

various information, humic acids are colloids, that behave somewhat like clays. Humic acids are macromolecules that are soluble in dilute alkali. They vary from dark brown to black in color. They are amorphous, polymeric substances with molecular weights ranging from 5,000 to 50,000. The cation exchange capacity (the total amount of exchangeable cations a soil can retain) ranges from 200 to 500 milliequivalents per 100 grams of soil at pH 7. When the cation exchange sites are mostly hydrogen, then the material is referred to as humic acid. When the predominant cation is sodium, then the material is referred to as humic acid, sodium salt. Similarly, material would be referred to as humic acid, potassium salt if the predominant cation were potassium.

A. Subchronic Toxicity

The following subchronic toxicity data (National Technical Information Service (NTIS) PB92-164946) was located through an internet search using humic as search term. An abstract is located on the National Library of Medicine Specialized Information Services (NLM/SIS). According to the abstract:

Male and female Sprague-Dawley rats were administered drinking water containing humic acids either non-disinfected or following ozonation (O3) ozonation/chlorination (O32) for 90 consecutive days. Test animals drank either of two concentration of humic acids, 0.25 and 1.0 g/L total organic carbon (TOC), while controls received phosphate-buffered, distilled water. No consistent significant treatment-related effects were observed in body weight gain, organ weights, food or water consumption, or hematological and clinical chemistry parameters. No target organs were identified from the histopathological examination of the tissues. The most significant observation, an increase in liver to body weight ratio for the male animals in the 1.0 g/LO3/CL2 humic acid group, was not observed in any other group, nor was it corroborated via any biochemical measurements or histopathological analysis.

B. Mutagenicity

An abstract discussing the mutagenicity of two coal-derived humic substances (Sulcis and South Africa, Eniricerche, Italy) was located through the NLM/SIS. Their mutagenic activity on TA98 and TA100 *Salmonella typhimurium* strains, both in the presence or the absence of metabolic activation (S9) was discussed. Both compounds showed no effect on the two strains, as observed with natural humic acid.

V. Aggregate Exposures

In examining aggregate exposure, FFDCA section 408 directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures, including drinking water from ground water or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

EPA establishes exemptions from the requirement of tolerances only in those cases where it can be demonstrated that the risks from aggregate exposure to pesticide chemical residues under reasonable foreseeable circumstances will pose no appreciable risks to human health. In order to determine the risks from aggregate exposure to pesticide inert ingredients, the Agency considers the toxicity of the inert in conjunction with possible exposure to residues of the inert ingredient through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings. If EPA is able to determine that a finite tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the inert ingredient, an exemption from the requirement of tolerance may be established.

A. Dietary Exposure

1. *Food.* Not only are humic substances abundant in nature, but they have been used in commercial agriculture for years to condition soils. Therefore, there is likely a substantial ongoing human dietary exposure to humate materials from these sources and increased dietary exposures from the use of humate materials as an inert ingredient in pesticide formulations is expected to be minimal.

2. *Drinking water exposure.* Humic substances occur in abundance in nature, including soils, fresh water, and oceans. Increased drinking water exposure from the use of humate materials in pesticide formulations would not be expected.

B. Other Non-Occupational Exposure

Humic substances occur in abundance in nature, including soils that are in and around the home. The potential for an increase in the existing non-dietary exposure to the general population, including infants and children, is unlikely as these pesticide formulations containing humate materials would be used in agricultural and horticultural settings.

VI. Cumulative Effects

Section 408(b)(2)(v) of FFDCA requires that, when considering whether to establish, modify or revoke a tolerance or tolerance exemption, the Agency consider "available information" concerning the cumulative effects of particular chemical's residues and "other substances that have a common mechanism of toxicity." The Agency has not made any conclusions as to whether or not humic acid, potassium salt shares a common mechanism of toxicity with other chemicals. However, humic acid, potassium salt is expected to be practically non-toxic to mammals. Due to the expected lack of toxicity, a cumulative risk assessment is not necessary.

VII. Determination of Safety for U.S. Population, Infants, and Children

Humic substances are present in abundance in the soil and the environment. Humic substances have been used in commercial agriculture for years to condition soils. Based on available information on these chemically related substances, the Agency believes that humic acid; humic acid, potassium salt; and humic acid, sodium salt are practically non toxic to mammals. Due to the ubiquitous nature of these naturally occurring materials, and the high molecular weights of the humic materials, no chronic or acute effects are expected to occur. There is no available information to indicate that these naturally occurring substances are carcinogenic, mutagenic, or expected to have any effect on the immune or endocrine systems. Because of its abundance in nature and lack of toxicity, the Agency did not use the safety factor analysis in evaluating the risk posed by humate substances and did not apply an additional tenfold safety factor to protect infants and children.

Based on the information in the preamble, EPA concludes that there is a reasonable certainty of no harm from aggregate exposure to residues of humic acid; humic acid, potassium salt; and humic acid, sodium salt. Accordingly, EPA finds that exempting these humate materials from the requirement of a tolerance will be safe.

IX. Other Considerations

A. Endocrine Disruptors

FQPA requires EPA to develop a screening program to determine whether certain substances, including all pesticide chemicals (both inert and active ingredients), "may have an effect in humans that is similar to an effect