

prepared by the petitioner and represents the view of the petitioner. The petition summary announces the availability of a description of the analytical methods available to EPA for the detection and measurement of the pesticide chemical residues or an explanation of why no such method is needed.

BASF Corporation

PP 0F6166

EPA has received a pesticide petition (PP 0F6166) from BASF, 26 Davis Drive, Research Triangle Park, NC 27709-3528 proposing, pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), to amend 40 CFR part 180 by establishing a tolerance for residues of imazapyr [2-[4,5-dihydro-4-methyl-4-(1-methylethyl)-5-oxo-1H-imidazol-2-yl]-3-pyridinecarboxylic acid], applied as the isopropylamine salt, in or on the raw agricultural commodity on grass forage at 125 parts per million (ppm) and hay at 35 ppm, fish at 1 ppm, shellfish at 0.1 ppm, milk at 0.01 ppm, and kidney at 0.5 ppm, meat by-products other than kidney at 0.05 ppm, meat at 0.05 ppm, and fat at 0.05 ppm of cattle, sheep, goats, and horses. EPA has determined that the petition contains data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data supports granting of the petition. Additional data may be needed before EPA rules on the petition.

A. Residue Chemistry

1. Plant metabolism—i.

Bermudagrass. Radiolabeled imazapyr was applied at 1.5 lb acid equivalents/acre (ae)/A to field-grown bermudagrass. Parent imazapyr accounted for the majority of the total radioactive residue (TRR) in all harvested samples. No metabolites were identified which require regulation.

ii. Ruminant. Goats were dosed with radiolabeled imazapyr at 17.7 ppm, 42.5 ppm, or 47 ppm dietary equivalents for 7 days. As assessed for goats receiving the 17.7 or 42.5 ppm doses, TRR in fat, liver and leg and loin muscle were non-detectable < 0.05 ppm. TRR in milk were a maximum of 0.01, 0.02, and 0.02 ppm for the three goats, respectively, while TRR in kidney were 0.08, 0.11, and 0.08 ppm, respectively. Of these residues, parent imazapyr accounted for 50–66% of the TRR in milk and 82–95% of the TRR in kidney. No metabolites were identified which require regulation.

iii. Confined crop rotation.

Radiolabeled imazapyr was applied to soil at a rate of 0.79 lb ae/A. Root (carrot), lettuce (leafy vegetables), and wheat (cereal grains), were planted at 330 through 540 days; shorter intervals were not required as rangeland and pastures are not normally rotated to other crops. The TRR in all harvested samples were <0.02 ppm and the major extractable component of these residues was parent imazapyr. Therefore, there is no reasonable expectation of inadvertent residues in rotational crops planted 12 months after application.

2. Analytical method. M 3023 is a reliable capillary electrophoresis method with ultraviolet (CE/UV) detection for the determination of imazapyr residues in grass forage and grass hay. M 3184 is a reliable CE/UV method for the determination of imazapyr residues in meat, kidney, other meat byproducts, and fat of cattle, sheep, goats, and horses. M 3075 is a reliable CE/UV method for the determination of imazapyr residues in milk. M 3066 is a reliable CE/UV method for the determination of imazapyr residues in fish and shellfish.

3. Magnitude of residues—i. Grass. Imazapyr was applied at a nominal rate of 0.75 lb ae/A to bluegrass, bermudagrass, tall fescue, and bromegrass for a total of 14 field trials. Residues of imazapyr were reached a maximum of 98 ppm in grass forage immediately after treatment and 27 ppm upon drying to grass hay cut 7 days after treatment. Therefore, tolerances of 125 ppm in/on grass forage and 35 ppm in/on grass hay are proposed.

ii. Ruminants. Lactating dairy cows were dosed orally each day for 28 or 29 consecutive days at feed equivalents of 0, 58, 157, 607, and 1,680 milligrams (mg) imazapyr per kilogram (kg) dry matter consumed. The 58 mg/kg dose is equivalent to 1.4 times the anticipated dietary burden for the worst-case cattle diet where 10% of the grass received an imazapyr spot treatment, the proposed label use for range and pasture grasses. At 58 mg/kg, imazapyr residues in milk were < 0.01 ppm; residues in muscle, fat, and liver were <0.05 ppm; and residues in kidney averaged 0.25 ppm. Furthermore, imazapyr residues in milk were shown not to be concentrated into milk fat. Therefore, the following tolerances for imazapyr residues in cattle, sheep, goats, and horses are proposed: Milk at 0.01 ppm; meat byproducts (except kidney) at 0.05 ppm; meat at 0.05 ppm; fat at 0.05 ppm; and kidney at 0.5 ppm.

iii. Fish and shellfish. Imazapyr was applied at 1.6 lb ae/A to two ponds containing fish and aquatic

invertebrates. Imazapyr residues were observed from the organisms collected from the treated ponds at only one site and only in the 3-hour-after-treatment samples. Average residues from these samples were: Bluegill, 0.636 ppm; tilapia, 0.233 ppm; catfish, 0.068 ppm; crayfish, 0.059 ppm. In a separate study, freshwater clams were exposed to a dose of imazapyr equivalent to 1.5 lb ae/A as applied to a 2.2-foot deep pond; residues of imazapyr in these clams remained <0.05 ppm at all intervals evaluated (up to 28 days post-treatment). Given these results, tolerances for imazapyr are proposed at 1 ppm for fish and 0.1 ppm for shellfish.

B. Toxicological Profile

1. Acute toxicity. Based on a battery of acute toxicity studies, imazapyr has been placed in toxicity category I for eye irritation, category IV for oral LD₅₀ and primary dermal irritation, and category III for dermal LD₅₀ and inhalation LC₅₀. Imazapyr was a non-sensitizer when tested for dermal sensitization (Buehler Method).

2. Genotoxicity. Studies on gene mutation and other genotoxic effects, Ames Salmonella Assay, CHO/HGPRT Point Mutation Assay, *in vitro* CHO cell chromosome aberration assay, dominant lethal assay, and unscheduled DNA synthesis (UDS) in primary rat hepatocytes yielded negative results.

3. Reproductive and developmental toxicity—i. For a rat developmental toxicity study at doses of 0, 100, 300, or 1,000 mg/kg body weight/day (b.w./day), the only clinical sign of toxicity was salivation in gravid dams at 1,000 mg/kg b.w./day. The No-Observed-Adverse-Effect Level (NOAEL) for maternal toxicity is 300 mg/kg b.w./day. There were no developmental findings in this study up to the limit dose of 1,000 mg/kg b.w./day, the highest dose tested (HDT).

ii. For a rabbit development toxicity study at doses of 0, 25, 100, and 400 mg/kg b.w./day, the maternal and developmental NOAEL is 400 mg/kg b.w./day HDT. Doses were based on pilot range-finder study, which tested at 0, 250, 500, 1,000, and 2,000 mg/kg b.w./day. The only toxic effect observed was increased salivation at 1,000 and 2,000 mg/kg b.w./day.

iii. A 2-generation rat reproduction study at doses of 0, 1,000, 5,000, or 10,000 ppm yielded a NOAEL of 10,000 ppm highest concentration tested (HCT) (800 mg/kg b.w./day for males, 980 mg/kg b.w./day for females, as based on food consumption data).

4. Subchronic toxicity—i. A 90-day dietary study in rats at doses of 0, 15,000, or 20,000 ppm resulted in a