

the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), to amend 40 CFR part 180 to establish an exemption from the requirement of a tolerance for the biochemical pesticide rhamnolipid biosurfactant in or on all food commodities.

Pursuant to section 408(d)(2)(A)(I) of the FFDCA, as amended, Jeneil Biosurfactant Company has submitted the following summary of information, data, and arguments in support of their pesticide petition. This summary was prepared by Jeneil Biosurfactant Company, and EPA has not fully evaluated the merits of the pesticide petition. The summary may have been edited by EPA if the terminology used was unclear, the summary contained extraneous material, or the summary unintentionally made the reader conclude that the findings reflected EPA's position and not the position of the petitioner.

A. Product Name and Proposed Use Practices

Rhamnolipid biosurfactant is intended for the prevention and control of plant pathogenic fungi on horticultural and agricultural crops. Fungal diseases are often spread by zoospores that are transported from one plant to another and from field to field. Rhamnolipid biosurfactant kills zoospores that cause fungal disease, on contact. Target pests are any zoosporic plant pathogenic microorganisms including the following genera: *Plasmodiophora*, *Polymyxa*, *Spongopora*, *Physoderma*, *Olpidium*, *Synchytrium*, *Rhizophydium*, *Achlya*, *Aphanomyces*, *Albugo*, *Peronospythora*, *Pachymetra*, *Pythium*, *Phytophthora*, *Trachysphaera*, *Basidiophora*, *Peronosclerospora*, *Plasmopara*, *Pseudoperonospora*, *Sclerophthora*, and *Sclerospora*. End-use formulations of rhamnolipid biosurfactant are applied through conventional equipment as a spray, fog, drench or seed soak to the point of saturation, and can also be incorporated into nutrient solutions for hydroponic plants and vegetables. The product will be diluted with water and applied to growing plants and agricultural commodities at a rate of 70 to 100 parts per million (ppm). One end-use formulation, Zonix Biofungicide (8.5% active ingredient), is proposed at this time.

B. Product Identity/Chemistry

1. *Identity of the pesticide and corresponding residues.* Rhamnolipid biosurfactant, CAS number: 147858-26-2; CAS name: Decanoic acid, 3-[[6-deoxy-2-O-(6-deoxy- α -L-mannopyranosyl)- α -L-

mannopyranosyl]oxy]-, 1-(carboxymethyl)octyl ester, mixture with 1-(carboxymethyl)octyl 3-[[6-deoxy- α -L-mannopyranosyl]oxy]decanoate. The basic composition of the active ingredient consists of a well-known carbohydrate (rhamnose sugar) and fatty acid (hydroxydecanoic acid). The active ingredient is a mixture of two types of rhamnolipid molecules, R1 (RLL) and R2 (RRLL) at a ratio of R2:R1 = 0.7 - 2.0. Chemical name of the rhamnolipid molecules is as follows: Molecule 1 (defined as R1 or RLL): Decanoic acid, 3-[[6-deoxy- α -L-mannopyranosyl]oxy]-, 1-(carboxymethyl) octyl ester; and molecule 2 (defined as R2 or RRLL): Decanoic acid, 3-[[6-deoxy-2-O-(6-deoxy- α -L-mannopyranosyl)- α -L-mannopyranosyl]oxy]-, 1-(carboxymethyl) octyl ester.

Rhamnolipid biosurfactant, in particular, causes the lysis of zoospores of plant pathogens. Zoospores, the unicellular, motile spore stage in the life cycle of plant pathogens, are vulnerable to rhamnolipid biosurfactants due to the fact that the membrane-bound spore lacks a protective cell wall. The rhamnolipid destroys the permeability of the plasma membrane and results in the loss of motility and rapid lysis of the zoospore. Rhamnolipid biosurfactants are effective against all zoosporic plant pathogens, such as downy mildews, *Pythium* and *Phytophthora*.

Biosurfactants are produced by a variety of microorganisms and have been shown to play a role in enhancing bioavailability and biodegradation of petroleum hydrocarbons, in the attachment and detachment of bacteria to surfaces, and in complexing metals efficiently. Biosurfactants have application in cosmetics, personal care products, detergents, textile processing, agricultural crop protection products, metal treatment and processing, leather processing, hard surface cleaning, electronics component cleaning, pulp and paper processing, paint formulation, hydrocarbon recovery, oil tank cleaning and oil sludge remediation.

Rhamnolipids are comprised of extracellular natural substances (glycolipids) produced during a controlled aerobic fermentation process utilizing a strain of the bacterium *Pseudomonas aeruginosa*. Rhamnolipids are recovered from the process by centrifugation, extraction, and subsequent purification. No bacteria are present in the manufactured product and the production processes are strict in quality control to assure no live organisms exist. Purified rhamnolipids can be quantified by weight and rhamnose determination.

2. *A statement of why an analytical method for detecting and measuring the levels of the pesticide residue are not needed.* An analytical method for residues is not applicable. It is not expected that, when used as proposed, rhamnolipid biosurfactant would result in residues that are of toxicological concern.

C. Mammalian Toxicological Profile

Rhamnolipid biosurfactant has been evaluated for toxicity through oral, dermal, inhalation and eye routes of exposure. Studies indicate the end-use product is Toxicity Category I for eye irritation (diluted end-use product is Toxicity Category IV for eye irritation), and Toxicity Category IV for all other routes of exposure. Studies resulted in an acute oral lethal dose (LD₅₀) >5,000 milligrams/kilogram (mg/kg), acute dermal LD₅₀ >5,000 mg/kg, acute inhalation lethal concentration (LC₅₀) 2.05 mg/L, primary eye irritation severe at 9.5% active ingredient and slight at 1.0% active ingredient, and primary skin irritation minimal.

A waiver has been requested for dermal sensitization based on the fact that the active ingredient is not toxic or irritating dermally, and a lack of reported effects by users of the surfactant in a variety of products. Rhamnolipid biosurfactants have been marketed for over 3 years as an emulsifier, dispersant and wetting agent. Since its discovery, no incidents of hypersensitivity have been reported by researchers, manufacturers or users. A waiver has been requested for genotoxicity based on the fact that rhamnolipid biosurfactant is not related to any known mutagen and does not belong to a chemical class of compounds containing known mutagens. The rhamnolipid molecules are simply glycolipids composed of a rhamnose sugar ring and a fatty acid tail. Individually these molecules are not considered toxic or mutagenic. Rhamnose is a comparatively rare sugar listed by FDA as a food additive. Fatty acids are ubiquitous in animals and plants, and are the major source of energy in the body. Consequently the breakdown products of rhamnolipids are of little toxicological concern. A waiver has been requested for 90-day oral toxicity, teratogenicity and immunotoxicity based on the physical mode of action of the product, the demonstrated lack of oral, dermal and inhalation toxicity, and the innocuous nature of the potential breakdown products of rhamnolipid biosurfactants. The mode of action of rhamnolipid biosurfactants is a physical action on the plant pathogen rather than a specific