (Dose) (mg/kg/day)	Risk Estimates % cPAD (Food Only)
General U.S. Population	0.000379	0.04
All Infants (<1 year old)	0.000789	0.1
Children 1-2 years old	**0.001412**	**0.1**
Children 3-5 years old	0.000971	0.1
Children 6-12 years old	0.000501	0.1
Youth 13-19 years old	0.000270	0.03
Adults 20-49 years old	0.000289	0.03
Adults 50-99 years old	0.000304	0.03
Females 13-49 years old	0.000293	0.03

[1]The model used application rates of 1 - 5 lb ai/acre which were adjusted for the tolerance exemption limitation of 0.1% maximum formulation and maximum application rates (0.05 lb inert/acre); Exposures were divided by an adjustment factor of 50 (0.1/0.02).

2.8.7.10 Cancer Dietary Risk Assessments

Quantification of cancer risk for O-PP is performed using the Reference Dose (1.0 mg/kg/day). The chronic Reference Dose is protective of concerns for the precursor events leading to development of bladder and liver tumors, reference (TXR 0053796). Therefore, the chronic dietary assessment performed for O-PP is inclusive of the cancer dietary risk assessment

2.8.7.11 Conclusions and Data Requirements

Dietary exposure to O-PP is not of concern for the post-harvest uses on citrus and pear, the residential uses, multiple commercial uses patterns or material preservatives uses and inert uses with probable food contact. The highest use rates considered for each use scenario, do not exceed the Agency's level of concern. No additional residue data is needed as this time.

2.9 Dietary Co-occurrence Risk Characterization

In order to conduct the dietary aggregate risk assessment, the Agency must determine the co-occurrence of dietary sources of chemicals. As mentioned and assessed above, dietary exposure to O-PP occurs from eight use sites: (1) indirect residential uses as a sanitizer on hard non-porous surfaces, (2) indirect commercial areas where sanitizers are used in eating establishments and kitchen areas such as stoves, countertops, and refrigerators, various food and beverage processing equipment; (3) Material preservatives uses such as adhesives and glues; (4) Paper additives and auxiliaries for food contact paper and (5) paper coatings; (6) Polymer plastic dispersions; (7) Inerts and (8) Direct conventional in raw agricultural commodities.

The Agency has determined that for the purposes of this risk assessment, the assumption of concurrent exposure from all product use sites would be overly conservative, considering (1) the extensiveness of use sites, (2) compounding conservative assumptions contained within the unrefined models, and (3) the number of products on the market.

Based on the use pattern of products comprised of O-PP used in food areas, the Agency determined that it is highly unlikely for an individual food commodity to contact residues from all areas treated with O-PP. This determination is further supported by the fact that all dietary models used in this assessment assume 100% residue transfer and account for the consumption of the same food items (*i.e.*, the commercial model utilizes average total food consumed, while the residential model uses average solid food consumed corrected for preparation patterns). Summation of exposure from all O-PP use sites in a co-occurrence assessment would result in compounding conservatisms. Therefore, the highest exposure from each use pattern or tolerance for residues was assessed and resulted in a combination of exposure from the following four use sites: Commercial areas, paper and paperboard (paper slurries and paper coatings), inerts and conventional uses. The co-occurrence table represents dietary assessments which result in total dietary exposure.

Table 18. Summary of Dietary Exposure Co-Occurrences

Dietary Source	Dietary Exposure Co-Occurrence in mg/kg/day (% cPAD)				
	Highest Exposed[3] Subpopulation Children 1-2 yrs	**Children 3-5 yrs**	**Infants (< 1 yr)**	**Females 13-49 yrs**	**General population**
Commercial[1, A]	**0.144 (**14%)	0.11 (11%)	0.10 (10%)	0.052 (5%)	0.057 (6%)
Slimicide[B]	**0.050 (5%)**	0.037 (4%)	0.036 (4%)	0.018 (2%)	0.02 (2%)
Paper Coating[2, C]	**0.414 (41%)**	0.31 (31%)	0.29 (29%)	0.14 (15%)	0.16 (16%)
Inerts	**0.0014 (0.14%)**	0.001 (0.1%)	0.0008 (0.1%)	0.00029 (0.03%)	0.00038 (0.04%)
Direct Food Use[E] (citrus and pear)	**0.371 (37%)**	0.23 (23%)	0.23 (23%)	0.036 (4%)	0.062 (2%)
Total Exposure	**0.98 (97%)**	0.68 (68%)	0.66 (66%)	0.25 (26%)	0.30 (24%)

[1]It should be noted that for the commercial uses with potential for food contact, the labels above the highest labeled concentrations presented in this table contain strict label instructions for removal of O-PP from surfaces following the allowed contact time. Those labels instruct the user to thoroughly scrub with detergent and rinse with water prior to placement of food.
[2]This highly conservative model assumes that 20% of food packaging paper is coated, paper coating is 10% the weight of paper, and that 100% of the chemical migrates from treated paper to food. Further, it's assumed that paper coating preservatives added toward the dry end of the process which result in higher end concentrations. Reg no (39967-24) has been identified as the highest application rate for paper coating at 0.6 % of the formulation or 0.43% of active ingredient. With no indications that this label is intended for non-food use, the Agency assumes a possibility for food contact.
[3]The highest exposed subpopulation is bold.
[A] Accounts for highest use rate (Reg No. 498-134) in commercial kitchen areas with possible food contact.
[B] Highest use rate identified for paper coating with food contact potential.
[C] Highest use rate with paper slurry uses on the label.
[D] Inert food uses for tolerance exemption at 0.1% of agricultural pesticide formulations.
[E] Tolerance level residues and percent crop

It should be noted that the updated dietary assessments have identified slightly different risk and exposure than the information published in Table 6 of the O-PP 2006 RED[5] for the following reasons:

1. A new dietary endpoint has been selected (May 2019).
2. Some dietary exposure models have been either updated and/or developed since 2006.
3. Since 2006, NHANES/WWEIA food composition data and body weight assumptions have increased for each subpopulation.
4. We currently rely on the Commercial Tier 1A model for assessment of sanitizing solutions with 180.940 (a) tolerance exemptions and FCSSM for assessing tolerance exemptions of 180.940 (b) and (c) use sites. If a chemical has use sites that fall within an

[5] M. Crowley et.al. 2-Phenylphenol and salts – Conventional Uses: Revised Occupational and Residential Exposure and Risk Assessment for the Reregistration Eligibility Decision (RED) Document. D328222. 4/10/2006.

a, b and c subcategory, the most conservative model (Commercial model Tier 1A-unrefined) is used to identify exposure and risk.

5. A newer version of DEEM has been used for direct dietary assessments (version 3.16), which uses food consumption data from the U.S. Department of Agriculture's (USDA's) National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA) from 2003-2008.
6. Currently, 4000 cm^2 is the default surface area assumption for commercial areas (food handling, *etc*.). A smaller surface of 2000 cm^2 was assumed as a suitable surface area for the commercial model in 2006.

2.10 Residential (Non-Dietary) Handler Exposure/Risk Characterization

There is the potential for residential handler exposure when using treated articles such as paints that are preserved with O-PP, when using surface disinfectants that contain O-PP as an a.i., or when using conventional insecticide products that also contain O-PP as a disinfectant. Inhalation exposures can be to O-PP as an aerosol in paints and spray solutions or to O-PP as a vapor in paints. No residential exposures are expected from the conventional uses of O-PP since it is only registered for post-harvest and is only applied inside a treatment facility.

2.10.1 Residential Handler Inhalation Exposure to O-PP Aerosols

The MOEs for residential handler exposures to O-PP aerosols were assessed as outlined in Table 19. The MOE of 400 for the airless spray application of preserved paint is of concern because it is less than the target MOE of 1000.

Table 19. Residential Handler Inhalation MOEs for O-PP Aerosols

Scenario	Application Rate[A]	Amount of Product Applied Day	Amount Ai Handled[E] (lb/day)	Unit Exposure (mg/m^3/lb ai)	Inhalation Exposure[I] (mg/m^3)	MOE[J] (LOC = 1000)
Antimicrobial Uses of Antimicrobial Products						
Airless Spray Application of Paint	5,700 ppm ai	150 lb of paint[B]	0.86	0.070[F]	0.060	400
Trigger spray & wipe	2,200 ppm ai (0.0184 lb ai/ga)	0.06 gallon[C]	0.0011	3.1[G]	0.0034	7,100
Aerosol Can Application	0.199% ai	1 16.5 oz can	0.0021	7.5[H]	0.016	1,500
Antimicrobial Uses of a Conventional Product (EPA Reg. No. 92564-37)						
Trigger Pump Spray Crack and Crevice Treatment	0.3% ai (0.025 lb ai/ga)	0.094 gallon[D]	0.0024	3.1[G]	0.0074	3,200

A. The application rates are the maximum rates from the labels.
B. Assuming 15 gallons of paint are used as listed in US EPA, 2012a. Paint density is 10 lbs per gallon.
C. AEJV (MRID 46799302).
D. Assuming that one half of a container is used as listed in US EPA, 2012a. The container contains 24 ounces.
E. Amount of AI Handled (lb/day) = Application Rate x Amount Product Applied or Treated.
F. Unit exposure of 560 ug/lb for the Applicator, Airless Sprayer scenario converted to an 8-hour TWA.
G. Trigger spray and wipe unit exposure from the AEATF II human exposure wipe study (MRID 48375601).
H. AEATF II human exposure aerosol study (MRID 48659001).
I. Inhalation Exposure (mg/m^3) = Amount Ai Handled (lb/day) * Unit Exposure (mg/m^3/lb ai)
J. MOE = HEC (24 mg/m^3) / Inhalation Exposure (mg/m^3)

2.10.2 Residential Handler Inhalation Exposure to O-PP Paint Vapors

O-PP is registered for use in paints with an application rate of 5,700 ppm ai. The exposure duration is assumed to be short term because painting is done on an episodic basis. Inhalation exposures to O-PP vapors from O-PP preserved paint were assessed using the EPA's Wall Paint Exposure Model (WPEM). WPEM was developed under a contract by Geomet Technologies for EPA OPPT to provide estimates of potential air concentrations and consumer/worker exposures to chemicals emitted from wall paint which is applied using a roller or a brush. WPEM uses mathematical models developed from small chamber data to estimate the emissions of chemicals from oil-based (alkyd) and latex wall paint. The emission data can then be combined with detailed use, workload and occupancy data (*e.g.*, amount of time spent in the painted room, *etc.*) to estimate exposure. Specific input parameters include: the type of paint (latex or alkyd) being assessed, density of the paint (default values available), and the chemical weight fraction, molecular weight, and vapor pressure. Detailed information and the executable model can be downloaded from http://www.epa.gov/opptintr/exposure/docs/wpem.htm.

For this exposure assessment, the WPEM default scenario for the homeowner painter (RESDIY) was used. This WPEM default scenario assumes that the homeowner is exposed to the chemical in paint when painting the bedroom of a house (Zone 1) and in adjacent rooms (Zone 2) after painting. This default scenario includes 3 hours of painting in Zone 1, 15 hours in Zone 2 and 6 hours outside of the house. The following chemical specific inputs and WPEM default assumptions were used in the model:

Chemical Specific Inputs

- The molecular weight of O-PP is 170.2 grams/mole (Table 1) and the vapor pressure is 0.002 mm Hg at 25 ºC (Table 2).
- The weight fraction is 0.0057 based on the application rate of 0.57 %.

WPEM Default Assumptions from the RESDIY Scenario

- The air exchange rate is 0.45 air changes per hour which is the median value from the Exposure Factors Handbook (US EPA, 1997).
- The painting is done in a house that has an internal volume of 15,583 ft^3 which is the mean value from the Exposure Factors Handbook (US EPA, 1997).

- The walls of one bedroom are painted and the painted surface area is 452 ft^2.
- One coat of paint which has a coverage of 400ft^2/gallon is applied.
- The paint is latex flat with a density of 4600 grams/gallon.
- The adult occupant is in the house being painted, but not in the painted area.
- The duration of painting is 3.42 hours and 1.13 gallons of paint are applied.

The WPEM model was set to run at one-minute intervals for 1 day (24 hours). To yield an average daily concentration that includes only the day of painting (for comparison to the HEC) the exposure frequency was set to 365 exposure events per year. The WPEM output is shown in Figure 1.

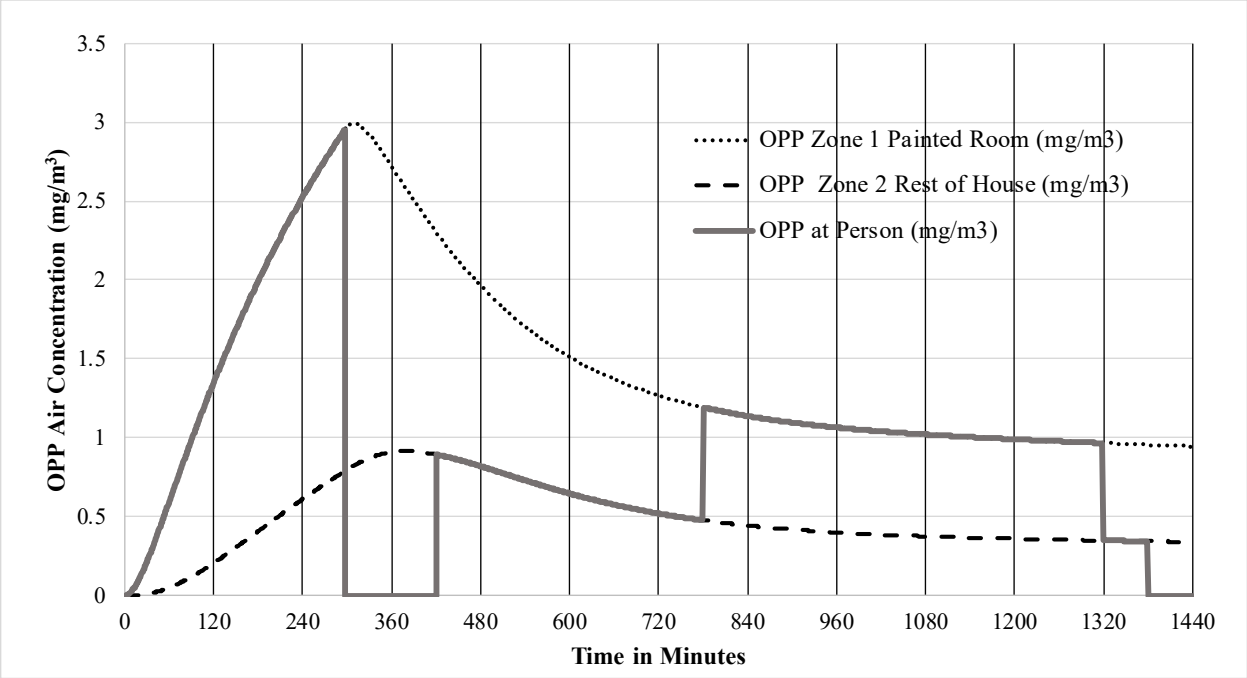


Figure 1 - Residential Painter Exposures to O-PP Vapors

The average daily concentration that corresponds to the "at person" line in Figure 1 was used to calculate the MOE as shown in Table 20. This MOE is of concern because it is less than the target MOE of 1000.

Table 20. Inhalation MOE for Residential Painters Exposed to O-PP Vapors

O-PP Vapor Pressure (mm Hg)	Weight Fraction	Time Spent Painting (hrs)	Painted Surface Area (ft^2)	Air Exchange Rate per hour	24-hour ADC[C] (mg/m^3)	MOE[D] (LOC = 1000)
0.002 @ 25C	0.0057 (5700 ppm)	3.42	452[A]	0.45[B]	0.895	9

A. Assuming the walls of one room are painted as specified in the RESDIY scenario of WPEM.
B. Default air exchange rate used in WPEM based on the Exposure Factors Handbook.
C. The 24-hour average daily air concentration (ADC) experienced by the residential painter on the day of painting.
D. MOE = 24 Hour HEC (8.1 mg/m^3) / 24 Hour ADC (mg/m^3)

2.10.3 Residential Handler Dermal Exposure

The MOEs for residential handler dermal exposures to O-PP were assessed as outlined in Table 21. The Surface Area of the hands (820 cm^2) is from OPPTS Guideline 875.1200 (US EPA, 1996). The MOE of 5.7 for the airless spray application of preserved paint is of concern because it is less than the target MOE of 10.

Table 21. Residential Handler Dermal MOEs

Scenario	Application Rate[A]	Amount of Product Applied per Day	Amount Ai Handled[D] (lb/day)	Unit Exposure (mg/lb ai)	Dermal Exposure[I] (mg/day)	Dermal Loading[J] (ug/cm^2)	MOE[K] (LOC = 10)
Antimicrobial Uses of Antimicrobial Products							
Airless Spray Application of Paint	5,700 ppm ai	150 lb of paint[B]	0.86	160[E]	138	124	1.6
Brush/Roller Application of Paint	5,700 ppm ai	20 lb of paint[B]	0.11	144[F]	15.8	14.6	14
Trigger spray & wipe	2200 ppm ai	0.06 gal[C]	0.0011	1740[G]	1.9	1.2	170
Aerosol Can Application	0.199% ai	One 16.5 oz can	0.0021	661[H]	1.4	0.38	530
Antimicrobial Uses of a Conventional Product (EPA Reg. No. 92564-37)							
Trigger Pump Spray Crack and Crevice Treatment	0.3% ai	0.094 gallon[B]	0.0024	1740[G]	4.2	2.6	77

A. The application rates are the maximum rates from the labels.
B. Standard Operating Procedures for Residential Pesticide Exposure Assessment (US EPA, 2012a)
C. AEJV (MRID 46799302).
D. Amount of AI Handled (lb/day) = Application Rate x Amount Product Applied or Treated.
E. Standard Operating Procedures for Residential Pesticide Exposure Assessment (US EPA, 2012a). Hands = 74%.
F. Short sleeve short pants value from the AEATF II brush/roller study (MRID 50521701). Hand exposure = 76%.
G. Trigger spray and wipe value from the AEATF II wipe study (MRID 48375601). Hand exposure = 50%.
H. Short sleeve short pants value from AEATF II aerosol study (MRID 48659001). Hand exposure = 22%.
I. Dermal Exposure (mg/day) = Amount Ai Handled (lb/day) * Unit Exposure (mg/m^3/lb ai)
J. Dermal Loading = [Dermal Exposure (mg/day) * Hand Exposure (%/100) * 1000 ug/mg]/Hand Area (820 cm^2)
K. MOE = POD (200 ug/cm^2) / Dermal Loading (ug/cm^2)

2.11 Residential Post-Application Exposure

2.11.1 Residential Post Application Exposures from O-PP Floor Applications

There is the potential for residential post-application incidental oral and dermal exposure to floor surfaces treated with floor cleaners preserved with O-PP antimicrobial end use products. The maximum application rate for the preservation of cleaners is 4,600 ppm, thus this rate is used to assess post application exposures.

Post Application Incidental Oral Exposure from O-PP Applied to Floors

Incidental oral exposures were assessed using the Post- application Hand-to-Mouth Exposure Algorithm from Section 7.2.3 of the Standard Operating Procedures for Residential Pesticide Exposure Assessment (US EPA, 2012a). This Algorithm includes the SHEDs Exponent term: $1 – (1\text{-SE})^{FHtM/NR}$, which is simplified to 0.962 by inputing the standard assumptions of 0.48 for saliva extraction efficiency (SE), 20 per hour for Frequency of Hand to Mouth Events (FHtM) and 4 per hour for Number of Hand Replenishments (NR). Because transferable residue data are not available for O-PP, the transfer factor was assumed to 1.0 for 100 percent residue transfer. As shown in Table 22, the incidental oral MOE from O-PP in floor cleaning products is 410. This MOE is not of concern because it is greater than the target MOE of 100.

Table 22. Incidental Oral MOE for O-PP Applied to Floors

Application[A] Rate (ppm ai)	Application Rate[B] (gm/gallon)	Surface Residue[C] (mg/cm^2)	Hand Residue[D] (mg/cm^2)	SHEDs Exponent Term[E]	Exposure[F] (mg/day)	Dose[G] (mg/kg/day)	Short/ Intermediate Term MOE[H]
4,100	15.5	0.0167	0.0167	0.962	2.51	0.220	450

A. Application Rate (ppm ai) = based on the recommended dosage of 2.3% for cleaning solutions listed on EPA Reg No. 39967-23 which contains 20% sodium o-phenylphenate.
B. Application Rate (gm/gallon) = Application Rate (ppm ai) * Cleaning Solution Density (8.35 lb/gallon) * 454 gm/lb
C. Surface Residue (SR) = Application Rate (gm/gal) * Coverage (1 gal/1000 sf) * (1 ft^2/929 cm^2) * 1000 mg/gm
D. Hand Residue (HR) = SR(mg/cm^2) * Transfer Factor (1.0)
E. SHEDs Exponent Term = $[1 – (1\text{-SE})^{FHtM/NR}]$, where SE = 0.48, FHtM = 20/hr and NR = 4/hr.
F. Exposure (mg/day) = HR(mg/cm^2) * F_M (0.13) * SA_H (150 cm^2) * ET (2 hrs) * NR (4/hr) * SHEDS Exponent Term
G. Dose (mg/kg/day) = Exposure (mg/day) / BW (11.4 kg child)
H. MOE = NOAEL (100 mg/kg/day) / Dose (mg/kg/day)

Post Application Dermal Exposure from O-PP Applied to Floors

Dermal exposures were assessed as shown in Table 23 by comparing the calculated dermal loading to the dermal POD of 200 ug/cm^2. The dermal MOE is 12 and is not of concern because it is greater than the target MOE of 10.

Table 23: Dermal MOE for O-PP Applied to Floors

Application Rate (ppm ai)	Application Rate[A] (gm/gallon)	Surface Residue[B] (mg/cm^2)	Transfer Factor	Dermal Loading[C] (ug/cm^2)	Dermal MOE[D] (LOC =10)
4100	15.5	0.0167	1.0	16.7	12

A. Application Rate (gm/gallon) = Application Rate (ppm ai) * Cleaning Solution Density (8.35 lb/gallon) * 454 gm/lb
B. Surface Residue (SR) = Application Rate (gm/gal) * Coverage (1 gal/1000 sf) * (1 ft^2/929 cm^2) * 1000 mg/gm
C. Dermal Loading (ug/cm2) = Surface Residue (mg/cm^2) * Transfer Factor * 1000 ug/mg

D. MOE = NOAEL (200 ug/cm^2) / Dermal Loading (ug/cm^2)

2.11.2 Residential Post Application Exposures from O-PP Carpet Applications

There is the potential for residential post-application incidental oral and dermal exposure to carpet surfaces treated with O-PP end use products to control odor causing bacteria. The exposure duration is anticipated to be short to intermediate term.

Post Application Incidental Oral Exposure from O-PP

These exposures were assessed using the Post- application Hand-to-Mouth Exposure Algorithm from Section 7.2.3 of the Standard Operating Procedures for Residential Pesticide Exposure Assessment (US EPA, 2012a). This Algorithm includes the SHEDs Exponent term: $1 – (1\text{-}SE)^{FHtM/NR}$, which is simplified to 0.962 by inputing the standard assumptions of 0.48 for saliva extraction efficiency (SE), 20 per hour for Frequency of Hand to Mouth Events (FHtM) and 4 per hour for Number of Hand Replenishments (NR). Because transferable residue data are not available for O-PP, the transfer factor was assumed to 1.0 for 100 percent residue transfer.

As shown in Table 24, the incidental oral MOE from O-PP in carpet treatment products is 320. This MOE is not of concern because it is greater than the target MOE of 100.

Table 24: Incidental Oral MOE for O-PP Applied to Carpets

Application Rate[A] (ppm ai)	Application Rate[B] (gm/gallon)	Surface Residue[C] (mg/cm^2)	Hand Residue[D] (mg/cm^2)	SHEDs Exponent Term[E]	Exposure[F] (mg/day)	Dose[G] (mg/kg/day)	Short/ Intermediate Term MOE[H]
2200	8.34	0.045	0.045	0.962	3.38	0.31	320

A. EPA Reg. No. 70385-3 which is a RTU product that contains 0.22% O-PP as a bacteriostat and deodorizing agent.
B. Application Rate (gm/gal) = Application Rate (ppm ai) * Density (8.35 lb/gallon) * 454 gm/lb
C. Surface Residue (SR) = Application Rate (gm/gal) * Coverage (1 gal/200 sf) * (1 ft^2/929 cm^2) * 1000 mg/gm
D. Hand Residue (HR) = SR(mg/cm^2) * Transfer Factor (1.0)
E. SHEDs Exponent Term = $[1 – (1\text{-}SE)^{FHtM/NR}]$, where SE = 0.48, FHtM = 20/hr and NR = 4/hr.
F. Exposure (mg/day) = HR(mg/cm^2) * F_M (0.13) * SA_H (150 cm^2) * ET (4 hrs) * NR (4/hr) * SHEDS Exponent Term
G. Dose (mg/kg/day) = Exposure (mg/day) / BW (11.4 kg child)
H. MOE = NOAEL (100 mg/kg/day) / Dose (mg/kg/day)

Post Application Dermal Exposure from O-PP Applied to Carpets

Dermal exposures were assessed as shown in Table 25 by comparing the calculated hand residue to the dermal POD of 200 ug/cm^2. Since transferable residue data are not available for O-PP applied to carpets, the transfer factor was assumed to be one for 100% transfer. The dermal MOE is 4.4 and is of concern because it is less than the target MOE of 10. In order for the dermal MOE to be 10, the transfer factor would need to be 0.45 for 45% transfer.

Table 25: Dermal MOE for O-PP Applied to Carpets

Application Rate[A] (ppm ai)	Application Rate[B] (gm/gallon)	Surface Residue[C] (mg/cm^2)	Transfer Factor	Dermal Loading[D] (ug/cm^2)	Dermal MOE[E] (LOC = 10)
2200	8.34	0.045	1.0	45	4.4

A. EPA Reg. No. 70385-3 which is a RTU product that contains 0.22% O-PP
B. Application Rate (gm/gal) = Application Rate (ppm ai) * Density (8.35 lb/gallon) * 454 gm/lb
C. Surface Residue (SR) = Application Rate (gm/gal) * Coverage (1 gal/200 sf) * (1 ft^2/929 cm^2) * 1000 mg/gm
D. Dermal Loading (ug/cm^2) = Surface Residues (mg/cm^2) * Transfer Factor * 1000 ug/mg
E. MOE = NOAEL (200 ug/cm^2) / Dermal Loading (ug/cm^2)

2.11.3 Residential Post Application Exposures from O-PP Preserved Plastics

Plastics and polymers can be treated with O-PP during production as a material preservative for the control of fungi and bacteria. These plastics and polymers can be subsequently used to manufacture toys. Therefore, unless the label specifically prohibits use in plastics and polymers used to manufacture toys, it is assumed children's post-application incidental oral exposures to treated toys may occur. It is assumed that not all plastic toys are treated with O-PP and the toys that are treated will not be used every day, therefore, exposure would occur intermittently. Thus, only short-term exposures durations were assessed. Children (1 to < 2 years old) are the index lifestage for this scenario.

The following equations are used to calculate the surface residue (SR), object residue (OR), and exposure (Exp):

$$SR = \frac{WF \times W \times CF \times F}{SA1}$$

Where:
- SR = Surface residue ($mg\ ai/cm^2$)
- WF = Weight fraction of ai in toy (% ai/100)
- W = Weight of toy (g)
- CF = Conversion factor (1,000 mg/g)
- AF = Fraction additive available at the surface of the toy (%/100)
- SA1 = Surface area of toy (cm^2)

$OR = SR * F_H$ $OR = SR * F_H$ Where: $OR = SR * F_H$ Where:
- OR = Object Residue Loading (mg/cm^2)
- SR = Surface Residue (mg/cm^2)
- F_O = Fraction available for transfer

$$Exp = OR * SAM * ET * NR * [1 - (1-SE)^{FOtM / NR}]$$

Where:
- Exp = Exposure (mg/day)
- OR = Object Residue (mg/cm^2)
- SAM = Surface area mouthed (cm^2)
- ET = Exposure time (hours/day)
- NR = Number of replenishment intervals per hour
- SE = Saliva extraction efficiency (%/100)
- FOtM = Number of object-to-mouth contacts per hour

The following assumptions are for the calculation of the surface residue (SR) and object residue (OR) values.

- WF: The weight fraction is 0.005 based on the application rate of 5000 ppm a.i.
- W: The weight of a 500 cm^2 toy is 50 grams, which is based on data showing that a polyethylene highchair sample has a density of 0.10 grams/cm^2 (AD standard assumption).
- AF: 0.5% of the O-PP impregnated within the plastic matrix is available at the surface of the toy which is subsequently available for human exposure (AD standard assumption).
- SA1: 500 cm^2 is a representative surface area of a plastic toy (AD standard assumption).

The following assumptions are for the use of the SHEDs model to calculate the exposure using the HR value calculated above. The SHEDs model assumptions are the recommended values from Table 9-7 of US EPA, 2012a.

- SAM: The surface area mouthed per event is 10 cm^2.
- NR: The number of replenishment intervals per hour is 4.
- ET: The exposure time is 4 hours/day for mouthing objects indoors.
- SE: The saliva extraction fraction is 0.48.
- FOtM: The number of object-to-mouth contacts per hour is 14.
- BW: The body weight is 11 kg for children 1 <2 years old.

Treated Toys Risk Summary

The MOE for incidental oral exposure to O-PP in plastic toys is summarized in Table 26. The MOE is 2,800 and the risk is not of concern.

Table 26: Incidental Oral MOE for O-PP in Plastic Toys

Weight Fraction	Surface Residue[A] (mg/cm^2)	Object Residue[B] (mg/cm^2)	SHEDs Term[C]	Exposure[D] (mg/day)	Dose[E] (mg/kg/day)	Incidental Oral MOE[F] (LOC = 100)
0.005	0.0025	0.0025	0.99	0.40	0.036	2,800

A. Surface Residue (SR) = $\frac{\text{WF (0.005)} * \text{Toy Weight (50 grams)} * 1000 \text{ mg/gm} * \text{Availability Factor (0.5/100)}}{\text{Toy Surface Area (500 cm}^2\text{)}}$

B. Object Residue (OR) = SR (mg/cm^2) * Transfer Factor (1.0)

C. SHEDs Term = $\{1 - [(1\text{-SE})^{FOtM/NR}]\}$ where SE = 0.48, FOtM = 14/hr and NR = 4

D. Exposure = Object Residue (mg/cm^2) * SAM (10 cm^2) * ET (4 hr) * NR (4/hr) * SHEDs Term

E. Dose = Exposure (mg/day) / BW (11 kg)

F. MOE = NOAEL / Dose where the NOAEL is 100 mg/kg/day and the target MOE is 100.

2.11.4 Residential Post Application Exposures from O-PP Preserved Textiles

There is the potential for residential post-application incidental oral and dermal exposure to household items and clothing manufactured from cotton textiles preserved with O-PP to prevent the growth of bacteria or fungi. The exposure duration is anticipated to be short- to intermediate-term.

Incidental Oral Exposures to Textiles

Incidental oral exposures were calculated using the following:

Incidental Oral Exposure = Amount of O-PP in Textile × Cloth Density × Surface Area Mouthed × Saliva Extraction Efficiency

Where:

- The application rates are 2,600 ppm ai and 17,000 ppm ai.
- The cloth density is 20 mg/cm^2 based on the density of cotton. This value is a standard assumption used in Office of Pesticide Programs risk assessments and was taken from the HERA Guidance Document Methodology (AISE/CEFIC, 2005)
- The surface area of fabric that is mouthed by a toddler per day is assumed to be 100 cm^2 (~16 in^2), which represents an estimate, for example, of the area of blanket or shirt sleeve.
- The saliva extraction efficiencies for mouthing fabric is 48% which is a standard assumption in the Residential SOPs (US EPA, 2012a).
- The body weight of a child is 11.4 kg between 1 and <2 years (U.S. EPA, 2012a).

Incidental Oral MOEs for Treated Textiles

The MOEs for incidental oral exposure to O-PP in textiles are summarized in Table 27. The MOEs are 430 for textiles treated at the low rate of 2,600 ppm and 71 for textiles treated at the high rate of 17,000 ppm. The MOE of 71 is of concern because it is less than the target MOE of 100.

Table 27: Incidental Oral MOEs for Textiles Incorporating O-PP

Application Rate (ppm)	Cloth Density (mg/cm^2)	O-PP Surface Residue (mg/cm^2)	Surface Area Mouthed (cm^2/day)	Saliva Extraction Efficiency	Exposure[A] (mg/day)	Dose[B] (mg/kg/day)	MOE[C] (LOC = 100)
2,600	20	0.052	100	48%	2.5	0.23	430
17,000		0.34			16.3	1.4	71

A. Exposure = Surface Residues × Surface Area Mouthed × Saliva Extraction Efficiency
B. Dose = Exposure (mg/day) / Body Weight (11.4 kg)
C. MOE = POD (100 mg/kg/day) / Daily Dose (mg/kg/day)

Post Application Dermal Exposure from O-PP Applied to Textiles

Dermal exposures were assessed as shown in Table 28 by comparing the calculated dermal loading to the dermal POD of 200 ug/cm^2. Since transferable residue data are not available for O-PP treated textiles, the transfer factor was assumed to be one for 100% transfer. The dermal MOEs are less than 10 at both application rates and are of concern. In order for the dermal MOEs to be 10, the transfer factor would need to be 0.38 at the low application rate (2600 ppm) and 0.06 at the high application rate (17,000 ppm).

Table 28: Dermal MOEs for Textiles Incorporating O-PP

Application Rate (ppm)	Cloth Density (mg/cm^2)	Surface Residues[A] (mg/cm^2)	Transfer Factor	Dermal Loading[B] (ug/cm^2)	MOE[C] (LOC = 10)
2,600	20	0.052	1.0	52	4

Application Rate (ppm)	Cloth Density (mg/cm^2)	Surface Residues[A] (mg/cm^2)	Transfer Factor	Dermal Loading[B] (ug/cm^2)	MOE[C] (LOC = 10)
17,000		0.34		340	0.6

A. Surface Residues (mg/cm^2) = Application Rate (ppm/1000000) * Cloth Density (mg/cm^2)
B. Dermal Loading (ug/cm^2) = Surface Residues (mg/cm^2) * Transfer Factor (1.0) * 1000 ug/cm^2
C. MOE = [POD (200 ug/cm^2) / Dermal Loading (ug/cm^2)

2.11.5 Residential Post Application Exposures from Total Release Fogger Applications

There is a product (EPA Reg Nos. 44446-67) that is used for fogging rooms greater than 5 ft by 5 ft as an adjunct or supplement to normal cleaning and disinfection procedures and practices. The label indicates that one unit should be used for each 6000 cubic feet of unobstructed area according to the following use directions:

"Place several layers of newspaper or pad on a stand or table in the center of room. To lock fogger valve in open position for automatic discharge, press valve button all the way down hooking in catch. Then place fogger on the stand or table. Leave room or building and keep room/building closed for two hours before airing out. Open all doors and windows and allow to air for five hours".

Calculation of Air Concentrations

The air concentrations after application were calculated using the following single chamber ventilation formula that is included in the EPA Multi- Chamber Concentration and Exposure Model (MCCEM):

$$C_T = C_0 * 0.5 [(T/0.693) * (Q/V)]$$

Where:
C_T = Air concentration at time T
C_0 = Air Concentration at time zero
Q = Ventilation rate in cubic meters per minute (CMM)
T = Elapsed time in minutes
V = Volume of room in cubic meters

Assumptions

The following assumptions were used in the above formula:

- The air concentration at time zero is based the six-ounce size of product EPA Reg No. 44446-67 which is a typical size for total release fogger products. All though this product is also sold in a 16.5-ounce container, it is assumed that this container is not used for total release fogging applications.

- The room volume is 6000 cubic feet (170 m^3) based on the label use directions.
- The ventilation rate is zero during the two-hour treatment period and 0.45 air changes per hour (ACH) during the airing out period.

The estimated air concentrations for O-PP at time zero immediate after application, after the 5-hour airing out period and as a 24-hour time weighted average (TWA) for a resident who is in the treated space for 24 hours after the airing out period is summarized in Table 29. The MOE based on these air concentrations is 430 which is of concern because it is less than target MOE of 1000.

Table 29: O-PP Total Release Fogging Applications Post Application Inhalation MOEs

Time Zero Air Concentration (mg/m^3)	Ventilation Rate[A] (ACH)	300 Minute Air Concentration (mg/m^3)	24 hr TWA[B] (mg/m^3)	MOE[C] (LOC =1000)
2.0	0.45	0.465	0.019	430

A. ACH = Air Changes per Hour
B. 24 hr TWA = Average Air concentration for the 24-hour period starting after the 300 Minute REI.
C. MOE = HEC (8.1 mg/m^3) / 24 Hour TWA (mg/m^3)

2.11.6 Residential Post Application Exposures from X-580 Fogger Applications

The product X-580 Spray Plus (EPA Reg No. 70385-3) which contains insecticides and O-PP is used for fogging applications as an insecticide and as a bacteriostat and deodorizing agent. The label indicates that the product should be applied using a cold or ultra-low volume (ULV) fogging equipment. The label does not specify an application rate but it does say to apply adequate amounts of product so that the treated surfaces remain wet for ten minutes and that application via ULV or micromist foggers would require the device to be placed on the heaviest setting.

The label indicates that three air exchanges of ventilation or air scrubbing must be completed prior to re-occupancy.

Calculation of Air Concentrations

The air concentrations after application were calculated using the same ventilation formula that is used above for the total release fogger scenario.

The following assumptions were used in the ventilation formula:

- The air concentration at time zero is based on the application of 64 ounces of fogging solution per 1000 cubic feet as specified on the other O-PP product (EPA Reg No. 1043-91) that is applied using fogging equipment.

- The room volume is 1000 cubic feet (28.3 m^3) based on the label use directions.
- The ventilation rate is 0.45 air changes per hour (ACH).
- The reentry time is 6.66 hours (400 minutes) based on the requirement for three air exchanges and the air exchange rate of 0.45 ACH.

The estimated air concentrations for O-PP at time zero immediate after application, after the 400-minute reentry period and as a 24-hour time weighted average (TWA) for a resident who is in the treated space for 24 hours after the reentry period are summarized in Table 30. The MOE based on these air concentrations is 11 which is of concern because it is less than the target MOE of 1000.

Table 30: O-PP X-580 Fogging Applications Post Application Inhalation MOEs

Time Zero Air Concentration (mg/m^3)	Ventilation Rate[A] (ACH)	400 Minute Air Concentration (mg/m^3)	24-hr TWA[B] (mg/m^3)	MOE[C] (LOC =1000)
147	0.45	7.57	0.71	11

A. ACH = Air Changes per Hour
B. 24 hr TWA = Average Air concentration for the 24-hour period starting after the 400 Minute REI.
C. MOE = HEC (8.1 mg/m^3) / 24 Hour TWA (mg/m^3)

2.12 Aggregate Exposure/Risk Characterization

As established by the Food Quality Protection Act (FQPA), in order for a pesticide registration to continue, it must be shown "that there is 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 is the total exposure to a single chemical (or its residues) that may occur from dietary (*i.e.*, food and drinking water), residential, and other non-occupational sources, and from all known or plausible exposure routes (oral, dermal, and inhalation).

In performing aggregate exposure and risk assessments, the Office of Pesticide Programs has published guidance outlining the necessary steps to perform such assessments (General Principles for Performing Aggregate Exposure and Risk Assessments, November 28, 2001; available at https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/general-principles-performing-aggregate-exposure-and-risk-assessments.htm. Steps for deciding whether to perform aggregate exposure and risk assessments are listed, which include: identification of toxicological endpoints for each exposure route and duration; identification of potential exposures for each pathway (food, water, and/or residential); reconciliation of durations and pathways of exposure with durations and pathways of health effects; determination of which possible residential exposure scenarios are likely to occur together within a given time frame; determination of magnitude and duration of exposure for all exposure combinations; determination of the appropriate technique (deterministic or probabilistic) for exposure assessment; and determination of the appropriate risk metric to estimate aggregate risk.

2.12.1 Acute Dietary Aggregate Risk

An acute dietary endpoint for O-PP was not selected; there was no adverse systemic effect identified in the database from a single exposure. As there is no acute dietary endpoint selected for O-PP and drinking water exposure is not of concern, an acute aggregate dietary assessment was not needed.

2.12.2 Short- and Intermediate-Term Aggregate Risk

Short- and intermediate-term aggregate oral exposures and risks were assessed for children that could be exposed to O-PP residues from the use of products in non-occupational environments. Short- and intermediate-term aggregate risks for children includes average dietary exposures to O-PP and incidental oral exposures from application of O-PP products to floors and carpets as well as incidental oral exposure from O-PP incorporation into plastic toys and textiles. The average dietary exposure for children 1-2 years of age includes co-occurrences of dietary exposure as shown in Table 18 of this assessment. Aggregate oral risk was calculated for this subpopulation, as they are the highest exposed subpopulation. The point of departure for assessing dietary and incidental oral risk is based on systemic effects from a two-generation reproduction toxicity study with a No Observed Adverse Effect Level (NOAEL) of 100 mg/kg/day and a total uncertainty factor of 100.

Short- and intermediate-term dermal aggregate risks were assessed for children from dermal exposures to O-PP from use on carpets and floors. The short-term dermal toxicity point of departure (NOAEL of 100 mg/kg/day from a 21-day dermal toxicity study) was based on skin irritation. A total uncertainty factor of 10 is used for the dermal risk assessment.

Inhalation exposures to O-PP from use in paint are not aggregated, as it is presumed that there is not simultaneous exposure to aerosols and vapors based on the application methods. Aggregate risk for oral exposure is assessed using the 'Total MOE' method as discussed in the Agency's publication "General Principles for Performing Aggregate Exposure and Risk Assessments" (U.S. EPA, 2001). This method is used as the acceptable (target) MOEs are the same for oral exposure and are based on the same study and toxicological effects. Similarly, aggregate risk for dermal exposure is also assessed using the Total MOE method, as the dermal endpoint and uncertainty factor is the same for all dermal exposure scenarios.

For short- and intermediate-term aggregate risk, the incidental oral exposure of children from floors and carpets treated with O-PP containing products, from plastic toys into which O-PP is incorporated as a materials preservative, and from textiles into which O-PP is incorporated was combined with average dietary exposures. It can be assumed that these incidental oral exposures could co-occur; thus, these exposures are included in the aggregate assessment. However, this

analysis also shows the effect on the aggregate risk if individual exposures are removed from the calculation.

Using the calculated MOEs in this risk assessment for children's incidental oral exposures from treated floors (MOE = 450), treated carpet (MOE = 320), textiles (MOE = 430), and plastic toys (MOE = 2800) in combination with the calculated MOE from dietary exposures (MOE = 100), the aggregate MOE for oral risk is illustrated in Table 31. Since the dietary exposure from the uses which were likely to co-occur fills the risk cup, aggregating with any additional use results in MOEs which are below the target MOEs as shown below in Table 31.

Table 31: Estimates of Aggregate Risk in Children from Oral Exposures to O-PP

Exposure Scenario	**Exposure (mg/kg/day)**	**Margin of Exposure (MOE)**	**Aggregate MOE** dietary plus individual exposure
Average Dietary Exposure	0.979	100	NA
Incidental Oral Exposure - flooring	0.22	450	83
Incidental Oral Exposure - carpet	0.31	320	78
Incidental Oral Exposure - textiles	0.23 (2600 ppm application rate)	430	83
Incidental Oral Exposure – plastic toys	0.036	2800	99

B. Aggregate MOE = POD (100 mg/kg/day) / Dietary Exposure (mg/kg/day) plus individual exposure (mg/kg/day)

There are a number of conservative assumptions made with respect to dietary exposures that contribute to the aggregate risk, including the assumption of 100% transfer of residue from indirect dietary uses of O-PP. It is likely that residue transfer is less than 100%, but the Agency has no residue transfer data with which to derive an actual percentage transfer. Also, the paper coating use of O-PP makes conservative assumptions of exposure. Thus, it is possible that the aggregate oral MOE is greater than 100.

Aggregate dermal risk from exposure to treated flooring, carpet, and textiles for children would be acceptable (*i.e.*, aggregate dermal MOE =10), if the assumption of percent transfer from textiles to skin as noted in Table 27 of this risk assessment is correct. If transfer is higher, then the aggregate dermal MOE would be less than 10 and would be of concern.

2.12.3 Chronic Dietary Aggregate Risk

Chronic dietary aggregate risk assessment includes exposures from direct food, indirect food, conventional uses, residential and drinking water potential as well as non-pesticidal uses of a pesticide chemical. Aggregate assessments also consider non-occupational exposures.

A chronic dietary endpoint was identified in the toxicology database and has been used for this chronic dietary risk assessment. Chronic aggregate exposure and risk was assessed from the direct food, indirect food, and inert uses for O-PP. There are no other chronic oral scenarios for inclusion in the chronic dietary assessment. The resulting calculations are shown in Table 18 of this risk assessment. All of the calculated exposures are below 100% of the cPAD for O-PP and are thus not of concern.

2.12.4 Cancer Aggregate Risk

The Reference Dose value selected for O-PP was determined to be protective of carcinogenicity, as exposures to O-PP are not likely to exceed those that contribute to the mode of action for carcinogenicity of the chemical and the Reference Dose value selected is lower than the exposures associated with the carcinogenic mode of action. As the current Reference Dose value is protective of carcinogenicity, cancer aggregate risk has been addressed in the chronic aggregate risk assessment for O-PP.

2.13 Cumulative Exposure/Risk Characterization

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to O-PP and any other substances and O-PP does not appear to produce a toxic metabolite produced by other substances. For the purposes of this action, therefore, EPA has not assumed that O-PP has a common mechanism of toxicity with other substances. In 2016, EPA's Office of Pesticide Programs released a guidance document entitled, *Pesticide Cumulative Risk Assessment: Framework for Screening Analysis* [https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/pesticide-cumulative-risk-assessment-framework]. This document provides guidance on how to screen groups of pesticides for cumulative evaluation using a two-step approach beginning with the evaluation of available toxicological information and if necessary, followed by a risk-based screening approach. This framework supplements the existing guidance documents for establishing common mechanism groups (CMGs)[6] and conducting cumulative risk assessments (CRA)[7].

2.14 Antimicrobial Uses Occupational Handler Exposure/Risk Characterization

There is the potential for occupational handler exposure when O-PP is used to preserve materials such as paints, when O-PP is used as a surface disinfectant or when O-PP is used for sapstain control. There is also the potential for occupational handler exposure when using treated articles, such as paints, that are preserved with O-PP. Inhalation exposures can be to O-PP as an aerosol

[6] *Guidance For Identifying Pesticide Chemicals and Other Substances that have a Common Mechanism of Toxicity* (USEPA, 1999)
[7] *Guidance on Cumulative Risk Assessment of Pesticide Chemicals That Have a Common Mechanism of Toxicity* (USEPA, 2002)

from spray applications of disinfectants and paints or to O-PP as a vapor from brush/roller applications of paints.

2.14.1 Occupational Handler Inhalation Exposures to O-PP Aerosols

The MOEs for occupational handler inhalation exposures to O-PP aerosols were assessed as outlined in Table 32. Several MOEs are of concern because they are less than 1000.

Table 32: Antimicrobial Uses Occupational Handler Inhalation Exposures to O-PP Aerosols

Scenario	Application Rate[A]	Amount of Product Applied or Material Treated per Day[B]	Amount Ai Handled (lb/day)[C]	Unit Exposure (mg/m^3/lb ai)	Inhalation Exposure[L] (mg/m^3)	MOE[M] (LOC = 1000)
Material Preservation Uses						
Open Pour Powders for Textile Preservation	5.6% ai	10,000 lbs of textiles	560	0.028[D]	15.7	1.5
Open Pour Powders for Paint Preservation	5,700 ppm ai	20,000 lbs of paint	114	0.028[D]	3.2	7.3
Open Pour Liquids for Textile Preservation	5.6% ai	10,000 lbs of textiles	560	0.00021[E]	0.12	200
Open Pour Liquids for Paint Preservation	5,700 ppm ai	20,000 lbs of paint	114	0.00021[E]	0.024	1,000
Airless Spray Application of Paint	5,700 ppm ai	500 lb of paint	2.85	0.070[F]	0.20	120
Hard Surface Uses						
Hand Held Fogger	0.22% (0.0184 lb ai/ga)	5 gal	0.092	1.1[G]	0.10	240
Spray & wipe	2200 ppm ai	0.414 gal	0.0076	3.1[H]	0.024	1,000
Low Pressure Handwand	2200 ppm ai	5 gal	0.092	0.017[I]	0.0015	16,000
High Pressure Handwand	2200 ppm ai	40 gal	0.736	0.019[J]	0.014	1,700
Air Deodorizer Uses						
Aerosol Can Application	0.199% ai	3 x 16.5 oz cans	0.0062	7.5[K]	0.047	510

A. The application rates are the maximum rates from the labels.
B. Standard assumptions used for occupational exposure assessments of AD chemicals.
C. Amount of AI Handled (lb/day) = Application Rate x Amount Product Applied or Treated.
D. Occupational powder unit exposure from the AEATF II human exposure solid pour study (MRID 49905201).
E. Conventional pour unit exposure from AEATF II human exposure liquid pour study (MRID 48917401).
F. Unit exposure of 560 ug/lb for the Applicator, Airless Sprayer scenario converted to an 8-hour TWA.
G. Unit exposure of 8916 ug/lb ai from the fogger exposure study (MRID 49602401) converted to an 8-hour TWA
H. Trigger spray and wipe unit exposure from the AEATF II human exposure wipe study (MRID 48375601).
I. Unit exposure of 140 ug/lb ai from the AHETF Greenhouse Backpack Sprayer Study converted to an 8-hour TWA
J. Unit exposure of 262 ug/lb ai for PHED Scenario #35 (HP Handwand, MLAP Liquids) converted to an 8-hour TWA.
K. AEATF II human exposure aerosol study (MRID 48659001).
L. Inhalation Exposure (mg/m^3) = Amount Ai Handled (lb/day) * Unit Exposure (mg/m^3/lb ai)
M. MOE = HEC (24 mg/m^3) / Inhalation Exposure (mg/m^3)

2.14.2 Occupational Handler Dermal Exposures

The MOEs for occupational handler dermal exposures to O-PP aerosols were assessed as outlined in Table 33. Several MOEs are of concern because they are less than 10.

Table 33: Antimicrobial Uses Occupational Handler Dermal MOEs

Scenario	Application Rate[A]	Amount of Product Applied or Material Treated per Day[B]	Amount Ai Handled (lb/day)[C]	Unit Exposure (mg/lb ai)	Dermal Exposure[M] (mg/day)	Dermal Loading[N] (ug/cm^2)	MOE[O] (LOC = 10)
Material Preservation Uses							
Open Pour Powders for Textile Preservation	5.6% ai	10,000 lbs of textiles	560	0.226[D]	127	53	3.8
Open Pour Powders for Paint Preservation	5,700 ppm ai	20,000 lbs of paint	114	0.226[D]	25.8	10.9	18
Open Pour Liquids for Textile Preservation	5.6% ai	10,000 lbs of textiles	560	10[E]	5,600	6,800	0.03
Open Pour Liquids for Paint Preservation	5,700 ppm ai	20,000 lbs of paint	114	10[E]	1,140	1,400	0.14
Airless Spray Application of Paint	5,700 ppm ai	500 lb of paint	2.85	42.6[F]	121	115	1.7
Brush/Roller Application of Paint	5700 ppm ai	50 lb of paint	0.285	115[G]	32.8	37.6	5.3
Hard Surface Uses							
Hand Held Fogger	0.22%	5 gal	0.092	None[H]	N/A	N/A	N/A
Spray & wipe	2200 ppm ai	0.414 gal	0.0076	1050[I]	7.98	9.0	22
Low Pressure Handwand	2200 ppm ai	5 gal	0.092	13.2[J]	1.2	0.047	4,300
High Pressure Handwand	2200 ppm ai	40 gal	0.736	2.5[K]	1.8	0.099	2,000
Air Deodorizer Uses							
Aerosol Can Application	0.199% ai	3 x 16.5 oz cans	0.0062	248[L]	1.5	1.1	180

A. The application rates are the maximum rates from the labels.
B. Standard assumptions used for occupational exposure assessments of AD chemicals.
C. Amount of AI Handled (lb/day) = Application Rate x Amount Product Applied or Treated.
D. Occupational powder value from the AEATF II human exposure solid pour study (MRID 49905201). Hands = 35%.
E. Conventional pour value from AEATF II human exposure liquid pour study (MRID 48917401). Hands = 99%.
F. Long sleeves, long pants, no gloves unit exposure from US EPA, 2018. Hands = 78%.
G. Long sleeve long pants value from the AEATF II brush/roller study (MRID 50521701). Hand exposure = 94%.
H. No data are available. The fogger exposure study (MRID 49602401) only measured inhalation exposures.
I. Trigger spray and wipe value from the AEATF II human exposure wipe study (MRID 48375601). Hands = 92%.
J. Unit exposure is for AHETF Greenhouse Backpack Sprayer Study (MRID 42623202). Hands = 3.2%
K. Unit exposure is for PHED Scenario #35 (HP Handwand, MLAP Liquids, Single Layer Gloves). Hands = 4.5%
L. Long sleeve long pants value from AEATF II aerosol study (MRID 48659001). Hand exposure = 58%.
M. Dermal Exposure (mg/day) = Amount Ai Handled (lb/day) * Unit Exposure (mg/m^3/lb ai)
N. Dermal Loading = [Dermal Exposure (mg/day) * Hand Exposure (%/100) * 1000 ug/mg] / Hand Area (820 cm^2)
O. MOE = POD (200 ug/cm^2) / Dermal Loading (ug/cm^2)

2.14.3 Sapstain Control Worker Inhalation Exposures

The MOEs for sapstain control worker inhalation exposures to O-PP aerosols were assessed as outlined in Table 34. The MOE of 48 for the cleanup crew is of concern because is less than 1000. The remaining MOEs, which range from 1000 to 1700, are not of concern.

Table 34: Sapstain Control Worker Inhalation MOEs for O-PP

Application Rate	Job Function	Unit Exposure[B] (mg/m^3/% ai)	Exposure[C] (mg/m^3)	Inhalation MOE[D] (LOC = 1000)
4.52 percent O-PP in the Treatment Solution[A]	Dip Tank Operator	0.0052	0.023	1000
	Millwright	0.0031	0.014	1700
	Chemical Attendant	0.0043	0.019	1300
	Clean-up Crew	0.111	0.50	48

A. Based on label 67869-24 which contains 20% ai.
B. Unit exposures are from the Sapstain Phase III study (MRID 455243-01).
C. Exposure (mg/m_3) = Application Rate (% ai) * Unit Exposure (mg/m^3/% ai)
D. Inhalation MOE = HEC (24 mg/m^3) / Exposure (mg/m^3)

2.14.4 Sapstain Control Worker Dermal Exposures

The MOEs for sapstain control worker dermal exposures were assessed as outlined in Table 35. The MOEs of 3 for the chemical attendants and 1 for the cleanup crew are of concern because they are less than 10. The remaining MOEs of 10 and 13 are not of concern.

Table 35: Sapstain Control Worker Dermal MOEs

Application Rate	Job Function	Unit Exposure[B] (mg/day/% ai)	Dermal Exposure[C] (mg/day)	Percent Hand Exposure[B]	Dermal Loading[D] (ug/cm^2)	Dermal MOE[E] (LOC =10)
4.52 percent O-PP in the Treatment Solution[A]	Dip Tank Operator	2.99	13.5	91	15	13
	Millwright	7.10	32.1	51	20	10
	Chemical Attendant	17.1	77.3	71	67	3.0
	Clean-up Crew	72.4	327.2	52	207	1.0

A. Based on label 67869-24 which contains 20% ai.
B. Unit exposures are from the Sapstain Phase III study (MRID 455243-01).
C. Dermal Exposure (mg/day) = Application Rate (% ai) * Unit Exposure (mg/day/% ai)
D. Dermal Loading (ug/cm^2) = [Dermal Exposure (mg/day) * Hand Exposure (%/100) * 1000 ug/mg] / Hand Surface Area (820 cm^2)
E. Dermal MOE = POD (200 ug/cm^2) / Dermal Loading (ug/cm^2)

2.14.5 Occupational Machinist Exposures to O-PP in Metal Working Fluids

O-PP is registered for use in metal working fluids, therefore there is the potential for machinists to be exposed when using treated MWFs. Both dermal and inhalation exposures are anticipated. The application rates range from 500 to 15000 ppm depending upon the product. EPA Reg No.

464-126 lists an application rate of 1000 to 15000 ppm and EPA Reg no. 39967-11 lists an application rate of 500 to 3000 ppm.

Inhalation Exposures

The inhalation MOE of 1,600 was calculated as outlined in Table 36 and is not of concern because it is greater than the LOC of 1000.

Table 36. Inhalation MOE for Machinists Using O-PP Treated MWF

Application Rate[A]	MWF Air Concentration (mg/m^3)	O-PP Air Concentration[C] (mg/m^3)	MOE[D]
15,000 ppm	1.0[B]	0.015	1,600

A. The application rate of 15000 ppm is listed on label 464-126.
B. Average 8 hr TWA for oil mist air (n=544 samples) measured by OSHA (2000 to 2009) corrected for 25% volatilization loss.
C. DBNPA Air Concentration = Application Rate (ppm) * MWF Air Concentration (1.0 mg/m^3).
D. MOE = 8 Hour HEC (24 mg/m^3) / O-PP Air Concentration (mg/m^3)

Dermal Exposures

The dermal exposure of machinists to MWFs treated with O-PP were assessed by using the thin film approach for comparison to the POD which is expressed as the amount of a.i. per given area of skin. This approach using the following equation:

Dermal Loading (ug/cm^2) = WF (Application Rate/1000000) x Qu (mg/cm^2) x 1000 ug/mg

The following assumptions were used in this assessment:

- WF. The weight fractions are based on the application rates.
- Qu. The quantity remaining on the skin is 10.3 mg/cm^2 based on the hand immersion with no wiping results for mineral oil reported in Cinalli 1992. This value is used by AD for evaluating dermal irritation effects, because these effects can be localized.

The dermal MOE of 1.3 and 39 were calculated as outlined in Table 37. The dermal MOE of 1.3 at the maximum application rate is of concern because it is less than the LOC of 10.

Table 37. Dermal MOEs for Machinists Using O-PP Treated Metal Working Fluids

O-PP Application Rate	Qu (mg/cm^2)	O-PP Dermal Loading[D] (ug/cm^2)	Dermal MOE[E] (LOC = 10)
15,000 ppm[A]	10.3[C]	154	1.3
500 ppm[B]		5.15	39

A. Maximum application rate for metal working fluids listed on EPA Reg No. 464-126.
B. Minimum application rate listed for Non-Mineral Oil Based Products listed on EPA Reg No. 39967-11.
C. Standard value used by AD based on hand immersion and wiping experiments reported in Cinalli, 1992.
D. O-PP Dermal Loading = O-PP Application Rate x MWF Thin Film Retention x 1000 ug/mg
E. MOE = Dermal NOAEL (200 ug/cm^2) / O-PP Loading (ug/cm^2).

2.14.6 Occupational Painter Inhalation Exposures to O-PP Vapors

There is the potential for occupational (*i.e.*, professional) painter inhalation exposure to O-PP vapors from O-PP preserved paints. Although painting is done by professional painters on a daily basis, the exposure duration for O-PP is assumed to be short to intermediate term because it is highly unlikely that painters would be using O-PP treated paint on a daily basis for more than six months at a time. The professional painter inhalation exposure to O-PP vapors was assessed using the WPEM Model. The WPEM default scenario (RESPROF) for the professional painter was used and this scenario assumes that two professional painters paint an entire apartment in a work day. The following chemical specific inputs and WPEM default assumptions were used:

Chemical Specific Inputs

- The molecular weight of O-PP is 170.2 grams/mole (Table 1) and the vapor pressure is 0.002 mm Hg at 25 ºC (Table 2).
- The weight fraction is 0.0057 based on the application rate of 5700 ppm O-PP.

WPEM Default Assumptions from the RESPROF Scenario

- The air exchange rate is 0.45 air changes per hour which is the median value from the Exposure Factors Handbook (US EPA, 1997).
- The painting is done in an apartment that has an internal volume of 7,350 ft^3 which is the mean value from the Exposure Factors Handbook (US EPA, 1997).
- The surface area painted is 2131 ft^2.
- One coat of primer which has a coverage of 200 ft^2/gallon and one coat of paint which has a coverage of 400ft^2/gallon are applied.
- The paint is latex flat with a density of 4600 grams/gallon.
- Two professional painters are exposed while painting an entire apartment.
- The duration of painting is 9.4 hours based upon the labor production rate of 337.5 ft^2 per hour for painting with a roller at 400 ft^2/gallon.
- The amount of paint used is 10.66 gallons for the primer coat and 5.33 gallons for the finish coat.

WPEM Model Results for the RESPROF scenario

The WPEM model results for the RESPROF scenario are shown in Figure 2.

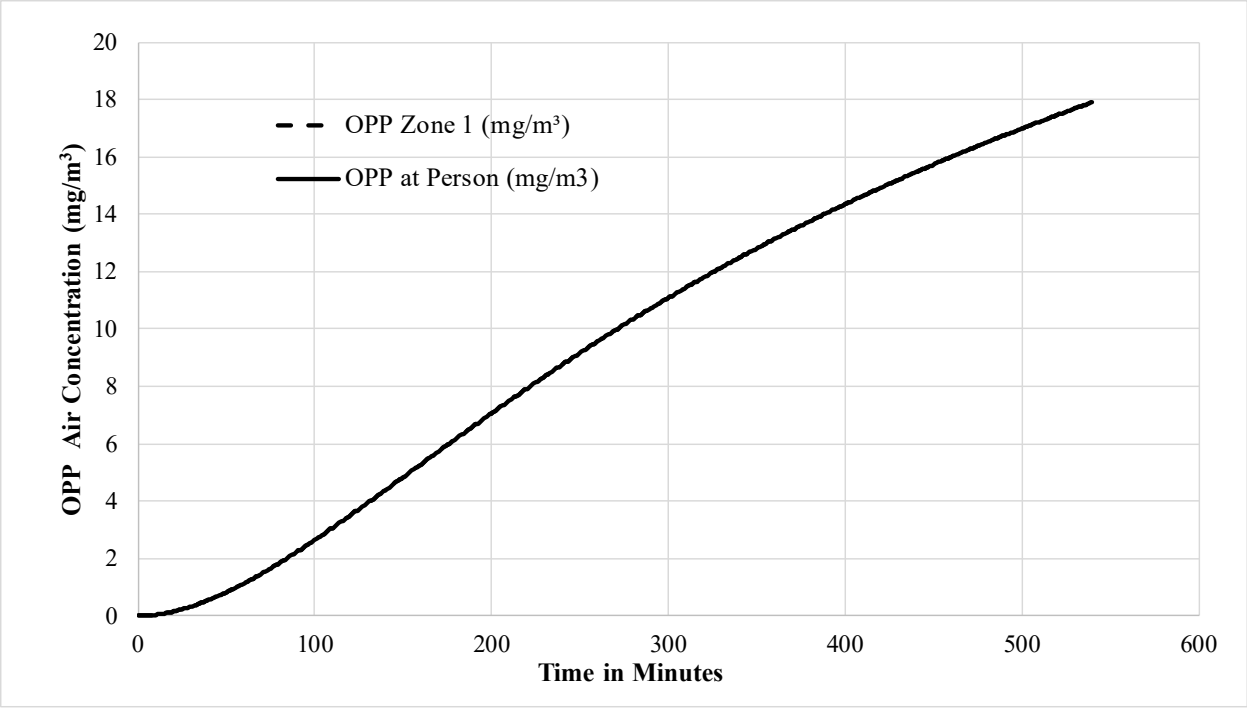


Figure 2 - Professional Painter Exposure to O-PP Vapors

Risk Summary

The WPEM results are compared to the 8-hour Human Equivalent Concentration (HEC) as shown in Table 38. The MOE is 2 which is of concern because it is less than the target MOE of 1000.

Table 38. Inhalation MOE for Professional Painters Exposed to O-PP Vapors

O-PP Vapor Pressure (mm Hg)	Weight Fraction	Time Spent Painting (hrs)	Painted Surface Area (ft^2)	Air Exchange Rate per hour	8-hour TWA[C] (mg/m^3)	MOE[D] (LOC =1000)
0.002 @ 25C	0.0057 (5700 ppm)	8.0	2131[A]	0.45[B]	11.3	2

A. Assuming the walls of one apartment are painted as specified in the RESPROF scenario of WPEM.
B. Default air exchange rate used in WPEM based on the Exposure Factors Handbook.
C. The 8-hour time weighted average (TWA) air concentration experienced by the professional painter on the day of painting.
D. MOE = 8 Hour HEC (24 mg/m^3) / 8 Hour TWA (mg/m^3)

2.14.7 Antimicrobial Uses Occupational Post Application Exposures

There is one product (EPA Reg No. 1043-91) that has use directions for fogging as an adjunct to

regular cleaning and disinfection in areas such as poultry operations, hatcheries, swine operations, animal care facilities, animal research facilities, livestock operations, veterinary facilities, zoos and kennels. Although the label specifies that the fogging be done using equipment with an automatic timer, there is the potential for post application exposure to workers who work in these areas after the fogging application. The label includes a waiting time of at least two hours after fogging is complete before reentering the treated area.

Calculation of Air Concentrations

The air concentrations after application were calculated using the following single chamber ventilation formula that is included in the EPA Multi- Chamber Concentration and Exposure Model (MCCEM):

$$C_T = C_0 * 0.5\ [(T/0.693) * (Q/V)]$$

Where:
C_T = Air concentration at time T
C_T = Air concentration at time T
C_0 = Air Concentration at time zero
Q = Ventilation rate in cubic meters per minute (CMM)
T = Elapsed time in minutes
V = Volume of room in cubic meters

Assumptions

The following assumptions were used in the above formula:

- The air concentration at time zero is based on product (1043-91) that contains 7.7% ai, which is applied at a dilution rate of 0.5 ounce in one gallon of water with a spray volume of 64 ounces of use dilution per 1000 cubic feet.
- The room volume is 1000 cubic feet (28.3 m^3) based on the spray volume.
- The ventilation rate is 2.0 air changes per hour (ACH).

The estimated air concentrations for O-PP at time zero immediate after application, after the 120-minute reentry interval and as an 8-hour time weighted average for a worker who is in the treated space for 8 hours after the REI are summarized in Table 39. The MOE of 1,100 is not of concern because it is less than the LOC of 1000.

Table 39: O-PP Fogging Applications Post Application Inhalation MOEs

Time Zero Air Concentration (mg/m^3)	Ventilation Rate[A] (ACH)	120 Minute Air Concentration (mg/m^3)	8 hr TWA[B] (mg/m^3)	MOE[C] (LOC =1000)
26.2	2.0	0.358	0.0226	1100

A. ACH = Air Changes per Hour
B. 8 hr TWA = Average Air concentration for the eight-hour period starting after the 120 Minute REI.
C. MOE = HEC (24 mg/m^3) / 8 Hour TWA (mg/m^3)

2.15 Conventional Uses Occupational Handler Exposure/Risk Estimates

Based on the anticipated use patterns and current labeling, types of equipment and techniques that can potentially be used, the Health Effects Division (HED) expects occupational handler dermal and inhalation exposures from the conventional uses of O-PP. Despite the potential for dermal exposures, risk estimates haven't been quantified due to the lack of dermal hazard for O-PP. The quantitative exposure/risk assessment developed for occupational handlers of the conventional uses of O-PP is based on the following scenarios:

- Mixing/loading (M/L) liquid concentrate solutions for post-harvest foaming, dipping, drenching, brushing, and spraying treatments;
- Loading RTU solution for thermo-fogging post-harvest treatment using an electrofogger;

Occupational Handler Exposure Data and Assumptions

A series of assumptions and exposure factors served as the basis for completing the occupational handler risk assessments. Each assumption and factor are detailed below on an individual basis.

Application Rates: The are currently 5 active conventional use labels. Label directions call for dilution in water. Application rates are calculated as pounds active ingredient per gallon of dilute solution (*i.e.*, lb ai/gallon solution) ranging from 0.002 to 0.17 lb ai/gallon solution (0.05 to 2% solution by weight). Other labels further list the amount of fruit per gallon of dilute solution (*i.e.*, lbs fruit/gallon solution). The RTU thermo-fogging product has an application rate of 0.0633 lb ai/2,200 lbs fruit, or 0.000029 lb ai/lb fruit. A summary of all registered conventional o-phenyl phenol products and application rates are presented in Section 2.3, Table 4.

Unit Exposures: It is the policy of HED to use the best available data to assess handler exposure. Sources of generic handler data, used as surrogate data in the absence of chemical-specific data, include PHED 1.1, the AHETF database, the Outdoor Residential Exposure Task Force (ORETF) database, or other registrant-submitted occupational exposure studies. For the assessment of loading RTU solution for thermo-fogging, HED relied on AHETF/PHED data. Some of these data are proprietary (*e.g.*, AHETF data), and subject to the data protection provisions of FIFRA. The standard values recommended for use in predicting handler exposure that are used in this assessment, known as "unit exposures", are outlined in the "Occupational Pesticide Handler Unit Exposure Surrogate Reference Table[8]", which, along with additional information on HED policy on use of surrogate data, including descriptions of the various sources, can be found at the Agency website[9].

[8] Available: https://www.epa.gov/sites/production/files/2018-06/documents/opp-hed-pesticide-handler-surrogate-unit-exposure-table-june-2018.pdf
[9] Available: https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/occupational-pesticide-handler-exposure-data

Many of the unit exposure values used for the assessment of conventional post-harvest uses are derived from a chemical-specific post-harvest commodity treatment study[10]. The exposure study is recommended as the primary data source for post-harvest commodity treatment exposure and risk assessment per the HED Science Advisory Council for Exposure (ExpoSAC) Policy/Guidance relating to the Assessment of Occupational Exposure for Post-Harvest Commodity Pesticide Treatments. The study was reviewed by Versar, Inc. with a secondary review by HED[11]. The study adequately followed test guidelines as well as ethical requirements[12]; it is considered useful and applicable for quantitative risk assessment of the use pattern.

Post-harvest treatment is primarily made via automatic dipping/drenching or spraying as the commodity passes down a conveyor belt. HED has concluded that the likelihood that non-automated post-harvest facilities are in operation is minimal, since large commercial facilities tend to dominate the market. While it is acknowledged that there may be exposure during the actual manual (non-automated) dip applications, HED does not currently have data to assess this type of scenario.

Area Treated: Assumptions for the amount treated per day values were based on the ExpoSAC Policy/Guidance relating to the Assessment of Occupational Exposure for Post-Harvest Commodity Pesticide Treatments (February 2018).

- If the application rate is given based on the amount of commodity (*e.g.*, per ton of fruit) to be treated, the default estimate is 144,000 lbs, calculated as the product of 90 lbs commodity per box, 200 boxes per hour, and 8 hours per day.[13] This is considered to be a conservative, high-end capacity estimate.
- If the estimate is given as a % solution and does not provide information on the amount of commodity to be treated, use a default estimate of 25,000 gallons. This is based on MRID 43432901 referenced above which used 20,000 – 35,000 gallon vats for treatment of approximately 15,000 lbs of pears (300 boxes/day, 50 lbs/box). Use of this estimate assumes a worker is producing a fresh batch of pesticide treatment. In most cases, one batch can be used for several treatments, so it is unlikely that this amount of volume is handled on a regular basis.

Exposure Duration: HED classifies exposures from 1 to 30 days as short-term and exposures 30 days to six months as intermediate-term. Exposure duration is determined by many things, including the exposed population, the use site, the pest pressure triggering the use of the pesticide, and the cultural practices surrounding that use site. For most agricultural uses, it is reasonable to believe that occupational handlers will not apply the same chemical every day for more than a one-month time frame; however, there may be a large agribusiness and/or

[10] Maxey, S.W., and Murphy, P.G. 1994. Evaluation of Post-Application Exposures to Sodium O-phenylphenate Tetrahydrate/O-phenylphenol to Workers during Post-Harvest Activities at Pear and Citrus Fruit Packaging Facilities. Unpublished study by Dow Chemical. October 19, 1994. EPA MRID 43432901.

[11] Crowley, M. (2005) Review of "Evaluation of Post-Application Exposures to Sodium o-Phenylphenate Tetrahydrate/o-Phenylphenol to Workers During Post-Harvest Activities at Pear and Citrus Fruit Packaging Facilities". Internal Memorandum from Matthew Crowley to Rosanna Louie. D209211.

[12] Sherman, K. (2012). Ethics Review of Worker Exposure Study. Internal Memorandum.

[13] For additional reference, see: http://tru-juice.com/tw/about-process.htm and http://edis.ifas.ufl.edu/ae184

commercial applicators who may apply a product over a period of weeks (*e.g.*, completing multiple applications for multiple clients within a region). For O-PP, based on the registered uses, short- and intermediate-term exposures are expected. For both short- and intermediate-term durations, the PODs selected are the same; therefore, risk estimates are considered protective of both durations.

Long-term exposures are not typically assessed for post-harvest uses due to cultural practices (*i.e.*, resistance management techniques and the sequential nature of crop cycles). While it may be possible for post-harvest uses to result in longer exposure durations due to receiving crops year-round, the occupational exposures are likely a series of short- or intermediate-term exposures, rather than a continuous long-term exposure duration.

Personal Protective Equipment: Estimates of inhalation exposure were calculated for various levels of personal protective equipment (PPE). For this assessment, baseline attire is defined as long-sleeved shirt, long pants, shoes plus socks, and no respirator. The registered labels, EPA Reg. Nos. 2792-28, 64864-45, 8764-1, 57227-7, require at a minimum, baseline attire, plus chemical resistant gloves. The remaining registered labels do not require handlers to wear any protective clothing or equipment. Some registered labels require additional personal protective equipment (PPE) such as protective eyewear or face shield.

Occupational Handler Non-Cancer Exposure and Risk Estimate Equations

The algorithms used to estimate non-cancer exposure and dose for occupational handlers can be found in Appendix E of this document.

Summary of Occupational Handler Non-Cancer Exposure and Risk Estimates

Most of the estimated conventional occupational handler inhalation exposure scenarios assessed result in potential risks of concern (*i.e.*, MOEs are < the LOC of 1,000). The exposure scenarios, mixing/loading liquid solutions for automated closed system brushing, dipping, foaming, and spraying, and mixing/loading liquid solutions for automated open system brushing, dipping, foaming, and spraying, result in an estimated risk of concern assuming a closed system or no respirator, respectively. The inhalation risk of concern for the open system exposure scenario is no longer of concern considering the addition of a protection factor 10 (PF10) respirator; the MOE = 2,000 which is > the LOC of 1,000. However, the closed system scenario assumes the use of engineering controls which is the maximum respiratory protection available and remains of concern (*i.e.*, the MOE of 510 is < the LOC of 1,000). The exposure scenario, loading/applying RTU for thermo-fogging of pears, is not of concern assuming no respirator. Table 40 presents the results of the conventional occupational handler exposure and risk assessment.

Table 40: Non-Cancer Occupational Handler Exposure and Risk Estimates

Exposure Scenario	Crop	Level of Concern (LOC)	Inhalation Unit Exposure (ug/lb ai)[1]	Maximum Application Rate[2]	Amount Handled (Gallons/ Solution)[3]	Inhalation Dose[4] (mg/kg/day)	Inhalation MOE (LOC = 1000)[5]
Mixer/Loader							
Mixing/Loading for Automated Closed System Brushing, Dipping, Foaming and Spraying	Citrus and Pears	1,000	0.083 (Engineering Controls)	0.17 - 2% solution (lb ai/gallon)	25,000 (gallons)	0.0044	**510**
Mixing/Loading for Automated Open System Brushing, Dipping, Foaming and Spraying			0.219 (No R)	0.17 - 2% solution (lb ai/gallon)	25,000 (gallons)	0.012	**200**
			0.0219 (PF10 R)			0.0012	2,000
Loading/Applying							
Loading/Applying RTU Solution for Thermo-Fogging	Pears		0.219 (No R)	0.000029 lb ai/lb fruit	1,440,000 lb fruit	0.00011	20,000

1 Mixing/loading for automated open and closed systems brushing, dipping, foaming and spraying based on the Occupational Exposure for Post-harvest Commodity (MRID 43432901); Level of mitigation: No Respirator (No R), Eng. Controls.
Mixing/loading for thermo-fogging based on the "Occupational Pesticide Handler Unit Exposure Surrogate Reference Table" (https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/occupational-pesticide-handler-exposure-data); No respirator (No R) and protection factor 10 respirator (PF10 R).
2 Based on registered labels.
3 Based on ExpoSAC Policy/Guidance "Assessment of Occupational Exposure for Post-Harvest Commodity Pesticide Treatments" (M. Crowley, FEB-2018).
4 Inhalation Dose = Inhalation Unit Exposure (µg/lb ai) × Conversion Factor (0.001 mg/µg) × Application Rate (lb ai/gal or lb ai/lb fruit) × Area Treated or Amount Handled (A or gal/day) ÷ BW (80 kg).
5 Inhalation MOE = Inhalation POD (2.27 mg/kg/day) ÷ Inhalation Dose (mg/kg/day).

2.16 Conventional Uses Occupational Post-Application Exposure/Risk Estimates

HED uses the term post-application to describe exposures that occur when individuals are present in an environment that has been previously treated with a pesticide (also referred to as re-entry exposure). Such exposures may occur when workers enter previously treated areas to perform job functions, including activities related to crop production, such as scouting for pests or harvesting. Post-application exposure levels vary over time and depend on such things as the type of activity, the nature of the crop or target that was treated, the type of pesticide application, and the chemical's degradation properties. In addition, the timing of pesticide applications, relative to harvest activities, can greatly reduce the potential for post-application exposure.

Occupational Post-Application Inhalation Exposure and Risk Estimates

There is the potential for occupational post-application inhalation exposures from the conventional post-harvest use of O-PP. During automated post-harvest commodity treatments, dermal and inhalation exposure is anticipated for workers performing sorting, culling, and packing tasks. Since the workers experience exposure following the treatment, this is technically

"post-application" exposure; however, unlike other post-application activities (*e.g*., harvesting, scouting, *etc*.), this treatment is not governed by the Worker Protection Standard (WPS) and potential re-entry intervals (REIs). Additionally, for workers in the warehouse or packaging facility not directly involved in the automated treatment process, there is potential for indirect inhalation exposure. Exposures for these various scenarios have been assessed using the HED ExpoSAC Policy/Guidance "Assessment of Occupational Exposure for Post-Harvest Commodity Pesticide Treatments" which relies on the O-PP exposure study data from MRID 43432901 (Maxey and Murphy, 1994). A series of assumptions and exposure factors served as the basis for completing the occupational post-application risk assessment. Each assumption and factor is detailed below on an individual basis.

Application Rates: The are currently 5 active conventional use labels. Label directions call for dilution in water. Application rates are calculated as pounds active ingredient per gallon of dilute solution (*i.e*., lb ai/gallon solution) ranging from 0.002 to 0.17 lb ai/gallon solution (0.05 to 2% solution by weight). Other labels further list the amount of fruit per gallon of dilute solution (*i.e*., lbs fruit/gallon solution). The RTU thermo-fogging product has an application rate of 0.0633 lb ai/2,200 lbs fruit, or 0.000029 lb ai/lb fruit. A summary of all registered conventional O-PP products and application rates are presented in Section 2.3, Table 4.

Exposure Duration: HED classifies exposures from 1 to 30 days as short-term and exposures 30 days to six months as intermediate-term. Exposure duration is determined by many things, including the exposed population, the use site, the pest pressure triggering the use of the pesticide, and the cultural practices surrounding that use site. For most agricultural uses, it is reasonable to believe that occupational post-application workers will not apply the same chemical every day for more than a one-month time frame; however, there may be a large agribusiness and/or commercial applicators who may apply a product over a period of weeks (*e.g*., completing multiple applications for multiple clients within a region).

For O-PP, based on the registered commodity post-harvest uses both short- and intermediate-term exposures are expected for occupational handlers in post-harvest facilities because it could be applied over several months to the registered crops. Additionally, the occupational inhalation POD is applicable to both durations; therefore, the assessment is protective of both short- and intermediate-term exposures. Long-term exposures are not expected because exposures resulting from post-harvest uses are likely a series of short- or intermediate-term exposures, rather than a continuous long-term exposure duration to O-PP.

Unit Exposures: Inhalation unit exposures expressed as amount of exposure per % active ingredient in solution for various PPE levels were based on data from MRID 43432901 (Maxey and Murphy, 1994). These data were previously reviewed by HED and are incorporated into the ExpoSAC Policy Post-Harvest Commodity Treatment (February 2018).

Personal Protective Equipment (PPE): Estimates of inhalation exposure were presented for workers involved in post-harvest activities following application assuming baseline attire and no respirator as well as with PF10 respirators. None of the registered conventional labels require respirators.

Exposure Time: The average occupational workday is assumed to be 8 hours.

Occupational Post-Application Non-Cancer Inhalation Risk Estimates:
Risks of concern have been identified for the post-harvest packing and sorting activities associated with O-PP usage assuming baseline attire (*i.e.*, no respirator), as well as with maximum available PPE (*i.e.*, the MOEs are < the LOC of 1,000 with the addition of a PF10 respirator). Table 41 presents the results of the conventional post-harvest packing and sorting activity assessment.

Table 41: Occupational Post-Application Non-Cancer Inhalation Exposure and Risk Estimates for O-PP

Crop/Site	Activities	Max App. Rate (% ai in solution)[1]	Inhalation Unit Exposure (µg/% ai)[2]	Inhalation Dose (mg/kg/day)[3]	Inhalation MOE[4] (LOC = 1000)
Citrus and Pears	Sorter	2%	6,720 (No R)	0.17	**14**
			672 (PF10 R)	0.017	**140**
	Packer		6,760 (No R)	0.17	**14**
			675 (PF10 R)	0.017	**140**

1. Maximum application rate based on representative label (EPA Reg. No. 64864-45).
2. Based on Table 2 in ExpoSAC Policy/Guidance "Assessment of Occupational Exposure for Post-Harvest Commodity Pesticide Treatments" (M. Crowley, FEB-2018); Level of mitigation: NR = no respirator; PF10 = protection factor 10 respirator.
3. Inhalation Dose = [Unit Exposure (µg/% ai) * Application Rate (2% ai in solution) * Adjustment Factor (0.001 µg/mg)] ÷ Body Weight (80 kg).
4. Inhalation MOE = Inhalation POD (2.27 mg/kg/day) ÷ Inhalation Dose.

Indirect inhalation exposures from the automated treatment process are also of concern assuming baseline attire (*i.e.*, no respirator; the MOE is 300 which is < the LOC of 1,000). With the maximum available PPE (*i.e.*, a PF10 respirator), indirect inhalation exposures are not of concern; the MOE = 3,000 which is > the LOC of 1,000. Table 42 presents the results of the indirect inhalation exposure assessment.

Table 42: Occupational Post-Application Non-Cancer Indirect Inhalation Exposure and Risk Estimates for O-PP

Crop/Site	Max App. Rate (% ai in solution)	Inhalation Unit Exposure (µg/% ai)[1]	Inhalation Dose (mg/kg/day)[2]	MOE[3] (LOC = 1000)
Citrus and Pears	2%	307 (NR)	0.0077	**300**
		30.7 (PF10)	0.00077	3,000

1. Based on Table 4 in ExpoSAC Policy/Guidance "Assessment of Occupational Exposure for Post-Harvest Commodity Pesticide Treatments" (M. Crowley, FEB-2018); Level of mitigation: NR = no respirator; PF10 = protection factor 10 respirator.
2. Inhalation Dose = [Unit Exposure (µg/% ai) * Application Rate (2% ai in solution) * Adjustment Factor (0.001 µg/mg)] ÷ Body Weight (80 kg)].
3. Inhalation MOE = Inhalation POD (2.27 mg/kg/day) ÷ Inhalation Dose.

Occupational Post-Application Dermal Exposure/Risk Estimates

Occupational post-application dermal exposures are anticipated for the registered conventional post-harvest uses of O-PP; however, a quantitative dermal assessment was not conducted as no toxicological hazard was identified.

Restricted Entry Restrictions
The WPS does not apply to the post-harvest treatments of O-PP; therefore, restricted entry intervals (REIs) are not required for those uses. However, for the thermal fogging uses of O-PP, there are re-entry restrictions on the registered labels based on ventilation requirements.

ENVIRONMENTAL RISK ASSESSMENT

3.1 Environmental Fate

O-PP is a weak acid with a pKa of approximately 9.95 at 25ºC (MRID 41605001), indicating that O-PP will exist primarily as the protonated acid in aqueous solution at environmental pH values (5-9).

O-PP and its salts are stable and persistent in abiotic aqueous medium at pHs 5, 7 and 9. O-PP is photolytically unstable in aqueous medium and has a half-life of 38.4 hours (1.6 days). When exposed to UV light (253.7 nm) it degrades into phenyl benzoquinone, phenyl hydroquinone, and 2-hydroxy benzofuran (Sarakha, *et. al,* 1989). O-PP has a photolytic half-life of 29.3 hours (1.22 days) in soil (MRID 50583001). O-PP was readily biodegradable within wastewater treatment plants (WWTPs) with 60-65% degradation observed by day 9 (MRID 495378101), however, the normal residence time of a chemical in a WWTP is expected to be ~8 hours[14], therefore >85% of O-PP is expected to be released from a WWTP. The Agency does not possess an activated sludge sorption isotherm study to determine how much sorption to sludge O-PP exhibits in WWTPs, therefore the Agency has assumed 0% sorption.

In an aerobic soil metabolism study dissipation of O-PP was driven almost entirely by sorption as 87% of O-PP residue had sorbed to soil within 2 days. The aerobic soil metabolism study did not use a range of solvents to maximize extraction of the residues. In a leaching adsorption desorption study (MRID 50410801 and 50410802) O-PP was observed to have a log Koc of 2.4-2.6 and O-PP is expected to be moderately mobile in soil.

When wood is treated for anti-sapstain use, Na O-PP leaches up to 58% when submerged in water the first day after application (at 1% application rate). By day 14, 78-82% of Na O-PP leached out from the treated wood (MRID 46601401).

[14] http://www.fao.org/docrep/t0551e/t0551e05.htm

Based on the above-mentioned environmental fate data the main routes of dissipation for O-PP are expected to be driven by a combination of biotic degradation, photodegradation, and sorption to soil. Both sodium and potassium salts will dissociate from O-PP upon use and react in the same way as O-PP.

3.1.1 Water Quality – Total Daily Maximum Load

O-PP is not identified as a cause of impairment for any water bodies listed as impaired under section 303(d) of the Clean Water Act, based on information provided at the Agency's National Pesticides Cause of Impairment of Waters website[15]. In addition, no Total Maximum Daily Loads (TMDL) have been developed for O-PP, based on information provided at the Agency's National Pesticide TMDL web site[16]. More information on impaired water bodies and TMDLs can be found at http://www.epa.gov/owow/tmdl/.

The Water Quality Portal (https://www.waterqualitydata.us/) was searched on July 26, 2019. All monitoring data was received in 2005 from the Oregon Department of Environmental Quality. Of the 27 samples collected, 22 had O-PP at levels below the LOD (<0.83 µg/L). Four samples recorded O-PP concentration levels of 20 ppb, 270 ppb, 3170 ppb, and 11.7 ppm. These samples were taken from effluent discharge from the Stadelman-Whitney discharge plant and a large orchard cold storage plant in Hood River County, Oregon. It is likely that these detections were from a misuse of the product, as a search of currently registered O-PP food processing plant/equipment uses[17] state that this product must be discharged according to the requirements of a National Pollutant Discharge Elimination System (NPDES) permit. Further, as of 7/31/11 the Stadelman-Whitney Plant had their NPDES permit terminated and now discharges directly to a WWTP[18].

3.2 Aquatic Exposure

The highest environmental exposure is expected from O-PP use in recirculating cooling towers, which is estimated by EPA's Down-the-Drain (DtD) screening model below.

Any exposure from use of O-PP as an antimicrobial (on agricultural/commercial/food handling/medical/residential premises and equipment) would be a result of the product traveling DtD to a WWTP. Even though these uses are applied at higher rates, they would not be used in the same quantity as a recirculating cooling tower use, which may process thousands of gallons

[15] http://iaspub.epa.gov/tmdl_waters10/attains_nation_cy.cause_detail_303d?p_cause_group_id=885
[16] http://iaspub.epa.gov/tmdl_waters10/attains_nation.tmdl_pollutant_detail?p_pollutant_group_id=885&p_pollutant_group_name=PESTICIDES
[17] Registration Numbers: 1043-91, 1043-92, 1677-128, 70627-6, and 83103-2.
[18] https://www.oregon.gov/deq/FilterDocs/whstmdl.pdf

of water per minute, and any risks from these uses are expected to be less than O-PP use in recirculating cooling towers.

Use of O-PP as a materials preservative or in sewage disposal lagoons are not expected to result in any significant environmental exposure as sewage lagoons are designed so that disposal occurs by evaporation only[19] and O-PP is not expected to leach out of materials it is preserving in any environmentally relevant concentrations.

3.2.1 Exposure Modeling

The DtD module of E-FAST (Exposure and Fate Assessment Screening Tool) (USEPA, 2007) was used to perform an upper bound and average screening level estimate of the potential for aquatic organisms located downstream of domestic wastewater treatment plants to be exposed to O-PP used in industrial recirculating water systems. Terrestrial exposures are not expected from antimicrobial uses.

Because the product label lists several ways O-PP may be used in cooling towers, EPA has modeled several scenarios to characterize potential exposures. First, the analysis was conducted using a moderately sized cooling tower (2,000 gallons/minute) and a large sized cooling tower (100,000 gallons/minute)[20]. The estimates from a large recirculating cooling tower are provided in Table 46 and the estimates from moderate sized cooling towers are in Table 47. Within each facility size, estimates were made for (1) low and high concentrations of O-PP (based on the label) and (2) low and average stream flow that the facility waste (*i.e.* O-PP) enters.

The Agency has conducted a high end (low flow) and an average analysis to determine the conditions under which there might be exposure and potential adverse risks to freshwater aquatic organisms. In this analysis, it was assumed that 100% of O-PP that enters a WWTP is also discharged. This was based on a ready biodegradation study (MRID 49538101) in which no degradation of O-PP was seen on Day 0, and the following sampling point on Day 2 showed 15% degradation. Chemicals are expected to remain within WWTP for ~ 8 hours prior to discharge[21] and without additional data, the Agency was unable to determine degradation potential within 8 hours. Therefore, the Agency has taken the conservative assumption that 0% will degrade prior to discharge.

[19] https://www1.health.gov.au/internet/publications/publishing.nsf/Content/ohp-enhealth-manual-atsi-cnt-l~ohp-enhealth-manual-atsi-cnt-l-ch2~ohp-enhealth-manual-atsi-cnt-l-ch2.11

[20] Determination of recirculation rates require information on evaporation rate, heat absorption through sensible heat, and temperature difference across cooling tower (https://www.awt.org/pub/019E3A00-DF82-84B1-E8A9-3599FC74D720). Currently the Agency uses recirculation rates based on the standard scenario developed by OPPT CEB (US EPA, 1991)."

[21] http://www.fao.org/3/t0551e/t0551e05.htm

The high-end scenario is based on the upper 10th percentile of the distribution of the ratio of 7Q10 stream flows to WWTP flows. The average case scenario is based on the median of the distribution of the ratio of 7Q10 stream flows to WWTP flows. The 7Q10 is the lowest 7 consecutive day stream flow over a 10-year period. For the high-end scenario, the ratio of stream flow to plant flow is relatively low since plant flows can contribute considerable volume to the flow of the stream and the resulting surface water concentrations can be relatively high. For the average case scenario, the ratio of stream flow to plant flow is more typical.

The DtD model is appropriate only for estimating magnitude of exposures in flowing water bodies and cannot be used to estimate potential exposures to aquatic organisms in estuarine/marine environments. More information on the DtD model assumptions and inputs may be found in Appendix D.

3.2.2 Ecotoxicity Data

Ecological effects data are used as measures of direct and indirect effects to aquatic and terrestrial organisms. Acute and chronic toxicity data will be used to evaluate the potential direct and indirect effects of O-PP and salts to plants and animals. Relevant data from the open literature available in ECOTOX also may be used to evaluate potential direct and indirect effects.

All data requirements and available ecotoxicity endpoints from studies submitted by registrants are tabulated in Appendix C. The Agency uses the most sensitive of these endpoints for assessing risk to each terrestrial and aquatic receptor group. The endpoints selected for the risk assessment for O-PP and salts are provided in Table 43 and represent the anion O-PP. Data gaps also are indicated.

Table 43: Selected Ecological Effects Endpoints for the anion O-PP used in the Ecological Risk Assessment

Receptor Group	Surrogate Species	Risk Scenario	Toxicity Endpoint	MRID Reference
Freshwater fish	Bluegill	Acute	96-h LC_{50} = 2.74 mg ai/L	110232
		Chronic	Data gap	--
Freshwater invertebrates	Waterflea	Acute	48-h EC_{50} = 2.4 mg ai/L	110222
		Chronic	Data gap	--
Estuarine/marine fish	Sheepshead minnow	Acute	Data gap	--
		Chronic	Not required	
Estuarine/marine invertebrates	Mysid shrimp	Acute	96-h LC_{50} = 0.28 mg ai/L	467512-03
		Chronic	Not required	--
	Mollusk	Acute	48-h IC_{50} = 0.66 mg ai/L	25816

Receptor Group	Surrogate Species	Risk Scenario	Toxicity Endpoint	MRID Reference
Sediment-dwelling invertebrates	Freshwater	Chronic	Not required- waived	--
Aquatic macrophytes/ Aquatic non-vascular plants	Green algae	Non-listed	EC_{50} = 1.39 mg ai/L	456882-01
	Blue-green algae	Listed	NOAEC = 0.03 mg ai/L	
Non-emergent aquatic macrophytes/Aquatic vascular plants	*Lemna*	Non-listed	7-day IC_{50} = 5.5 ppm ai/L	467512-09
		Listed	7-day IC_{05} = 0.73 ppm ai/L	
Emergent rooted aquatic macrophytes-Seedling emergence	Rice	Non-listed	EC_{25} > 886 ppm ai	467512-07
		Listed	NOAEC = 886 ppm ai (7% emergence inhibition)	
Emergent rooted aquatic macrophytes-Vegetative vigor	Rice	Non-listed	EC_{25} > 886 ppm ai	467512-07
		Listed	NOAEC = 886 ppm ai (2% dry wt)	
Terrestrial plants-Seedling emergence	--	Non-listed	Not required	--
		Listed	Not required	--
Terrestrial plants-Vegetative vigor	--	Non-listed	Not required	--
		Listed	Not required	
Birds	Northern Bobwhite	Acute	LD_{50} = 885 mg ai/kg-bw	425002-04
		Chronic	Not required	--
Mammals	Rat	Acute	LD_{50} = 591 mg/kg-bw	433342-04
		Chronic	NOAEL >500 mg/kg/day	439288-01
Nontarget insects	Honeybee	Acute dermal (contact)	48-hr LD_{50} = >100 ug/ai/bee	50417701
		Acute oral	Not required for antimicrobial uses	--
		RT_{25}-wood preservative	Not required for antimicrobial uses	--

3.2.3 Concentrations of Concern (COCs)

The results of the DtD analysis are expressed as number of days of exceedance of concentrations of concern (COCs) for fish, aquatic invertebrates, and aquatic plants. Based on the sensitive ecotoxicity endpoints tabulated above, a COC is the aquatic concentration of active ingredient that if exceeded is expected to cause adverse effects. COCs are determined for each receptor group for federally listed (endangered/threatened) and nonlisted species as follows:

Receptor group	**Non-listed spp.**	**Listed spp.**
Fish	0.5 x LC50	0.05 x LC50
Aquatic invertebrates	0.5 x EC50	0.05 x EC50
Aquatic plants	1.0 x EC50 (or IC50)	1.0 x NOEC

Table 44 below lists the COCs for aquatic organisms exposed to O-PP.

Table 44: Concentration of Concerns for Non-Listed and Listed Aquatic Organisms

Receptor Group	Concentration of Concern (COC)	
	Non-Listed spp. (µg/L)	Listed spp. (µg/L)
Freshwater fish	1,370	137
Freshwater invertebrates	1,200	120
Aquatic Plants	1,390	30

3.2.4 Estimating Environmental Release (kg O-PP/site/day)

The Office of Pollution Prevention and Toxics (OPPT) Chemical Engineering Branch's (CEB) generic scenario for recirculating cooling towers (USEPA, 1991) was used to estimate daily releases to surface water of O-PP in blow-down water in kilograms per site per day. Blow-down, also sometimes referred to as "Draw-off", is the portion of circulating water flow that is removed to reduce Total Dissolved Solids (TDS) and other impurities. Reducing TDS minimizes formation of scale, biological growth, and corrosion, which if unchecked can reduce the efficiency of cooling towers to remove heat from process water to the atmosphere. For more information, please refer to Appendix D.

Table 45 shows the environmental releases (kg/day/site) for O-PP in moderate and large sized cooling towers based on the label information.

Table 45: Environmental Releases of O-PP Based on Label[1] Information

Recommended application conditions	Label use (Oz. product/ 1,000 gal)	Product[2] (ppm)	Active ingredient concentration (ppm)[3]	Release (kg/site/day) for mid-size cooling tower (2,000 gal/min)[4]	Release (kg/site/day) for large size cooling tower (100,000 gal/min)[4]
Continuous Method (Low-End)	3.3	25	2.5	0.17	8.37
Continuous Method (High-End)	6.6	50	5	0.33	16.74
Slug or Intermittent Method	13.2	100	10	0.67	33.48

1- VeriGuard® Plus, Reg. No. 67869-44

2- Stated on label
3- The product contains 10% O-PP, therefore the corrected AI concentration is (ppm product) x (0.10)
4- The Environmental release (kg O-PP/site/day) is based on the quantity of O-PP within the blowdown. Environmental release = (0.006) (ppm O-PP) (Recirculation rate) (5580 x 0.000001 min-kg/day-gal). Where 0.006 is the percentage of cooling tower water that is assumed to be released to surface water via blowdown (*i.e.* 0.6%), 5580 x 0.000001 min-kg/day-gal is a conversion factor, and the recirculation rate of the cooling water (gal/min) is either 2,000 or 100,000 gal/min.

3.2.5 Down-the-Drain Results

Tables 46 and 47 present screening-level estimates of numbers of days of exceedance of COCs for freshwater organisms downstream of domestic WWTPs assuming (1) all releases occur over the course of one year, (2) 100 percent of O-PP used in recirculating cooling towers is discharged to domestic WWTPs, and (3) 0% of O-PP that enters domestic WWTPs is removed during wastewater treatment. The environmental release (kg/site/day) is based on the initial doses of 3.3 to 13.2 applied fluid ounces of product per 1000 gallons of water in the system as indicated on the label (Table 3). Surface water concentrations are based on the distribution of plant flows and stream flows. Model results are expressed as per days per year of exceedance of concentrations of concerns for aquatic organisms downstream of recirculating cooling towers. For detailed information on the features, data, and methods on which the model in E-FAST version 2.0 are based, refer to the latest version of the documentation manual for E-FAST (USEPA, 2007).

The Agency considers risks to be of potential concern if the number of days of exceedance of the COC is greater than 1 day/year for acute exposure.

3.2.6 Risks to Aquatic Plants and Animals

Table 46: Days Per Year of Exceedance of Acute COCs for O-PP to Aquatic Organisms in Large Cooling Towers

Receptor group	Status/ COC (µg/L)	Continuous Method[1] (2.5 ppm)		Continuous Method[1] (5 ppm AI)		Highest Labeled Concentration[1] (10 ppm AI)	
		High-End[2]	Average[3]	High-End[2]	Average[3]	High-End[2]	Average[3]
Aquatic Plants	Non-listed (1,390)	57	6	94	10	141	15
	Listed (30)	324	56	346	77	356	105
Fish	Non-listed (1,370)	57	6	95	10	142	15
	Listed (137)	218	26	274	38	318	53
	Non-listed (1,200)	64	6	103	11	153	17

Freshwater invertebrates	Listed (120)	229	28	283	40	324	56

[1]VeriGuard® Plus, Reg. No. 67869-44

[2]Based on EFAST receiving streams at low flow

[3]Based on EFAST receiving streams at average flow

Table 47: Days Per Year of Exceedance of Acute COCs for O-PP to Aquatic Organisms in Moderate-sized Cooling Towers

Receptor group	Status/ COC (µg/L)	Continuous Method[1] (2.5 ppm)		Continuous Method[1] (5 ppm AI)		Highest Labeled Concentration[1] (10 ppm AI)	
		High-End[2]	Average[3]	High-End[2]	Average[3]	High-End[2]	Average[3]
Aquatic Plants	Non-listed (1,390)	2	0	3	0	5	1
	Listed (30)	54	5	88	9	136	14
Fish	Non-listed (1,370)	2	0	3	0	6	1
	Listed (137)	13	1	25	2	48	5
Freshwater invertebrates	Non-listed (1,200)	2	0	3	0	6	1
	Listed (120)	10	1	28	3	53	5

[1]VeriGuard® Plus, Reg. No. 67869-44

[2]Based on EFAST receiving streams at low flow

[3]Based on EFAST receiving streams at average flow

3.3 Ecological Risk Characterization

Data submitted to the Agency demonstrates that O-PP is moderately toxic to most of the tested nontarget aquatic organisms. The only exceptions were the estuarine and marine fish and invertebrates which were highly toxic to O-PP. The terrestrial nontarget organism were practically nontoxic to O-PP with the exception of honey bees which were very highly toxic to O-PP. No exposure data was available to further document risk to honey bees. However, exposure to honey bees and other terrestrial nontarget organisms is not expected from the registered uses of O-PP. No chronic toxicity data was available for this chemical. These data endpoints were used to determine the risk to freshwater fish, freshwater invertebrates and aquatic plants from the release of cooling tower water containing O-PP into the environment. Two sizes of cooling towers were evaluated in this model (moderate and large sized). The results were tabulated as days of exceedance of the concentration of concern (COC) per year for each cooling tower size based on the receiving streams being at low flow (high-end) or average flow. The results were further partitioned based on the amount of chemical applied to the cooling water (low, moderate or high). The Agency considers risks to be of potential concern if the number days of exceedance of the COC is greater than 1 day/year for acute exposure.

3.3.1 Aquatic Risk Estimates

The only risk estimates calculated were for freshwater fish, freshwater invertebrates and aquatic plants. These were the only endpoints that were modelled for exposure to cooling tower discharges.

Exposure from use of O-PP in agricultural/commercial/food handling/medical/residential premises and equipment would be a result of the product traveling DtD to a WWTP. These uses would not be used in the same quantity as a recirculating cooling tower use, which may process thousands of gallons of water per minute, and any risks from these uses are expected to be less than O-PP use in recirculating cooling towers.

Use of O-PP as a materials preservative or in sewage disposal lagoons are not expected to result in any significant environmental exposure as sewage lagoons are designed so that disposal occurs by evaporation only[22] and O-PP is not expected to leach out of materials it is preserving in any environmentally relevant concentrations.

There are other uses of O-PP, such as wood preservative applications, which may result in environmental exposure, however, EPA assumes that the exposure from the recirculating cooling tower use is the worst-case scenario. Therefore, the cooling tower scenario was used to assess the exposure of O-PP to the environment.

3.3.1.1 Freshwater Fish, Acute

The results demonstrate that the COC for non-listed fish was exceeded for streams at low flow (high-end) for both moderate and large sized cooling towers. The average flow streams exceeded the COC for large sized cooling towers but not for moderate sized cooling towers at all three concentrations. For the listed species, the COC was exceed for all of the situations except for the high flow streams from the moderate sized cooling tower at the lowest concentration of O-PP (2.5ppm).

3.3.1.2 Freshwater Invertebrates, Acute

The results demonstrate that the COC for both the listed and non-listed aquatic invertebrates was exceeded for streams at low flow (high-end) for both the moderate and high sized cooling towers at all three O-PP concentrations. For the average flow streams, the COC was exceeded for both the listed and non-listed species for the large sized cooling tower at all three concentrations. For

[22] https://www.epa.gov/sites/production/files/2014-09/documents/lagoon-pond-treatment-2011.pdf

the moderate sized cooling tower, the only exceedance is for the two highest concentrations of O-PP (5 and 10 ppm) with the average flow streams for listed species.

3.3.2 Aquatic Plants

The results demonstrate that the COC for both listed and non-listed aquatic plants was exceeded for both low flow (high-end) and average flow streams at all three O-PP concentrations with the large sized cooling tower. For the moderate sized cooling tower, the low flow (high-end) streams exceeded the COC for all three concentrations. The average flow streams with the moderate cooling tower only exceeded the COC for the listed species at all three concentrations but did not exceed the COC for the non-listed species.

3.3.3 Incident Data

There were no reported ecological incidents for O-PP in the Agency's Incident Data System (IDS) as of 8/2/2019.

3.3.4 Summary of Major Risk Presumptions

Quantifying potential risk to aquatic nontarget organisms can be difficult when dealing with cooling tower water discharges. The COC was exceeded in many of the screening-level exposure scenarios modeled, indicating potential risk. Using a moderate sized cooling tower and only discharging into average flow streams does seem to reduce the potential risk of using this chemical. The Agency lacks the data to determine if making any changes to the use patterns of O-PP as they relate to cooling towers will mitigate the potential risk to nontarget aquatic organisms. However, due to the expected dilution of O-PP once it enters a stream after leaving the cooling tower, the concentration of the chemical should drop below toxic levels. Therefore, potential risk to nontarget aquatic organisms would be minimal. Since O-PP is only moderately toxic to aquatic organisms, dilution to nontoxic levels would be even more probable. Therefore, the potential risks to nontarget aquatic organisms illustrated by these results are mitigated by the dilution of O-PP to nontoxic levels once it enters a stream. Ecological risks from conventional uses were separately assessed with the conclusion that the current outdoor uses as a crack and crevice treatment would not result in risk of concern (U.S. EPA, 2019).

3.3.5 Major Uncertainties and Data Gaps

The Agency was unable to refine an O-PP WWTP removal due to a missing ASSI study and a ready biodegradation study that lacked sufficient sampling intervals. Therefore, the Agency has taken a conservative assumption that 0% of O-PP will degrade prior to discharge. A major

uncertainty is the lack of chronic eco-toxicity data for nontarget aquatic organisms. Therefore, no assessment for chronic toxicity was completed in this document.

LISTED SPECIES OF CONCERN

Consistent with EPA's responsibility under the Endangered Species Act (ESA), the Agency will evaluate risks to federally listed threatened and endangered (listed) species from registered uses of pesticides in accordance with the Joint Interim Approaches developed to implement the recommendations of the April 2013 National Academy of Sciences (NAS) report, *Assessing Risks to Endangered and Threatened Species from Pesticides.* The NAS report[23] outlines recommendations on specific scientific and technical issues related to the development of pesticide risk assessments that EPA and the Services must conduct in connection with their obligations under the ESA and FIFRA. EPA will address concerns specific to O-PP in connection with the development of its final registration review decision for O-PP.

In November 2013, EPA, the U.S. Fish and Wildlife Service, National Marine Fisheries (the Services), and USDA released a white paper containing a summary of their joint Interim Approaches for assessing risks to listed species from pesticides. These Interim Approaches were developed jointly by the agencies in response to the NAS recommendations and reflect a common approach to risk assessment shared by the agencies as a way of addressing scientific differences between the EPA and the Services. Details of the joint Interim Approaches are contained in the November 1, 2013 white paper[24], *Interim Approaches for National-Level Pesticide Endangered Species Act Assessments Based on the Recommendations of the National Academy of Sciences April 2013 Report.*

Given that the agencies are continuing to develop and work toward implementation of the Interim Approaches to assess the potential risks of pesticides to listed species and their designated critical habitat, this ecological risk assessment supporting the registration review of O-PP does not describe the specific ESA analysis, including effects determinations for specific listed species or designated critical habitat, to be conducted during registration review. While the agencies continue to develop a common method for ESA analysis, the risk assessment for the registration review of O-PP describes only the level of ESA analysis completed at this time. This assessment allows EPA to focus its future evaluations on the types of species where the potential for effects exists, once the scientific methods being developed by the agencies have been fully vetted. Once the agencies have fully developed and implemented the scientific methods necessary to complete risk assessments for listed species and their designated critical habitats, these methods will be applied to subsequent analyses as part of completing this registration review.

[23] https://www.nap.edu/catalog/18344/assessing-risks-to-endangered-and-threatened-species-from-pesticides
[24] U.S. EPA, April, 2013, https://www.epa.gov/sites/production/files/2015-07/documents/interagency.pdf

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APPENDIX A: Toxicology Profile

Acute Toxicity Profile – *Ortho*-Phenylphenol (PC 064103).				
Guideline No.	**Study Type**	**MRID(s)**	**Results**	**Toxicity Category**
870.1100	Acute oral rat	43334201	LD_{50} = 2733 mg/kg TXR 011300	III
870.1200	Acute dermal rabbit	00078779	LD_{50} > 5000 mg/kg TXR 011300	III
870.1300	Acute inhalation rat (technical)	42333101	LC_{50} > 0.036 mg/L TXR Not Available [a]	I [a]
	Phenolic HG (10.9% formulation) [b]	45378142	LC_{50} = 1.09 mg/L No TXR available	III
	Preventol WB (13% formulation) [c]	42974101	LC_{50} > 5.19 mg/L Review not located	IV
870.2400	Acute eye irritation	00139884[d]	Study was waived and assigned Category I	I
870.2500	Acute dermal irritation rabbits	43334202	Corrosive TXR 011300	I
870.2600	Skin sensitization Guinea pig	43334203	Not a sensitizer TXR 011300	NA

NA = not applicable

[a] D188084, HED Archives file name R038123. A 4-hour exposure study with Dowcide 1 (99.9% a.i.). Toxicity Category could not be estimated from this study because only one concentration was tested (0.036 mg/1) and no mortality was observed. Default category I was assigned.

[b] [Phenolic HG – 10.5% ortho-benzyl para-chlorophenol; 10.9% OPP]

[c] [Preventol WB -29.7% 4-chloro-3-methylphenol; 13% OPP; 14% 1,2-propanediol; 6.7% NaCl; 36.8% water]

[d]the study was only of seven days' duration and irritation was still observed. The study was waived and a Category I assigned instead of conducting another study.

Subchronic, Chronic, and Other Toxicity Studies Profile.[1]			
Guideline No.	**Study Type**	**MRID No. (year)/ Classification/Doses**	**Results**
870.3100	90-Day oral toxicity (rat) O-PP , 99% a.i.	40760206 (1984), 92154015 (1990) Acceptable/guideline 0, 1560, 3130, 6250, 12500 or 25000 ppm M: 0, 182, 391, 761, 1669, and 2798 mg/kg/day F: 0, 202, 411, 803, 1650, and 3014 mg/kg/day	NOAEL = 1669/1650 mg/kg/day. LOAEL = 2798/3014 mg/kg/day based on significantly reduced body weight in male and female rats (>30%), increased relative kidney weight in male rats (16-17%) and female rats (12-15%), transitional cell hyperplasia of the kidney in males (27% incidence vs. 0% control), slight pyelonephritis in both sexes (27% males, 25% females vs. 0% control) and interstitial nephritis in both sexes (36% males, 25% females vs. 0% control). TXR 0009997 (original DER) TXR 0057868 (revised DER)
870.3200	21-Day dermal toxicity (rat) O-PP, 99.82% a.i.	42881901 (1993) Acceptable/guideline 0, 100, 500, 1000 mg/kg/day	**Dermal** NOAEL = 100 mg /kg/day LOAEL = 500 mg /kg/day based on increased incidence of dermal irritation (erythema, edema, acanthosis, and hyperkeratosis). **Systemic** NOAEL = 1000 mg/kg/day LOAEL was not observed. TXR 010739
870.3700a	Prenatal developmental in (rat) OPP, 99.69% a.i.	92154037 (1978, 1990) Acceptable/guideline 0, 100, 300 or 700 mg/kg/day	**Maternal** NOAEL = 700 mg/kg/day. LOAEL was not observed. **Developmental** NOAEL = 700 mg/kg/day. LOAEL was not observed. TXR 0011300 (original DERR) TXR 0057868 (revised DER)
870.3700b	Prenatal developmental in (rabbit) OPP, 99.88% a.i.	41925003 (1991) Acceptable/guideline 0, 25, 100 or 250 mg/kg/day	**Maternal** NOAEL = 100 mg/kg/day LOAEL = 250 mg/kg/day, based on, and histopathology of the kidney (renal inflammation and tubular degeneration). **Developmental** NOAEL = 250 mg/kg/day LOAEL was not observed. TXR 0057868

Subchronic, Chronic, and Other Toxicity Studies Profile.[1]			
Guideline No.	**Study Type**	**MRID No. (year)/ Classification/Doses**	**Results**
870.3800	Reproduction and fertility effects (rat) OPP, > 99.5% a.i.	43928801 Acceptable/guideline 0, 20, 100, or 500 mg/kg/day	**Parental/Systemic** NOAEL = 100 mg/kg/day. LOAEL = 500 mg/kg/day based on decreased body weights, and effects on the urinary tract (bladder, kidneys and ureter) in males **Reproductive** NOAEL = 500 mg/kg/day. LOAEL was not observed. **Offspring** NOAEL = 100 mg/kg/day. LOAEL = 500 mg/kg/day based on reduced body weight. (TXR 0055645)
870.4100b	Chronic toxicity (dog) OPP, 99.77% a.i.	41656401 (1990) Acceptable/guideline 0, 30, 100 or 300 mg/kg/day	NOAEL = 300 mg/kg/day. LOAEL was not observed. TXR 0011300 (original DER) TXR 0057868 (revised DER)
870.4200	Carcinogenicity (rat) Na-O-PP	40760203 (1983 or 1985) Core-supplementary 0, 0.25, 0.7, or 3% Na-O-PP males 0, 0.25, 0.5 or 1% Na-O-PP females 0, 95, 270 or 770 mg Na-O-PP/kg/day males 0, 113, 224 or 466 mg Na-O-PP/kg/day females 0, 61, 174 or 496 mg O-PP /kg/day males 0, 73, 144 or 300 mg O-PP /kg/day females	Based on the available data, Na-O-PP appears to be carcinogenic in male and female rats. This study does not satisfy the chronic toxicity requirement (83-la) and the carcinogenicity (oncogenicity) requirement (83-2a) in rodent due to severe study design and reporting deficiencies. TXR 009997
870.4200	Carcinogenicity (mouse) O-PP, 99.88%	43545501 (1995) Core-minimum 0, 250, 500, or 1000 mg/kg/day	NOEL was not observed. LOEL = 250 mg/kg/day, based on increased liver and reduced spleen weights and gross observations in the liver of all treated animals (TXR 0011737). No treatment related neoplastic observations at 250 mg/kg/day. CARC considered the 500 mg/kg/day dose to be adequate and not excessive (TXR 0053796).

Subchronic, Chronic, and Other Toxicity Studies Profile.[1]			
Guideline No.	**Study Type**	**MRID No. (year)/ Classification/Doses**	**Results**
870.4300	Combined Chronic Toxicity/ Carcinogenicity (rat) O-PP, 99.5% a.i.	43954301, 448322701, 44852701 (1996) Acceptable/guideline 0, 800, 4000, or 8000 ppm males 0, 800, 4000 and 10000 ppm females 0, 39, 200, or 402 mg/kg/day males 0, 49, 248, or 647 mg/kg/day females	NOAEL = 200 mg/kg/day (males) LOAEL = 402 mg/kg/day (males) based on decreased (>10%) absolute body weight, and increased incidence of non-neoplastic findings of the urinary bladder (hyperplasia, mineralization, necrosis) and kidney (cyst, hyperplasia, and infarct). TXR 0012002 (original DER) TXR 0057868 (revised DER)
Mutagenicity (Brusick et al., Environmental and Molecular Mutagenesis 45(5): 460-481. MRID 92154309	No indication of gene mutations in bacteria or in mammalian cells such as Chinese hamster ovary (CHO) cells. Positive results with mouse lymphoma ($Tk^{+/-}$) were generally associated with cytotoxicity. Similarly, clastogenicity, which was the most frequently observed type of genotoxicity, was consistently linked with cytotoxicity. For O-PP, the most common type of structural chromosome damage was chromosome breaks, an event that Brusick describes as typically resulting in cell death. Mixed results were found in studies assessing direct interaction with DNA damage. Based on the weight-of -the-evidence analysis, it was concluded that positive findings in genetic toxicology tests were related to excessive cytotoxicity, not direct DNA damage. TXR 0053796		
870.7485	Metabolism and pharmacokinetics (rat)	The metabolism and pharmacokinetics of O-PP have been examined in studies from the peer reviewed scientific literature (Reitz et al., 1983[MRID 92154032]; Bartels et al., 1998). Biotransformation of O-PP initially involves formation of phenolic metabolites (such as 2,4'-dihydroxyphenyl and phenylhydroquinone) in the liver through the action of cytochrome P-450 (demonstrated by Ozawa et al. [Xenobiotica 30(10), 1005-1017, 2000], by rat CYP2C11 and possibly CYP2E1, and human CYP1A2. O-PP, phenylhydroquinone,(PHQ) and 2,4'-dihydroxybiphenyl can themselves undergo conjugation reactions through the action of either sulfotransferase or glucuronidation phase II reactions. Phenylhydroquinone can also be converted to phenyl-1,4-benzoquinone (PBQ) by a secondary peroxidase-mediated activation in the kidney and/or bladder involving the prostaglandin endoperoxide synthase (PHS) complex. Excretion of OPP is primarily in urine, where > 80% of an administered dose is excreted. Fecal excretion is a minor route (1-5%), and biliary excretion is approximately 20% of the administered dose. At doses above 200 mg/kg, saturation of phase II pathways occurs and there is increased formation of the PHQ and PBQ metabolites. These metabolites have been linked to the cytotoxicity of OPP to the kidney and urinary bladder. (TXR 0053796)	

Subchronic, Chronic, and Other Toxicity Studies Profile.[1]			
Guideline No.	**Study Type**	**MRID No. (year)/ Classification/Doses**	**Results**
870.7600	Dermal penetration (human)	MRID 44145801 Acceptable/non-guideline 0.4% solution of *ortho*-phenylphenol through human skin	Dermal absorption of approximately 43% after an 8-hour exposure. An ethics review was conducted and concluded that there is no barrier in law or regulation to EPA relying on the study in its actions under FIFRA or §408 of FFDCA. TXR 1001021 Timchalk *et al.* 1998, Human & Experimental Toxicology, Vol 17, pp. 411-417, Arling M. 5/21/2019 (ethics review memo)
870.7800	Immunotoxicity	The HASPOC, based on a WOE approach, considering all of the available hazard and risk information for OPP, recommends that the immunotoxicity study is not required for OPP at this time. TXR 0057473	

[1]several other toxicity studies were available in the OPP toxicity database; however, these studies contained significant deficiencies. The current table of toxicity studies contains data that were determined acceptable for risk assessment purposes.

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APPENDIX B: Environmental Fate Profile

The Agency anticipates that >85% of O-PP will be discharged from a recirculating cooling tower based on a ready biodegradability study (<15% degradation observed by day 2, MRID 49538101). The Agency does not possess an activated sludge sorption isotherm study to determine how much O-PP may sorb to sludge, therefore, the Agency has taken the conservative estimate that 0% will sorb.

Following discharge from a WWTP, the main route of dissipation is expected to be from biotic degradation, aqueous photolytic degradation, and sorption to soil. O-PP demonstrated sorption to soil in an anaerobic soil metabolism study, the reported half-life was 3.6 hours (unextracted residue was 86.9% by day 2). The log Koc of O-PP is 2.4 - 2.6, and O-PP is expected to be moderately mobile in soil (MRID 50410801 and 50410802). O-PP is not expected to bioconcentrate in fish with a bioconcentration factor of 22X.

Wood treatment uses of O-PP are anticipated to result in high leach rates of O-PP.

Water and Sediment

Hydrolysis
O-PP is hydrolytically stable under abiotic conditions at pH 5, 7, and 9 (MRID 43994201)

Aqueous Photolysis
O-PP degrades photolytically in water with a half-life of 38.4 hours (1.6 days) (MRID 49537803). Exposure to UV degrades *O-PP* to form phenylbenzoquinone (PBQ), phenylhydroquinone (PHQ) and 2-hydroxy benzofuran (Sarakha, *et. al,* 1989).

Octanol-Water Partition Coefficient and Bioconcentration in Fish
The Log Kow of *O-PP* is 3.3 (Table 2), which is above the level of concern for potential bioconcentration in fish (<3). However, the submitted bioconcentration in fish study (MRID 49537801) demonstrated limited bioconcentration factors of 22X for whole Zebra fish.

Aerobic/Anaerobic Aquatic Metabolism
Data have not been submitted for these studies, however, the aerobic soil metabolism study has been used to supplement additional information on *O-PP* degradation.

Leachability from Treated Wood
A study (MRID 46601401) was conducted using the American Wood-Preservers Association guideline (E11-97) where wooden blocks were impregnated with 1% and 4% solution of Na O-PP and submerged under water for 14 days. The water was routinely replaced with fresh water and concentrations of Na O-PP in the leachate water were determined. The 1% treated samples

leached 58% of the a.i. within the first day and the 4% treated wood leached 52% of the a.i. By the conclusion of the study (day 14), 78-82% of the a.i. had leached out.

The leach rate for 1% treated wood was: 71 µg of Na O-PP/cm^2/day and for 4% treated wood the leach rate was: 192 µg of Na O-PP /cm^2/day; after day 14, the leach rate was: 0.5 µg of Na O-PP /cm^2/day for the 1% treated wood and 2 µg/cm^2/day for the 4% treated wood. At the conclusion of the study, acetonitrile recovered an additional 20-24% of Na O-PP was from the wooden blocks.

Soil

Soil Leaching Adsorption/Desorption Batch Equilibrium
O-PP had a Freundlich K_{ads} value range from 12.2-124.2 L/kg and Log Koc values of 2.4-2.6 (MRID 50410801 and 50410802). O-PP is expected to be moderately mobile in soil.

Aerobic Soil Metabolism
Aerobic transformation of [C^{14}] O-PP was tested on sandy loam soil (pH 6.0) for 127 days in darkness at 20ºC. Dissipation of O-PP was driven almost entirely by sorption as unextracted radioactivity increased to a maximum of 86.9% on day 2 and was 79.0% by day 127. This study did not use a range of solvents to maximize extraction of residues, therefore, it is not possible to know how much of the residue was O-PP or a degradate of O-PP. No transformation products were identified. The half-life for extractable O-PP was approximately 3.6 hours.

Fate and Transport in WWTP

Activated Sludge Respiration Inhibition
This study was not submitted. Based on the toxicity controls in the ready biodegradability study (MRID 49538101), O-PP was not toxic to WWTP microorganisms up to 1 mg/L.

Ready Biodegradability
In a ready biodegradability study (MRID 49538101) 60% to 65% of O-PP ultimately degraded by day 9 in biotic treatments, classifying the chemical as readily biodegradable.

Activated Sludge Sorption Isotherm
No ASSI study was submitted and this study is outstanding. In the absence of this study the Agency has assumed 0% sorption during wastewater treatment.

Table. Environmental Fate Data for *Ortho*-phenylphenol

Guideline No.	Study	Result	Citation (MRID unless otherwise stated)

835.1110	Activated Sludge Sorption Isotherm	Data Gap	Data Gap
835.1230	Adsorption/Desorption	Log Koc 2.4-2.6, moderately mobile	50410801 50410802
835.2120	Hydrolysis	Stable at pH 5, 7, and 9	43994201
835.2240	Photodegradation in Water	Half-life 38.4 hours (1.6 days), degradates: PHQ, PBQ, and 2-hydroxybenzofuran	49537803, Sarakha, *et. al,* 1989
835.2410	Photodegradation on Soil	Half-life 29.3 hours (1.22 days)	50583001
835.3110	Ready Biodegradability	Readily biodegradable, 60-65% degradation by day 9	49538101
835.4100	Aerobic Soil Metabolism	Half-life 3.6 hours, driven by sorption (86.9% unextracted radioactivity by day 2)	49537802
835.4300	Aerobic Aquatic Metabolism	Waived	49537804
835.4400	Anaerobic Aquatic Metabolism	Waived	50413201
850.1730	Fish BCF	Zebra Fish at 5 and 50 ppb BCF = 22X whole fish	49537801
850.6800/ 850.3300	Activated Sludge Respiration Inhibition Test	Waived, not toxic up to 1 mg/L	49538101
SS-Leaching	Wood Leaching Test	71-192 µg /cm^2/day (Day 1)	46601401

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APPENDIX C: Ecotoxicity Profile

Toxicity to Terrestrial Receptors

Birds

Available acute oral studies categorize O-PP and salts as being slightly to practically nontoxic to birds (Table). Neither acute oral data with a passerine species, nor chronic data have been submitted. Therefore, guidelines 850.2100and 850.2300) are expected to be required.

Table 1 – Avian Toxicity Data

Test Species	Test Material (% a.i.)	Toxicity[25]	Toxicity Category	MRID/ Study Classification
Mallard (*Anas platyrhynchos*)	O-PP (99.2)	LD_{50} > 2250 mg ae/kg-bw NOAEL ≥ 2250 mg ae/kg-bw, no mortality or body weight gain effect	Practically nontoxic	00160150/ Acceptable
Northern bobwhite (*Colinus virginianus*)	Na- O-PP (75.9)[26]	LD_{50} = 885 mg ae/kg-bw (1000 mg a.i./kg-bw) NOAEL = 55.3 mg ae/kg-diet (62.5 mg a.i./kg-diet)	Slightly toxic	42500204/ Acceptable
Mallard (*Anas platyrhynchos*)	O-PP (99.2)	LC_{50} > 5620 mg ae/kg-diet NOAEC = 3160 ae/kg-diet, reduction in body weight gain	Practically nontoxic	160151/ Acceptable
Mallard (*Anas platyrhynchos*)	Na- O-PP (75.9)[26]	LC_{50} > 4980 mg ae/kg-diet (>5620 mg a.i./kg-diet) NOAEC = 1580 mg ae/kg-diet (1780 mg a.i./kg-diet), reduction in body weight gain	Practically nontoxic	42500206/ Acceptable
Northern bobwhite (*Colinus virginianus*)	O-PP (99.2)	LC_{50} > 5620 mg ae/kg-diet NOAEC ≥ 5620 ae/kg-diet, no mortality or reduction in body weight gain	Practically nontoxic	160149/ Acceptable
Northern bobwhite (*Colinus virginianus*)	Na- O-PP (75.9)[26]	LC_{50} > 4980 mg ae/kg-diet (>5620 mg a.i./kg-diet) NOAEC = 1580 mg ae/kg-diet (1780 mg a.i./kg-diet), reduction in body weight gain	Practically nontoxic	42500205/ Acceptable

Nontarget Insects

[25] For O-PP mg a.i. is equal to mg acid equivalent (ae), whereas mg a.i. of Na O-PP were converted to mg ae by multiplying by the molar weight ratio of O-PP to Na O-PP (170.2/192.19 = 0.886).

[26] The test substance is actually sodium *ortho*-phenylphenate tetrahydrate (Na O-PP ·$4H_2O$) but is represented in the table as Na O-PP without the weight percent of water. With the weight percent of water added, the purity of the test substance is >99%.

Table 19 – Honey Bee Toxicity Data

Test Species	Test Material (% a.i.)	Exposure Type/ duration	Toxicity Endpoint[30]	MRID/ Study Classification/ Comments
Honey bee *(Apis mellifera*)	O-PP (99.9)	Acute contact/ 48-hour	48-h LD_{50} = >100 µg a.i./bee NOAEC = 25 µg a.i./bee LOAEC = 50 µg a.i./bee	50417701/ Acceptable

Nontarget insect toxicity data (850.3020) requirement has been fulfilled which will support the assessment of the wood preservative use of O-PP and salts.

Toxicity to Aquatic Receptors

Freshwater Fish

The available acute toxicity studies (850.1075) categorize O-PP and salts as being moderately toxic to freshwater fish (Table 48). The guideline (850.1075) for acute toxicity testing is satisfied. Chronic data (fish early-life stage, 850.1400) are expected to be required.

Table 48 – Freshwater Fish Toxicity Data

Species, Age or size	Test Material (% a.i.)	Exposure Type/ pH/ hardness[27]/ temperature	Toxicity Endpoint[28]	Toxicity Category	MRID/ Study Classification/ Comments
Rainbow trout (*Oncorhynchus mykiss*)	Na- O-PP (71.48%)	Flow-through	--	--	46751206/ Unacceptable Percent recoveries were below acceptable range
Rainbow trout (*Oncorhynchus mykiss*), 1.1 g	O-PP (95%)	Static/ 7.1/ 35/ 10±1 °C	96-h LC_{50} = 2.75 ppm ae 95% CI = 2.4-3.2 ppm ae Probit slope = NA NOAEC = 2.4 ppm ae, mortality, loss of equilibrium, dark coloration	Moderately toxic	110232/ Supplemental/ Solvent concentration used unknown

[27] As mg/L calcium carbonate ($CaCO_3$).

[28] For O-PP mg a.i. is equal to mg ae, whereas mg a.i. of tests expressed as Na- O-PP where converted to mg ae by multiplying by the molar ratio of O-PP to Na O-PP (170.2/192.19 = 0.886) and results expressed as the tetrahydrate sodium salt (Na O-PP ·$4H_20$) were converted to mg ae by multiplying by the molar weight ratio of O-PP to Na O-PP ·$4H_20$ (170.2/264.28 = 0.664).

Species, Age or size	Test Material (% a.i.)	Exposure Type/ pH/ hardness[27]/ temperature	Toxicity Endpoint[28]	Toxicity Category	MRID/ Study Classification/ Comments
Rainbow trout (*Oncorhynchus mykiss*), 0.21 g, 2.8 cm SL	O-PP (99.25%)	Static/ 7.4-8.2/ 78/ 12.1-12.5 ºC	96-h LC_{50} = 4.0 ppm ae 95% CI = 3.6-4.5 ppm ae Probit slope = NA NOAEC = 1.8 ppm ae, immobilization, melanized fish	Moderately toxic	156044/ Acceptable
Bluegill sunfish (*Lepomis macrochirus*)	Na O-PP (71.48%)	Flow-through	--	--	46751210 Unacceptable Percent recoveries were below acceptable range
Bluegill sunfish (*Lepomis macrochirus*), 1.0 g	O-PP (95%)	Static/ 7.1/ 35/ 20±1 ºC	96-hr LC_{50} = 2.74 ppm ae 95% CI = 2.4-3.1 ppm ae Probit slope = 12.09 NOAEC = 1.0 ppm ae, loss of equilibrium, dark coloration	Moderately toxic	110232/ Supplemental/ Solvent concentration used unknown
Bluegill sunfish (*Lepomis macrochirus*), 0.4 g, 37.9 mm	Na O-PP ·$4H_20$ (97%)	Static/ 7.0/ 51.3/ 18.3 ºC	96-h LC_{50} = 3.9 ppm ae (6.1 ppm ts) Probit slope = NA	Moderately toxic	110135 (TN 640), 110203/ Supplemental
Bluegill sunfish (*Lepomis macrochirus*), 0.15 g, 2.0 cm SL	O-PP 99.25%	Static/ 7.5-7.9/ 77/ 17.1-17.4 ºC	96-h LC_{50} = 4.6 ppm ae 95% CI = 4.4-4.8 ppm ae Probit slope = 31.1 NOAEC = 3.2 ppm ae, immobilization, abnormal swimming	Moderately toxic	156044/ Acceptable
Fathead minnow (*Pimephales promelas*), 0.37 g, 2.8 cm SL	O-PP 99.25%	Static/ 7.2-7.7/ 76/ 16.8-17.3 ºC	96-h LC_{50} = 4.7 ppm ae 95% CI = 3.6-6.0 ppm ae Probit slope = NA NOAEC = 3.6 ppm ae, mortality	Moderately toxic	156044/ Acceptable
Fathead minnow (*Pimephales promelas*), 0.53 g, 3.4 cm SL	O-PP 99.25%	Static/ 7.2-7.9/ 76/ 17.1-17.4 ºC	96-h LC_{50} = 5.5 ppm ae 95% CI = 4.7-6.6 ppm ae Probit slope = NA NOAEC = 5.1 ppm ae, mortality	Moderately toxic	156044/ Acceptable

CI = confidence interval; NA: Not applicable; N.R. = Not reported; SL = standard length; TN = test number; ts = test substance not corrected for percent a.i.

Freshwater Invertebrates

The available acute toxicity studies for the waterflea categorize O-PP and salts as being moderately toxic to freshwater invertebrates (Table 20). The guideline (850.1010) for acute toxicity testing is satisfied. Chronic data (daphnid life-cycle, 850.1300) are expected to be required.

Table 49 – Freshwater Invertebrate Toxicity Data

Test Species	Test Material (% a.i.)	Exposure Type/ pH/ hardness[27]/ temperature	Toxicity Endpoint[29]	Toxicity Category	MRID/ Study Classification/ Comments
Waterflea (*Daphnia magna*), <24 hours old	Na O-PP ·4H_2O (97)	Static/ 25 °C (room)	48-h EC_{50} = 2.4 ppm ae (3.8 ppm ts) 95% CI = 2.0-3.0 ppm ae (3.1 – 4.6 ppm ts)	Moderately toxic	110222/ Acceptable
Waterflea (*Daphnia magna*), <24 hours old	O-PP (99.2)	Static/ 7.9-8.1/ 148/ 19.7-21.0 °C	48-h EC_{50} = 2.51 ppm ae 95% CI = 1.5-3.9 ppm ae NOAEC = 0.78 ppm ae	Moderately toxic	156044/ Acceptable

CI = confidence interval; NA: Not applicable; N.R. = Not reported; SL = standard length; TN = test number; ts = test substance not corrected for percent a.i.

Estuarine/Marine Fish and Invertebrates

Two acute toxicity studies are available for invertebrates, but no data are available for fish. *Ortho*-phenylphenol and salts are moderately to highly toxic to estuarine/marine invertebrates (Table 50). The guideline (850.1035, 850.1025 or 1055) for acute toxicity testing with estuarine/marine invertebrates is satisfied. Acute toxicity data (850.1075) are expected to be required for fish. Chronic data are expected to be required for fish (early life-stage, 850.1400) and an invertebrate (mysid life-cycle, 850.1350).

[29] For O-PP mg a.i. is equal to mg ae, whereas mg a.i. of the tetrahydrate sodium salt (Na- O-PP ·4H_2O) were converted to mg ae by multiplying by the molar weight ratio of O-PP to Na O-PP ·4H_2O (170.2/264.28 = 0.664).

Table 50 – Estuarine/Marine Fish and Invertebrate Toxicity Data

Test Species	Test Material (% a.i.)	Exposure Type/ pH/ salinity[30]/ temperature	Toxicity Endpoint[30]	Toxicity Category	MRID/ Study Classification/ Comments
Sheepshead minnow (*Cyprinodon variegatus*)	Na O-PP	Flow-through	--	--	46751208/ Unacceptable Percent recoveries were below acceptable range
Mysid shrimp (*Americamysis bahia*), 5-6 days old[31]	Na O-PP (71.48[32])	Flow-through/ 8.1-8.3/19-22 ppt/ 19-26 ºC	96-h LC_{50} = 0.28 ppm ae (0.32 ppm a.i.) 95% CI: 0.23-0.37 ppm ae (0.26-0.42 ppm a.i.) 96-h NOAEC = 0.063 ppm ae (0.071 ppm a.i.) Mean measured	Highly toxic	46751203/ Acceptable
Eastern oyster (*Crassostrea virginica*) shell deposition, 43 $\pm$ 3.4 mm valve height	Na O-PP (71.48[32])	Flow-through/ 7.9 -8.1/ 30-32 ppt/ 20-23 ºC	96-h IC_{50} = 3.44 ppm ae (3.89 ppm a.i.) 95% CI = 2.76-3.67 ppm ae (3.12-4.15 ppm a.i.) 96-h NOAEC = 0.80 ppm ae (0.88 ppm a.i.)	Moderately toxic	46751202/ Acceptable
Quahog clam (*Mercenaria mercenaria*), 2-cell embryo	Na O-PP (75.9[33])	Static	48-h IC_{50} = >8.86 ppm ae (>10 ppm a.i.)	---	25816, 5002007/ Supplemental/ Mollusc guidelines not in existence at time of study. Unknown test temperature and water quality. A solvent control was not included but solvents were tested.
Quahog clam (*Mercenaria mercenaria*), 2 day old larvae	Na O-PP (75.9[33])	Static	10-d IC_{50} = 0.66 ppm ae (0.75 ppm a.i.) (survival and length)	Highly toxic	

CI = confidence interval; NA: Not applicable; N.R. = Not reported; SL = standard length; TN = test number; ts = test substance not corrected for percent a.i.

[30] For O-PP mg a.i. is equal to mg acid equivalent (ae), whereas mg a.i. of Na O-PP were converted to mg ae by multiplying by the molar weight ratio of O-PP to Na O-PP (170.2/192.19 = 0.886).
[31] Range finding was conducted with < 24 hour old and 5-6 day old mysids, no difference in sensitivity was observed in the range-finding between these age classes.
[32] The test substance is actually Na O-PP ·$4H_2O$ but is represented in the table as Na O-PP without the weight percent of water. With the weight percent of water added the purity of the test substance Na O-PP ·$4H_2O$ is 98.16%.
[33] The test substance is actually Na O-PP ·$4H_2O$ but is represented in the table as Na O-PP without the weight percent of water. With the weight percent of water added the purity of the test substance Na O-PP ·$4H_2O$ is >99%.

Aquatic Plants

Five aquatic plant studies are available to establish the toxicity of O-PP and salts to vascular and non-vascular aquatic plants (Table 51). The guidelines for testing three algal species (850.4500) and cyanobacteria (850.4550) are satisfied. Guideline 850.4400 for testing a vascular aquatic plant is not satisfied (the submitted study did not adhere to dosing progression standards). Data from this study and the non-vascular plant studies are expected to be sufficient to conduct the risk assessment and a new study is not expected to be required at this time.

Table 51: Aquatic Plants Toxicity Data

Test Species	Test Material (% a.i.)	Exposure Type/ pH/ temperature	Toxicity Endpoint[30]	MRID/ Study Classification/ Comments
Duckweed (*Lemna gibba*)	Na O-PP (71.48[32])	Static renewal days 3 & 5/ 7.8-8.0 new, 8.4-9.4 aged / 24 ºC	7-day IC_{50} = 5.5 ppm ae (6.2 ppm a.i.) 7-day IC_{05} [34] = 0.63 ppm ae (0.71 ppm a.i.) Mean measured concentrations	46751209/ Supplemental[35]
Green algae (*Selenastrum capricornutum*)	O-PP (99.91)	Static/ 7.41-8.90/ 24±2 ºC	96-h IC_{50} = 1.39 ppm ae 96-h NOAEC = 0.42 ppm ae Mean measured concentrations	45688201/ Acceptable
Blue-Green alga (*Anabaena flos-aquae*)	Na O-PP (71.48[32])	Static/ 6.8-7.8/ 24±2 ºC	96-h IC_{50} = 2.0 ppm ae (2.3 ppm a.i.) 96-h NOAEC = 0.030 ppm ae (0.034 ppm a.i.)	46823801/ Supplemental/ 4X dose progression, age of medium, reduced PAR
Freshwater diatom (*Navicula pelliculosa*)		Static/ 7.2-9.4/ 24±2 ºC/	96-h IC_{50} = 1.7 ppm ae (1.9 ppm a.i.) 96-h NOAEC = 0.52 ppm ae (0.59 ppm a.i.)	46751205/ Acceptable
Marine diatom (*Skeletonema costatum*)			96-h IC_{50} = 5.7 ppm ae (6.4 ppm a.i.) 96-h NOAEC = 2.1 ppm ae (2.4 ppm a.i.)	46751201/ Acceptable

NA = Not applicable; N.R. = Not reported; ppt: parts per thousand; PAR = Photosynthetically active radiation

Emergent Rooted Aquatic Macrophytes

The available studies testing rice *(Oryza sativa)* are presented in Table 52. Inhibition of emergence and growth in rice was 7% and 5%, respectively, in Tier I tests. The guideline requirements (850.4225, 850.4250) are satisfied for Tier I testing. Tier II testing is not required, because inhibition in emergence and growth was less than 25% in the Tier I tests.

[34] Where a NOAEC cannot be calculated, an IC_{05} will be used as a surrogate. Because of the problems with the IC_{50} being lower than the LOAEC, the hypothesis method was deemed problematic and the IC_{05} used rather than asking for a repeat of the study.

[35] Dosing progression did not adhere to guideline standards (e.g., doses separated by a dilution factor of 4-5X instead of recommended 2X); results in this study occurred between highest and second highest treatment levels, making the IC_{50} lower than the LOAEC.

Table 52: –Emergent Rooted Aquatic Plant Toxicity Data

Test Species	Test Material (% a.i.)	Toxicity Endpoint[30]	MRID/ Study Classification/ Comments
Rice (*Oryza sativa*) – seedling emergence (Tier I)	Na O-PP (71.48[32])	IC_{25} >886 ppm ae (>1000 mg a.i./L) NOAEC = 886 ppm ae (<1000 mg a.i./L) 7% emergence inhibition after 14 days (1000 mg a.i./L)	46751207 Acceptable
Rice – vegetative vigor (Tier I)		IC_{25} >886 ppm ae (>1000 mg a.i./L) NOAEC = 886 ppm ae (<1000 mg a.i./L) 2% inhibition in dry weight after 14 days (1000 mg a.i./L)	46751204 Acceptable

Terrestrial Plants

Seedling emergence and vegetative vigor data are expected to be required (with the exception of data for rice).

Sediment-dwellers

No data are available. Chronic toxicity data (no guideline number) are expected to be required for sediment-dwelling freshwater (2 species) and estuarine/marine (1 specie) invertebrates, because O-PP and salts are expected to sorb to soil and persist (i.e., half-life ≥10 days) in aquatic sediments.

Appendix C References

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MRID 51597: McCann, J.A. (1974) Letter sent to Charles College dated Oct 22, 1974 Fish toxicity data. (U.S. Environmental Protection Agency, Animal Biology Laboratory, unpublished study; CDL:224700-T).

MRID 110135: Pitcher, F. (1973) Dowicide A: Bluegill: Test No. 640. (U.S. Environmental Protection Agency, Pesticides Regulation Div., Animal Biology Laboratory; unpublished study; CDL:129165-A).

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MRID 46751203: Hoberg, J. (2006) OPP/SOPP - Acute Toxicity to Mysids (*Americamysis bahia*) Under Flow - Through Conditions. Project Number: 12550/6383, 050369. Unpublished study prepared by Springborn Smithers Laboratories. 61 p.

MRID 46751206: Hoberg, J. (2006) OPP/SOPP - Acute Toxicity to Rainbow Trout (*Oncorhynchus mykiss*) Under Flow-Through Conditions. Project Number: 12550/6390, 050411. Unpublished study prepared by Springborn Smithers Laboratories. 56 p.

MRID 46823801: Hoberg, J. (2006) OPP/SOPP - Growth Inhibition Test with Freshwater Blue-Green Alga (*Anabaena flos-aquae*). Project Number: 12550/6387, 050373. Unpublished study prepared by Springborn Smithers Laboratories. 66 p.

MRID 48135402: Caspers, N. (2010) OSRI Rationale: *Ortho*-Phenylphenol: EDSP Order Numbers: EDSP-064103-225, EDSP-064103-226: Life Cycle Test with Water Fleas -- *Daphnia magna*. Project Number: 51/A/88. Unpublished study prepared by Bayer AG. 43 p.

MRID 48135403: Caspers, N. (2010) OSRI Rationale: *Ortho*-Phenylphenol: EDSP Order Numbers: EDSP-064103-225, EDSP-064103-226: Preventol O Extra: *Daphnia magna* Reproduction Test. Project Number: 1092/A/01/DL. Unpublished study prepared by Bayer AG. 24 p.

MRID 48135404: Caunter, J.; Williams, T. (2002) OSRI Rationale: Ortho-Phenylphenol: EDSP Order Numbers: EDSP-064103-225, EDSP-064103-226: Preventol O Extra: Determination of Effects on the Reproduction of Fathead Minnow (Pimephales promelas). Project Number: AH0603A, 07950/2000, BL7213/B. Unpublished study prepared by AstraZeneca UK, Ltd. 62 p.

MRID 48672606: Lehman, C. ; Fiting, J. ; Hutchinson, K. ; et al. (2012) *Ortho*-PhenylPhenol: The Fish Short-Term Reproduction Assay Using the Fathead Minnow, *Pimephales promelas*. Project Number: 111032. Unpublished study prepared by The Dow Chemical Co. 147p.

MRID 48672607: Lehman, C.; Hutchinson, K.; Fiting, J.; et al. (2011) *Ortho*-PhenylPhenol: The Amphibian Metamorphosis Assay Using the African Clawed Frog, *Xenopus laevis*. Project Number: 111018. Unpublished study prepared by The Dow Chemical Co. 202p.

MRID 48916901: Lehman, C.; Hutchinson, K.; Fiting, J. et al. (2012) *Ortho*-Phenylphenol: The Amphibian Metamorphosis Assay Using the African Clawed Frog, *Xenopus laevis*. Project Number: 111018. Unpublished study prepared by The Dow Chemical Company. 204p.

MRID 50417701: Tome, H.V.V. and Porch J.R. (2017) O-Phenylphenol: An Acute contact Toxicity Study with the Honey Bee. Conducted by EAG laboratories, EAG, Inc., Easton, MD. Sponsored by Lanxess Corporation, Pittsburgh, PA.

APPENDIX D: Risk Estimation Methods

Risk estimation integrates the results of the exposure and ecotoxicity data to evaluate the potential for the active ingredient and its transformation products to cause adverse effects to nontarget organisms. Depending on the uses being assessed, risk estimates are determined from calculations of acute and chronic risk quotients (RQs) or, for down-the-drain (DtD) assessments, from concentrations of concern (COCs).

Down-the-Drain Methodology

The DtD module of E-FAST[36] (Exposure and Fate Assessment Screening Tool) is used when discharge into the aquatic environment is from municipal (*i.e.,* domestic) waste water treatment plants (WWTPs) or from industrial sources of discharge (*e.g.*, cooling towers). The ecotoxicity data used in the model are the same as those used for RQ calculations. The levels of concern for listed and nonlisted aquatic organisms also are factored into the calculations for estimating the COCs.

For antimicrobials disposed to municipal WWTPs, the DtD module is used with the Probabilistic Dilution Model (PDM) option. This option estimates the number of days per year that the COC is exceeded for listed and nonlisted freshwater fish, freshwater invertebrates, and aquatic plants. Key input data include: (1) percent removal of active ingredient during wastewater treatment; (2) acute and chronic ecotoxicity endpoints for each receptor group; and (3) WWTP influent volume derived from such sources as production volume data, marketing data, and/or data on fraction of antimicrobial leached/removed from an end-use product.

Methodology for Estimating Water Column Exposure to Aquatic Organisms from Release of O-PP from Recirculating Cooling Towers

The General Population and Ecological Exposure from Industrial Releases module of E-FAST (Exposure and Fate Assessment Screening Tool) was used to estimate potential risks from exposure of aquatic organisms to O-PP downstream of recirculating cooling towers. Key input parameters required to run this module of E-FAST include:

- Environmental release of O-PP to surface water (kg/site/day);
- Concentrations of concern (COC) for aquatic organisms (ug/L);
- Standard Industrial Classification (SIC) code(s) selected to represent recirculating cooling tower facilities;
- Wastewater treatment removal of O-PP (percent);
- Annual number of days of release to surface water (days per year); and

[36] Additional information on E-FAST is available on the EPA website https://www.epa.gov/tsca-screening-tools/e-fast-exposure-and-fate-assessment-screening-tool-version-2014

- Selection of high-end or average case scenario.

A discussion of the basis of high-end and average case scenario results is included at the end of this Appendix. The approach used to estimate aquatic exposures to O-PP from release of blowdown water from recirculating cooling towers can be described in four steps:

- Step 1: Estimate environmental release to surface water from recirculating cooling tower blowdown water from recirculating cooling tower blowdown water (kg/site/day);
- Step 2: Determine percent removal during wastewater treatment;
- Step 3: Derive concentrations of concern (COC) for aquatic organisms from LC_{50} and NOAEC values; and
- Step 4: Estimate aquatic exposures from releases of recirculating cooling tower blowdown water to surface water using the general population exposures from industrial releases module of E-FAST.

STEP 1: Estimate Environmental Release to Surface Water from Recirculating Cooling Tower Blowdown Water (B) in kilograms per site per day

A generic scenario developed by OPPT/CEB (Office of Pollution Prevention and Toxics/Chemical Engineering Branch) for recirculating cooling towers (USEPA, 1991) was used to estimate daily releases to surface water of O-PP in blowdown water in kilograms per site per day.

The following equation is used to estimate releases of antimicrobial pesticide to surface water from blowdown:

$B = (0.6\%) (X_R) (R) (5760 \times 10^{-06}$ min-kg/day-gal)

where:

B = release of antimicrobial pesticide via blowdown water to surface water (kg/site/day);

X_R = concentration of antimicrobial pesticide in recirculating water (ppm); and

R = recirculation rate of cooling water (gallons per minute).

The conversion factor, 5760×10^{-06} min-kg/day-gal is derived from:
(1440 min/day) (4 kg/gal) (10^{-06} ppm) in which the blowdown water is assumed to have a specific gravity of 1.0, thus 1-liter weighs 1 kilogram, and the conversion of 3.78 liters per gallon is expressed in kilograms per gallon and rounded up to the nearest significant figure. The value, 0.6% is the percentage of cooling tower water that is assumed to be released to surface water via blowdown.

The following input values were used in this calculation:

- X_R: concentration of O-PP in recirculating cooling tower water – 2.5 to 10 ppm O-PP (derived from information on the label for "VeriGuard® Plus" (EPA Reg. No. 67869-44) based on the range of product application rates (3.3 to 13.2 fluid ounces per 1000 gallons of water).

- R: recirculation rate of cooling water– 2,000 gallons per minute for a moderate-size cooling tower (default value based on standard scenario developed by OPPT/CEB)) and 100,000 gallons per minute for a large-size cooling tower (default value based on standard scenario developed by OPPT/CEB).

The table that follows presents values of environmental releases of O-PP modeled for large-size and moderate-size cooling towers according to product application rate.

STEP 2: Determine Percent Removal During Wastewater Treatment

The Agency has assumed that 0% of O-PP will be removed during WWT. This is based on the ready biodegradability study (MRID 49538101). The Agency does not possess an activated sludge sorption isotherm study and therefore assumed no sorption of O-PP.

There is no information on the product label to indicate that blowdown water must be treated prior to discharge to surface water. Consequently, exposures and risks to aquatic organisms were also estimated assuming that blowdown water could be discharged directly to surface water without treatment. In this case, it was assumed that there would be no removal of O-PP from blowdown water prior to its discharge to surface water.

STEP 3: Estimate Concentrations of Concern (COC) for Aquatic Organisms

The results of the DtD module are expressed as number of days of exceedance of COCs for aquatic organisms. The Agency uses the most sensitive ecotoxicology endpoints for surrogate species to assess risk to each aquatic receptor group, such as freshwater fish, freshwater invertebrate, sediment-dwelling invertebrate, and aquatic plants.

- COCs for acute effects were determined by dividing LC_{50} values from acute toxicity tests on aquatic vertebrates and invertebrates by 2.
- COCs for chronic effects for non-listed species were based on No Observed Adverse Effects Concentration (NOAEC) values from tests on aquatic vertebrates and invertebrates.
- COCs for listed endangered and threatened aquatic organisms were determined by dividing LC_{50} values from acute toxicity tests on aquatic vertebrates and invertebrates by 20.
- Acute COCs for aquatic vascular plants and algae are based on EC_{50} values.
- COCs for endangered algae and aquatic vascular plants are based on NOAEC values.

STEP 4: Estimate General Population and Ecological Exposure from Industrial Releases

E-FAST, version 2.0, was used to determine the magnitude and frequency of exposure of aquatic organisms from releases of O-PP via blowdown water from recirculating cooling towers.

For detailed information on the features, data, and methods on which the models in E-FAST, version 2.0, are based, refer to the latest version of the Documentation Manual for E-FAST, version 2.0 (USEPA, 2007). This discussion is limited to summarizing the steps required to estimate exposure of aquatic organisms to blowdown water from industrial use of O-PP in recirculating cooling towers using the General Population and Ecological Exposure from Industrial Releases module of E-FAST with the PDM (probabilistic dilution model) option. The user is guided through a series of menus or pages that provide prompts indicating where the user should input data. Key input parameters needed to run this module and option include:

- Environmental release to surface water in kg/site/day (estimated from Step 1);
- Percent removal of O-PP during wastewater treatment (from Step 2); and
- Concentrations of Concern (COC) for aquatic organisms (estimated from Step 3).

One of the first screens that appears when running the General Population and Ecological Exposure from Industrial Releases module of E-FAST is the physical/chemical and fate inputs screen; Upon accessing this screen, the user must enter the following information:

- Chemical identification (e.g., CAS number);
- Chemical name or abbreviation;
- Bioconcentration factor (measured or estimated) (used to estimate human exposure from ingestion of fish);
- Percent wastewater treatment removal (measured or estimated);
- Percent adsorption to wastewater treatment sludge (measured or estimated); and
- Percent drinking water treatment removal (in the absence of data, assume no removal).

The user must also select the appropriate models for estimating exposure to aquatic organisms. (In this instance, the appropriate model to use is the general population and ecological exposure from industrial releases to surface water model with the option to also run the probabilistic dilution model.) Next, the user accesses the "Release Information Page". This page consists of three sub-pages including:

- general release information;
- select a facility; and
- select a SIC code.

The "select a facility" subpage, which accesses a database of site-specific information for manufacturing facilities, is not applicable for estimating exposures from processing and industrial use. To estimate exposures to aquatic organisms from surface water releases from processing or industrial use, the user must provide input values for the "general release information" subpage and the "select a SIC code" subpage. On the general release's information subpage, the user must input the following:

- type (media) of release (i.e., surface water, landfill, and/or ambient air); in this case, the user would select "surface water".

- amount of release in kg/site/day, based on the results from CEB's generic scenario (from Step 1 of this appendix);
- days per year of release, based on results from CEB's generic scenario; the default value for the recirculating cooling towers scenario is 360.
- Upon being present with a choice of selecting "SIC code analysis" or "facility analysis", select SIC code analysis. A menu of SIC code descriptions will appear on the screen and the user will be prompted to select one; in this instance, the appropriate SIC code description would be "Steam Electric Power Plants".
- Input the number of cooling tower sites; since there is no production volume information available for O-PP used in recirculating cooling towers that can be used to derive this input, no value is entered.
- In the box, "enter release activity", the user has the option to enter a description of the release; in this case, an apt description might be "indirect release of cooling tower blowdown".
- Place a check in the box, "include PDM run".
- Enter three values for concentrations of concern.
- Select results for high end or average exposure.
- Finally, check the box, "Release activities completed? Continue to Exposure Factors page." Upon checking this box, the Exposure Factors page will appear.

The information in the exposure factors page is not used to estimate exposures to aquatic organisms, but is used to quantify human exposures from ingestion of drinking water and fish. This page includes default values for body weight, exposure duration, averaging time, and acute and chronic drinking water and fish ingestion rates. These values are automatically selected unless the user changes them.

Description of High-End Versus Average Case Scenario

The General Population and Ecological Exposure from Industrial Releases module of E-FAST uses environmental releases estimated in Step 1 of this Appendix, stream dilution factors (i.e., the ratio of stream flow to industrial wastewater treatment plant flows), and wastewater treatment removal efficiency to provide both high-end and median time-averaged surface water concentrations of a chemical substance immediately downstream of a discharge point. Stream flows are not single point estimates since streams have a highly variable seasonal flow pattern. PDM uses probability distributions as inputs and calculates the resulting probability distribution of the stream concentration.

To determine stream dilution factors for industrial uses of chemical substances such as O-PP used in recirculating cooling towers, a representative SIC code must be selected. The model will develop a distribution of stream dilution factors based on the ratio of stream flows to plant flows for facilities that belong to a specified SIC code. The distribution of stream flow values used is those immediately downstream of the facilities that belong to a specified SIC code. For

this risk assessment, stream dilution factors (SDFs) for recirculating and once-through cooling systems were based on the ratio of receiving stream flows to facility effluent flows for those facilities included in the steam electric power plants SIC code (SIC 4911). For the high-end scenario, results of the number of days per year that COCs are exceeded are based on the upper 10^{th} percentile of SDFs. For the average case scenario, results of the number of days per year that COCs are exceeded are based on the 50^{th} percentile of SDFs. For the upper 10^{th} percentile SDFs, or high-end scenario, the stream flow to plant flow ratio is relatively low since plant flows can contribute considerable volume to the flow of the stream and resulting surface water concentrations can be relatively high. For the 50^{th} percentile SDF, the stream flow to plant flow ratio is more typical.

APPENDIX E. Summary of Occupational Non-cancer Algorithms

Occupational Non-cancer Handler Algorithms

Potential daily exposures for occupational handlers are calculated using the following formulas:

$$E = UE * AR * A * 0.001\ mg/ug$$

where:

E	=	exposure (mg ai/day),
UE	=	unit exposure (µg ai/lb ai),
AR	=	maximum application rate according to registered label (lb ai A or lb ai/gal), and
A	=	area treated or amount handled (e.g., A/day, gal/day).

The daily doses are calculated using the following formula:

$$ADD = \frac{E * AF}{BW}$$

where:

ADD	=	average daily dose absorbed in a given scenario (mg ai/kg/day),
E	=	exposure (mg ai/day),
AF	=	absorption factor (dermal and/or inhalation), and
BW	=	body weight (kg).

Margin of Exposure: Non-cancer risk estimates for each application handler scenario are calculated using a Margin of Exposure (MOE), which is a ratio of the toxicological endpoint to the daily dose of concern. The daily dermal and inhalation dose received by occupational handlers are compared to the appropriate POD (i.e., NOAEL) to assess the risk to occupational handlers for each exposure route. All MOE values are calculated using the following formula:

$$MOE = \frac{POD}{ADD}$$

where:

MOE	=	margin of exposure: value used by HED to represent risk estimates (unitless),
POD	=	point of departure (mg/kg/day), and
ADD	=	average daily dose absorbed in a given scenario (mg ai/kg/day).

APPENDIX F. Submission of Analytical Standards

The analytical reference standards for o-phenylphenol, or updated certificates of analysis (COAs), should be sent to the Analytical Chemistry Branch (ACB), which is located at Fort Meade, MD. It should be sent to the attention of either Theresa Cole or Thuy Nguyen at the address listed below, along with a letter of transmittal. **Please note that the full 9-digit ZIP Code is required, or the mail will be returned to the registrant.**

USEPA
National Pesticide Standards Repository
Analytical Chemistry Branch/BEAD/OPP
701 Mapes Road
Fort George G. Meade, MD 20755-5350

The letter of transmittal should include the assay of the standard, name of the analytical method used, a statement of principal impurities, purification procedures employed, storage requirements, and special precautions for safe handling. Replacement of standards, or updated COAs, may be required periodically if supplies are exhausted, if the standards expire, or if decomposition occurs during storage. Material Safety Data Sheets (MSDSs) must accompany all analytical standards as specified by the Occupational Safety and Health Administration (OSHA) in 29 CFR §1910.1200.

APPENDIX G. International Residue Limits Sheet

O-phenylpnenol/Sodium *o*-phenylphenate (064103/064104; 7-1-2019)

Summary of US and International Tolerances and Maximum Residue Limits				
Residue Definition:				
US	Canada		Mexico	Codex
40 CFR §180.129 (a): Plant: combined residues of *o*-phenylpnenol and sodium *o*-phenylphenate, each expressed as *o*-phenylpnenol.	*o*-phenylpnenol, sodium salt (calculated as orthophenylphenol)			Plant: Sum of 2-phenylpnenol and sodium 2-phenylphenate, free ang conjugated, expressed as 2-phenylpnenol
Commodity[1]	*Tolerance (ppm) /Maximum Residue Limit (mg/kg)*			
	US	Canada	Mexico[2]	Codex[3]
Fruit, citrus, group 10-10	10	10 Citrus fruits		10 Citrus fruits, Po 0.5 Orange juice, PoP
Pear	**20**	25 Pear		**20** Pear[4], Po
MRLs with NO US Registration				
				60 Citrus pulp, dry, PoP
US tolerances for theses commodities were revoked in the 2006 RED.		25 Apples		
		10 Bell peppers		
		10 Cantaloupes		
		20 Carrot roots		
		5 Cherries		
		10 Cucumbers		
		20 Nectarines		
		20 Peaches		
		10 Pineapples		
		20 Plums		
		15 Sweet potato roots		
		10 Tomatoes		
Completed: S. Keel; 7/1/2019				

[1] Includes only commodities of interest for this section. Currently there are several additional tolerances listed in 40 CFR §180.129(a), which should have been revoked following the publication of 2006 RED. HED has updated the 40 CFR §180.129(a) for registration review. A summary of tolerance revisions for o-phenylphenol and its sodium salt is presented in Table 5.

[2] Mexico adopts US tolerances and/or Codex MRLs for its export purposes.

[3] Po = postharvest treatment, such as treatment of stored grains. PoP = processed postharvest treated commodity, such as processing of treated stored wheat.

[4] **Pear**

Codex MRL: The Pear Bureau Northwest, USA provided data on supervised trials for the postharvest treatment of pears with Na-O-PP. Ten independent trials in duplicate were conducted in the US using EPA Reg. No. 57227-7 (transferred from 8611-2, with 22.6% Na- O-PP, 1.1 kg ai/L) and matching GAP (postharvest dip treatment in 0.49 kg ortho-phenylphenate tetrahydrate/hl solution for 2 min., followed by a rinse for 2 sec.). The maximum residues of O-PP in pears collected after 20-27 days of frozen storage were 5.9, 6.3, 6.4, 6.9, 7.9, 8.0, 8.9, 10, 12, and **13** mg/kg. The Meeting estimated a maximum residue level of 20 mg/kg for O-PP in pears and an STMR (supervised trial median residue) of 8 mg/kg (Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group (JMPR), 16 ~ 25 September 2002).

US tolerance: The tolerance of 25 ppm was based on residue data from supervised trials with Na- O-PP conducted in the US on pear treated postharvest by dipping in 0.4-0.99% Na- O-PP aqueous solutions for 10 seconds, Residues of O-PP in/on rinsed pear samples ranged from 1-25 ppm. Residues in/on samples without rinsing ranged from 1-22 ppm (Report of JMPR, 8 ~ 15 December 1969). The Codex Committee proposed in 2003 an MRL of 20 mg/kg for O-PP in/on pears based on field trial data provided by Pear Bureau Northwest, USA, and revoked the previous MRL of 25 mg/kg, which was based on US data reported in the 1969 JMPR (Report of the Thirty-fifth Session of the Codex Committee on Pesticide Residues, 31 March ~ 5 April 2003, ALINORM 03/24A). HED will adopt the updated Codex MRL and set the tolerance for pear commodities at 20 ppm to harmonize with Codex.