

4. *Subchronic toxicity.* Waivers have been requested for the 90-day feeding, dermal and inhalation studies. The conditions of potential exposure requiring these studies are not triggered. Acetic acid is a food acid and is naturally occurring. Acetic acid is absorbed from the gastrointestinal tract and through the lungs and is readily, although not completely, oxidized in the organism. Acetic acid is proposed to be used as a hay and grain preservative at low concentrations, and for animal food only, and these low concentrations are lower than is found in commercially available vinegar (5% to 7%). Therefore, there would be no expected subchronic effects from the limited exposure expected to acetic acid, and the waivers should be granted.

5. *Chronic toxicity.* Waivers have been requested for chronic toxicity requirements for acetic acid. However, the results of two Russian studies reported the induction of hyperplasia in rats at 60 mg/kg bwt. This result is similar to induction of hyperplasia in rats by propionic acid in a 2-year study.

6. *Animal metabolism.* Acetic acid is a food acid and is naturally occurring. Acetic acid is utilized as an energy source in the body by combining first with Co-enzyme A to form Acetyl-CoA which then enters the Krebs's citric acid cycle by combining with oxaloacetate to yield citrate. This process is active in all animals and higher plants and is carried out in the mitochondria. Acetic acid is proposed to be used as a hay and grain preservative at low concentrations, and for animal food only. There are no expected adverse effects.

7. *Metabolite toxicity.* Acetic acid is a food acid and is naturally occurring in the environment as well as in plants and animals. Acetic acid is utilized as an energy source in the body by combining first with Co-enzyme A to form Acetyl-CoA which then enters the Krebs's citric acid cycle by combining with oxaloacetate to yield citrate. This process is active in all animals and higher plants and is carried out in the mitochondria.

C. Aggregate Exposure

1. *Dietary exposure.* Acetic acid is a food acid and is naturally occurring in plants and animals. Acetic acid is utilized as an energy source in the body by combining first with Co-enzyme A to form Acetyl-CoA which then enters the Krebs's citric acid cycle by combining with oxaloacetate to yield citrate. This process is active in all animals and higher plants and is carried out in the mitochondria.

Acetic acid is most commonly encountered by the human population

in the form of vinegar, varying in concentration of acetic acid, from 4–7%. Acetic acid is considered generally recognized as safe (GRAS) by FDA when directly added to foods (20 CFR 184.1005). There are no reports in the literature of contact sensitization to vinegar.

Used in accord with instructions for the preservation of grain and hay, the concentration of acetic acid on the commodities used for animal food, will be less than 2%. Dietary exposure to acetic acid used in this application will therefore pose no threat to humans or the environment.

2. *Non-dietary exposure.* The only non-dietary exposure to acetic acid is the occupational exposure. Acetic acid end-use products are sprayed on grains and hay at application rates in ranges of less than 3% on the commodity, depending on the moisture content of the treated crop. Based on the use patterns, the potential for exposure of applicators and workers in the field being treated with acetic acid could be significant. However, applicators are generally confined in the cab of the tractor pulling the collecting systems to which the applying sprays are attached. The hay or grain collected would contain less than 3% of the acetic acid and therefore subsequent exposure to the crop would cause no significant exposure to the acetic acid.

Certain protective clothing is recommended for acetic acid users due to eye and skin hazards associated with the handling of concentrated acetic acid and the use of such clothing and protective equipment is presented on the label.

D. Cumulative Effects

Acetic acid is used similarly as propionic acid, for the preservation of hay and grains. Under an aerobic conditions propionic acid acts as a carbon source for various microbes and is metabolized to acetic acid, methane, carbon dioxide, and water. For propionic acid, the metabolite of acetic acid poses no problems because acetic acid is also found in the food chain, is naturally occurring, and is applied in the same manner as propionic acid as a pesticide. For propionic acid all environmental fate data requirements are waived for the uses this petition requests for acetic acid. There should be no concern for cumulative effects for acetic acid as well.

E. Safety Determination

Human health assessment—i. U.S. population. Acetic acid is a normal component of metabolism in the human body and humans ordinarily consume

acetic acid as vinegar, as a natural component of common foods, and as an added ingredient. Dietary exposure from pesticidal use would be very low.

ii. *Infants and children.* As noted above acetic acid is produced by the human body. Humans include infants and children as well as adults. For the same reasons as above, dietary exposure from pesticidal use would be of minimal concern.

F. Tolerance Exemptions for the Proposed Uses

The petitioner proposes that the use of acetic acid as a grain and hay preservative be granted an exemption from the requirement of a tolerance, as proposed below:

1. Post-harvest application of acetic acid, when used as a fungicide or preservative is exempted from the requirement of a tolerance for residues in or on the following raw agricultural commodities: Alfalfa, barley grain, Bermuda grass, bluegrass, brome grass, clover, corn grain, cowpea hay, fescue, lespedeza, lupines, oat grain, orchard grass, peanut hay, peavine hay, rye grass, sorghum grain, soybean hay, sudan grass, Timothy, vetch, and wheat grain, or commodities described as grain or hay.

2. Acetic acid is exempt from the requirement of a tolerance for residues in or on meat, and meat by-products: Cattle, sheep, hogs, goats, horses, and poultry, milk, and eggs when applied as a bactericide/fungicide to livestock drinking water, poultry litter, and storage areas for silage and grain.

3. Post-harvest application of acetic acid when used as a fungicide/preservative is exempted from the requirement of a tolerance for residues in or on the following raw agricultural commodities: Cottonseed, peanuts, rice grain, and soybeans.

Noticeably, this tolerance exemption request re-establishes the same exemption criteria as was previously granted for acetic acid for this use.

G. International Tolerances

There are no known international tolerances for residues of acetic acid in food or animal feed.

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