Ferric Phosphate

Crop Production

Identification of Petitioned Substance

Chemical Name: Ferric phosphate

Other Names:

Iron (III) Phosphate
Ferric Orthophosphate
Iron (III) Orthophosphate
Ferric Phosphate Hydrate
Iron Orthophosphate
Iron Phosphate
Iron Phosphate Hydrate
$FePO_4$

Occurs in nature as the minerals:

beraunite
cacoxenite
dufrenite konindia
phosphosiderate
strengite

Trade Names: Include but are not necessarily limited to:
Bayer Advanced Dual Action Slug and Snail Bait, Bayer Advanced Natria Snail & Slug Killer Bait Ready-to-Use (by Monterey Co.), Ferramol®, First Choice® Sluggo® Snail and Slug Bait, Garden Safe® Slug & Snail Bait, Neu 1165M Slug and Snail Bait, ORTHO Bayer Advanced Natria™ Snail and Slug Killer Bait, Ortho® EcoSense™ brand slug & snail killer, Safer's® Ferramol® Slug and Snail Bait, Safer's® Slug and Snail Bait, Scott's® EcoSense™ Slug and Snail Bait, Sluggo®, Sluggo®-AG, SLUGGO® PLUS Insect, Slug & Snail Pellets, Sluggo® Slug & Snail Bait, Sluggo® Snail and Slug Bait Worry Free® Brand by Lilly Miller®

CAS Number: 10045-86-0

Other Codes:
EPA Fact Sheet - 034903
EPA - #667702-3
EINECS – 233-149-7
FDA Registration as GRAS in 21 CFR § 184.1301
Former CAS Number(s): 150070-02-3, 58782-48-2
OPP Chemical Code: 34903
STATE OF CALIFORNIA, State Regulatory Authority Registration #67702-3-AA

Characterization of Petitioned Substance

Composition of the Substance: $FePO_4$ (anhydrous)- Fe 37.03%, O 42.43%, P 20.54%.

Properties of the Substance: Anhydrous or dihydrate, orthorhombic or monoclinic crystals or amorphous powder. Molecular weight 150.83 g/mol (anhydrous).

Product Chemistry	
Physical State	crystals or powder
Color	white, grayish-white, or light pink
Odor	odorless
Melting Point	not known – loses water of hydration at 140°C
Boiling Point	not known – loses water of hydration at 140°C
Specific Gravity	2.87
Water Solubility	practically insoluble in water
Solubility, other	slowly soluble in nitric acid (HNO_3); readily soluble in hydrochloric acid (HCl)

Specific Uses of the Substance:

Ferric phosphate is used as food and feed supplement, particularly in bread enrichment. It is used as a fertilizer and as a molluscicide for a variety of slugs and snails including *Deroceras reticulatum*, *D. laeve*, *Arion subfuscus*, *A. circumscriptus*, *A. hortensis, A rufus, A. ater, Limax flavus, L. tenullus, Ariolimax columbianus, Helix spp., Helicella spp.* and *Cepaea spp*.

Approved Legal Uses of the Substance:

The primary commercial use of ferric phosphate as addressed for the applications discussed here is as the active ingredient in slug and snail bait. Other ingredients which attract slugs and snails are used to facilitate their consumption of ferric phosphate. Ferric phosphate also occurs naturally at different concentrations in soil as fertilizer. Uses as diverse as an iron supplement in breakfast cereals have been listed by the Environmental Protection Agency (EPA) (Listed by the EPA from Tribelhorn, 1991).
[1] http://www.epa.gov/ttnchie1/old/ap42/ch09/s092/reference/ref01_c09s92_1995.pdf

Action of the Substance:

While not actually a bait itself, the combinations of ferric phosphate with other substances to serve as a bait/molluscicide were described in the original petition as "The bait is a strong attractant to slugs and snails, which consume the bait product. The iron phosphate accumulates in the calcium spherules of their digestive glands; this interferes with calcium metabolism, and in turn, disrupts feeding and mucus production. The slugs and snails will stop feeding, and death due to starvation will occur three to six days later." (NOP petition, W. Neudorff, GmbH, KG, Germany, 2003)

See also the EPA fact sheet 1998 and 2001:
http://www.epa.gov/pesticides/biopesticides/ingredients/factsheets/factsheet_034903.htm#description

[1] All internet materials cited in this document were accessed as of June, 2010.

Status

Domestic: U. S. Regulatory Agencies:

Environmental Protection Agency (EPA)

EPA issued a notice, published in the Federal Register of January 22, 1997 (62 FR 3287) (FRL-5582-4), which announced that W. Neudorff GmbH KG, Postfach 1209 an der Muhle 3, D-31860 Emmerthal Germany, had submitted an application to register the pesticide product NEU 1165M Slug and Snail Bait (EPA File Symbol 67702-G), containing the active ingredient iron phosphate at 1.0 percent, an active ingredient not included in any previously registered products at that time. The application was approved on August 14, 1997, and was published in the Federal Register of September 30, 1997 (62 FR 51106) (FRL-5744-4), as NEU 1165M Slug and Snail Bait for domestic/non commercial food use on vegetable gardens, fruits (including citrus) and berries; also for outdoor ornamentals, greenhouses, and lawns (EPA Registration Number 67702-3). On March 16, 1998, an amendment of this registration (67702-3) was approved to add commercial sites. The current use sites are listed on the last approved label. Other products are currently on the market which incorporate ferric phosphate as the only active ingredient as well as some that include additional active ingredients.

Food and Drug Administration (FDA)

The FDA listed ferric phosphate as generally recognized as safe (GRAS) in 1988, 2010 (see below).

TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES (CONTINUED)

PART 184_DIRECT FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS SAFE--Table of Contents

Subpart B_Listing of Specific Substances Affirmed as GRAS

Sec. 184.1301 Ferric phosphate.

(a) Ferric phosphate (ferric orthophosphate, iron (III) phosphate, $FePO_4 \cdot x\ H_2O$, CAS Reg. No. 10045-86-0) is an odorless, yellowish-white to buff-colored powder and contains from one to four molecules of water of hydration. It is prepared by reaction of sodium phosphate with ferric chloride or ferric citrate.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), pp. 118-120, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408.

(c) In accordance with Sec. 184.1(b)(1), the ingredient is used in food as nutrient supplement as defined in Sec. 170.3(o)(20) of this chapter, with no limitation other than current good manufacturing practice. The ingredient may also be used in infant formula in accordance with section 412(g) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 350a(g)) or with regulations promulgated under section 412(a)(2) of the act (21 U.S.C. 350a(a)(2)).

(d) Prior sanctions for this ingredient different from the uses established in [[Page 505]] this section do not exist or have been waived. [53 FR 16865, May 12, 1988]

Other:

OMRI – The Organic Materials Review Institute (OMRI) states that ferric phosphate (synthetic) is allowed with restrictions for crop production. http://www.omri.org/simple-opl-search/results/ferric%20phosphate May be used as a slug and snail bait if the requirements of 205.206(e) are met, which requires the use of preventive,

mechanical, physical, and other pest, weed, and disease management practices. Ferric phosphate (synthetic/nonsynthetic) is also allowed with restrictions in livestock feed ingredients and livestock health care.

International Groups:

European Union (EU) – Ferric phosphate is authorized under Regulation (EEC) No 2092/97 and carried over by Article 16(3) (c) of Regulation (EC) No 834/2007 for use as a molluscide in the protection of plants.

Codex – Ferric Phosphate is not listed in the Codex Alimentarius Commission's *Annex 2: Permitted Substances for the Production of Organic Foods, 2004*.

Canada - The Canadian General Standards Board CAN/CGSB-32.311-2006 Amended October 2008 and December 2009 states in regard to "ferric phosphate (ferric orthophosphate): "Permitted as molluscicide. To be used in such a way as to prevent runoff into water bodies. Shall not be in contact with crops."

IFOAM – The International Federation of Organic Agriculture Movements (IFOAM) Indicative List of Substances for Organic Production and Processing, dated April 24, 2008, lists iron phosphate for use as a molluscicide.

Japan – Ferric phosphate was listed in the Japanese Agricultural Standard for Organic Plants (Notification No. 1605 of the Ministry of Agrictlture, Forestry and Fisheries of October 27, 2005) Last Partial Revision: Notification No. 1180 of August 27, 2009. **http://www.maff.go.jp/e/jas/specific/pdf/1180_2009.pdf.** However, its uses, properties, and status were not described.

Evaluation Questions for Substances to be used in Organic Crop or Livestock Production

Evaluation Question #1: A) Does the substance contain an active ingredient in either of the following categories: copper and sulfur compounds, toxins derived from bacteria; pheromones, soaps, horticultural oils, fish emulsions, treated seed, vitamins and minerals; livestock parasiticides and medicines and production aids including netting, tree warps and seals, insect traps, sticky barriers, row covers, and equipment cleansers. (B) Does the substance contain synthetic inert ingredients that are not classified by the EPA as inerts of toxicological concern (i.e., EPA List 4 inerts)? (7 U.S.C. § 6517(c)(1)(B)(i)). Does the synthetic substance contain inert ingredients which are not on EPA List 4, but are exempt from a requirement of a tolerance, per 40 CFR part 180?

A) Although described for use as a bait, no advertisements, literature, or citations were found with detailed recommendations for use of ferric phosphate in conjunction with, or as part of a trapping system. Distributor and vendor labels that were observed contained instructions for various patterns and densities to apply the substance directly over the soil, sometimes after having applied water. Also, the term "bait" is commonly found in the names listed on labels of products that contain ferric phosphate as a form of slug control, and in some cases, is part of the copyrighted name, e.g., Sluggo® Snail and Slug Bait. One trade name was found to contain the word "killer" in relation to slugs and snails, Ortho® EcoSense™ brand slug & snail killer, and the descriptions may include the length of time for death to occur after ingestion and describe or imply the time for subsequent desiccation, along with descriptions or advertisements of a lawn or garden devoid of slug carcasses.

In an advertisement by Monterey Lawn and Garden Products, Inc., the product Sluggo® Plus Insect, Slug & Snail Pellets is listed as containing 0.97% of a mixture of Spinosad A and Spinosad B (EPA Reg. No. 67702-24-54705) (EPA Est. No. 48498-CA-1). It is further described: "For Outdoor Use around Residential Sites:

Active Ingredient:
Iron Phosphate:……0.97%
Spinosad (a mixture of spinosyn A
and spinosyn D):……0.07%
Other Ingredients:……...98.96%

Total:…….100.00%

Spinosad is described in a product safety assessment. (The Dow Chemical Company, June 27, 2008) as a mixture of spinosyn A and spinosyn D, where: Spinosyn A CAS No. 131929-60-7 and Spinosyn D CAS No. 131929-63-0.

The product overview from Dow Chemical Company describes Spinosad as: "the active ingredient in a series of insecticide products formulated by Dow AgroSciences, a wholly owned subsidiary of The Dow Chemical Company. Spinosad is formulated using various formulation technologies such as a suspension concentrate (SC), water dispersible granule (WG), wettable powder (WP), bait concentrates and numerous solid insect baits. Liquid formulations have solid spinosad in suspension in propylene glycol (CAS# 57-55-6). Spinosad-containing formulations are sold under many trade names around the globe.

Spinosad was accepted for review and registered under the U.S. Environmental Protection Agency (EPA) Reduced Risk Pesticide Program. Spinosad is a broad-spectrum insecticide used to control Lepidoptera larvae (caterpillars), Diptera (flies), Thysanoptera (thrips), Coleoptera (beetles) and many other crop-damaging pests. Spinosad is registered for use in over 82 countries for more than 250 crops including uses in turf, tree farms, ornamental plants and trees, plantations, greenhouses, commercial aquatic plants, and control of fire ants.

Spinosad is allowed by USDA National Organic Standards Board, Mayacert, BCS Öko-Garantie GmbH, and others; certain formulations are listed for use by the Organic Materials Research Institute (OMRI) for organic use in the US and various other countries. Formulations certified for organic use in certain countries include, Entrust® Naturalyte® insect control for organic agriculture, GF 120® NF Naturalyte Fruit Fly Bait, Success® 0.02 CB and Conserve® Pro fire ant bait.

B) No descriptions from product labels could be found which listed any synthetic inert ingredients that are not classified by the EPA as inerts of toxicological concern (i.e., EPA List 4 inerts). (7 U.S.C. § 6517(c)(1)(B)(i)). No descriptions from product labels could be found which listed any synthetic substance contained as inert ingredients which are not on EPA List 4, but are exempt from a requirement of a tolerance, per 40 CFR part 180. However, in a United States Patent Application (1995) an invention is described which contains ferric phosphate and a chelating agent, ethylene diamine tetracetic acid (EDTA) (edetic acid), and in later formulations ethylene diamine succinic acid (EDDS) (International Patent Application, 1999: Patent number WO 99/39576).

Evaluation Question #2: Discuss whether the petitioned substance is formulated or manufactured by a chemical process, or created by naturally occurring biological processes. (7 U.S.C. § 6502 (21)

Ferric phosphate occurs naturally in the soil; however, to obtain concentrations for use as a molluscicide, the product must be synthetically produced. To produce ferric phosphate synthetically, an aqueous iron sulfate solution is mixed with an aqueous disodium phosphate solution in a stainless steel boiler. The mixture is heated up to 50-70 ˚C in order to precipitate ferric phosphate. The precipitate is filtered from the solution, washed with distilled water, and dried with hot air. The ferric phosphate powder is then ready to be packed into containers for shipping. The only by-products of this process are sodium sulfate and water. Sodium sulfate is precipitated with lime and used as a secondary raw material. The water is released into a wastewater clarification plant.

Evaluation Question #3: Describe the most prevalent processes used to manufacture or formulate the petitioned substance. Further, describe any chemical change that may occur during manufacture or formulation of the petitioned substance when this substance is extracted from naturally occurring plant, animal, or mineral sources. (7 U.S.C. § 6502 (21))

Regarding manufacture of ferric phosphate, please see question 2 above. No references were found regarding the possible extraction of ferric phosphate from naturally occurring plants or animals. Regarding natural mineral

sources, to obtain concentrations for use as a molluscicide, the product must be synthetically produced (see question 2.).

Evaluation Question #4: Describe the persistence or concentration of the petitioned substance and/or its by-products in the environment. (7 U.S.C. § 6518 (m) (2))

Examples of the solubilization of phosphate from ferric phosphate by soil microorganisms such as *Penicillium radicum* (Whitlaw et. al, 1998) and others, (Rose, 1957) are common in the literature. It is also reported to occur naturally in the soil as fertilizer.

Evaluation Question #5: Describe the toxicity, mode of action and breakdown products of the petitioned substance, any known toxic or other adverse action of the substance, and/or its breakdown products. (7 U.S.C. § 6518 (m) (2))

As stated in the original petition: "The bait is a strong attractant to slugs and snails, which consume the bait product. The iron phosphate accumulates in the calcium spherules of their digestive glands; this interferes with calcium metabolism, and in turn, disrupts feeding and mucus production. The slugs and snails will stop feeding, and death due to starvation will occur three to six days later." (NOP petition, W. Neudorff, GmbH, KG, Germany, 2003). The EPA describes ferric phosphate as ubiquitous in nature. It is a solid. It is not volatile and does not readily dissolve in water, which minimizes its dispersal beyond where it is applied. It is applied to soil as part of a pellet that also contains bait to attract snails and slugs. When the pests eat the pellets, the iron phosphate interferes with calcium metabolism in their gut, causing the snails and slugs to stop eating almost immediately. They die three to six days later. (Iron (Ferric) Phosphate (034903) Fact Sheet Issued: 3/01). http://www.epa.gov/pesticides/biopesticides/ingredients/factsheets/factsheet_034903.htm#description and October, 1998: http://www.epa.gov/pesticides/biopesticides/ingredients/tech_docs/tech_034903.htm

Evaluation Question #6: Describe any environmental contamination that could result from the petitioned substance's manufacture, use, misuse, or disposal. (7 U.S.C. § 6518 (m) (3))

While reported as occurring naturally in soil, ferric phosphate, if combined with chelating agents such as EDTA or EDDS may cause the accumulation of larger concentrations of iron than would be expected under normal conditions. Meers, et al., (2005) demonstrated the effectiveness of EDTA and EDDS in the phytoextraction of heavy metals from soil, as well as its tendency to persist (half life at minimum tested dose 36 days, with higher doses at 40 days or more). Safer's® Slug and Snail Bait II and Safer's® Slug and Snail Killer are listed as containing a combination of ferric phosphate and EDTA (Health Canada's Pest Management Regulatory Agency, PMRA 2010). Other trade names listing the combination exist. A combination of ferric phosphate and EDTA was voted "no" unanimously during the NOSB meeting of November 27 – 30, 2007, Kane, (2007). If the Safer's® version (containing EDTA), or a variation of it were mixed in a container labeled as the ferric phosphate only version, it would result in a non-approved combination and the potential for misuse could be high.

Evaluation Question #7: Describe any known chemical interactions between the petitioned substance and other substances used in organic crop or livestock production or handling. Describe any environmental or human health effects from these chemical interactions. (7 U.S.C. § 6518 (m) (1))

Mammalian toxicity potentials have been partially researched, and are thus of interest in regard to human health considerations.

For example, the EPA (2008) reported 5 domestic animal deaths, 8 major domestic animal incidents and 106 moderate and minor domestic animal incidents from the use of iron phosphate slug and snail baits marketed in the USA up to May 7, 2008. It is important to be aware of the mammalian toxicity of molluscicides that are

combinations of iron phosphate and EDTA or EDDS. EDTA has been reported to have an oral mammalian toxicity of 30 mg kg^{-1} to rats (Tamm and Speiser, 2006) and mice (Safety Data for ETDA, 2008) compared with an oral toxicity of metaldehyde of 630 mg kg^{-1} to rats and 250–1000 mg kg^{-1} to dogs (Berg, 1986). However, the mammalian toxicity of EDDS does not appear to have been published."

Edwards, et al. (2009) conducted a study which compared the effects of metaldehyde and iron phosphate alone, with those of iron phosphate plus chelating agents EDDS and EDTA, and of the chelating agents alone on earthworms. "Earthworms are considered to be key soil-inhabiting invertebrates due to their great importance in soil formation, fertility, and nutrient turnover (Edwards and Bohlen, 1996; Edwards, 2004). Because of this, they have been suggested as critical indicators of soil quality (Berry, et al., 1996; Blair et al., 1996), and for the same reason, earthworms were selected by the European Union (EU) and Organization for Economic Cooperation and Development (OECD) to be used as one of a set of critical assays to assess the toxicity of chemicals to the environment (Edwards, 1983, 1984; OECD, 1984)." He also stressed the importance of his findings regarding the combination of ferric phosphate with chelating agents. While usually listed under the category of "inert" ingredients and not specifically banned in organic production, the combination of EDTA or EDDS with ferric phosphate should be considered, especially since patent applications with such combinations have been filed (International Patent Application, 1999: Patent number WO 99/39576). The existence of the patents indicates some intent by the owners. In Edwards's discussion he states: "Another important issue is the level of mammalian toxicity of iron phosphate-based molluscicides containing EDTA or other chelating agents (Tamm and Speiser, 2006), especially since if chelating agents increased the uptake of iron from soils into crops they may be fed upon by humans. There also have been reports from the US EPA of mortality or illness of domestic animals that consumed iron phosphate-based molluscicides.

QUOTATION: "Clearly, molluscicides containing iron phosphate and EDTA or EDDS chelating agents may present significant environmental hazards to earthworms, domestic animals and humans and these issues need further investigation. The registration statuses of these chemicals in USA and Europe should be reviewed in light of these new data and conclusions "(Edwards, et al. 2009). This also illustrates a mode by which ferric phosphate could be introduced into the food chain.

See Question 8 below, and Figure 1.

Evaluation Question #8: Describe any effects of the petitioned substance on biological or chemical interactions in the agro-ecosystem, including physiological effects on soil organisms, crops, and/or livestock. (7 U.S.C. § 6518 (m) (5))

See Question #7 above.

In reference to Edwards, et al. (2009), the comparison of metaldehyde and iron phosphate alone, with those of iron phosphate plus chelating agents EDDS and EDTA, as well as the chelating agents alone on earthworms should be considered. The results included his research as well as other tests (OECD 1984) summarized in Figure 1 and Table 1.

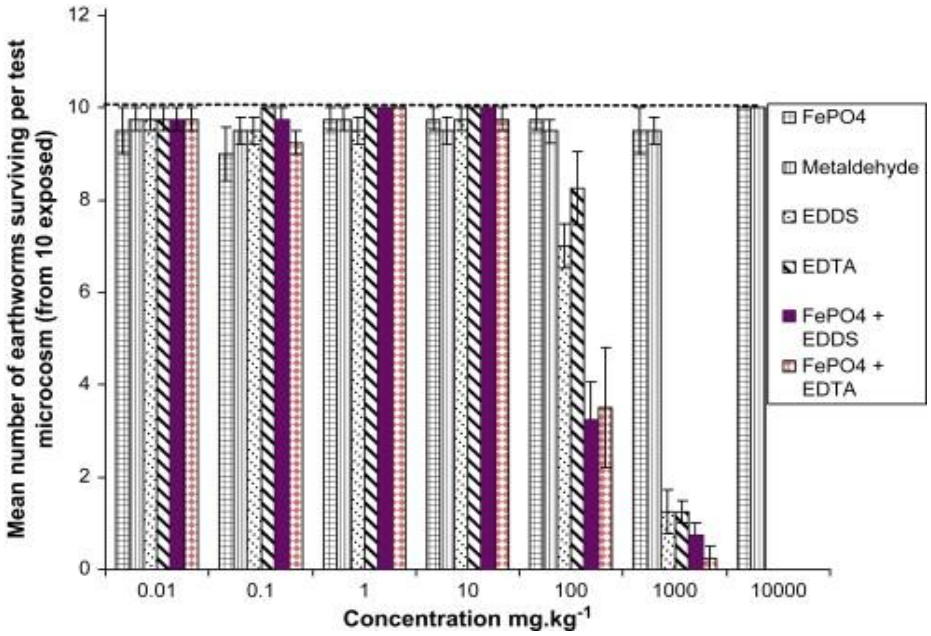

Figure 1. Effects of molluscicides on earthworm (*Eisenia fetida*) activity in artificial soil (OECD test). Number surviving (±SE).

Clearly, metaldehyde and iron phosphate had no significant effects on the earthworms at any of the concentrations tested. However, EDTA and EDDS had significant effects ($P \leq 0.05$) on earthworm numbers at concentrations between 100 and 1000 mg kg^{-1} (ppm). The combinations of iron phosphate with both EDTA and EDDS had even greater effects on the earthworm numbers. This conclusion is emphasized by the LD_{50} calculations for metaldehyde, iron phosphate, EDTA and EDDS and their mixtures, which are summarized in Table 1.

Table 1. (as summarized by Edwards, et. al., 2009) (reproduced [quoted] directly)

Toxicity of molluscicides to earthworms (OECD artificial soil test) (calculated LD_{50} values and confidence limits).

Molluscicide	LD_{50} (Oral) (mg kg^{-1})	Confidence limits
Metaldehyde	>10,000 –	
Iron phosphate	>10,000 –	
Ethylene diamine tetracetic acid (EDTA)	156.46	- 136.01 +179.98
Ethylene diamine disuccinic acid (EDDS)	145.57	- 113.67 +186.41
Iron phosphate + EDTA	78.16	- 63.91 - 95.58
Iron phosphate þ EDDS	82.98	- 69.16 +99.55

This shows that metaldehyde and iron phosphate had very high LD_{50} values of more than 10,000 mg kg^{-1}, EDTA had an LD_{50} value of 156 mg kg^{-1}, EDDS of 145.57 mg kg^{-1}, iron phosphate + EDTA of 78.16 mg kg^{-1} and iron phosphate + EDDS of 82.98 mg kg^{-1}.

The Canadian General Standards Board CAN/CGSB-32.311-2006 Amended October 2008 and December 2009 states in regard to "ferric phosphate (ferric orthophosphate): "Permitted as molluscicide. To be used in such a way as to prevent runoff into water bodies. Shall not be in contact with crops." The document did not contain

explanations, discussions, or methods regarding how ferric phosphate could be applied or used without contact with crops.

Evaluation Question #9: Discuss and summarize findings on whether the petitioned substance may be harmful to the environment. (7 U.S.C. § 6517 (c) (1) (A) (i) and 7 U.S.C. § 6517 (c) (2) (A) (i))

The petitioned substance, ferric phosphate, has been believed to be very stable in the environment and pose little or no harm to the environment when used as recommended. See EPA report results below, and cited FDA reports earlier. More recent research by Edwards, et al. (2009) and earlier studies, as well as the OECD test results (1984), indicate that when combined with chelating agents such as EDTA or EDDS, the efficacy increases dramitcally. It also shows that such combinations can have lethal results to unintended beneficial organisms (earthworms). Assuming the reports of mammalian toxicity are accurate, that would demonstrate the potential for some level of persistence in the food chain. The patent application for a combination of ferric phosphate with spinosad indicates that ferric phosphate is likely to be used in combination with other substances to some degree. As concluded by Edwards (2009), more research would be necessary to fully predict or estimate the potential environmental impact, especially if ferric phosphate is used in combination with chelating agents.

In addition to questions 7 and 8 above, the EPA (1998) states:

Ecological Effects

Ecological Effects Hazard Assessment A number of ecological effects toxicology data requirements were waived based on the known lack of toxicity of iron phosphate to birds, fish and non-target insects, its low solubility in water, conversion to less soluble form in the environment (soil), and its use pattern (soil application). An acute oral toxicity study in Bobwhite quail (NOEL & LD50 greater than 2000 mg kg^{-1}) indicated that iron phosphate was practically nontoxic to avian species. Based on these factors, the data requirements for the toxicity studies in Mallard duck, rainbow trout, freshwater invertebrates, and non-target insect/honeybees are waived. It is likely that there will be exposure to ground-feeding non-target insects and earthworms. Submitted studies involving ground beetles, rove beetles and earthworms demonstrated that the product will not affect these organisms at up to two times the maximum application rate.

Environmental Fate and Ground Water Data Exposure assessments on this type of product (biochemical pesticide) are not performed unless human health or ecological effects issues arise in the toxicity studies for either of these disciplines. Since no endpoints of concern were identified, there is no requirement for environmental fate data.

Ecological Exposure and Risk Characterization Exposure to daphnids and other aquatic invertebrates would not occur based on current label use directions. Exposure to honeybees is also not expected to occur, due to the composition and particle size of the end-use product and its use pattern (soil application). Non-target insects, such as ground beetles and earthworms, could encounter the end-use product; however, in tests of rove beetles, ground beetles and earthworms, no effects were observed at up to twice the maximum application rate. Thus, the acute risk to aquatic invertebrates, non-target insects, and earthworms is considered minimal to nonexistent.

Evaluation Question #10: Describe and summarize any reported effects upon human health from use of the petitioned substance. (7 U.S.C. § 6517 (c) (1) (A) (i), 7 U.S.C. § 6517 (c) (2) (A) (i)) and 7 U.S.C. § 6518 (m) (4))

Please see question no. 8 above. Also, the EPA (1998) states following information:

Human Health Effects

Toxicology

All toxicity data requirements have been satisfied for the purpose of the registration. The information submitted to support the acute toxicity requirements for iron phosphate indicate toxicity category IV for acute oral toxicity, category IV for acute dermal toxicity, category III for primary eye irritation, and category IV for primary dermal irritation. Acute inhalation, dermal sensitization, genotoxicity, immunotoxicity, developmental toxicity and sub-chronic (90 day) oral toxicity studies were waived because of iron phosphates' FDA GRAS (generally regarded as safe) status, the abundance of iron in nature, its low toxicity, its use as a nutritional supplement, and its low water-solubility, which would decrease its absorption across the intestinal epithelium. The Agency has no information to suggest that ferric phosphate has any effect on the immune and endocrine systems.
No unreasonable adverse effects to human health are expected from the use of iron phosphate.

Potential for the Transfer of the Pesticide to Drinking Water

Although the potential exists for a minimal amount of iron phosphate to enter ground water or other drinking water sources, phosphate has an extremely low solubility in water. Thus, the amount would, in all probability, be undetectable or more than several orders of magnitude lower than those levels considered necessary for safety. Both percolation through soil and municipal treatment of drinking water would reduce the possibility of exposure to iron phosphate through drinking water. Therefore, the potential of significant transfer to drinking water is minimal to nonexistent.

Aggregate Exposure

Dietary exposure of ferric phosphate via food or water exists due to its use as a nutritional supplement and its ubiquitous presence in nature. Residues from use of the biochemical pesticide, ferric phosphate, will not significantly add to the current dietary exposures.

Increased non-dietary exposure of ferric phosphate via non-commercial greenhouse, home lawn and garden or ornamental use will be minimal. Exposure by the inhalation route would be non-existent because ferric phosphate is not volatile and the formulation of the product is a solid matrix of non-respirable size. In summary, the potential aggregate exposure, derived from non-dietary and non-occupational exposure should be minimal.

Cumulative Effects

Because of its low toxicity, low rate of application, and use patterns, the Agency believes that there is no reason to expect any cumulative effects from ferric phosphate and other substances.

Acute and Chronic Dietary Risks for Sensitive Subpopulations, Particularly Infants and Children

A battery of acute toxicity/pathogenicity studies is considered sufficient by the Agency to perform a risk assessment for biochemical pesticides.

In considering health risk from iron phosphate, it is important to keep the ubiquitous nature of this mineral in mind. Despite decades of widespread use of iron as a nutritional supplement, there have been no confirmed reports of immediate or delayed allergic reactions with significant oral exposure.

One might presume that only the reports of mammalian toxicity cited in question 9 are likely to be of potential concern.

Evaluation Question #11: Describe all natural (non-synthetic) substances or products which may be used in place of a petitioned substance. (7 U.S.C. § 6517 (c) (1) (A) (ii)) Provide a list of allowed substances that may be used in place of the petitioned substance. (7 U.S.C. § 6518 (m) (6))

Examples have been reported in various semi-professional literature, albeit they are intended more for home and garden use rather than agricultural purposes. Some of these include but are not limited to: a product advertised as meeting the Program Standards set forth by the National Organic Program (NOP) final rule 7CFR Part 205, from Lawn and Gardens Products, Inc., called All Natural Snail and Slug Spray RTU contains, as active ingredients: Rosemary, Sesame, Peppermint, Thyme, Cinnamon, and Garlic. Other ingredients include: Beeswax, Calcium Carbonate, Carrageenan, Cellulose, Citric Acid, Glycerine, Kaolin, Ground Mustard, Palm Oil, Sodium Bicarbonate, Sodium Chloride, Wintergreen Oil, and Water.

Evaluation Question #12: Describe any alternative practices that would make the use of the petitioned substance unnecessary. (7 U.S.C. § 6518 (m) (6))

One of the most effective molluscicides is the combination of ferric phosphate with metaldehyde. Toxicity of metaldehyde is said be well documented (Edwards, et al., 2009) and it is not on the NOP approved or petitioned list of substances for organic production.

As in question 11 above, many of the "natural" remedies or deterrents for slugs and snails are abundant in the semi-professional literature, such as home and gardening publications and blog sites on the internet. Techniques such as spot spraying with ammonia solutions (which would not be permitted under certified organic conditions) [concentrations not specified], spraying with salt solutions (concentrations and type not specified), the direct removal of any slugs or snails observed and placement into a container of soap [type not specified] and water, alcohol, or other harsh solution to kill them. Birds, small mammals, and especially toads, have been said to be predators on slugs and snails, but are obviously not readily controllable. The sources did not specify a number of predators necessary per unit of affected area required to make the use of ferric phosphate completely unnecessary.

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Monterey Lawn and Garden Products, Inc., P.O. Box 35000 Fresno, California 93745-5000 Email: info@montereylawngarden.com June 27, 2008. The Dow Chemical Company, Product advertisement for: Sluggo® Plus Insect, Slug & Snail Pellets. http://www.montereylawngarden.com/pdf/sluggo-plus.pdf

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