

TABLE 2. — REGISTRANTS REQUESTING AMENDMENTS TO DELETE USES IN CERTAIN PESTICIDE REGISTRATIONS

Company No.	Company Name and Address
003125	Bayer Corporation, 8400 Hawthorne Road, P.O. Box 4913, Kansas City, MO 64120.
004816	AgrEvo Environment Health, 95 Chestnut Ridge Road, Montvale, NJ 07645.
059639	Valent U.S.A. Corporation, 1333 N. California Blvd., P.O. Box 8025, Suite 600, Walnut Creek, CA 94596.

III. Existing Stocks Provisions

The Agency has authorized registrants to sell or distribute product under the previously approved labeling for a period of 18 months after approval of the revision, unless other restrictions have been imposed, as in special review actions.

List of Subjects

Environmental protection, Pesticides and pests, Product registrations.

Dated: September 4, 1997.

Linda A. Travers,

Director, Information Resources Services Division, Office of Pesticide Programs.

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ENVIRONMENTAL PROTECTION AGENCY

[PF-762; FRL-5741-1]

Notice of Filing of Pesticide Petitions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the initial filing of pesticide petitions proposing the establishment of regulations for residues of certain pesticide chemicals in or on various food commodities.

DATES: Comments, identified by the docket control number PF-762, must be received on or before October 17, 1997.

ADDRESSES: By mail submit written comments to: Public Information and Records Integrity Branch (7506C), Information Resources and Services Division, Office of Pesticides Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person bring comments to: Rm. 1132, CM #2, 1921 Jefferson Davis Highway, Arlington, VA.

Comments and data may also be submitted electronically by following the instructions under "SUPPLEMENTARY INFORMATION." No confidential business information should be submitted through e-mail.

Information submitted as a comment concerning this document may be

claimed confidential by marking any part or all of that information as "Confidential Business Information" (CBI). CBI should not be submitted through e-mail. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice. All written comments will be available for public inspection in Rm. 1132 at the address given above, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: The product manager listed in the table below:

Product Manager	Office location/telephone number	Address
William Jacobs, Acting (PM 14), ..	Rm. 219, CM #2, 703-305-6406, e-mail: jacobs.william@epamail.epa.gov.	1921 Jefferson Davis Hwy, Arlington, VA
Joanne Miller (PM 23), ..	Rm. 237, CM #2, 703-305-6224, e-mail: miller.joanne@epamail.epa.gov.	Do.

SUPPLEMENTARY INFORMATION: EPA has received pesticide petitions as follows proposing the establishment and/or amendment of regulations for residues of certain pesticide chemicals in or on various food commodities under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that these petitions contain data or information regarding the elements set forth in section 408(d)(2); 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.

The official record for this notice of filing, as well as the public version, has been established for this notice of filing

under docket control number [PF-762] (including comments and data submitted electronically as described below). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The official record is located at the address in "ADDRESSES" at the beginning of this document.

Electronic comments can be sent directly to EPA at: opp-docket@epamail.epa.gov

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form

of encryption. Comment and data will also be accepted on disks in Wordperfect 5.1 file format or ASCII file format. All comments and data in electronic form must be identified by the docket number [PF-762] and appropriate petition number. Electronic comments on this notice may be filed online at many Federal Depository Libraries.

List of Subjects

Environmental protection, Agricultural commodities, Food additives, Feed additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: September 2, 1997.

James Jones,

Acting Director, Registration Division, Office of Pesticide Programs.

Summaries of Petitions

Petitioner summaries of the pesticide petitions are printed below as required by section 408(d)(3) of the FFDCA. The summaries of the petitions were prepared by the petitioners and represent the views of the petitioners. EPA is publishing the petition summaries verbatim without editing them in any way. 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.

1. AgrEvo USA Company

PP 9F3714 and 3F4182

EPA has received two pesticide petitions (PP 9F3714 and 3F4182), requests from AgrEvo USA Company, Wilmington, DE 19808, proposing pursuant to section 408(d) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 346a(d), to amend 40 CFR 180.430(b) by changing the time-limited tolerances to permanent tolerances; and by establishing a regulation to permit residues of fenoxaprop-ethyl and its metabolites 2-[4-[(6-chloro-benzoyloxy)phenoxy]propanoic acid and 6-chloro-2,3-dihydrobenzoxazol-2-one in or on the raw agricultural commodities: barley grain at 0.05 part per million (ppm) and barley straw at 0.10 ppm. The proposed analytical method involves homogenization, filtration, partition and cleanup with analysis by gas chromatography using halogen-selective electron capture detection. EPA has determined that these petitions 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 these petitions. Additional data may be needed before EPA rules on these petitions.

A. Residue Chemistry

1. *Plant metabolism.* The nature of the residue of this pesticide is adequately understood. This was demonstrated in metabolism studies in plants (cotton, rice, soybeans and wheat) and livestock (goat and hen) using both chlorophenyl-labeled and dioxiphenyl-labeled test material. Fenoxaprop-ethyl degrades rapidly *via* ester hydrolysis to fenoxaprop free acid, which is the

principal observed metabolite. Subsequent cleavage of the phenoxy linkage of this metabolite produces the benzoxazolone metabolite.

2. *Analytical method.* An adequate analytical method is available for enforcement purposes. This method accounts for combined residues of fenoxaprop-ethyl and its metabolites, fenoxaprop free acid and 6-chloro-2,3-dihydrobenzoxazol-2-one. An acid hydrolysis/extraction procedure is used to liberate and/or cleave the residue to the common benzoxazolone moiety. After clean-up and derivatization, the residues are determined by gas chromatography using a halogen-selective electron capture detector. The residues are ultimately expressed as fenoxaprop-ethyl equivalents. The analytical method has passed the independent laboratory validation according to PR Notice 88-5, as well as US EPA laboratory validation, and has been approved for regulatory enforcement purposes. The method is published in the Pesticide Analytical Manual (PAM II).

3. *Magnitude of residues.* Extensive field residue trials have been conducted with fenoxaprop-ethyl on barley and wheat throughout the major cereal-growing regions of the United States. Applications at the maximum use rate resulted in no detectable residues of fenoxaprop-ethyl in or on the raw agricultural commodities barley and wheat (grain, straw). Likewise, there were no detectable residues in the processed commodities (flour and bran) in samples obtained from processing studies on barley and wheat using exaggerated application rates. EPA therefore established temporary tolerances based on the Limits of Quantification (LOQ) of 0.05 ppm for fenoxaprop-ethyl and its metabolites on barley grain, and 0.10 ppm on barley straw, as well as time-limited tolerances of 0.05 ppm on wheat grain, and 0.5 ppm on wheat straw. In addition, time-limited tolerances for the following commodities were established (55 FR 50393, December 6, 1990): cattle fat, meat, mbyp at 0.05 ppm; goat fat, meat, mbyp at 0.05 ppm; hog fat, meat, mbyp at 0.05 ppm; horse fat, meat, mbyp at 0.05 ppm; sheep fat, meat, mbyp at 0.05 ppm; and milk at 0.02 ppm.

B. Toxicological Profile

The toxicology of fenoxaprop-ethyl has been thoroughly evaluated by EPA as part of previous regulatory actions. These studies, that were conducted with the racemate, are considered to be valid, reliable and adequate for the purposes of evaluating potential health risks and for establishing tolerances for both the

racemic and isomer-enriched forms of the active ingredient. These studies include the following:

1. *Acute toxicity.* Acute toxicity studies supporting an EPA Toxicity Category III classification (rat oral and dermal LD₅₀ values of 2,397 mg/kg/day and >2,000 mg/kg/day, respectively).

2. *Genotoxicity.* A battery of genotoxicity studies, none of which indicated any genotoxic potential. The studies submitted included: *in vitro* human lymphocyte chromosomal aberration, mouse micronucleus, *in vitro* unscheduled DNA synthesis, *Ames Salmonella* bacterial point mutation and yeast DNA repair assays.

3. *Reproductive and developmental toxicity.* Two 2-generation rat reproduction studies with no evidence of reproductive effects in either study. In the first study, the EPA concluded that 30 ppm was the NOEL for parental toxicity but that, because of kidney and liver weight changes, no NOEL was determined for the offspring. In a second study at the same dose levels, the EPA concluded that 5 ppm (0.4 mg/kg/day) was the NOEL for both adults and offspring.

4. *Subchronic toxicity.* A number of developmental toxicity studies in rats, rabbits, mice and monkeys. The maternal and developmental NOEL's in these studies were similar, and ranged from 10 to ≥50 mg/kg/day. In rabbits, the maternal and developmental NOEL's were considered to be 12.5 and 50 mg/kg/day, respectively. In one of the rat studies, the developmental NOEL (10 mg/kg/day) was lower than the maternal NOEL (32 mg/kg/kg). However, in a second rat study conducted using the same dose levels, the maternal and developmental NOEL were both 32 mg/kg/day. In the monkey study, no clear developmental effects were noted even at a dose level (50 mg/kg/day) which was lethal to 45% of the monkeys. Thus, the overall weight of evidence indicates the lack of any specific developmental effect and no increased sensitivity to the embryo or fetus.

5. *Chronic toxicity.* A 2-year mouse oncogenicity study with no indication of carcinogenicity at dose levels up to 40 ppm (6 mg/kg/day), the highest dose tested. However, this high-dose level did not meet the EPA's criteria for a Maximum Tolerated Dose (MTD); thus a new study was conducted. In this study, an increased incidence of various non-neoplastic liver lesions as well as an increased incidence of primarily benign liver tumors were noted at 115 and 320 ppm. Although this study has not yet been reviewed by the EPA Cancer Peer Review Committee, AgrEvo believes that both of these dose levels exceeded the

MTD. No neoplastic or non-neoplastic lesions were noted at 40 ppm (6.2 mg/kg/day), which was considered the NOEL.

6. *Animal metabolism.* Absorption, distribution, metabolism and excretion studies in several species indicate that fenoxaprop-ethyl is well absorbed after oral administration and relatively rapidly metabolized and excreted. No evidence of bioaccumulation was noted after repeated dosing.

7. *Metabolite toxicology.* All significant metabolites have been identified and tested as part of the overall toxicology requirements for the parent compound, and expressed in the existing and/or pending tolerances.

C. Aggregate Exposure

1. *Dietary exposure.* The dietary exposure is discussed below under the topics food and drinking water.

(a) *Food.* A dietary exposure assessment was performed for fenoxaprop-ethyl using the Exposure 1 software system (TAS, Inc.) and the 1977-78 USDA consumption data. The first assessment calculated the Theoretical Maximum Residue Contribution (TMRC). The TMRC is a "worst-case" estimate that assumes that 100% of the listed crops have been treated and that all commodities including meat and milk contain residues at the tolerance level. A more realistic exposure assessment was also conducted using estimates of percent crop treated and anticipated residue levels.

(b) *Drinking water.* The potential for fenoxaprop-ethyl to leach into groundwater was assessed in various laboratory studies as well as in terrestrial field dissipation studies conducted in several locations and soil types. The degradation of fenoxaprop-ethyl and its main metabolites occurs rapidly in both laboratory and the field, with half-lives in soil ranging from 9 to 14 days. No evidence of leaching of parent or degradation products was observed. The compound is immobile and the potential to leach into groundwater is negligible. Fenoxaprop-ethyl adsorbs strongly to soil ($K_{oc} = 12,500$ to $18,880$) and has a low water solubility (0.9 mg/l at pH 7), which results in minimal field runoff and a low potential for contamination of surface water. Together, these data indicate that residues of fenoxaprop-ethyl are not expected in drinking water. Therefore, the contribution of any such residues to the total dietary intake of fenoxaprop-ethyl will be negligible. There is no established Maximum Contaminant Level (MCL) or Health

Advisory Level (HAL) for residues of fenoxaprop-ethyl in drinking water.

2. *Non-dietary exposure.* Fenoxaprop-ethyl is registered for selective postemergence grass control in turfgrass including sod farms, commercial and residential turf and ornamentals. All of these applications are done by professional applicators; there are no homeowner uses. Thus, the only non-occupational exposure would be from dermal contact during reentry to treated areas. Insufficient information is currently available to conduct a reliable assessment of potential exposure from reentry on turf. Studies to quantitate this exposure are now being conducted by the Outdoor Residential Exposure Task Force (ORETF). However, AgrEvo believes that such exposures are relatively low and, based on the available toxicology data, are unlikely to pose a significant risk to human health.

D. Cumulative Effects

Fenoxaprop-ethyl is a member of the aryloxy phenoxy-propionate class of herbicides. It is an inhibitor of fatty acid biosynthesis in both plants and animals, and induces peroxisome proliferation in rodents. Like other peroxisome proliferators, it induces liver tumors in mice at exaggerated dose levels. However, the precise mechanism by which peroxisome proliferators induce liver tumors in rodents has not yet been determined. In addition, humans are considered to be far less sensitive to the peroxisome proliferative effects of these compounds than are rodents. Furthermore, the methodology to evaluate the potential aggregate risks from multiple chemicals with a common mechanism of action has not yet been defined. Therefore, only exposure from fenoxaprop-ethyl is being addressed at this time.

E. Safety Determination

1. *U.S. population.* The toxicity and residue data bases for fenoxaprop-ethyl are considered to be valid, reliable and essentially complete. The EPA Carcinogenicity Peer Review Committee has not yet reviewed the results of the recently completed mouse oncogenicity study in which liver tumors were noted. However, AgrEvo believes that quantitative oncogenic risk assessment is inappropriate for the following reasons:

(a) Evidence of oncogenicity was limited to a single site (liver) in a single species (mouse), and occurred only at dose levels that were considered by AgrEvo to have exceeded the MTD.

(b) No evidence of genotoxicity has been observed.

(c) Fenoxaprop-ethyl is known to be a peroxisome proliferator and the tumors were noted only in conjunction with significant non-neoplastic hepatotoxicity.

(d) The relevance of mouse liver tumors, particularly those caused by hypolipidemic peroxisomal proliferators, to human risk assessment is considered minimal, especially at the extremely low dose levels to which humans would typically be exposed.

Thus, a standard margin of safety (exposure) approach is considered appropriate to assess the potential for fenoxaprop-ethyl to produce both oncogenic and non-oncogenic effects. The EPA has previously adopted an RfD value of 0.0025 mg/kg/day for fenoxaprop-ethyl. This value was based on the Agency's conclusion of a 5 ppm NOEL for both parents and offspring in the second multigeneration rat reproduction study and a 100-fold safety (uncertainty) factor. However, in converting the NOEL dietary concentration of 5 ppm to test material intake (mg/kg/day), the EPA used a standard conversion factor for food consumption in adult rats rather than study specific results. Based on actual food consumption values, the NOEL for this study was really equivalent to an average dose level of approximately 0.4 mg/kg/day for the adults and approximately 1 mg/kg/day for the offspring. Furthermore, AgrEvo believes that the results of the original rat reproduction study and the 2-year rat chronic toxicity study support the conclusion that the NOEL for adult toxicity in the second rat reproduction study was not 5 ppm but 30 ppm (2.5 mg/kg/day). Therefore, AgrEvo believes that the RfD should have been based on the NOEL of approximately 0.9 mg/kg/day from the 2-year dog study or, since rats are the most sensitive species to fenoxaprop-ethyl, the NOEL of approximately 1 mg/kg/day for offspring in the second reproduction study. This would result in an RfD of 0.01 mg/kg/day, not 0.0025 mg/kg/day. Nevertheless, for this risk assessment, AgrEvo used the RfD value of 0.0025 mg/kg/day assigned by EPA.

The aggregate exposure of the general population to fenoxaprop-ethyl from the established and pending tolerances utilizes about 17% of the RfD using worst-case assumptions (100% crop treated and tolerance level residues for all commodities, including livestock). Assuming more realistic estimates of percent crop treated and anticipated residues, only 2% of the RfD was utilized. The RfD represents the level at or below which daily aggregate exposure over a lifetime would not pose

a significant risk to human health. There is generally no concern for exposures which utilize less than 100% of the RfD, particularly when conservative assumptions are utilized for the calculations. Therefore, there is a reasonable certainty that no harm will result to the general population from aggregate risk to residues of fenoxaprop-ethyl.

2. *Infants and children.* Data from rat and rabbit developmental toxicity studies and rat multigeneration reproduction studies are generally used to assess the potential for increased sensitivity of infants and children. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from potential exposure during prenatal development. Reproduction studies provide information relating to reproductive and other effects on adults and offspring from potential prenatal and postnatal exposure to the pesticide.

The overall weight of the evidence from the developmental toxicity studies and multigeneration rat reproduction studies indicates that the toxicity of fenoxaprop-ethyl to infants and children is comparable to its toxicity to adults. No reproductive effects were noted in either of the two multigeneration studies. Developmental effects were noted in rats and rabbits, but generally only at dose levels that induced maternal toxicity. No clear developmental effects were noted in monkeys even at dose levels that were lethal to 45% of the mothers. In general, the maternal and developmental NOEL's in the various studies were comparable and ranged from 10 to 50 mg/kg/day.

FFDCA section 408 provides that EPA may apply an additional safety factor for infants and children to account for pre- and post-natal toxicity and the completeness of the data base. However, the toxicology data base for fenoxaprop-ethyl is complete according to existing Agency data requirements and does not indicate any developmental or reproductive concerns. Furthermore, the existing RfD of 0.0025 mg/kg/day already provides an approximately 400-fold safety factor relative to the NOEL (1 mg/kg/day) for offspring in the multigeneration rat reproduction study and a 4,000-fold safety factor relative to the lowest developmental NOEL (10 mg/kg/day) observed in the developmental toxicity studies. Thus, the existing RfD is considered appropriate for assessing potential risks to infants and children and an additional uncertainty factor is not warranted.

Using worst-case assumptions (100% crop treated and tolerance level residues for all commodities, including

livestock), aggregate exposure to residues of fenoxaprop-ethyl is expected to utilize about 65% of the RfD in non-nursing infants (less than 1-year old), 42% of the RfD in children aged 1 to 6-years old, 28% of the RfD in children aged 7 to 12-years old, and 16% of the RfD in nursing infants. Using more realistic estimates of percent crop treated and anticipated residues, the percent of RfD utilized would be no more than 8% (non-nursing infants less than 1-year old) for these population subgroups. Therefore, there is a reasonable certainty that no harm will result to infants or children from aggregate exposure to fenoxaprop-ethyl residues.

F. International Tolerances

As no residues were detected (LOQ < 0.05 ppm) in wheat and barley grain, there are no Codex, Canadian or Mexican Maximum Residue Limits (MRLs) for residues of fenoxaprop-ethyl in these commodities. Therefore, international harmonization is not an issue for these tolerances. (PM 23)

2. BOC GASES

PP 7F4809

EPA has received a pesticide petition (PP 7F4809) from BOC GASES c/o the Sloane Group, 52 Amogerone Crossway, Greenwich, CT, 06830. The Petition proposes, pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C 346a to establish a temporary tolerance for the use of ECO₂FUME in accordance to 40 CFR 180.225, 180.375, 185.200, 185.3800. As required by section 408(d) of FFDCA, as recently amended by the Food Quality Protection Act (FQPA), BOC Gases included in the petition a summary of the petition and authorization for the summary to be published in the **Federal Register** in a notice of receipt of the petition. The summary represents the view of BOC GASES, the EPA is in the process of evaluating the petition. As required by section 408(d)(3), EPA is including the summary as a part of this notice of filing. EPA may have minor edits to the summary for purposes of clarity.

This petition is submitted by BOC GASES, under section 408 of the Federal Food Drug and Cosmetic Act (21 U.S.C. 346a), as most recently amended by the FQPA. This submission proposes a temporary tolerance for purposes of an experimental use permit for the fumigant ECO₂FUME. This petition is associated with a request for an experimental use permit for a non-crop destruct program for ECO₂FUMETM. This pesticide contains 2% Phosphine

(PH₃) and 98% Carbon Dioxide (CO₂) by weight as a cylinderized gaseous mixture.

This Petition requests that the temporary tolerance mirror 40 CFR part 180 and 185 and thereby establishing a temporary tolerance for the following raw agricultural commodities from the post harvest treatment with ECO₂FUMETM: Almonds, Avocados, Bananas, Barley, Beans, (cocoa), Beans, (coffee), Brazil nuts, Cabbage, (Chinese), Cashews, Citrus citron, Cocoa beans, Coffee beans, Corn, Corn pop, Cottonseed, Dates, Eggplants, Endive (escarole), Filberts, Grapefruit, Kumquats, Lemons, Lettuce, Limes, Mangos, Millet, Mushrooms, Nuts, (Brazil), Nuts, (Pistachios), Oats, Oranges, Papayas, Peanuts, Pecans, Peppers, Persimmons, Pimentos, Pistachio nuts, Plantains, Rice, Rye, Safflower seed, Salsify tops, Sesame seed, Sorghum, Soybeans, Sunflower seed, Sweet potatoes, Tangelos, Tangerines, Tomatoes, Vegetables, seed and pod (except soybeans), Walnuts, and Wheat Data pertaining to the product chemistry, use patterns, safety, residues, removing residues, detecting residues, endocrine effects and exposure to infants and children, have been submitted.

This petition is based on the following facts:

1. CO₂ is exempt from tolerances (40 CFR 180.1049), and hence no tolerance is required for this active ingredient ECO₂FUMETM contains a very low percentage of phosphine.

2. A tolerance has already been established for phosphine generated from aluminum phosphide and magnesium phosphide.

3. Quantities of phosphine utilized with the ECO₂FUMETM process are significantly lower than the quantities generated in the use of the metal phosphides.

4. Literature data show phosphine residues levels from the use of ECO₂FUMETM are less than 0.001 ppm.

5. Unlike metal phosphides, the application method is controlled and precise with predictable residue results. The petitioners agree that this summary or any information it contains may be published as a part of the notice of filing of the petition and as part of a proposed or final regulation issued under Sec. 408 of the FFDCA.

A. Product Chemistry Data

1. *Analytical methodology.* ECO₂FUMETM mixture: Phosphine 2% and CO₂ 98%. Analysis of gases and gas mixtures are conveniently and accurately carried out using gas chromatography. The GC/MS technique

developed by AGAL, Pymble for analyzing trace contaminants, particularly other derivatives of phosphine in the ECO₂FUMETM mixture is detailed in the submission.

2. *Chemical and physical properties of end use product.* All BOC produced and purchased gases are the subject to a Quality Control program. In addition to works instructions and works tests representative, samples of individual batch are verified for purity by analytical chemists in BOC's laboratories.

2.1 *Color* - colorless gas

2.2 *Odor* - Odor of rotting fish above 2 ppm phosphine ("carbide" odor)

2.3 *Bulk Density* - Not applicable

2.4 *Density* - Specific Gravity is

1.5. (Air=1) i.e. heavier than air

2.5 *Viscosity* - 1.4×10^{-4} poise

2.6 *Flammability hazard*

ECO₂FUMETM consists of mixture of 2.6% by volume (2% by weight) of phosphine in carbon dioxide and is non-flammable.

3. *Specifications formulation.*

ECO₂FUMETM [20g/kg PH₃ in CO₂] Chemically Pure Grade Phosphine of typical purity (990g/kg) sufficient to give...20g/kg Carbon Dioxide - balance to give...980g/kg - Phosphine: [PH₃]; CAS registry no. 7803-51-2, molecular weight 34.00 - Carbon Dioxide: [CO₂]; CAS registry no. 124-38-9, molecular weight 44.01

Use Pattern

1. *Fields of use.* ECO₂FUMETM is used for the control of eggs, larvae, pupae, and/or adults of the following stored product pests: Angoumois grain moth, bean weevil, cadelle, cereal leaf beetle, cigarette beetle, coffee bean weevil, confused flour beetle, cowpea beetle, dried fruit beetles, flat grain beetles, fruit flies, granary weevil, Indian meal moth, Khapra beetle, larger wax moth, lesser grain borer, lesser wax moth, maize weevil, Mediterranean flour moth, merchant grain beetle, mottled grain moth, pink bollworm, psocids, raisin moth, redlegged ham beetle, rice weevil, rust-red flour beetle, sawtoothed grain beetle, skin and hide beetles, spider beetles, stored product mites, tobacco moth, tropical warehouse moth, warehouse beetle, yellow mealworm.

Treatment for the above pests at the specified rates will kill any cockroaches, rats and mice present.

2. *Use level of product—i. Dosage.* Seventy-five g/m³ of ECO₂FUMETM (equivalent to 1.5 g/m³ of phosphine) in well-sealed storages.

ii. *Minimum exposure.* Temperatures above 25°C.. 7 days, temperatures above

150-25°C..10 days. ECO₂FUMETM should be used in storages in which the standard of gastightness is consistent with a decay of an excess external pressure from 500 Pa (2" w.g.) to 250 Pa (1" w.g.) in not less than 5 minutes in filled storages.

3. *Situations—i. Foods.* Raw cereal grains (such as barley, maize, millets, oats, rice, rye, sorghum, wheat) and other food commodities such as animal feeds, breakfast cereals, brewing malt, chocolate products, cocoa beans, coffee beans, dried fruits, dried vegetables, flour, milled cereal products, nuts, oilseeds, other dried foods, seeds, soybeans, tapioca, etc.

ii. Tobacco and tobacco products.

iii. Timber and cane products; Building and structures.

4. *Limitations—i. Directions for use.*—Mixing. The ECO₂FUMETM gas mixture is ready for use as per label directions.

ii. *General instructions.* Only experienced and properly instructed persons should use ECO₂FUMETM. While in the container ECO₂FUMETM is a liquid mixture under pressure, which turns to gas when released. The gas must be confined along with commodities being fumigated under a gas-proof cover or in a container of structure that is airtight.

iii. *Restraints.*

DO only apply ECO₂FUMETM in well-sealed storages.

DO only apply ECO₂FUMETM with the high-pressure kit (CIG Kit 416600)

DO use extreme caution when handling ECO₂FUMETM.

DO perform fumigation and aeration in accordance with label.

DO show prominently warning signs: "DANGER--POISON GAS--KEEP AWAY"

DO NOT enter fumigation area and keep animals, children, and unauthorized persons away until the area is shown to be free from phosphine as indicated by a gas-measuring device.

5. *Withholding periods.* A period of three days after completion of ventilation before using treated commodities for human consumption or for stock food. Treated commodities may be safely transported after completion of the recommended ventilation period.

6. *Protection of livestock, wildlife and others.* As a general precautionary measure, the following advice will appear on the label. Store in a cool well ventilated, locked area out of reach of children or unqualified persons and away from habitation. Cylinder always remains the property of BOC, and should be returned for refilling.

C. Toxicology of End Use Product and Technical Active Ingredient

Toxicology summary. Toxicological evaluation of fumigation usage of phosphine has been based upon phosphine gas. ECO₂FUME, the non-flammable gaseous phosphine mixture, is dispensed via gas-tight distribution systems. The proposed use of non-flammable ECO₂FUME offers improved operator safety, accurate controllable dosage and the elimination of fire hazard. Toxicity study results show phosphine to be a highly toxic inhalation poison. Oral toxicity while not relevant for gaseous phosphine (although a concern with metallic phosphides) has been cleared in long-term feeding studies. Dermal toxicity is not an anticipated concern, as phosphine gas is not absorbed through the skin. Eye irritation may be a concern in acute exposure, but all operators will be required to wear protective eyewear. Acute animal studies show that albino rats can tolerate 5 ppm over several months but 10 ppm with continual exposure causes mortality. Single dose studies indicate 40 ppm for 6 hours have 100% mortality. Long-term animal studies show rats have no toxic effects when fed on a diet of metallic phosphide or on phosphine-fumigated diets. As no specific antidote is known, symptomatic treatment is required. Chronic exposure affects the visual, motor and gastro-intestinal tract. Long-term exposure to low concentration can cause anemia and bronchitis. Organs with the greatest oxygen requirement appear to be especially sensitive to damage. The NOEL for ECO₂FUME is 2mg/kgbw/day and ADI is 0.02mg/kgbw/day.

The 1986 ACGIH has recommended a Threshold Limit Value (TLV-TWA) of 0.3 ppm (0.4 mg/m³) with a STEL of 1 ppm for phosphine. Using a tidal volume of 0.5 liters, 12 breaths/min, a body weight of 80kg and the TLV-TWA of 0.4mg/m³ gives a NOEL of 0.04mg/kgbw/day for phosphine.

D. Residue Testing

1. *Summary.* Analytical techniques for the determination of phosphine residues in a range of stored food studies with a limit of detection better than 0.0001mg/kg are available. Analytical methods have been used to obtain data on the amount of phosphine which remains in these commodities after treatment with ECO₂FUMETM at typical and exaggerated dosage levels and on its persistence during storage. Results show that residues fall quickly to below internationally recommended levels. Maximum residue limits for

cereal grains are 0.1 mg/kg and is 0.01mg/kg for processed foods after treatment with PH₃ generated from metal phosphides. This corresponds to the levels set both by Environmental Protection Agency/the NH & MRC of Australia and the Codex Alimentarius Commission of the WHO/FAO.

2. *Analytical methodology.* The maximum residue limit recommended by the Codex Alimentarius Commission of the WHO/FAO for phosphine in raw cereals is 0.1mg/kg and in milled cereals and a range of foodstuffs including nuts it is 0.01mg/kg. An improved method for the determination of phosphine residues in a range of stored foodstuffs with a limit of detection better than 0.0001mg/kg is described by K.A. Scudamore and G. Goodship (Ref: "Determination of Phosphine Residues in Fumigated Cereals and other Foodstuffs." Pestic. Sci. 1986, 37; 385-395). The method has been used to obtain data on the amount of phosphine, which remains in these commodities after treatment at typical dosage levels and on its persistence during storage. Results show that in cereal grains and nuts residues fall quickly to below. Internationally recommended levels although ultra trace amounts (less than 0.001 mg/kg) of phosphine could be detected several months after treatment in all the commodities examined.

3. *Crop residue data.* While phosphine is not applied to growing plants or crops it is a well-established fumigant of cereal grain and stored products.

4. *Fate of residues.* The possible reactions of absorbed phosphine within the commodity matrices to form inorganic phosphorous compounds have been detailed. In warm-blooded animals, phosphorous acid and phosphoric acid are formed or else phosphate. The volatile nature of phosphine (boiling point minus 87°C) and its limited solubility ensures that any phosphine absorbed in a foodstuff during treatment would be negligible and rapidly lost. Residue of phosphine held for any length of time is less than 0.001 mg/kg i.e., 0.001 ppm. Phosphoric acid has many uses including an acidulate and flavor in beverages of the soft drink type.

5. *Maximum residue limits—i. Overseas.* The maximum residue limit recommended by the Codex Alimentarius Commission of the WHO/FAO for phosphine in raw cereals is 0.1 mg/kg and in milled cereals and a range of foodstuffs including nuts is 0.01 mg/kg. (Ref: "Codex Maximum Limits for Pesticide Residues" Codex Alimentarius Commission Volume XIII, Rome 1983).

ii. *Australia.* The 100th session of the National Health and Medical Research Council, November 1985 gave the maximum residue limit in cereal grains of 0.1 mg/kg; and in flour and other milled cereal products, breakfast cereals, dried fruit, dried vegetables, all other dried foods, spices, nuts, peanuts, cocoa, beans and honey a limit of 0.01 mg/kg. The maximum residue limit is set at or about the limit of analytical determination. If the substance were to occur at or below this limit it is considered that no hazard to human health would occur. (Ref: "Standard for Maximum Residue Limits of Pesticides, Agricultural Chemical, Feed Activities, Veterinary Medicines and Noxious Substances in Food" Commonwealth Dept. of Health, Commonwealth of Australia 1986. ISBN 0644 04688 0).

iii. *U.S.A.* Tolerances have been established for commodities fumigated by the fumigant PH₃ generated from metal phosphides. Maximum residue limits for cereal grains are 0.1 mg/kg and is 0.01mg/kg for processed foods after treatment with PH₃ generated from metal phosphides.

E. Residue Detection and Removal

See Section D Above

F. Endocrine Effects

Phosphine degrades to phosphates and phosphoric acid or else phosphates, in warm-blooded animals (Ref: "The Agrochemicals Handbook", Royal Society of Chemistry, 1986). It has been shown that there is no overt toxicity associates with the residue low levels (order 0.001 ppm) of phosphine products, in fact, a major buffering system of the body utilizes polybasic phosphates; and phosphoric acid is used as an acidulate and flavor in beverages of soft drink type (Ref: The Merck Index, 9th Edition, 7153).

G. Exposure to Infants and Children

Summary. Commodities fumigated with PH₃ at the recommended dosage levels leaves very little residue in the order of 0.001ppm (see part D) Long term feeding studies showed that ingestion of PH₃ fumigated dirt by the rat for 2 years does not cause any marked modification of growth, food intake, nitrogen balance, body composition, functional behavior or the incidence of type of tumors. The product should however, at all times be kept out of reach of children or other uncertified applicators due to acute inhalation toxicity.

H. Reasonable Grounds

ECO₂FUMETM is a mixture of two well known fumigants PH₃ and CO₂.

Tolerances have already been established for PH₃ generated from Aluminum and Magnesium phosphide. Maximum residue limits for cereal grains are 0.1 mg/kg and is 0.01mg/kg for processed foods after treatment with PH₃ generated from metal phosphides. CO₂ is exempt from tolerance. Use of ECO₂FUMETM results in approximately 75% less PH₃ being used for fumigation as compared to PH₃ from metal phosphides ECO₂FUMETM has recorded residue levels of below 0.001ppm. (PM 14)

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ENVIRONMENTAL PROTECTION AGENCY

[PF-753; FRL-5735-5]

Notice of Filing of Pesticide Petitions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the initial filing of pesticide petitions proposing the establishment of regulations for residues of certain pesticide chemicals in or on various food commodities.

DATES: Comments, identified by the docket control number PF-753, must be received on or before October 17, 1997.

ADDRESSES: By mail submit written comments to: Public Information and Records Integrity Branch (7506C), Information Resources and Services Division, Office of Pesticides Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person bring comments to: Rm. 1132, CM #2, 1921 Jefferson Davis Highway, Arlington, VA.

Comments and data may also be submitted electronically by following the instructions under "SUPPLEMENTARY INFORMATION." No confidential business information should be submitted through e-mail.

Information submitted as a comment concerning this document may be claimed confidential by marking any part or all of that information as "Confidential Business Information" (CBI). CBI should not be submitted through e-mail. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice. All written comments will be available for public