

Due to its being used in small percentages in the proposed formulations, oral ingestion of quantifiable amounts of copper will not result from use of copper hydroxide as an inert. Copper compounds are irritating to the gastric mucosa. Ingestion of large amounts of copper results in prompt emesis. This protective reflex reduces the amount of copper ion available for absorption into the human body. Additionally, at high levels humans are also sensitive to the taste of copper. Because of this organoleptic property, oral ingestion would also serve to limit high doses. Only a small percentage of ingested copper is absorbed, and most of the absorbed copper is excreted. The copper ion occurs naturally in many foods and the metabolism of copper is well understood. There are several factors unique to copper which indicate that additional studies are not needed to regulate copper hydroxide as an inert in pesticide formulations. One of the foremost of these is the fact that copper is a required nutritional element for both plants and animals. It appears that more evidence is available to define the adverse effects of a deficiency in the diet than to show the toxic effects of an excess intake. In fact, no account has been found in the literature reviewed which describes a toxic effect to normal humans from ingestion of common foodstuffs containing copper. Because copper toxicity to man through the diet has been shown in normal persons, little is known about the minimum levels of dietary copper necessary to cause evidence of adverse effects. This situation is likely due, to an effective homeostatic mechanism that is involved in the dietary intake of copper and that protects man from excess body copper. This complex mechanism integrates absorption, retention, and excretion to stabilize the copper body burden. Given that copper is ubiquitous and is routinely consumed as part of the daily diet, it is unlikely that with current exposure patterns there would be any long-term adverse effects. The hydroxide ion is also ubiquitous in plants, animals including humans, and the environment. The use of copper hydroxide as an inert will not result in any increased burden on the environment or living organisms.

C. Aggregate Exposure

1. *Dietary exposure.* Twelve Food and Drug Administration (FDA) total diet studies, conducted from mid 1982–1984, examined dietary intake of copper for age groups 14–16, 25–30, and 60–65 years. The copper intake ranged from 0.77 (14–16 year old females) to 1.24

mg/day (25–30 year old males). Use of copper hydroxide as an inert at rates at an order of magnitude lower than current pesticide rates will not result in any quantifiable increase in exposure to copper from dietary sources.

i. *Food.* The main source of copper for infants, children, and adults, regardless of age, is the diet. Copper is typically present in mineral rich foods like vegetables (potato, legumes (beans and peas)), nuts (peanuts and pecans), grains (wheat and rye), fruits (peach and raisins), and chocolate in levels ranging from 0.3 to 3.9 parts per million (ppm). A single day's diet may contain 10 mg or more of copper. The daily recommended allowance of copper for adults nutritional needs is 2 mg.

ii. *Drinking water.* Copper is a natural element found in the earth's crust. As a result, most of the world's surface water and ground water that is used for drinking purposes contains copper. Naturally occurring copper in drinking water is safe for human consumption, even in rare instances where it is at levels high enough to impart a metallic taste to the water. The Agency has set a maximum contaminant level for copper at 1.3 ppm. Use of copper hydroxide as an inert at rates at an order of magnitude lower than current pesticide rates will not result in any quantifiable increase in exposure to copper from drinking water.

2. *Non-dietary exposure.* Copper is a naturally occurring element present in the earth's crust, and it is therefore naturally occurring in soil, water and air. Soils would be considered copper deficient if they contain less than 2 ppm available copper in the context of plant health. Air concentrations of copper are relatively low. A study based on several thousand samples assembled by EPA's Environmental Monitoring Systems Laboratory showed copper levels ranging from 0.003 to 7.32 micrograms per cubic meter. Use of copper hydroxide as an inert at rates at an order of magnitude lower than current pesticide rates will not result in quantifiable increase in exposure to copper from non-dietary sources.

D. Cumulative Effects

Exposure to copper occurs over a lifetime from numerous sources and does not result in any known toxicity. Use of copper hydroxide as an inert will not result in quantifiable increase in cumulative exposure to copper.

E. Safety Determination

1. *U.S. population.* Copper is an essential trace element for which the National Academy of Sciences has issued a recommended daily allowance

of up to 3 mg/day for adults. Accordingly, there is reasonable certainty that no harm will result from aggregate exposure of the U.S. population to copper. The use of copper hydroxide as an inert in pesticide formulations will not result in any measurable increase in exposure to copper.

2. *Infants and children.* Copper is also a component of the diet of infants and children and also an essential element of their diet. The use of copper hydroxide as an inert in pesticide formulations will not result in any measurable increase in exposure of infants and children to copper.

F. International Tolerances

There does not appear to be any international tolerances for copper or copper hydroxide, and no CODEX maximum residue levels has been established for any food crops at this time.

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ENVIRONMENTAL PROTECTION AGENCY

[FRL–7521–6]

Public Water Supply Supervision Program Revision for the Commonwealth of Puerto Rico

AGENCY: Environmental Protection Agency.

ACTION: Notice of tentative approval and solicitation of request for a public hearing for Public Water Supply Supervision Program Revision for the Commonwealth of Puerto Rico

SUMMARY: Notice is hereby given that the Environmental Protection Agency (EPA) has determined to approve an application by the Commonwealth of Puerto Rico to revise its Public Water Supply Supervision Primacy Program to incorporate regulations no less stringent than the EPA's National Primary Drinking Water Regulations (NPDWR) for the following: Lead and Copper Rule Technical Correction; Final Rule, promulgated by EPA on June 30, 1994 (59 FR 33860), Synthetic Organic Chemicals and Inorganic Chemicals; Final Rule, promulgated by EPA on July 1, 1994 (59 FR 34320), Analytical Methods Technical Corrections; Final Rule, promulgated by EPA on December 5, 1994 (59 FR 62456), Analytical Methods Technical Corrections; Final Rule, promulgated by EPA on June 29, 1995 (60 FR 34083), Analytical Methods for Radionuclides Technical Corrections, promulgated by EPA on