

pesticide chemical residues or an explanation of why no such method is needed.

BASF Corporation

PP 3F6560

EPA has received a pesticide petition (PP 3F6560) from BASF Corporation, 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 chlorfenapyr, [4-bromo-2-(4-chlorophenyl)-1-(ethoxymethyl)-5-(trifluoromethyl)-1H-pyrrole-3-carbonitrile] on all food items in food handling establishments where food products are held, processed, and/or prepared at 0.01 parts per million (ppm). 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 support granting of the petition. Additional data may be needed before EPA rules on the petition.

A. Residue Chemistry

1. *Plant metabolism.* The nature of the residues of chlorfenapyr in plants (tomato, citrus, potato and head lettuce) is adequately understood and the residue of concern consists of the parent molecule. The metabolic pathway of chlorfenapyr in the laying hen and the lactating goat was also similar to that in laboratory rats.

2. *Analytical method.* The GC analytical method, M 2398, which is proposed as the enforcement method for the residue of chlorfenapyr in or on food commodities, has a limit of quantitation (LOQ) of 0.01 ppm.

3. *Magnitude of residues.* A study, based on protocol recommendations outlined in EPA's Residue Chemistry Test Guidelines, (OPPTS Harmonized Test Guideline 860.1460: Food Handling), was conducted with chlorfenapyr formulated as a 24% wettable powder.

Applications were made to all potential sites within a commercial kitchen, including the perimeter of the restaurant kitchen, areas under cabinets and overhead cabinets, behind and on sides of cabinets and appliances, within the ceiling voids, and around pipes, cords, cables, counter legs, and wheels. The areas in which the product was applied are typical of those treated in a professional pest control operation in a commercial kitchen.

The test was conducted using a wettable powder (WP) formulation at the maximum label rate for indoor use of 0.5% active ingredient (a.i.)/1,000 ft², which is also the approved maximum rate for indoor use in non-food/feed areas for the SC formulation (suspension in water), EPA Registration No. 241-392. The WP formulation has a larger particle size and will be more easily dispersed than the SC formulation, and therefore will best characterize the potential for exaggerated exposures to food items.

Results from this study were that magnitudes of residues in all composite meal samples, both covered and uncovered, were below the LOQ of 10 parts per billion (ppb). Thus, there is a reasonable expectation that no finite residues of chlorfenapyr will result in food items following crack and crevice or spot applications of either the 25% wettable powder or the 21% suspension concentrate.

B. Toxicological Profile

The toxicity of chlorfenapyr has been studied extensively and there is a complete data base to address the acute and chronic effects, effects on genetic material, the potential for carcinogenicity or teratogenicity, and effects on reproductive performance or growth of offspring. Toxicological data submitted previously that support this petition for tolerances of chlorfenapyr include:

1. *Acute toxicity.* Based on EPA's toxicity category criteria, the acute toxicity category for chlorfenapyr technical, EPA Registration No. 241-366, is Category II or moderately toxic (signal word WARNING) and the acute toxicity category for the 2SC formulation, EPA Registration Nos. 241-374 and 241-392, is Category III or slightly toxic (signal word CAUTION). Males appear to be more sensitive to the effects of chlorfenapyr than females. The acute toxicity profile indicates that absorption by the oral route appears to be greater than by the dermal route. The following are the results from the acute toxicity tests conducted on the technical material.

- i. Rat Oral, LD₅₀ of 441/1,152 milligrams/kilogram body weight (mg/kg bwt) modifying factor (M/F) - Toxicology Category II.
- ii. Rabbit Dermal LD₅₀: >2,000 mg/kg bwt M/F Toxicology Category III.
- iii. Acute Inhalation LC₅₀: 0.83/ >2.7 milligrams per liter (mg/L) M/F Toxicology Category III.
- iv. Eye irritation: Moderately irritating - Toxicology Category III.
- v. Dermal irritation: Non-irritating - Toxicology Category IV.

vi. Dermal sensitization: Non-sensitizer - Non sensitizer.

vii. Acute neurotoxicity: NOEL 45 mg/kg bwt. Not an acute neurotoxicant

2. *Genotoxicity.* Chlorfenapyr technical (94.5%) was examined in a battery of *in vitro* and *in vivo* tests to assess its genotoxicity and its potential for carcinogenicity. These tests are summarized below.

- i. Microbial/Microsome Mutagenicity Assay: Non-mutagenic.
- ii. Mammalian Cell CHO/HGPRT Mutagenicity Assay: Non-mutagenic.
- iii. *In vivo* Micronucleus Assay: Non-genotoxic.
- iv. *In vitro* Chromosome Aberration Assay in CHO: Non-clastogenic.
- v. *In vitro* Aberration Assay in CHLC: Non-clastogenic.
- vi. Unscheduled DNA Synthesis (UDS) Assay: Non-genotoxic.

3. *Reproductive and developmental toxicity.* Reproductive and developmental toxicity. Chlorfenapyr is neither a reproductive nor developmental toxicant and is not a teratogenic agent in the Sprague-Dawley rat or the New Zealand white rabbit. This is demonstrated by the results of the following studies:

i. *Rat oral teratology.* No observed effect level (NOEL) for maternal toxicity 25 mg/kg bwt/day and NOEL for fetal/developmental toxicity at 225 mg/kg bwt/day.

ii. *Rabbit oral teratology.* NOEL for maternal 5 mg/kg bwt/day and NOEL for fetal/developmental toxicity 30 mg/kg bwt/day.

iii. *Rat 2-generation reproduction.* NOEL for parental toxicity/growth and offspring development 60 parts per million (ppm) (5 mg/kg bwt/day) and NOEL for reproductive performance 600 ppm (44 mg/kg bwt/day)

4. *Subchronic toxicity.* The following are the results of the subchronic toxicity test that have been conducted with chlorfenapyr.

i. 28-Day rabbit dermal - NOEL 100 mg/kg bwt/day.

ii. 28-Day rat feeding - NOEL <600 ppm (<71.6 mg/kg bwt/day).

iii. 28-Day mouse feeding - NOEL <160 ppm (<32 mg/kg bwt/day).

iv. 13-Week rat dietary - NOEL 150 ppm (11.7 mg/kg bwt/day).

v. 13-Week mouse dietary - NOEL 40 ppm (8.2 mg/kg bwt/day).

vi. 13-Week dog dietary - NOEL 120 ppm (4.2 mg/kg bwt/day).

5. *Chronic toxicity.* Chlorfenapyr is not oncogenic in either Sprague-Dawley rats or CD-1 mice and is not likely to be carcinogenic in humans. The following are the results of the chronic toxicity tests that have been conducted with chlorfenapyr: