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Prevention, Pesticides and Toxic Substances (7510P)
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Caprylic (Octanoic) Acid Summary Document: Registration Review

Caprylic (Octanoic) Acid
Registration Review: Initial Docket
June 2008

Approved By:

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I. PRELIMINARY WORK PLAN

Introduction

The Food Quality Protection Act (FQPA) of 1996 amended the Federal Fungicide Insecticide and Rodenticide Act (FIFRA) to mandate a new program: registration review. All pesticides distributed or sold in the United States generally must be registered by EPA, based on scientific data showing that they will not cause unreasonable risks to human health, workers, or the environment when used as directed on product labeling. The new registration review program is intended to make sure that, as the ability to assess and reduce risk evolves and as policies and practices change, all registered pesticides continue to meet the statutory standard of no unreasonable adverse effects. Changes in science, public policy, and pesticide use practices will occur over time. Through the new registration review program, the Agency periodically reevaluates pesticides to make sure that as change occurs, products in the marketplace can continue to be used safely. Information on this program is provided at
http://www.epa.gov/oppsrrd1/registration_review/

The Agency has begun to implement the new registration review program pursuant to FIFRA Section 3(g) and will review each registered pesticide every 15 years to determine whether it continues to meet the FIFRA standard for registration. The public phase of registration review begins when the initial docket is opened for each case. The docket is the Agency's opportunity to state what it knows about the pesticide and what additional risk analyses and data or information it believes are needed to make a registration review decision.

The EPA Registration Review Team examined the hazard and exposure databases for caprylic (octanoic) acid (Case 5028) to determine whether current science policy or database adequacy has materially affected the overall risk picture. Caprylic acid is an antimicrobial pesticide used as a food contact surface sanitizer in commercial food handling establishments on dairy equipment, food processing equipment, breweries, wineries, and beverage processing plants. It is also used as disinfectant in health care facilities, schools/colleges, animal care/veterinary facilities, industrial facilities, office buildings, recreational facilities, retail and wholesale establishments, livestock premises, restaurants, and hotels/motels. In addition, caprylic acid is used as an algaecide, bactericide, and fungicide in nurseries, greenhouses, garden centers, and interiorscapes on ornamentals. Products containing caprylic acid are formulated as soluble concentrate/liquids and ready-to-use liquids.

Risk Assessment Status & Anticipated Risk Assessment and Data Needs

Human Health Risk Assessment Status

Caprylic acid was first registered on October 26, 1994, having been registered after 1984, the 1988 FIFRA Amendments excludes this active ingredient from the

process of Reregistration. Therefore, a Reregistration Eligibility Decision (RED) has not been issued for caprylic acid.

The Agency has screened the hazard and exposure databases for caprylic acid and does not anticipate that additional toxicity or exposure data will be needed for registration review. In addition, the Agency does not expect that any additional human health risk assessments will need to be conducted.

For a detailed discussion of the anticipated human health exposure and risk assessment needs, please refer to *"Caprylic Acid*: *Human Health Effects Scoping Document for Registration Review"* (DP351520), dated April 29, 2008 which is appended to this document.

Toxicology Profile

Heptanoic, caprylic, and nonanoic acids are a group of short-chained linear fatty acids of seven, eight, and nine carbon atoms in length, respectively. Based on their structural similarities, toxicity data can be used almost interchangeably as surrogate data for these three substances. Based on the evidence presented, the Agency used the surrogate data from heptanoic and nonanoic acid to supplement the available information on caprylic acid. However, the primary source of information for this assessment was an Agency Risk assessment by R. Quick, (D330286), dated December 4, 2006 for a proposed use on ornamentals. In addition, the documentation supporting the establishment of an exemption from the requirement of a tolerance for decanoic acid (68 FR 7935, 2/19/03) was also used, as well as, the capric acid (decanoic acid) registration review human health scoping document.

Acute Toxicity

Data and information from the open technical literature are acceptable to satisfy the requirement for acute toxicity studies. Acute oral LD50 values for caprylic acid range from 1283 mg/kg to 10,080 mg/kg bw in rats, and a dermal LD50 value greater than 5000 mg/kg was reported in rabbits. No acute inhalation data are available for caprylic acid; however, studies have been conducted on heptanoic acid (98.5%) and nonanoic acid (97%). The LC50 values were greater than 4.6 mg/l for heptanoic acid and 0.46 mg/l - 3.8 mg/l for nonanoic acid. The test substance caused a moderate dermal reaction when 0.5 ml was applied to the skin. Additional information can be found at: http://www.epa.gov/chemrtk/pubs/summaries/alipalde/c13033tc.htm)

Studies conducted using nonanoic acid resulted in classification into the following Toxicity Categories: primary, dermal and eye irritation (Toxicity Category II), acute oral toxicity (Toxicity Category IV), acute dermal and inhalation toxicity (Toxicity Category III). Sensitization test results showed that nonanoic acid is not considered a dermal sensitizer. Based on the information on nonanoic acid, caprylic acid is not likely to be a dermal sensitizer (MRID 43843501-06).

Subchronic Toxicity

No data on caprylic acid are available for subchronic and chronic toxicity. However, there are subchronic and chronic toxicity data for heptanoic acid and nonanoic acid (pelargonic acid). In a 14-day rat oral toxicity study, no systemic toxicity was observed in either sex dosed with pelargonic acid (nonanoic acid) as high as 20,000 ppm (1,834 mg/kg/day), the highest dose tested. In addition, no adverse effects were caused on survival, clinical signs, body weight gain, food consumption, hematology, clinical chemistry or gross pathology. For each dose, three animals per sex were tested. However, the study did not report organ weights and histopathology. This was considered a deficiency in this study. Nevertheless, the Agency determined that, because no systemic toxic effects were observed at a very high dose level approaching 2,000 mg/kg/day, a 90-day oral study was not necessary (Kuhn, 1995; MRID 43843507).

Groups (10/sex/group) of rats (Sprague-Dawley) 45 days of age were given heptanoic acid by gavage in corn oil (10 ml/kg at doses of 0, 875, 1750, and 3500 mg/kg bw/day) daily for 27 days. Clinical signs included languid behavior, dyspnea, polypnea, tremors, wheezing, ataxia and excess salivation. Significant decreases in body weight and food consumption (male only) were observed compared to those of the control group. Hyperkeratosis of the non-glandular stomach was reported in high-dose males and females at necropsy. No significant findings in low- and mid-dose groups that could be related to administration of the test material. Clinical chemistry and hematological examinations revealed no significant changes compared to those for the control group. A NOAEL of 1750 mg/kg/day and a LOAEL of 3500 mg/kg/day were determined based on decreased body weights and food consumption and gross lesions of the stomach (http://www.epa.gov/chemrtk/pubs/summaries/alipalde/c13033tc.htm; Terrill, 1990b).

A 28-day dermal toxicity study conducted on rabbits was submitted to the Agency under TSCA section 8(e). Five male and five female New Zealand white rabbits were dermally treated with pelargonic acid present in mineral oil. In all, 10 applications were made (5 per week) at a dose level of 500 mg/kg/day. A 2-week recovery period was allowed for selected rabbits. During the first and second week of treatment, slight body weight loss and decreased food consumption were observed. One female rabbit showed ocular discharge and hypoactivity during the second week of treatment. All rabbits dermally treated with pelargonic acid by day 14 showed signs of severe erythema and moderate edema. Dermal reactions consisting of moderate desquamation, moderate fissuring, eschar, exfoliation and necrosis were also observed at day 14. By day 29, all dermal reactions had reversed. It was evident that at the treatment level of 500 mg/kg/day of pelargonic acid, significant dermal signs of toxicity were observed but no significant systemic reaction (http://www.epa.gov/chemrtk/pubs/summaries/alipalde/c13033tc.htm; C7-C9 Consortium. 2004; Auletta, 1981).

A similar dermal study was conducted using heptanoic acid. A single dose of 500 mg/kg/day of heptanoic acid in mineral oil (25% solution) was administered to New Zealand White rabbits (5/sex/group) daily for five days a week for two weeks with a two-

week recovery period. Most animals exhibited a weight loss after 2 weeks of treatment, but showed normal weight gains during the additional two-week recovery period compared to controls. All animals showed localized severe erythema, slight to severe edema, necrosis, desquamation and exfoliation by the second week of treatment. Ocular irritation and decreased food consumption were also observed in some animals. All animals were free of signs of dermal and systemic toxicity at the end of the two-week recovery period. Microscopic examination revealed epidermal necrosis, epidermal hyperplasia, and hyperkeratosis at the application site. A NOAEL of less than 500 mg/kg/day was determined http://www.epa.gov/chemrtk/pubs/summaries/alipalde/c13033tc.htm; C7-C9 Consortium. 2004; Auletta, 1981).

A supplemental study on chronic toxicity/carcinogenicity in mice was conducted for 80 weeks. A dose of 50 mg of pelargonic acid was dermally applied to each mouse twice/day for 80 weeks. Histopathology showed no non-neoplastic or neoplastic lesions on skins and internal organs of mice. The Agency concluded that although this study was not exactly conducted according to guideline, it adequately assesses the chronic toxicity and the carcinogenic potential of pelargonic acid via the dermal route (Suskind, 1985; MRID 43961801).

Dietary and Drinking Water Assessment

Caprylic acid has been classified by the Food and Drug Administration (FDA) as a direct food additive that is Generally Recognized as Safe (GRAS) when this naturally-occurring component of food is added as a flavoring agent or adjuvant to various foods. Dietary exposure is expected to occur from the FDA direct food additive uses as well as the EPA indirect food additive uses on dairy equipment, food processing equipment and utensils, and in eating establishments. However, EPA has established exemptions from the requirement of a tolerance for residues of caprylic acid in foods [40 CFR 180.940(a), - (b), and -(c)] because there are no adverse systemic effects on man attributable to oral exposure.

The current antimicrobial indoor uses of caprylic acid are not expected to result in residues in drinking water supplied by residential wells or municipal sources. In addition all use sites are indoors except for the registered ornamental use which includes the option to apply their product on ornamental plants raised outdoors. As a result, dietary exposure via drinking water may occur but is likely to be very low. Based on the low toxicity, knowledge that caprylic acid is naturally-occurring, is already a component of the human diet, and is recognized by the FDA as a GRAS chemical, a dietary and drinking water risk assessment is not required.

Occupational and Residential Assessment

There are currently no residential uses of caprylic acid. However, there is the opportunity for postapplication and bystander exposure of adults and children to caprylic acid resulting from its use in schools, gyms, restaurants, hospitals, etc. as

sanitizers/disinfectants. Although exposure is likely as a result of these uses, risk assessments are not applicable as there are no adverse systemic effects on man attributable to dermal, inhalation, or inadvertent oral exposure.

In addition, occupational exposure to mixer/loader/applicators is likely from the registered uses in food and beverage processing facilities, industrial, institutional, and commercial facilities, and on ornamentals. A quantitative risk assessment is not needed because of the low toxicity, adverse systemic effects attributable to the dermal and inhalation routes of exposure to caprylic acid are not expected. Label instructions and the requirement that handlers wear certain personal protective equipment (PPE) such as gloves and eye covering are sufficient to protect workers from the localized, irritation effects of exposure to caprylic acid.

Aggregate Assessment

Exposure to caprylic acid could result from food, drinking water, and postapplication/bystander sources; all of these could contribute to aggregate risk. As caprylic acid induces no adverse systemic effects via any route of exposure, an aggregate risk assessment is also not needed.

Incidents

The Agency consulted the OPP Incident Data System (IDS) to investigate the incidence of human poisonings resulting from caprylic acid exposure for purposes of this Registration Review Scoping Document. In addition, the following sources were searched for incident reports associated with toxic effects of caprylic acid: Poison Control Centers, California Department of Pesticide Regulation (1982-2005), National Pesticide Telecommunications Network (NPTN), and the published scientific literature.

A total of 29 incidents involving 260 individuals associated with products containing caprylic acid have been reported in the IDS. The bulk of these were reported by the registrant, Ecolab, Inc. from 1999 to 2004. In every case, the specific end-use product name was known. The most common symptoms included: irritation of the lungs, throat, eyes, and skin, nausea, dizziness, and vomiting. The severity of the symptoms ranged from mild to severe such as eye redness to corneal abrasions or skin rash to blisters, edema, and erythema. In a few cases, victims developed blackened areas on the skin, fainted, or coughed blood. Most patients were hospitalized. It must be noted that all five antimicrobial products implicated also contained other active ingredients. Although caprylic acid is a moderate eye irritant (Toxicity Category II) and a mild dermal and inhalation irritant (Toxicity Category III), at least one other active ingredient in every implicated end-use product is expected to be more severely irritating than caprylic acid, especially at the concentrations formulated. It should be noted that there are no residential uses of caprylic acid. However, workers handling the undiluted antimicrobial product directly, i.e., during pouring and mixing the end-use product in/with water prior to application, would be most at risk. Clearly, personal protective equipment (PPE)

including goggles and chemical-resistant gloves are needed for handlers. Current labels bear the appropriate warning statements and PPE based on available toxicity and incident data.

Anticipated Physical/ Chemical Property Data Needs

All product chemistry data requirements have been fulfilled for caprylic acid. Additional product chemistry data are not needed for the registration review of caprylic acid. For a detailed discussion of the status of the environmental and ecological risk assessments for caprylic acid please refer to "*Summary of Product Chemistry, Environmental Fate and Ecotoxicity Data for the Caprlic Acid Registration Review Decision Document"* (DP 351519), dated May 8, 2008, which is appended to this document.

Environmental Fate Assessment Status and Data Needs

Caprylic acid is classified as a saturated fatty acid, a group of substances which is completely biodegradable and found extensively in nature. Specifically, caprylic acid occurs in a number of plants, and animal sources such as animal oils, fats, butter, coconut oil, etc. It is a food-grade substance, non-volatile and relatively inert to aqueous hydrolysis. Caprylic acid is a minimal risk and low concern inert, a normal constituent in animal diet and is readily metabolized by all forms of life. Microorganisms rapidly degrade fatty acids in soil. The breakdown products of fatty acids are expected to be carbon dioxide and water. The Agency has no environmental fate data on caprylic acid and there are no additional data needed at this time. Unless a toxicological concern is identified, the Agency believes that, due to the nature of caprylic acid and its registered use patterns, environmental fate studies are unnecessary. Additional information can be found in the document titled: "Summary of Product Chemistry, Environmental Fate, and Ecotoxicity Data for the Caprylic Acid Registration Review Decision Document," dated May 8, 2008. This evaluation is appended to this document.

Ecological Risk Assessment Status and Data Needs

An ecological risk assessment was not conducted for caprylic acid and the Agency does not anticipate needing additional ecological data at this time. Caprylic acid is naturally occurring in vegetable oils and animal fats. Fatty acids are a significant part of the normal daily diet of mammals, birds and invertebrates. Fatty acids normally are metabolized, forming simple compounds that serve as energy sources and structural components used in all living cells. Based on its low toxicity, the biodegradable nature of this chemical, and the fact that it is readily metabolized by all forms of life, the Agency has waived all ecological effects data requirements for this active ingredient. Additional information can be found in the document titled: "Summary of Product Chemistry, Environmental Fate, and Ecotoxicity Data for the Caprylic Acid Registration Review Decision Document," dated May 8, 2008. This evaluation is appended to this document.

Risk to Threatened and Endangered Species

Based on indoor use patterns, low exposure levels, and low toxicity potential of caprylic acid, the Agency expects that the registered uses of caprylic acid will have "no effect" (NE) on endangered or threatened terrestrial or aquatic species, or their designated critical habitats, as listed by the U.S. Fish and Wildlife Service (USFWS) and the National Oceanic and Atmospheric Administration (NOAA). However, EPA will review any comments made by the public on this document and will conduct an environmental risk assessment, if new information provided during the public comment period warrants such action.

Timeline

EPA has created the following estimated timeline for the completion of the caprylic acid registration review. The Agency does not anticipate requiring additional studies for this chemical.

Registration Review for Caprylic Acid Projected Registration Review Timeline	
Activities	**Time (Quarters are calendar years)**
Phase 1 - Opening Docket	
Open Public Comment Period for Caprylic Acid Docket	June 2008
Close Public Comment Period	September 2008
Phase 2 - Case Development	
Develop Final Work Plan (FWP)	November 2008
Registration Review Decision	
Open Public Comment Period for Proposed Reg. Review Decision	January 2009
Close Public Comment Period	March 2009
Final Decision and Begin Post-Decision Follow-up	May 2009
Total (years)	1

Guidance for Commenter

The public is invited to comment on EPA's preliminary registration review work-plan and rationale. The Agency will consider all comments as well as any additional information or data provided in a timely manner prior to issuing a final work plan for the caprylic acid case.

Stakeholders are also specifically asked to provide available information and data in the following areas:

1. Confirmation on the following label information:
    a. Sites of application
    b. Formulations
    c. Application methods and equipment
    d. Maximum application rates
    e. Frequency of application, application intervals and maximum number of applications
    f. Geographic limitations on use
2. Use or potential use distribution
3. Use history
4. Usage/use information for non-agricultural uses (e.g., materials preservation)
5. Typical application interval
6. State or local use restrictions
7. Ecological incidents (non-target plant damage and avian, fish, reptilian, amphibian and mammalian mortalities) not already reported to the Agency
8. Monitoring data
9. Structure Activity Relationships

State Water Quality Concerns (Clean Water Act Section 303(d)):

Caprylic acid 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: http://oaspub.epa.gov/tmdl/waters_list.impairments?p_impid=3. The Agency invites submission of other existing water quality data for this chemical. To the extent possible, data should conform to the quality standards in Appendix A of the "OPP Standard Operating Procedure: Inclusion of Impaired Water Body and Other Water Quality Data in OPP's Registration Review Risk Assessment and Management Process," (http://www.epa.gov/oppsrrd1/registration_review/water_quality_sop.htm), in order to ensure they can be used quantitatively or qualitatively in pesticide risk assessments.

Trade Irritants

Through the registration review process, the Agency solicits information on trade irritants and, to the extent feasible, take steps toward facilitating irritant resolution. Growers and other stakeholders are asked to comment on any trade irritant issues resulting from the lack of Maximum Residue Limits (MRLs) or disparities between U.S. tolerances and MRLs in key export markets, providing as much specificity as possible regarding the nature of the concern. Caprylic acid is registered for use as a food contact surface sanitizer in commercial food handling establishments. Caprylic acid is

characterized by low toxicity, and is considered generally recognized as safe (GRAS) by the Food and Drug Administration (FDA) for use in foods. There are no MRLs established for caprylic acid. Therefore, the Agency does not anticipate current uses of caprylic acid posing concerns as a trade irritant.

Environmental Justice

EPA seeks to achieve environmental justice, the fair treatment and meaningful involvement of all people, regardless of race, color, national origin, or income, in the development, implementation, and enforcement of environmental laws, regulations, and policies. To help address potential environmental justice issues, the Agency seeks information on any groups or segments of the population who, as a result of their location, cultural practices, or other factors, may have atypical, unusually high exposure to caprylic acid compared to the general population. Please comment if you are aware of any sub-populations that may have atypical, unusually high exposure compared to the general population.

Structure Activity Relationships:

EPA must rely upon information of appropriate quality and reliability for each decision made by the Agency. In the Office of Pesticide Programs (OPP), the evaluation process for a pesticide chemical traditionally begins with the applicant's submission of a set of studies conducted with the specific pesticide chemical of interest. The use of the results of such testing (measured data) is a logical, scientifically rigorous process that identifies the physical, chemical, and environmental fate properties of the pesticide, as well as the dose and endpoints at which an adverse effect can occur in various animal species.

Today, there is significant interest in alternative techniques, i.e., techniques other than data generation that could significantly inform the Agency's decision-making process. Recently, OPP has made increasing use of structure activity relationship (SAR) as part of its regulatory decision-making process. In the SAR process, a chemical's molecular structure is compared to that of other chemicals for which data are available. These structural similarities are then used to make predictive judgments about a chemical's physical, chemical, and biological properties. Thus, the chemical's physical, chemical, and biological properties are a function of (or directly related to) the chemical's molecular structure. Quantitative SAR is referred to as QSAR. To develop a QSAR, a selected set of measured data on a single physical, chemical, or biological property is used to derive a model (an equation) to predict the value of that property.

Since SAR assessments and QSAR modeling are another set of tools that are available to Agency scientists, OPP has begun a process shift that envisions shifting from the current study-by-study approach to an approach in which the use of predicted data, generated using validated models, is considered along with information from open literature and studies specifically generated under Part 161 requirements. All relevant information would be considered as part of a weight-of-the-evidence evaluation.

At this time, EPA believes that for certain endpoints, especially physical/chemical and fate properties, that SAR and QSAR might be effectively utilized to fulfill these data requirements for many antimicrobial pesticide chemicals. When considering biological properties, at this time, EPA believes that SAR and QSAR can be most effectively utilized in the evaluation of chemicals that exhibit lower toxicity for human health and/or ecotoxicity parameters. This is appropriate because the risk assessment for lower toxicity chemicals can be stream-lined, i.e., a screening-level assessment procedure rather than multiple tiers of assessments with progressively more data requirements.

Next Steps

Following closure of the 90-day comment period, the Agency will prepare a Final Work Plan for this pesticide.

II. FACT SHEET

Caprylic Acid Background Information

- Registration review case number: 5028
- PC Code: 128919
- CAS Registry#: 124-07-2
- Technical registrants: Ecolab
- First approved for use in a registered product: October 1994
- Antimicrobials Division Chemical Review Manager (CRM): ShaRon Carlisle, Carlisle.sharon@epa.gov
- Antimicrobials Division Product Manager (PM): Adam Heyward, heyward.adam.@epa.gov

Chemical Identity/Structure of Caprylic acid:

Table 1.1 Chemical Identity	
Common Name	Caprylic acid
Chemical Name	n-octanoic acid
Empirical Formula	$C_8H_{16}O_2$
Molecular Weight	144.24
Chemical Structure: $CH_3(CH_2)_6COOH$	

Use & Usage Information

- Caprylic acid is registered as a food contact surface sanitizer in commercial food handling establishments. In addition, caprylic acid is used as an algaecide, bactericide, and fungicide in nurseries, greenhouses, garden centers, and interiorscapes on ornamentals.
- There are seven registered products containing caprylic acid as an active ingredient. A manufacturing use product containing caprylic acid has not been registered.
- Caprylic acid has been classified by the Food and Drug Administration (FDA) as a direct food additive that is Generally Recognized as Safe (GRAS) when this naturally-occurring component of food is added as a flavoring agent or adjuvant to various foods.
- The Food and Drug Administration (FDA) has established a food additive clearance for capric (decanoic) acid when used as a flavoring agent or adjuvant to various foods at 0.0001-0.04%. In addition, it can be used as a citrus coating, to

aid in the lye peeling of fruits and vegetables and as binders, emulsifiers and anticaking agents in food.
- The percentage of active ingredients in the end-use products range up to 6.0 %.
- For additional usage information and details, please refer to Appendix A, *Application Information for Caprylic Acid*

Earlier Regulatory Actions

- No recent registration actions have occurred for caprylic acid

Human Health Risk Assessment Status

In 2006, a risk assessment for a proposed use on ornamental plants was completed. This assessment was qualitative in nature; risks were not calculated due to the lack of adverse systemic effects and rapid breakdown of caprylic acid. No other human health, dietary, residential or occupational risk assessments have been performed for the active ingredient, caprylic acid. All registered use sites of caprylic acid products can be applied to commercial facilities, i.e., there are no uses directly in a residential setting. However, there is the opportunity for postapplication and bystander exposure of adults and children to caprylic acid resulting from its use in schools, gyms, restaurants, hospitals, etc. Although exposure is likely as a result of these uses, risk assessments are not applicable as there are no adverse systemic effects on man attributable to dermal, inhalation, or inadvertent oral exposure.

The Agency has screened the hazard and exposure databases for caprylic acid and does not anticipate that additional toxicity or exposure data will be needed for registration review. The Agency does not expect that any additional human health risk assessments will need to be conducted for the caprylic acid Registration Review. For a detailed discussion of the anticipated risk assessment and data needs for human health please refer to "*Caprylic Acid: Human Health Effects Scooping Document for the Registration Review Decision Document"* (DP 351520) which is appended to this document.

Ecological Risk Assessment Status

Based on the current use patterns and toxicity data, the Agency does not anticipate conducting an environmental fate or ecological risk assessment for caprylic acid. In addition, no data are needed.

Based on indoor use patterns, low exposure levels, and low toxicity potential of caprylic acid, the Agency expects that the registered uses of caprylic acid will have "no effect" (NE) on endangered or threatened terrestrial or aquatic species, or their designated critical habitats, as listed by the U.S. Fish and Wildlife Service (USFWS) and the National Oceanic and Atmospheric Administration (NOAA). However, EPA will review any comments made by the public on this document and will conduct environmental risk assessment, if new information provided during the public comment period warrants such action.

For additional information, please refer to "*Summary of Product Chemistry, Environmental Fate and Ecotoxicity Data f the Caprylic Acid Registration Review Decision Document"* (DP 351519), which is appended to this document.

Tolerances

There have been three exemptions from the requirement of a tolerance established for the residues of caprylic acid by EPA and FDA. In addition, there is an exemption for octanoic acid as a sanitizer as well. The regulations are:

(1) 21 CFR 172.860 Fatty acids may be safely be used in food and in the manufacture of food components.
(2) 21 CFR 173 315 Caprylic acid may be used not to exceed 1% in lye peeling solutions of fruits and vegetables.
(3) 21 CFR 184.1025 Caprylic acid is GRAS when used as a direct food substance.
(4) Octanoic acid has clearances as a sanitizer on food contact surfaces under 40 CFR 180.940 (a)(b)(c)

Data Call-In Status

Based on the low toxicity, and low exposure, the Agency does not anticipate conducting risk assessments for Caprylic Acid. Therefore, EPA does not anticipate needing additional data and is therefore not issuing a data call-in for caprylic acid.

Labels

There are seven registered products for the active ingredient caprylic acid. A list of registration numbers is included in Table 1. Product registration labels may also be obtained from the Pesticide Product Label System (PPLS) website at: http://oaspub.epa.gov/pestlabl/ppls.home.

Table 1. Registered Active Products of Caprylic Acid

EPA Reg. No.	Product Name	Formulation Type	Percent Active Ingredient Caprylic Acid	Registrant
1677-90	MANDATE	EP	6.0	Ecolab Inc.
1677-158	VORTEXX	EP	3.3	Ecolab Inc.
1677-199	QUANTUM TB DISINFECTANT	EP	0.138	Ecolab Inc.
1677-204	65 DISINFECTING HEAVY DUTY ACID BATHROOM CLEANER	EP	3.05	Ecolab Inc.
1677-207	KX-6176	EP	2.72	Ecolab Inc.
1677-209	KX-6178	EP	2.85	Ecolab Inc.
49538-4	STBX-013	EP	3.30	Pyton Corporation

Incidents

A total of 29 incidents involving 260 individuals associated with products containing caprylic acid have been reported in OPP Incident Data System (IDS). The bulk of these were reported by the registrant, Ecolab, Inc. from 1999 to 2004. The most common symptoms included: irritation of the lungs, throat, eyes, and skin, nausea, dizziness, and vomiting. The severity of the symptoms ranged from mild to severe such as eye redness to corneal abrasions or skin rash to blisters, edema, and erythema. It must be noted that all five antimicrobial products implicated also contained hydrogen peroxide and peroxyacetic acid in addition to caprylic acid. Although caprylic acid is a moderate eye irritant (Toxicity Category II) and a mild dermal and inhalation irritant (Toxicity Category III), at least one other active ingredient in every implicated end-use product is expected to be more severely irritating than caprylic acid, especially at the concentrations formulated.

Those handling the undiluted antimicrobial product directly, i.e., during pouring and mixing the end-use product in/with water prior to application, would be most at risk. Clearly, personal protective equipment (PPE) including goggles and chemical-resistant gloves are needed for handlers. Current labels bear the following precautionary statements: "*Causes irreversible eye damage and skin burns. May be fatal if inhaled or absorbed through the skin. Harmful if swallowed. Do not get in eyes, on skin, or on clothing. Do not breathe vapor or spray mist. Wear protective eyewear (goggles, face shield, or safety glasses), protective clothing, and rubber gloves*" and "*When spraying or fogging, wear a mask or pesticide respirator jointly approved by Mine Safety and Health Administration and the National Institute for Occupational Safety and Health*." These are appropriate warning statements and PPE based on available toxicity and incident data.

III. GLOSSARY of TERMS & ABBREVIATIONS

ai	Active Ingredient
AR	Anticipated Residue
ASTM	American Society for Testing and Materials
AWPA	American Wood Preserver's Association
CBI	Confidential Business Information
CFR	Code of Federal Regulations
cPAD	Chronic Population Adjusted Dose
CSF	Confidential Statement of Formula
CSFII	USDA Continuing Surveys for Food Intake by Individuals
DCI	Data Call-In
DEEM	Dietary Exposure Evaluation Model
DFR	Dislodgeable Foliar Residue
DNT	Developmental Neurotoxicity
DWLOC	Drinking Water Level of Comparison
EC	Emulsifiable Concentrate Formulation
EDWC	Estimated Drinking Water Concentration
EEC	Estimated Environmental Concentration
EP	End use Product
EPA	Environmental Protection Agency
EUP	End-Use Product
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
FQPA	Food Quality Protection Act
FOB	Functional Observation Battery
GENEEC	Tier I Surface Water Computer Model
IR	Index Reservoir
LC_{50}	Median Lethal Concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm.
LD_{50}	Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LOC	Level of Concern
LOAEL	Lowest Observed Adverse Effect Level
µg/g	Micrograms Per Gram
µg/L	Micrograms Per Liter
mg/kg/day	Milligram Per Kilogram Per Day
mg/L	Milligrams Per Liter
MOE	Margin of Exposure
MRID	Master Record Identification (number). EPA's system of recording and tracking submitted studies.
MUP	Manufacturing-Use Product
NA	Not Applicable
NAWQA	USGS National Ambient Water Quality Assessment
NPDES	National Pollutant Discharge Elimination System
NR	Not Required
NOAEL	No Observed Adverse Effect Level
OPP	EPA Office of Pesticide Programs

OPPTS	EPA Office of Prevention, Pesticides and Toxic Substances
PAD	Population Adjusted Dose
PAIRA	Pure Active Ingredient Radiolabelled
PCA	Percent Crop Area
PDP	USDA Pesticide Data Program
PHED	Pesticide Handler's Exposure Data
PHI	Preharvest Interval
phr	Pounds Per Hundred
ppb	Parts Per Billion
PPE	Personal Protective Equipment
ppm	Parts Per Million
PRZM/EXAMS	Tier II Surface Water Computer Model
Q_1*	The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model
RAC	Raw Agriculture Commodity
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RQ	Risk Quotient
RTU	Ready to Use
SCI-GROW	Tier I Ground Water Computer Model
SAP	Science Advisory Panel
SF	Safety Factor
SLN	Special Local Need (Registrations Under Section 24©) of FIFRA)
TGAI	Technical Grade Active Ingredient
TEP	Typical End-Use Product
USDA	United States Department of Agriculture
UF	Uncertainty Factor
WPS	Worker Protection Standard

IV. APPENDICES

Application Information for Caprylic Acid (5028)
Appendix A

Use Site	Formulation	Method of Application	Application Rate/ No. of Applications	Use Limitations
Agricultural premises and equipment				
Farms, Livestock Quarters, Poultry and swine premises, Poultry Hatcheries.	Soluble concentrate 1677-207 1677-209	Spray, mop, brush Soak	1-2 ounces of end use product per 2 gallons of water	Remove animals and feed from facility. Clean all surfaces thoroughly with proper detergent and rinse with water before sanitizing treatment. Ventilate closed spaces.
Hard non-porous, non-food contact surfaces (floor, walls tables, benches, etc.)	Ready to use 1677-199	Spray, mop, brush Soak	Thoroughly wet surface. Allow surface to remain wet for at least 10 minutes.	
	Soluble concentrate 1677-158	Coarse spray	1 ounce of end use product per 8 gallons water. Five minute contact time.	
Seedlings, cuttings, plants, trees, flowers and bulbs (Ornamental only), Greenhouses and outdoor nurseries	Soluble concentrate 49538-4	Immersion, coarse spray, pressure spray, fogger. Irrigation systems.	Curative applications: 1:500 of clean water. Wet foliage thoroughly. Apply for one to consecutive three days then use preventive application. Apply 100 gallons of prepared spray mixture per acre	***There are significant restrictions and requirements for the use of this chemical in an irrigation system. The have been listed in full at the end of this appendix.
			Preventive applications: 1:1500 of clean water. Apply every five to seven days. Wet plant surfaces	

Use Site	Formulation	Method of Application	Application Rate/ No. of Applications	Use Limitations
			thoroughly including upper and lower foliage, stems, branches and stalks. Apply 100 gallons of prepared spray mixture per acre.	
Cut Flowers	Soluble concentrate 49538-4	Coarse spray	1:2500 of clean water. Apply as a post harvest treatment prior to storage or shipment. Repeat application weekly for flowers in storage.	
Bareroot Nursery Stock	Soluble concentrate 49538-4	Coarse spray, immersion	Curative applications: 1:500 of clean water. Wet foliage thoroughly.	
Greenhouse structures and equipment, benches walkways, walls and floors	Soluble concentrate 49538-4	Power spray, mop, brush, sponge	1:150 to 1:1500 of clean water. 10 minute contact time.	Preclean surfaces to be treated. Allow to air dry.
Agricultural transportation equipment (Cars, truck, etc)	Soluble concentrate 1677-207	Spray, mop, brush Soak	1-2 ounces of end use product per 2 gallons of water	Remove animals and feed from facility. Clean all surfaces thoroughly with proper detergent and rinse with water before sanitizing treatment. Ventilate closed spaces.
Shoe Baths	Soluble concentrate 1677-209	Soak	One ounce of end use product per 1-8 gallons of water. Use enough solution to make a 1 inch deep shoe bath. One minute contact time.	Scrape excess dirt and soil from waterproof boots before using solution.

Use Site	Formulation	Method of Application	Application Rate/ No. of Applications	Use Limitations
		Foam application	One ounce of end use product per 1-8 gallons of water. Use an approved foam generator to make enough solution to make a 0.5-2.0 inch deep shoe bath. One minute contact time.	
	Soluble concentrate 49538-4	Soak	¼ ounce of end use product per gallon of water	Scrape excess dirt and soil from waterproof boots before using solution.
Food handling/storage establishments premises and equipment				
Hard non-porous, food contact surfaces (floor, walls tables, benches, etc.)	Soluble concentrate 1677-158 1677-207 1677-209	Immersion Coarse spray circulation	1-2 ounces of end use product per 4.5-8.0 gallons of water. One minute contact time, drain thoroughly then air dry. Do Not rinse.	Clean all surfaces thoroughly with proper detergent and rinse with water before sanitizing treatment.
Hard non-porous, food contact surfaces (floor, walls tables, benches, etc.)	Soluble concentrate 1677-209	Foam application	1 ounce of end use product and one 1-1.4 ounces of approved foam generator per 6-8 gallons of water. Apply foam using approved equipment. One	Clean all surfaces thoroughly with proper detergent and rinse with water before sanitizing treatment. Drain thoroughly and allow to air dry. No rinse is necessary.

Use Site	Formulation	Method of Application	Application Rate/ No. of Applications	Use Limitations
			minute contact time.	
Manufacturing, filling and packaging equipment in aseptic processes (sterilization)	Soluble concentrate 1677-158	Coarse spray circulation	25 oz of end use product per 4 gallons of water. 30 min contact time.	Clean all surfaces thoroughly with proper detergent and rinse with water before treatment. Thoroughly rinse food contact surfaces with potable water.
Food Processing equipment in Dairies, Dairy Farms, Breweries, Wineries, Beverage and Food Processing Plants	Soluble concentrate 1677-90 1677-158 1677-207 1677-209	Circulation (For CIP systems)	1-2 ounces of end use product per 4.5-8.0 gallons of water. Two minute contact time, drain thoroughly then air dry.	Clean all surfaces thoroughly with proper detergent and rinse with water before sanitizing treatment. Prepared use solutions may not be reused for sanitizing, but may be reused for other purposes, such as cleaning.
	Soluble concentrate 1677-90 1677-158 1677-207	Immersion Coarse spray	1-2 ounces of end use product per 4.5-6.0 gallons of water. Two minute contact time, drain thoroughly then air dry.	Clean all surfaces thoroughly with proper detergent and rinse with water before sanitizing treatment. Prepared use solutions may not be reused for sanitizing, but may be reused for other purposes, such as cleaning.
	Ready to use 1677-199	Spray, mop, brush Soak	Thoroughly wet surface. Allow surface to remain wet for at least 10 minutes.	Preclean heavily soiled areas.
Cheese manufacturing establishments	Soluble concentrate 1677-158 1677-207	Immersion/ Coarse spray	1-2 ounces of end use product per 4.5-6.0 gallons of water. Two minute contact time, drain thoroughly then air dry.	Clean all surfaces thoroughly with proper detergent and rinse with water before sanitizing treatment. Prepared use solutions may not be reused for sanitizing, but may be reused for other purposes, such as cleaning.

Use Site	Formulation	Method of Application	Application Rate/ No. of Applications	Use Limitations
Conveyors	Soluble concentrate 1677-158 1677-207 1677-209	Automatic feeder	1-2 ounces of end use product per 4.5-8.0 gallons water. One minute contact time.	
Conveyors	Soluble concentrate 1677-158 1677-207 1677-209	Coarse spray	During interruptions in operations, 1-2 ounces of end use product per 4.5-8.0 gallons of water. One minute contact time.	Conveyor must be free of food products before sanitizing by coarse spray.
Eating, drinking, food prep utensils	Soluble concentrate 1677-158	Immersion	1-2 ounces of end use product per 6 gallons of water. Two minute contact time, drain thoroughly then air dry.	Clean all surfaces thoroughly with proper detergent and rinse with water before sanitizing treatment. Prepared use solutions may not be reused for sanitizing, but may be reused for other purposes, such as cleaning.
	Soluble concentrate 1677-158	Immersion (elevated temperature)	1 ounce of end use product per 14 gallons of water. Inject end use product into final rinse water cycle of warewashing machine. 120 deg F minimum temperature.	
Bottle rinse (sanitizing)	Soluble concentrate 1677-158	Immersion	1-2 ounces of end use product per 6 gallons of water. Two minute contact	No rinse necessary.

Use Site	Formulation	Method of Application	Application Rate/ No. of Applications	Use Limitations
			time, drain thoroughly then air dry.	
	Soluble concentrate 1677-207	Immersion	1 ounce of end use product per 4.5-6.0 gallons water. One minute contact time	Drain thoroughly. No rinse necessary.
Container rinse (antimicrobial rinse) w/the addition of a surfactant	Soluble concentrate 1677-158	Immersion	9-26 ounces of end use product per 10 gallons of water. Add 6.7 ounces of approved surfactant per 10 gallons of prepared end use product. Apply at 40-60 deg Celsius for at least seven (7) seconds.	Clean all surfaces thoroughly with proper detergent and rinse with water before sanitizing treatment. Drain thoroughly and rinse with a disinfected water rinse free of pathogenic bacteria.
Bottle rinse (bottled water uses)	Soluble concentrate 1677-158	Immersion	9-26 ounces of end use product per 10 gallons of water at 40-60 deg Celsius for at least seven (7) seconds	Clean all surfaces thoroughly with proper detergent and rinse with water before sanitizing treatment. Drain thoroughly and rinse with a disinfected water rinse free of pathogenic bacteria.
Container rinse (antimicrobial rinse)	Soluble concentrate 1677-158	Immersion	9-26 ounces of end use product per 10 gallons of water at 40-60 deg Celsius for at least seven (7) seconds	Clean all surfaces thoroughly with proper detergent and rinse with water before sanitizing treatment. Drain thoroughly and rinse with a disinfected water rinse free of pathogenic bacteria.
Hard non-porous, outside surfaces of airtight, sealed packaging containing food	Soluble concentrate 1677-158	Immersion, coarse spray.	1-2 ounces of end use product per 4.5-6.0 gallons water. One minute contact	Drain thoroughly. No rinse necessary.

Use Site	Formulation	Method of Application	Application Rate/ No. of Applications	Use Limitations
or non-food products	1677-207		time	
Commercial, institutional and industrial premises and equipment				
Hard non-porous, non-food contact surfaces (floor, walls tables, benches, etc.)	Soluble concentrate 1677-158 1677-207 1677-209	Mop, sponge, brush, coarse spray.	1-4 ounces of end use product per 2-4 gallons of water. 10 minute contact time.	Preclean heavily soiled areas. Remove solution with a clean wet mop, cloth or wet vacuum.
	Soluble concentrate 1677-209	Mop, sponge, brush, coarse spray.	1-5 ounces of end use product per 8 gallons of water. 5 minute contact time.	Clean all surfaces thoroughly with proper detergent and rinse with water before sanitizing treatment. Drain thoroughly and allow to air dry. No rinse needed
Packaging equipment (non-food contact)	Soluble concentrate 1677-158 1677-207	Mop, sponge, brush, coarse spray.	1-5 ounces of end use product per 8 gallons of water. 5 minute contact time.	Clean all surfaces thoroughly with proper detergent and rinse with water before sanitizing treatment. Drain thoroughly and rinse with a disinfected water rinse free of pathogenic bacteria.
Medical premises and equipment				
Hospitals, Nursing Homes, Health Care Facilities, day care centers, Veterinary Clinics, Animal Life Science Laboratories.	Soluble concentrate 1677-158	Mop, sponge, brush, coarse spray.	1-4 ounces of end use product per 4 gallons. Wet all surfaces thoroughly, 10 minute contact time.	Preclean heavily soiled areas. Blood and body fluids must be thoroughly cleaned before application. Remove solution with a clean wet mop, cloth or wet vacuum.
	Ready to use 1677-199	Spray, mop, brush Soak	Thoroughly wet surface. Allow surface to remain wet for at least 10 minutes.	
	Soluble	Mop, sponge,	6-8 ounces of end use	Wipe with damp cloth or sponge and then

Use Site	Formulation	Method of Application	Application Rate/ No. of Applications	Use Limitations
Hospitals, Nursing Homes, Health Care Facilities, day care centers, Veterinary Clinics, Animal Life Science Laboratories.	concentrate 1677-204	brush, coarse spray.	product per gallon of water. Wet all surfaces thoroughly, 10 minute contact time.	rinse surface.
Pharmaceutical and cosmetic surfaces	Soluble concentrate 1677-158	Mop, sponge, brush, coarse spray.	1 ounce of end use product per 4 gallons. Wet all surfaces thoroughly, 10 minute contact time.	Preclean heavily soiled areas. Product contact surfaces must be rinsed with sterile water.
Residential and public access premises				
Industrial Facilities, Schools, Colleges, Office Buildings, Recreational Facilities, Retail and Wholesale Establishments, Animal Care Facilities, Veterinary Facilities	Ready to use 1677-199	Spray, mop, brush Soak	Thoroughly wet surface. Allow surface to remain wet for at least 10 minutes.	Preclean heavily soiled areas.
	Soluble concentrate 1677-158 1677-207	Foam application	1 ounce of end use product and one 1-1.4 ounces of *Liquid K* (approved foam generator) per 6-8 gallons of water. Apply foam using approved equipment. Five minute contact time.	Clean all surfaces thoroughly with proper detergent and rinse with water before sanitizing treatment. Drain thoroughly and allow to air dry. No rinse is necessary.
	Soluble concentrate 1677-209	Foam application	1-5 ounces of end use product and one 1.4 ounces of *Liquid K* (approved foam generator) per 8 gallons of water. Apply	Clean all surfaces thoroughly with proper detergent and rinse with water before sanitizing treatment. Drain thoroughly and allow to air dry. No rinse is necessary.

Use Site	Formulation	Method of Application	Application Rate/ No. of Applications	Use Limitations
Industrial Facilities, Schools, Colleges, Office Buildings, Recreational Facilities, Retail and Wholesale Establishments, Animal Care Facilities, Veterinary Facilities			foam using approved equipment. Five minute contact time.	
	Soluble concentrate 1677-158	Fogging	3 to 14 ounces of end use product per 8 gallons of water per 1000 cu.ft. of room volume.	All food products and packaging materials must be removed from the room or carefully protected. Vacate area of all personnel until hydrogen peroxide air concentration is below 0.5ppm. Food contact areas must be rinsed thoroughly with potable water
	Soluble concentrate 1677-207 1677-209		1-2 ounces of end use product per 2 gallons of water per 1000 cu.ft. of room volume.	
	Soluble concentrate 1677-158	Coarse spray	1 ounce of end use product per 8 gallons water. Five minute contact time.	Clean all surfaces thoroughly with proper detergent and rinse with water before sanitizing treatment. Drain thoroughly and allow to air dry. No rinse is necessary.
Animal Kennels, cages	Ready to use 1677-199	Spray, mop, brush Soak	Thoroughly wet surface. Allow surface to remain wet for at least 10 minutes.	Remove animals and feed from facility. Clean all surfaces thoroughly with proper detergent and rinse with water before sanitizing treatment.
Bathrooms, Showers stalls and floors, bath mats, etc.	Soluble concentrate 1677-158	Mop, sponge, brush, coarse spray.	1 ounce of end use product per 4 gallons of water. Wet all surfaces thoroughly, 10 minute contact time.	Remove solution with a clean wet mop, cloth or wet vacuum.
	1677-204	Mop, sponge, brush, coarse spray.	6-8 ounces of end use product per gallon of water. Wet all surfaces thoroughly, 10 minute	Wipe with damp cloth or sponge and then rinse surface.

Use Site	Formulation	Method of Application	Application Rate/ No. of Applications	Use Limitations
			contact time.	
Industrial Processes and water systems				
Evaporative Coolers	Soluble concentrate 49538-4	Soak, spray, immersion	Initial Dose: 1:500 dilution of clean water to control algae Maintenance Dose: 1:2500 of clean water weekly	
Human water drinking systems				
Water filters	Soluble concentrate 1677-158	Coarse spray, immersion	9-26 ounces of end use product per 10 gallons of water at 25-45 deg Celsius for at least 5 minutes.	Drain thoroughly and rinse with a disinfected water rinse free of pathogenic bacteria.
Aquatic areas				
Irrigation Systems (flooded floors, flooded benches, recycled water systems, humidification and misting systems	Soluble concentrate 49538-4	Approved irrigation system or mister	Contaminated water: Treat with a dilution of 1:2500 water Clean water: Treat with a dilution of 1:50,000 water	***There are significant restrictions and requirements for the use of this chemical in an irrigation system. The have been listed in full at the end of this appendix.
Mist Propagation systems	Soluble concentrate 49538-4	Injection	Inject at a 1:5000 dilution rate for four to ten consecutive days, increase rate to 1:25000 and maintain continuous application throughout propagation cycle. At first sign of disease return dilution rate to 1:5000	***There are significant restrictions and requirements for the use of this chemical in an irrigation system. The have been listed in full at the end of this appendix.

*** **USE DIRECTIONS FOR CHEMIGATION**

The following precautions must be observed when using this product in any type of irrigation system:

Apply this product only through overhead sprinkler, including center pivot, lateral move, end tow, side (wheel) roll, big gun, solid set, or hand move; drip (trickle); or flood (basin) irrigation system(s).

Crop injury, lack of effectiveness, or illegal pesticide residues in the crop can result from nonuniform distribution of treated water.

Ensure that the irrigation system used is properly calibrated, If you have questions about calibration, you should contact State Extension specialists, equipment manufacturers or other experts.

Do not connect an irrigation system, (including greenhouse system), used for pesticide application to a public water system unless the pesticide safety devices for public water systems are in place.

A person knowledgeable of the chemigation system and responsible for its operation, or under supervision of the responsible person, shall shut the system down and make necessary adjustments should the need arise.

REOUIREMENTS FOR SPRINKLER & DRIP CHEMIGATION

Observe all tile requirements in the USE DIRECTIONS FOR CHEMIGATION section and the following additional requirements:

The system must contain a functional check valve, vacuum relief valve, and low pressure drain appropriately located on the irrigation pipeline to prevent water source contamination from backflow.

The pesticide injection pipeline must contain a functional, automatic, quick-closing check valve to prevent the flow of fluid back toward the injection pump.

The pesticide injection pipeline must also contain a functional, normally closed, solenoid-operated valve located on the intake side of the injection pump and connected to the system interlock to prevent fluid from being withdrawn from the supply tank when the irrigation system is either automatically or manually shut down. The system must contain functional interlocking controls to automatically shut off the pesticide injection pump when the water pump motor stops.

The irrigation line or water pump must include a functional pressure switch which will stop the water pump motor when the water pressure decreases to the point where pesticide distribution is adversely affected. Systems must use a metering pump, such as a positive displacement injection pump (e.g., diaphragm pump) effectively designed and constructed of materials that are compatible with pesticides and capable of being fitted with a system interlock.

Do not apply when wind speed favors drift beyond the area intended for treatment.

SYSTEMS CONNECTED TO PUBLIC WATER SYSTEMS

Public water system means a system for the provision to the public of piped water for human consumption it such system has at least 15 service connections or regularly serves an average of at least 25 individuals daily at least 60 days out of the year.

Chemigation systems connected to public water systems must contain a functional, reduced-pressure zone, backflow preventer (RPZ) or the functional equivalent in the water supply line upstream from the point of pesticide introduction. As an option to the RPZ, the water from the public water system should be discharged into a reservoir tank prior to pesticide introduction. There shall be a complete physical break (air gap) between the outlet end of the fill pipe and the top or overflow rim of the reservoir tank of at least twice the inside diameter of the fill pipe.

The pesticide injection pipeline must contain a functional, automatic, quick-closing check valve to prevent the flow of fluid beck toward the injection pump.
The pesticide injection pipeline must contain a functional, normally closed, solenoid-operated valve located on the intake side of the injection pump and connected to the system interlock to prevent fluid from being withdrawn from the supply tank when the irrigation system is either automatically or manually shut down.
The system must contain functional interlocking controls to automatically shut off the pesticide injection pump when the water pump motor stops, or in cases where there is no water pump, when the water pressure decreases to the point where pesticide distribution is adversely affected.
Systems must use a metering pump, such as a positive displacement injection pump (e.g. diaphragm pump) effectively designed and constructed of materials that are compatible with pesticides and capable of being fitted with a system interlock.

POSTING

Posting of areas to be chemigated is required when 1) any part of a treated area is within 300 feet of sensitive areas such as residential areas, labor camps, businesses, day care centers, hospitals, in-patient clinics, nursing homes, or any public areas such as schools, parks, playgrounds, or other public facilities not including public roads, or 2) when the chemigated area is open to the public such as golf courses or retail greenhouses. Posting must conform to the following requirements. Treated areas shall be posted with, signs at all usual points of entry and along routes of approach from the listed sensitive areas. When there are no usual points of entry, signs must be posted in the corner of the treated areas and in any other location affording maximum visibility to sensitive areas. The printed side of the sign should face away from the treated area towards the sensitive area. The signs shall be printed in English. Signs must be posted prior to application and must remain posted until foliage has dried and soil surface water has disappeared. Signs may remain in place indefinitely as long as they are composed of materials to prevent deterioration and maintain legibility for the duration of the posting period. All words shall consist of letters at least 2 112 inches tall, and all letters and the symbol shall be a color which sharply contrasts with their immediate background. At the top of the sign shall be the words KEEP OUT, followed by an octagonal stop symbol at least 8 inches in diameter containing the word *STOP*. Below the symbol shall be the words *PESTICIDES IN IRRIGATION WATER.*

REQUIREMENTS FOR FLOOD CHEMIGATION

Observe all the requirements in the USE DIRECTIONS FOR CHEMIGATION section and the following additional requirements:
Systems using a gravity flow pesticide dispensing system must meter the pesticide into the water at the head of the field and downstream of a hydraulic discontinuity such as a drop structure or weir box to decrease potential for water source contamination from back flow if water flow stops.
Systems utilizing a pressurized water and pesticide injection system must meet the following requirements:
The system must contain a functional check valve, vacuum relief valve, and low pressure drain appropriately located on the irrigation pipeline to prevent water source contamination from backflow.
The pesticide injection pipeline must contain a functional, automatic, quick-closing check valve to prevent the flow of fluid back toward the injection pump.
The pesticide injection pipeline must also contain a functional, normally closed, solenoid-operated valve located on the intake side of the injection pump and connected to the system interlock to prevent fluid from being withdrawn from the supply tank when the irrigation system is either automatically or manually shut down.
The system must contain functional interlocking controls to automatically shut off the pesticide injection pump when the water pump motor stops.
The irrigation line or water pump must include a functional pressure switch which will stop the water pump motor when the water pressure decreases to the point where pesticide distribution is adversely affected.

Systems must use a metering pump, such as a positive displacement injection pump (e.g., diaphragm pump) effectively designed and constructed of materials that are compatible with pesticides and capable of being fitted with a system interlock.

CHEMIGATION APPLICATION INSTRUCTIONS:
Remove scale, pesticide residues, and other foreign matter from the chemical supply tank and entire injector system. Flush with clean water. Failure to provide a clean tank, void of scale or residues may cause product to lose effectiveness or strength.
Determine treatment rates as indicated in the directions for use and make proper dilutions.
Prepare a solution in the chemical tank by filling the tank with the required water and then adding product as required. The product will immediately go into suspension without any required agitation.
Do not apply in conjunction with any other pesticides or fertilizers, as this may cause reduced performance of the product.

APPENDIX B

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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

6/24/08

MEMORANDUM

SUBJECT: Caprylic Acid (Octanoic Acid): Human Health Effects Scoping Document for the Registration Review Decision.
DP Barcode: D351520 **Reg. Review Case No.:** 5028
PC Code: 128919 **CAS No.:** 124-07-2

FROM: William J. Hazel, Ph.D., Chemist
Risk Assessment and Science Support Branch (RASSB)
Antimicrobials Division (7510P)

TO: ShaRon Carlisle, Chemical Review Manager
Antimicrobials Division (7510P)

THRU: Norman Cook, Chief
Risk Assessment and Science Support Branch (RASSB)
Antimicrobials Division (7510P)

Introduction

The Antimicrobials Division (AD) of EPA's Office of Pesticide Programs (OPP) has evaluated the status of the human health assessments for caprylic acid which is an antimicrobial pesticide used as a food contact surface sanitizer in commercial food handling establishments. The team examined the hazard and exposure databases for caprylic acid (also known as octanoic acid) to determine whether current science policy or database adequacy has materially affected the overall risk picture. Caprylic acid was first registered 10/26/94. A Reregistration Eligibility Decision (RED) has not been made for caprylic acid because, having been first registered after 1984, it has not been subject to reregistration as per the 1988 Amendments to FIFRA.

Six of the seven EPA-registered caprylic acid end-use products are formulated as soluble concentrate/liquids (SC/L) and contain 2.72-6 % ai (w:w). The final product is a 0.138% Ready-to-use Liquid (RTU-L). Most of these products also contain several of the following compounds: phosphoric acid, citric acid,

decanoic acid, peroxyacetic acid, peroxycaprylic acid, and hydrogen peroxide. A manufacturing-use product containing caprylic acid has not been registered.

The six Ecolab, Inc. registered end-use products are used as sanitizers on dairy equipment, food processing equipment, breweries, wineries, and beverage processing plants. Several of these are also used as disinfectants in health care facilities, schools/colleges, animal care/veterinary facilities, industrial facilities, office buildings, recreational facilities, retail and wholesale establishments, livestock premises, restaurants, and hotels/motels. One product (EPA Reg. No. 49538-4) is registered to Phyton Corp.; this product is used as an algicide, bactericide, and fungicide in nurseries, greenhouses, garden centers, landscapes, nurseries, and interiorscapes on ornamentals, nonbearing trees, bedding plants, seedlings, bulbs, and cut flowers.

Caprylic acid has been classified by the Food and Drug Administration (FDA) as a direct food additive that is Generally Recognized as Safe (GRAS) when this naturally-occurring component of food is added as a flavoring agent or adjuvant to various foods at 0.001-0.04% (21 CFR 184.1025). Caprylic acid is one of seven fatty acid GRAS materials that may be safely used in food (21 CFR 172.860, used as a citrus coating (21 CFR 172.210), used to aid the lye peeling of fruits and vegetables (21 CFR 173.315), and the salts of which may be used in foods as binders, emulsifiers, and anticaking agents (21 CFR 172.863). Caprylic acid is exempt from the requirement of a tolerance when used as a food contact surface sanitizer in public eating places at a treatment concentration of ≤52 ppm [40 CFR 180.940(a)], on dairy processing equipment at ≤176 ppm [40 CFR 180.940(b)], and on food processing equipment and utensils at ≤234 ppm [40 CFR 180.940(c)]; these regulations were duplicated from 21 CFR 178.1010.

All use sites are indoors except for the ornamental uses registered by the Phyton Corp. which includes the option to apply their product on ornamentals raised outdoors. As a result, dietary exposure via drinking water may occur but is likely to be very low. Dietary (food) exposure is expected to occur from the FDA-purview direct food additive uses as well as the EPA-purview indirect food additive uses on dairy equipment, on food processing equipment and utensils, and in eating establishments. However, FDA classifies caprylic acid as being GRAS. Further, EPA has established exemptions from the requirement of a tolerance for residues of caprylic acid in foods [40 CFR 180.940(a), -(b), and -(c)] because there are no adverse systemic effects on man attributable to oral exposure. The Agency reiterates these conclusions at this time. As there is no hazard component of risk associated with registered uses, a dietary (food and drinking water) risk assessment is not required.

All registered use sites of caprylic acid products appear to be commercial facilities, i.e., there are no uses directly in a residential setting. However, there is the opportunity for postapplication and bystander exposure of adults and children to caprylic acid resulting from its use in schools, gyms, restaurants, hospitals,

etc. Although exposure is likely as a result of these uses, risk assessments are not applicable as there are no adverse systemic effects on man attributable to dermal, inhalation, or inadvertent oral exposure.

Exposure to caprylic acid could, thus, result from food, drinking water, and postapplication/bystander sources; all of these could contribute to aggregate risk. As caprylic acid induces no adverse systemic effects via any route of exposure, an aggregate risk assessment is also not needed.

Although occupational exposure to mixer/loader/applicators is likely from the registered uses in food and beverage processing facilities, industrial, institutional, and commercial facilities, and on ornamentals, a quantitative risk assessment is not required because, again, adverse systemic effects on man attributable to the dermal and inhalation routes of exposure to caprylic acid are not expected. Label instructions and the requirement that handlers wear certain personal protective equipment (PPE) are sufficient to protect workers from the localized, irritation effects of exposure to caprylic acid.

The primary source of information for this assessment was the 12/4/06 AD risk assessment by R. Quick, et al. on the Phyton Corp. registration request for STBX-013 proposed for use on ornamentals (File No. 49538-U; D330286); this qualitative assessment concluded with registration of these ornamental uses. Also of use was the documentation supporting the establishment of an exemption from the requirement of a tolerance for decanoic acid (68 FR 7935, 2/19/03) which was, in turn, used to inform the capric acid (decanoic acid) human health scoping document of the Registration Review. No new toxicity data for caprylic acid have been submitted to the Agency since this Final Rule was issued. The purpose of this scoping document is to determine whether sufficient data are available to support registration review, whether new human health assessments are needed to support registration review, and to report why the Agency feels it may be appropriate to conduct new risk assessments under the registration review process.

Section 1. Chemical Identity

Table 1.1 Chemical Identity	
Common Name	Caprylic acid
Chemical Name	n-octanoic acid
Empirical Formula	$C_8H_{16}O_2$
Molecular Weight	144.24
PC Code	128919
CAS Registry Number	124-07-2
Registration Review Case No.	5028

Chemical Structure: $CH_3(CH_2)_6COOH$	

Caprylic acid is an oily liquid at room temperature (25 C) which melts at 16.7 C. It is slightly soluble in water (0.7 g/L) and soluble in ethanol and diethyl ether. The dissociation constant, pK_a, is 4.89. The specific gravity is 0.9105 g/ml. Caprylic acid has a rancid odor.

Caprylic acid is a straight chain fatty acid eight carbons in length that occurs naturally. Caprylic acid is widely distributed in animal and vegetable fats and occurs at up to 70% by weight in two *Lythraceae* seed oils, 1-4% in milk fat, and 6-8% in coconut and palm oils. The Agency has previously reviewed and accepted chemistry, environmental fate, ecotoxicity, and human toxicity data for two other naturally-occurring and very similar straight chain fatty acids: decanoic acid (10 carbons long) and nonanoic acid (9 carbons long). Data in Agency files that support the registration of decanoic and nonanoic acids are considered relevant to caprylic acid Registration Review. Also, OPP's Biopesticides and Pollution Prevention Division (BPPD) issued a 1/17/06 technical guidance document for sucrose octanoate and sorbitol octanoate, two sugar esters of caprylic acid. The octanoate anion released upon enzymatic hydrolysis of such esters in biological systems (including humans) is identical to the anion resulting from simple dissociation of caprylic acid which occurs at pHs above the pK_a of 4.89. Therefore, the conclusions reached in the 1/17/06 EPA Technical Guidance Document for the Octanoate Esters are relevant to this caprylic acid Human Health Scoping Document. Further, the salts of fatty acids were assessed by the Agency in September, 2003 for their pesticide inert ingredient uses. Scientific conclusions reached by the Lower Toxicity Pesticide Chemical Focus Group on the salts of fatty acids are also relevant to this Scoping Document. The "Soap Salts" reregistration eligibility document (RED) dated September, 1992 is useful, but of partial utility for this analysis because it addresses all fatty acid soap components ranging from 8 to 18 carbon atoms in length. Data in Agency files cited in the "Soap Salts" RED for oleic acid/oleates, octadecanoic acid, stearates, and tall oils are less relevant to this Scoping Document due to a much higher number of carbon atoms in their fatty acid chains which results in significant changes in physical properties. In addition, information is also found in EPA/OPPT files: the 2004 Test Plan and Robust Summaries for C_7-C_9 Aliphatic Aldehydes and Carboxylic Acids.

Section 2. Toxicology

Caprylic acid is considered to be a GRAS chemical and may be directly added to food (21 CFR 184.1025). Exemptions from the requirement of a tolerance have been established for residues of caprylic acid when used according to good manufacturing practice as an ingredient in antimicrobial pesticide products provided adequate draining is permitted before food contact as per the following regulations:

- 40 CFR 180.940(a): when used on dairy processing equipment, food processing equipment and utensils, and in public eating places at a diluted end-use concentration not to exceed 52 ppm;
- 40 CFR 180.940(b): when used on dairy processing equipment and food processing equipment and utensils at a diluted end-use concentration not to exceed 176 ppm; and
- 40 CFR 180.940(c): when used on food processing equipment and utensils at a diluted end-use concentration not to exceed 234 ppm.

Toxicology Profile

Heptanoic, caprylic, and nonanoic acids are a group of short-chained linear fatty acids of seven, eight, and nine carbon atoms in length, respectively. Based on their structural similarities, toxicity data can be used almost interchangeably as surrogate data for these three substances. Based on the evidence presented, the Agency used the surrogate data from heptanoic acid and nonanoic acid to supplement the available information on caprylic acid. Also supportive were the data on the octanoate esters, salts of fatty acids, soap salts, and OPPT data on carboxylic acids.

Acute Toxicity

Data and information from the open technical literature are acceptable to justify the data waiver request and satisfy the requirement for acute toxicity studies. Acute oral LD50 values for caprylic acid range from 1283 mg/kg to 10,080 mg/kg bw in rats, and a dermal LD50 value greater than 5000 mg/kg was reported in rabbits. No acute inhalation data are available for caprylic acid; however, studies have been conducted on heptanoic acid (98.5%) and nonanoic acid (97%). The LC50 values were greater than 4.6 mg/l for heptanoic acid and 0.46 mg/l - 3.8 mg/l for nonanoic acid. Caprylic acid is a dermal irritant. It caused a moderate dermal reaction at a dose of 0.5 ml of the undiluted liquid test material. (http://www.epa.gov/chemrtk/pubs/summaries/alipalde/c13033tc.htm)

Studies conducted using nonanoic acid resulted in classification into the following Toxicity Categories: primary eye irritation (Toxicity Category II), acute oral toxicity (Toxicity Category IV), acute dermal and inhalation toxicity (Toxicity Category III). Sensitization test results showed that nonanoic acid is not

considered a dermal sensitizer. Based on the information on nonanoic acid, caprylic acid is not likely to be a dermal sensitizer.

Subchronic Toxicity

No data on caprylic acid are available for subchronic and chronic toxicity. However, there are subchronic and chronic toxicity data for heptanoic acid and nonanoic acid (pelargonic acid).

In a 14-day rat oral toxicity study, no systemic toxicity was observed in either sex dosed with pelargonic acid (nonanoic acid) as high as 20,000 ppm (1,834 mg/kg/day), the highest dose tested. In addition, no adverse effects were caused on survival, clinical signs, body weight gain, food consumption, hematology, clinical chemistry or gross pathology. For each dose, three animals per sex were tested. However, the study did not report organ weights and histopathology. This was considered a deficiency in this study. Nevertheless, the Agency determined that, because no systemic toxic effects were observed at a very high dose level approaching 2,000 mg/kg/day, a 90-day oral study was not necessary (Kuhn, 1995; MRID 43843507).

Groups (10/sex/group) of rats (Sprague-Dawley) 45 days of age were given heptanoic acid by gavage in corn oil (10 ml/kg at doses of 0, 875, 1750, and 3500 mg/kg/day) daily for 27 days. In the high-dose animals, clinical signs included languid behavior, dyspnea, polypnea, tremors, wheezing, ataxia and excess salivation. Significant decreases in body weight and food consumption (high-dose males only) were observed compared to those of the control group. Hyperkeratosis of the non-glandular stomach was reported in high-dose males and females at necropsy. No significant findings in low- and mid-dose groups could be related to administration of the test material. Clinical chemistry and hematological examinations revealed no significant changes compared to those of the control group. A NOAEL of 1750 mg/kg/day and a LOAEL of 3500 mg/kg/day were determined based on decreased body weights and food consumption and gross lesions of the stomach (http://www.epa.gov/chemrtk/pubs/summaries/alipalde/c13033tc.htm; C7-C9 Consortium. 2004; Terrill, 1990b).

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A 28-day dermal toxicity study conducted on rabbits was submitted to the Agency under TSCA section 8(e). Five male and five female New Zealand white rabbits were dermally treated with nonanoic acid dissolved in mineral oil. In all, 10 applications were made (5 per week) at a dose level of 500 mg/kg/day. A 2-week recovery period was allowed for selected rabbits. During the first and second week of treatment, slight body weight loss and decreased food consumption were observed. One female rabbit showed ocular discharge and hypoactivity during the second week of treatment. All rabbits dermally treated with nonanoic acid by day 14 showed signs of severe erythema and moderate

edema. Dermal reactions consisting of moderate desquamation, moderate fissuring, eschar, exfoliation and necrosis were also observed at day 14. By day 29, all dermal reactions had reversed. It was evident that, at the treatment level of 500 mg/kg/day of nonanoic acid, significant dermal signs of irritation were observed but no significant systemic reaction (http://www.epa.gov/chemrtk/pubs/summaries/alipalde/c13033tc.htm; C7-C9 Consortium. 2004; Auletta, 1981).

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A similar dermal study was conducted using heptanoic acid. A single dose of 500 mg/kg/day of heptanoic acid in mineral oil (25% solution) was administered to New Zealand White rabbits (5/sex/group) daily for five days a week for two weeks with a two-week recovery period. Most animals exhibited a weight loss after 2 weeks of treatment, but showed normal weight gains during the additional two-week recovery period compared to controls. All animals showed localized severe erythema, slight to severe edema, necrosis, desquamation and exfoliation by the second week of treatment. Ocular irritation and decreased food consumption were also observed in some animals. All animals were free of signs of dermal and systemic toxicity at the end of the 2-week recovery period. Microscopic examination revealed epidermal necrosis, epidermal hyperplasia, and hyperkeratosis at the application site. A NOAEL of less than 500 mg/kg/day was determined (http://www.epa.gov/chemrtk/pubs/summaries/alipalde/c13033tc.htm; C7-C9 Consortium. 2004; Auletta, 1981).

A supplemental study on chronic toxicity/carcinogenicity in mice was conducted for 80 weeks. A dose of 50 mg of pelargonic acid was dermally applied to each mouse twice/day for 80 weeks. Histopathology showed no nonneoplastic or neoplastic lesions on skin and internal organs of mice. The Agency concluded that, although this study was not exactly conducted according to guideline, it adequately assesses the chronic toxicity and the carcinogenic potential of pelargonic acid via the dermal route (Suskind, 1985; MRID 43961801).

Chronic/Carcinogenicity

A supplemental study on chronic toxicity/carcinogenicity in mice was conducted for 80 weeks. A dose of 50 mg of nonanoic acid was dermally applied to each mouse twice/day for 80 weeks. Histopathology showed no non-neoplastic or neoplastic lesions on skins and internal organs of mice. The Agency concluded that, although this study was not exactly conducted according to guidelines, it adequately assesses the chronic toxicity and the carcinogenic potential of nonanoic acid via the dermal route.

Reproductive and Developmental Toxicity

In a developmental toxicity study (Chernoff/Kavlock assay), caprylic acid was administered via gavage to Sprague-Dawley rats once daily at dose levels of

1125 and 1500 mg/kg/day on gestation days 6 through 15. Decreased body weight in dams was observed in both dose levels, but there was no effect on number of implants, perinatal loss (%), or pup weight at either dose. A significant decrease ($p<0.05$) in the number of live pups was recorded at the high dose. The LOAEL for maternal toxicity and NOAEL for developmental toxicity was 1125 mg/kg/day. The study concluded that caprylic acid induced a significant decrease in the number of live pups in Sprague-Dawley rats but only at a dose which causes maternal toxicity. The tested doses are in excess of the Agency's limit dose for toxic effects. The type and level of exposure expected from the use of this chemical is much lower than the dose level used in the study.

Additional data indicated that *Cekanioc*® C8 acid (CAS No. 25103-52-0), a structural isomer of caprylic acid, was not teratogenic or a selective developmental toxicant in rats (14). *Cekanioc*® C8 acid was administered via gavage to 25 confirmed-mated females at doses of 0, 200, 400, and 800 mg/kg/day on gestation days 6-15. At 800 mg/kg/day, significant reductions in maternal body weight gain and food consumption were reported with clinical signs shown (limited to anogenital staining and alopecia). A statistically significant increase in the incidence of total variations was reported in the same dosage group, which was within the historical controls, and not considered biologically significant. There were no significant differences in fetal weight, malformation incidence, or fetal viability in any of the treatment groups. The maternal NOAEL was 400 mg/kg/day based on clinical signs, decreased body weight gain, and decreased food consumption, and the developmental NOAEL was 800 mg/kg/day.

Mutagenicity/Carcinogenicity

The Ames assay (*Salmonella*/reverse mutation assay) showed caprylic acid to be non-mutgenic in strains TA98, TA100, TA1535, TA1537, and TA1538 at concentrations up to 50,000 µg/plate with or without S9 metabolic activation. Caprylic acid was also negative in the unscheduled DNA synthesis assay at a concentration of 300 µg/mL (Fischer or Sprague-Dawley rat hepatocytes). No *in vivo* mutagenicity data are available for caprylic acid. Nonanoic acid gave a negative result in an *in vivo* micronucleus assay.

As described above, a summary of the results of a dermal carcinogenicity study in mice with nonanoic acid was submitted. Fifty mice were treated twice-weekly with 50 mg doses of undiluted nonanoic acid for 80 weeks. No evidence of severe dermal or systemic toxicity was seen. Histopathology revealed no tumors of the skin or the internal organs.

Section 3. Dietary Exposure

Food Exposure

Based on the knowledge that caprylic acid is naturally-occurring, is already a component of the human diet, is a GRAS chemical, has a long history of use, and does not cause any significant toxicology concerns, toxicity endpoints have not been selected. As there is no significant systemic toxicity associated with antimicrobial use of caprylic acid, quantitation of dietary exposure and subsequent calculation of dietary risk have not been conducted. Therefore, the Agency upholds the existing exemptions from the requirement of tolerances cited above.

Drinking Water Exposure

The current antimicrobial indoor uses of caprylic acid are not expected to result in residues in drinking water supplied by residential wells or municipal sources. It is possible that use of caprylic acid as a surface sanitizer in dairies and beverage processing plants may result in low concentrations of caprylic acid in beverages. Also, the limited outdoor use of the Phyton, Corp product may result in low residue levels in drinking water. However, taking into account the lack of systemic toxicity of caprylic acid and the existing tolerance exemptions, there is no need to quantify residues in drinking water or to assess risk.

Section 4. Residential Exposure

All registered use sites of caprylic acid products appear to be commercial facilities, i.e., there are no uses directly in a residential setting and no opportunity for exposure in the home. However, there is the opportunity for postapplication and bystander exposure of adults and children to caprylic acid resulting from its use in schools, gyms, restaurants, hospitals, etc. Although exposure is likely as a result of these uses, risk assessments are not applicable to caprylic acid as there are no adverse systemic effects on man attributable to dermal, inhalation, or inadvertent oral exposure.

Section 5. Aggregate Risk

Exposure to caprylic acid could result from food, drinking water, and postapplication/bystander sources; all of these could contribute to aggregate exposure. As caprylic acid induces no adverse systemic effects via any route of exposure, an aggregate risk assessment is also not required.

Section 6. Occupational Exposure

Occupational exposure of mixers/loaders/applicators is likely from the registered uses on dairy equipment, food and beverage processing plants, institutional and commercial establishments, and ornamental plants/facilities. However, a

quantitative risk assessment is not required because, again, adverse systemic effects on man attributable to the dermal and inhalation routes of exposure to caprylic acid are not expected. Label instructions and the requirement that applicators wear certain personal protective equipment (gloves and eye covering) are sufficient to protect workers from the localized, irritation effects of exposure to caprylic acid. The Phyton Corp. product label bears a worker restricted entry interval (REI) of 2 hours for fogging applications only. There is a restricted entry interval (REI) of zero hours for all other application methods. The proposed REI's appear adequate for caprylic acid given the use patterns, dosages used, and low toxicity.

Section 7. Human Incident Reports

The Agency consulted the OPP Incident Data System (IDS) to investigate the incidence of human poisonings resulting from caprylic acid exposure for purposes of this Registration Review Scoping Document (personal communication with J. Chen, 4/29/08). During the assessment phase of the Registration Review, IDS will be revisited and the following sources will be searched for incident reports associated with toxic effects of caprylic acid: Poison Control Centers, California Department of Pesticide Regulation (1982-2005), National Pesticide Telecommunications Network (NPTN), and the published scientific literature.

IDS contains reports of incidents from various sources, including registrants, other federal and state health and environmental agencies and individual consumers, submitted to OPP since 1992. Reports submitted to IDS represent anecdotal reports or allegations only, unless otherwise stated. Typically, no conclusions can be drawn implicating the pesticide as a cause of any of the reported health effects. Nevertheless, sometimes with enough cases and/or enough documentation, risk mitigation measures may be suggested.

A total of 29 incidents involving 260 individuals associated with products containing caprylic acid have been reported in IDS. The bulk of these were reported by the registrant, Ecolab, Inc. from 1999 to 2004. In every case, the specific end-use product name was known. The most common symptoms included: irritation of the lungs, throat, eyes, and skin, nausea, dizziness, and vomiting. The severity of the symptoms ranged from mild to severe such as eye redness to corneal abrasions or skin rash to blisters, edema, and erythema. In a few cases, victims developed blackened areas on the skin, fainted, or coughed blood. Most patients were hospitalized. It must be noted that all five antimicrobial products implicated also contained hydrogen peroxide and peroxyacetic acid in addition to caprylic acid. One product also contained acetic acid and a soap and another product contained phosphoric acid and citric acid at high percentages and decanoic (capric) acid. Although caprylic acid is a moderate eye irritant (Toxicity Category II) and a mild dermal and inhalation

irritant (Toxicity Category III), at least one other active ingredient in every implicated end-use product is expected to be more severely irritating than caprylic acid, especially at the concentrations formulated. All of these active ingredients are weak acids but phosphoric acid and citric acid are stronger acids than caprylic and the former would be expected to be more corrosive than the latter on that basis alone. However, the most serious irritation effects could be induced by the peroxyacetic acid which is a strong oxidizing agent that is very reactive with organic materials such as those comprising human tissues. Those handling the undiluted antimicrobial product directly, i.e., during pouring and mixing the end-use product in/with water prior to application, would be most at risk. Clearly, personal protective equipment (PPE) including goggles and chemical-resistant gloves are needed for handlers. Current labels bear the following precautionary statements: "Causes irreversible eye damage and skin burns. May be fatal if inhaled or absorbed through the skin. Harmful if swallowed. Do not get in eyes, on skin, or on clothing. Do not breathe vapor or spray mist. Wear protective eyewear (goggles, face shield, or safety glasses), protective clothing, and rubber gloves" and "When spraying or fogging, wear a mask or pesticide respirator jointly approved by Mine Safety and Health Administration and the National Institute for Occupational Safety and Health." These are appropriate warning statements and PPE based on available toxicity and incident data.

Section 8. Cumulative Risk

EPA does not have, at this time, available data to determine whether caprylic acid has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. For the purposes of this Registration Review, EPA has assumed that caprylic acid does not have a common mechanism of toxicity with other substances because it elicits no adverse systemic effects when used as an antimicrobial as registered.

Section 9. Endocrine Disruption

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

effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require the wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program [EDSP].

The Agency has no direct information regarding any potential endocrine effects of caprylic acid in mammalian systems. There is no information from the available scientific literature to suggest that this fatty acid would have endocrine effects. However, based on the weight of the evidence of available data, no effects related to an endocrine system have been identified or suggested for caprylic acid. For the purposes of this Registration Review, EPA has assumed that caprylic acid does not disrupt endocrine systems because it elicits no adverse systemic effects when used as an antimicrobial as registered

Section 10. Overall Conclusions

The fatty acids are a significant part of the normal daily diet, for they are the major component of dietary lipids (fats and oils) which often constitute up to 90 g/day although about 30 g/day is recommended. As discussed in this document, there are many FDA-approved uses of caprylic acid as a direct food additive. Residues from the pesticide uses of caprylic acid are not expected to approach levels of naturally-occurring fatty acids in commonly eaten foods. Taking into consideration all available information on fatty acids including FDA's designation of certain fatty acids such as caprylic acid as GRAS, their presence in food products naturally or as direct food additives, and use in cosmetics, the uses of caprylic acid as an active ingredient in pesticide products are unlikely to pose a significant risk to the general public or any population subgroup. Exposures from the aforementioned uses are expected to result in human exposure below any dose level that could possibly induce an adverse systemic effect. As a result, the Agency has used a qualitative approach to assessing human health risks from exposure to caprylic acid. Nondietary exposure of the general population, including infants and children, to caprylic acid residues is expected to occur due to its use in restaurants, schools, retail establishments, etc. although such exposure is likely to be minimal. Regardless of the extent of exposure, however, risks will be negligible because caprylic acid is not systemically toxic. Accordingly, EPA continues to support the determination that the existing exemptions from the requirement of a tolerance for residues of caprylic acid will be safe.

As caprylic acid is irritating to the skin and eyes, protection of handlers mixing, loading, and applying end-use products containing this antimicrobial is necessary. All six registered SC/L products, containing 2.72-6 % ai (w:w), bear the precautionary label statements that eye covering and rubber gloves both be worn. The 0.138% RTU-L product label simply advises that contact with eyes and clothing be avoided as the material is moderately irritating to the eyes; this

appears to be sufficient as the Agency has classified this RTU product as being Toxicity Category IV (a mild eye irritant).

The Agency has screened the hazard and exposure databases for caprylic acid and does not anticipate that additional toxicity or exposure data will be needed for registration review. The Agency does not expect that any additional human health risk assessments will need to be conducted for the caprylic acid Registration Review.