

stover at 0.35 ppm; pea and bean, dried shelled, except soybean, subgroup 6C at 0.15 ppm.

EPA has determined that the petitions contain 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 support granting of the petitions. Additional data may be needed before EPA rules on the petitions. This notice includes summaries of the petitions prepared by FMC Corporation, Philadelphia, PA 19103.

A. Residue Chemistry

1. *Plant metabolism.* The metabolism of sulfentrazone in plants is adequately understood for the existing and proposed tolerances.

2. *Analytical method.* The proposed analytical method for determining residues of sulfentrazone is hydrolysis followed by gas chromatographic separation.

3. *Magnitude of residues.* The magnitude of residues is adequately understood for the proposed commodities.

B. Toxicological Profile

1. *Acute toxicity.* A battery of acute toxicity studies placed technical sulfentrazone in toxicity categories III and IV. No evidence of sensitization was observed following dermal application in guinea pigs. In an acute neurotoxicity study in rats at gavage doses of 0, 750, or 2,000 milligrams/kilogram (mg/kg), the no observable adverse effect level (NOAEL) of 250 mg/kg and the lowest observable adverse effect level (LOAEL) of 750 mg/kg were based upon increased incidences of clinical signs, Functional Observation Battery (FOB) findings, and decreased motor activity which were reversed by day 14 post-dose. There was no evidence of neuropathology.

2. *Genotoxicity.* A reverse gene mutation assay (*salmonella typhimurium*) yielded negative results, both with and without metabolic activation. A mouse lymphoma forward gene mutation assay yielded negative results with equivocal results without activation. A mouse micronucleus assay test was negative following intraperitoneal injection of 340 mg/kg.

3. *Reproductive and developmental toxicity.* In a dermal developmental study in the rat at doses of 0, 5, 25, 50, 100, and 250 mg/kg/day, a maternal (systemic) NOAEL was established at 250 mg/kg/day. Significant treatment-related increases in the fetal and litter incidences of incompletely ossified lumbar vertebral arches, hypoplastic or

wavy ribs, and incompletely ossified or nonossified ischia or pubes occurred at the high-dose (250 mg/kg/day). An additional significant increase in the high-dose fetal incidence of variations in the sternebrae (incompletely ossified or unossified) was not judged to be treatment-related. At 250 mg/kg/day, the mean numbers of thoracic vertebral and rib ossification sites were significantly decreased, a high-dose effect of treatment with sulfentrazone consistent with the significant treatment-related hypoplasia observed in the skeletal evaluation of the ribs. Therefore, the developmental (fetal) LOAEL is 250 mg/kg/day based on decreased fetal body weight; increased incidences of fetal variations: Hypoplastic or wavy ribs, incompletely ossified lumbar vertebral arches, and incompletely ossified ischia or pubes; and reduced number of thoracic vertebral and rib ossification sites. The developmental (fetal) NOAEL is 100 mg/kg/day.

A developmental toxicity study in rabbits was conducted at gavage dose levels of 0, 100, 250, or 375 mg/kg/day. Treatment-related incidences of decreased feces and hematuria were noted at 250 mg/kg/day or greater. In addition, at the 375 mg/kg/day dose level, 5 rabbits aborted. Significant reductions in mean body weight change were observed for the dosing period (GD 7–19) and for the study duration (GD 0–29, both before and after adjustment for gravid uterine weight) at the 250 and 375 mg/kg/day dose levels. Therefore, the maternal (systemic) LOAEL is 250 mg/kg/day, based upon increased abortions, clinical signs (hematuria and decreased feces), and reduced body weight gain. The maternal (systemic) NOAEL is 100 mg/kg/day. Skeletal evaluation in fetuses revealed dose-related and treatment-related findings at the 375 mg/kg/day dose level. These included significant increases in both the fetal and litter incidences of fused caudal vertebrae (a malformation) and of partially fused nasal bones (a variation). In addition, at 375 mg/kg/day, significant treatment-related reductions in ossification site averages were observed for metacarpals and both forepaw and hindpaw phalanges. Therefore, the developmental (fetal) LOAEL is 250 mg/kg/day, based upon increased resorptions, decreased live fetuses per litter, and decreased fetal weight. The developmental (fetal) NOAEL is 100 mg/kg/day.

A 2-generation reproduction study in the rat at dietary levels of 14, 33, or 46 mg/kg/day in males and 16, 40, or 56 mg/kg/day in females established a NOAEL for systemic and reproductive/developmental parameters of 14 mg/kg/

day for males and 16 mg/kg/day for females. The LOAEL for systemic and reproductive/development parameters was 33 mg/kg/day for males and 40 mg/kg/day for females. Systemic effects were comprised of decreased body weight gains, while reproductive/developmental effect at the LOAEL included degeneration and/or atrophy in the testes, with epididymal sperm deficits, in the second (F1) generation males. Male fertility in the F1 generation was reduced at higher doses; litter size, pup survival, and pup body weight for both generations were also effected at higher doses.

4. *Subchronic toxicity.* A 90-day subchronic toxicity study was conducted in rats, with dietary intake levels of 0, 3.3, 6.7, 19.9, 65.8, 199.3, or 534.9 mg/kg/day for males and 0, 4, 7.7, 23.1, 78.1, 230.5, or 404.3 mg/kg/day for females respectively. NOAELs of 19.9 mg/kg/day in males and 23.1 mg/kg/day in females were based on clinical anemia.

A 90-day subchronic feeding study was conducted in mice by dietary admix at doses of 0, 10.3, 17.8, 60.0, 108.4, or 194.4 mg/kg/day for males and 0, 13.9, 29.0, 79.8, 143.6, or 257.0 mg/kg/day for females, respectively. NOAELs of 60 mg/kg/day (males) and 79.8 mg/kg/day (females) were based on decreases in body weights and/or gains; decreased erythrocytes, hemoglobin (Hgb) and hematocrit (HCT) values; and splenic microscopic pathology.

In a 90-day subchronic feeding study in dogs administered by dietary admix at doses of 0, 10, 28, or 57 mg/kg/day for males and 0, 10, 28, or 73 mg/kg/day for females, a NOAEL of 28 mg/kg/day was determined for both males and females based on decreases in Hgb and HCT, elevated alkaline phosphatase levels, increased liver weights and microscopic liver as well as splenic changes.

A 90-day subchronic neurotoxicity study in the rat was conducted at dietary levels of 30, 150, or 265 mg/kg/day in males, and 37, 180, or 292 mg/kg/day in females, with a NOAEL of 30 mg/kg/day in males and 37 mg/kg/day in females. The LOAEL was 150 mg/kg/day for males and 180 mg/kg/day for females based on increased incidences of clinical signs, decreased body weights, body weight gains, and food consumption in females and increased motor activity in females at week 13. There were no neurohistopathological effects on the peripheral or central nervous system.

5. *Chronic toxicity.* A 12-month feeding study in dogs was dosed at levels of 0.0, 24.9, or 61.2 mg/kg/day for male dogs and 0.0, 10.4, 29.6, or 61.9