notice may be filed online at many Federal Depository Libraries.

List of Subjects

Environmental protection.

Dated: April 13, 1998.

Lois A. Rossi,

Director, Special Review and Reregistration Division, Office of Pesticide Programs.

[FR Doc. 98–10850 Filed 4–28–98; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

[OPP–30452; FRL–5783–2]

Zeneca Ag Products; Applications to Register Pesticide Products

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces receipt of applications to register pesticide products containing new active ingredients not included in any previously registered products pursuant to the provisions of section 3(c)(4) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended.

DATES: Written comments must be submitted by May 29, 1998.

ADDRESSES: By mail, submit written comments identified by the document control number [OPP–30452] and the file symbols to: Public Information and Records Intregrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring comments to: Environmental Protection Agency, Rm. 119, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA.

Comments and data may also be submitted electronically to: opp-docket@epamail.epa.gov. Follow the instructions under ''SUPPLEMENTARY INFORMATION.'' No Confidential Business Information (CBI) should be submitted through e-mail.

Information submitted as a comment concerning this notice may be claimed confidential by marking any part or all of that information as CBI. Information so marked 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. The public docket is available for public inspection in Rm. 119 at the Virginia address given above, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding holidays.

FOR FURTHER INFORMATION CONTACT: By mail: James Tompkins, Product Manager (PM-25), Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. 257, CM #2, 1921 Jefferson Davis Highway, Arlington, VA 22202, (703 305–7391, e-mail: tompkins.james@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA received applications as follows to register pesticide products containing active ingredients not included in any previously registered products pursuant to the provision of section 3(c)(4) of FIFRA. Notice of receipt of these applications does not imply a decision by the Agency on the applications.

I. Products Containing Active Ingredients Not Included In Any Previously Registered Products

1. File Symbol: 10182–UEA. Applicant: Zeneca Ag Products, 1800 Concord Pike, P.O. Box 15458, Wilmington, DE 19850–5458. Product Name: Achieve 40DG Herbicide. Herbicide. Active ingredient: Tralkoxydim 2-cyclohexen-1-one, 2-[1-(ethoxyimino)propyl]-3-hydroxy-5-(2,4,6-trimethylphenyl)-(9Cl) at 40 percent. Proposed classification/Use: General. For selective control of wild oats, green and yellow foxtail, annual ryegrass, and Persian Darnel on wheat and barley.

2. File Symbol: 10182–UET. Applicant: Zeneca Ag Products. Product Name: Achieve 80DG Herbicide. Herbicide. Active ingredient: Tralkoxydim 2-cyclohexen-1-one, 2-[1-(ethoxyimino)propyl]-3-hydroxy-5-(2,4,6-trimethylphenyl)-(9Cl) at 80 percent. Proposed classification/Use: General. For selective control of wild oats, green and yellow foxtail, annual ryegrass, and Persian Darnel on wheat and barley.

3. File Symbol: 10182–UEL. Applicant: Zeneca Ag Products. Product Name: Tralkoxydim Technical Wet Paste. Herbicide. Active ingredient: Tralkoxydim, 2-[1-(ethoxyimino)proply-3-hydroxy-5-mesitylcyclohex-2-enone at 81 percent. Proposed classification/Use: General. For Manufacturing uses only.

Notice of approval or denial of an application to register a pesticide product will be announced in the **Federal Register**. The procedure for requesting data will be given in the **Federal Register** if an application is approved.

Comments received within the specified time period will be considered before a final decision is made; comments received after the time specified will be considered only to the extent possible without delaying processing of the application.

II. Public Record and Electronic Submissions

The official record for this notice, as well as the public version, has been established for this notice under docket number [OPP–30452] (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 notice 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 5.1/6.1 or ASCII file format. All comments and data in electronic form must be identified by the docket number [OPP–30452]. Electronic comments on this notice may be filed online at many Federal Depository Libraries.

Authority: 7 U.S.C. 136.

List of Subjects

Environmental protection, Pesticides and pest, Product registration.

Dated: April 10, 1998.

Susan Lewis,

Acting Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 98–10841 Filed 4–28–98; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

[PF–803; FRL–5783–4]

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–803, must be received on or before May 29, 1998.

ADDRESSES: By mail submit written comments to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), 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
Bipin Gandhi (PM-5)	Rm. 4W53, CS #1, 703–308–8380, e-mail:gandhi.bipin@epamail.epa.gov.	1921 Jefferson Davis Hwy, Arlington, VA
Indira Gairola	Rm. 4W57, CS #1, 703–308–8371, e-mail: gairola.indira@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 Comestic 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–803] (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–803) and appropriate petition number. Electronic comments on 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: April 13, 1998

Susan Lewis,

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. BFGoodrich Specialty Chemicals

PP 8E4958, 8E4961, 8E4962

EPA has received a pesticide petition (PP 8E4958,8E4961,8E4962) from BFGoodrich Specialty Chemicals, 9911 Brecksville Road, Cleveland, OH 44141, proposing pursuant to section 408(d) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 346a(d), to amend 40 CFR part 180 to establish an exemption from the requirement of a tolerance for acrylic acid terpolymer, partial sodium salt in or on raw agricultural commodities when used as inert ingredients in the pesticide formulations applied to growing crops, raw agricultural commodities after harvest or to animals, under 40 CFR 180.1001(c) and (e). 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. Toxicological Profile

The Acrylate Terpolymers Good-RiteK-781,K-797, and K-798 conform to the definition of polymer given in 40 CFR 723.250(b) and meets the following criteria that are used to identify low risk polymers:

1. The Acrylate Terpolymers are not cationic polymers, nor are they reasonably anticipated to become cationic polymers in a natural aquatic environment.

2. The Acrylate Terpolymers contain as an integral part of their composition the atomic elements carbon, hydrogen, oxygen, sulfur and nitrogen. It also contains the monatomic counterion Na+.

3. The Acrylate Terpolymers do not contain as an integral part of their composition, except as impurities, any elements other than those listed in 40 CFR 723.250(d)(2)(ii).

4. The Acrylate Terpolymers are not designed, nor are they reasonably anticipated to substantially degrade, decompose, or depolymerize.

5. The Acrylate Terpolymers are not manufactured or imported from monomers and/or other reactants that are not already included on the Toxic Substances Control Act (TSCA) Chemical Substance Inventory or manufactured under an applicable TSCA Section 5 exemption.

6. The Acrylate Terpolymers are not water absorbing polymers.

7. The only reactive functional groups the Acrylate Terpolymers contain is a carboxylic acid.

8. The Acrylate Terpolymers have a number average molecular weight greater than 1,000 and less than 10,000 Daltons (and oligomer content less than 10 percent below MW 500 and less than 25 percent below MW 1,000).

B. Aggregate Exposure

In the past decade Acrylate copolymers and terpolymers have been used in a variety of applications, most notably water treatment including boiler and retort waters, cooling waters, membrane separations systems and are now de rigor in these applications. In these and similar applications, reasonable levels of incidental exposure to the neat polymer is expected and accepted without regard. ANSI/NSF Standard 60 Drinking Water Treatment Chemical Additives listing has been extended to similar acrylate co-and ter-polymers. The chemical characteristics of these polymers and the published health and safety data indicates that aggregate exposure to Acrylate terpolymers, as listed in the current petitions, as inert ingredients in the preparation and application of pesticide formulations for use on growing crops, raw agricultural commodities after harvest or to animals poses no harm.

C. Cumulative Effects

At this time there is no information to indicate that any toxic effects produced by the Acrylate terpolymers would be cumulative with those of any other chemical. Given the terpolymers' categorization as ''low risk polymers'' (40 CFR 723.250) and their proposed use an inert ingredients in pesticide formulations, there is no reasonable expectations of increased risk due to cumulative exposure to the Acrylate terpolymers.

D. International Tolerances

BFGoodrich is petitioning that the Acrylate terpolymers be exempt from the requirement of a tolerance based upon their status as low risk polymers as per 40 CFR 723.250. Therefore, an analytical method to determine residues of the Acrylate terpolymers in raw agricultural commodities treated with pesticide forumlations containing the Acrylate terpolymers has not been proposed.

There are no Codex maximum residue levels(MRLs) established for the Acrylate terpolymers. (Bipin Gandhi)

2. Platte Chemical Company

PP 6E4742

EPA has received a pesticide petition (PP 6E4742) from Platte Chemical Company, 419 18th Street, P.O. Box 667, Greeley, CO 80632, proposing pursuant to section 408(d) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 346a(d), to amend 40 CFR part 80 to establish an exemption from the requirement of a tolerance for residues of the inert ingredient Modal Alder Bark (MAB) alder bark flour (ABF) when used in pesticide formulations applied to growing crops, or in or on raw agricultural commodities after harvest. 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*. MAB is not absorbed or metabolized by plants. The ABF remains on the treated surface, where it decomposes to its natural constituents including, cellulose, hemicelluloses, lignin and various compounds such as suberins and phenolic acids. These decomposition products are further degraded by various bacteria and fungi to simple sugars, carbohydrates, gases and other molecular compounds. Eventually ABF will be completely decomposed by natural processes to nutrients which can be utilized by other plants.

2. *Analytical method*. No analytical method is available for determining MAB, *per se*. Although various methods are available to determine the various components of alder bark (e.g., content of cellulose, lignin, polysaccharides, etc.), these methods are not specific to MAB and can not distinguish whether the components are derived from ABF or from other plant or soil sources.

3. *Magnitude of residues*. Since ABF is not absorbed or metabolized by plants, no residues of MAB are expected to result in or on raw agricultural commodities. For example, potato commodities grown from seed potato pieces treated with formulations containing MAB do not have residues of the inert ingredient. Furthermore, any residues would be associated with the potato seed pieces, which shrivel as the daughter plants withdraw nutrients during ''seedling''growth. Consequently, the spent seed pieces are not harvested and will not be eaten. Finally, any MAB adhering to the harvested potatoes would be removed by brushing and washing.

B. Toxicological Profile

1. *Acute toxicity*. The use of MAB (ABF) as an inert ingredient in pesticide formulations is not expected to result in adverse effects due to its non-hazardous character, minimal potential for exposure, and projected absence of dietary exposure. There is a wealth of available information about the absence of, or minor health effects from, exposure to various wood flours, dusts, shavings, and other wood/bark components. Ingestion of wood flour, sawdust or wood shavings is neither lethal, nor toxic, and is even considered to be a source of non-nutritive dietary fiber. Dermal contact with wood or bark flour is not associated with death or toxicity, although dermal allergies (contact dermatitis) have been reported in certain sensitive individuals. Acute inhalation exposure to wood dusts for a limited time is not considered to be an occupational hazard if dust levels are below established Permissible Exposure Levels (PEL) for non-toxic particulate matter (i.e., unspecified dust particles). MAB is not expected to produce any more eye irritation than any chemically inert particulate, such as clay or wheat flour. In persons who may have a specific alder wood allergy, eye irritation or conjunctivitis is possible even though there are no known reports of such incidences. Alder wood dust is not a sensitizer nor is ABF expected to be a sensitizer.

2. *Genotoxicity*. Evidence from studies with wood-related compounds indicate that MAB is not genotoxic. ABF is composed mostly of cellulose, hemicelluloses and lignins, which are not mutagenic.

3. *Reproductive and developmental toxicity*. MAB is not expected to be a developmental or reproductive toxin, based on extensive testing of the three principle components (cellulose, hemicelluloses and lignins) of ABF. Additionally, wood flours have been used for numerous years to increase dietary fiber in animal feeds and human diets with no known adverse reproductive or developmental toxicity.

4. *Subchronic toxicity*. There is no subchronic exposure to MAB from its use as a pesticidally inert ingredient. However, chronic toxicity data adequately address possible

toxicological effects that may result from subchronic exposure to ABF.

5. *Chronic toxicity*. There is minimal-to-no chronic toxicological risk from the use of MAB as an inert ingredient in pesticide formulations. There are no known adverse reactions to chronic consumption or ingestion of wood flour. Ingestion of wood flour, sawdust or wood shavings for extended periods of time is not hazardous. Instead, it is considered to be a non-nutritive dietary supplement. In fact, the Food and Drug Administration (FDA) has allowed the use of wood flours in various prepared foods, such as bread, to increase dietary fiber levels and reduce caloric intake.

Adverse effects of exposure to wood dust are limited to allergic reactions, such as rhinitis and contact dermatitis, and from chronic (lifetime) occupational exposure (*via* inhalation) to high concentrations of wood dust. Based on the absence of chronic effects from ingestion, the limited irritant and allergic effects from dermal contact, limited exposure to ABF from seed potato treatment, and the absence of chronic exposure by any route, Platte Chemical Company concludes that there is minimal-to-no chronic toxicological risk from the use of MAB in pesticide products.

6. *Animal metabolism*. There is no known human metabolism or metabolic products from human ingestion of non-nutritive dietary fiber from wood products. In humans, the polymers of plants such as cellulose from plant cell walls (linkages), some pectins, hemicellulose, gums, mucilages and lignin, are not easily digested and are passed through the gastrointestinal tract as non-nutritive dietary fiber. Wood flour and sawdust are commonly used in animal feeds. In ruminants, such wood products are reduced to cellulose, hemicelluloses and lignins by endogenous bacterial/microbial populations in the gut. These wood product degradates are further reduced to simple sugars, carbohydrates, carbon dioxide and indigestible biomass. The indigestible biomass is readily excreted.

7. *Metabolite toxicology*. There is no known evidence of metabolite toxicity from the ingestion of wood or ABF by either livestock or humans. In humans, no metabolites are produced after ingestion of non-nutritive dietary fiber such as ABF.

8. *Endocrine disruption*. No endocrine or estrogenic effects are expected from the use of MAB for the following reasons:

i. The production of MAB includes oven drying the bark, which removes moisture and volatile organic compounds.

ii. ABF does not penetrate and will not be absorbed by skin.

iii. Alder bark is primarily composed of naturally-occurring, non-digestible cellulose, hemicelluloses and lignin; and most importantly.

iv. There is no non-occupational exposure to MAB when used as a pesticidally inert ingredient.

C. Aggregate Exposure

1. *Dietary exposure*. Ingestion of MAB or its residues would simply increase the level of non-nutritive fiber in the diet, which has been shown to have beneficial health effects by reducing the incidence of diverticulosis, cancer of the colon and coronary heart disease as well as facilitating weight loss. Also, health claims for fiber-containing foods have been made for more than a century and the effects of fiber in promoting bowel evacuation are widely recognized.

2. *Food*. The use of MAB in potato seed piece pesticides does not result in any significant dietary exposure to ABF. Residues, if any, surround the potato seed pieces, which shrivel as the daughter plants withdraw nutrients during ''seedling'' growth. Consequentially, the spent seed pieces are not harvested and will not be eaten. Brushing and washing potatoes to remove particulates, such as soil, would simultaneously remove any residues of MAB. However, should ABF residues adhere to harvested potatoes, the only effect would be to increase the level of non-nutritive dietary fiber. Were this to be the case, ingestion of MAB residues would be beneficial and of no toxicological concern since MAB can be considered to be a non-nutritive source of dietary fiber, which has been shown to improve health and lessen the incidence of diverticulosis, colon cancer and coronary heart disease.

3. *Drinking water* . The use of MAB as an inert ingredient in pesticide formulations does not lead to alder bark particles in the drinking water. Wood and bark particles do not leach into the groundwater. Any particles that may be transported into water bodies will absorb moisture and either sediment out of the water column or be removed with other particulate matter during drinking water treatment. Similarly, any natural water-extractable components (humic acids, fulvic acids, etc.) of MAB are natural products that will also be removed during drinking water treatment.

4. *Non-dietary exposure*. The only anticipated human exposure to MAB from non-dietary sources would be through occupational exposure during product use.

D. Cumulative Effects

The use of MAB as an inert ingredient in pesticide formulations does not result in any cumulative effects, since there is no non-occupational exposure to MAB.

E. Safety Determination

1. *U.S. population*. The use of MAB does not pose a safety concern for the US human population due to the non-toxic nature of ABF (oral, dermal and acute exposure) and the absence of non-occupational exposure.

2. *Infants and children*. Infants and children are not exposed to MAB from its use in pesticide formulations or the treatment of potato seed pieces.

F. International Tolerances

No international tolerances have been established for ABF, wood flour or wood cellulose.

3. Wheelabrator Water Technologies, Inc.

PP 6E4732

EPA has received a pesticide petition (PP 6E4732) from Wheelabrator Water Technologies, Inc., 8201 Eastern Boulevard, Baltimore, Maryland 21224. proposing pursuant to section 408(d) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 346a(d), to amend 40 CFR part 180 to establish an exemption from the requirement of a tolerance for biosolids in or on the raw agricultural commodity Granulite. 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. *Residues in the raw agricultural commodity and processed food/feed*. A tolerance for substances potentially present in biosolids for raw or processed foods is not anticipated to be needed, based on the very low risk posed by residues in raw food/feed, as discussed throughout this application for a tolerance exemption for Granulite heat-dried biosolids.

2. *Background information and use profile*. Granulite is a heat-dried biosolids (sewage sludge) product. Biosolids are the solid, semi-solid, or liquid residue generated from domestic wastewater treatment, and have been used for centuries as a soil conditioner and fertilizer. Regulations regarding the use and disposal of biosolids have been introduced over the years to protect

human health and the environment, culminating in the 40 CFR part 503 rule promulgated in 1992, which regulates biosolids based on a comprehensive risk assessment consucted by EPA. This rule has since undergone relatively minor revisions, including the deletion of chromium from the regulation; changes to the limits for molybdenum and selenium; and a narrowing of a focus of future biosolids rulemaking to dioxins/furans and polychlorinated biphenyls (PCBs). Land application of biosolids enhances soil conditions and plant growth on agricultural, forest, reclaimed, and public use (e.g., recreational, highway) lands. Over 5 million dry metric tons of biosolids are generated annually in the U.S. at publicly owned treatment works. A minimum of 33% of the biosolids generated annually are land applied (this percentage has probably increased significantly in recent years), while the remaining are incinerated or disposed of using surface disposal. Of the biosolids that are land applied, an estimated 67% are applies to agricultural lands, 3% to forests, 9% to reclamation sites, and 9% to public use sites. Biosolids are land applied by either incorporating or injecting the biosolids into the soil or spreading the biosolids on the soil surface.

B. Toxicological Profile

EPA has determined that the limits for inorganic pollutants (metals) calculated in the EPA biosolids risk assessment protect humans (including children), animals, and plants from reasonably anticipated adverse effects *via* the 14 different exposure pathways evaluated. The 40 CFR part 503 rule regulates metals based on these risk assessment limits, and regulates pathogens based on an operational standard requiring certain pathogen and vector controls that reduce pathogens to low levels (as described in ''Safety Determination: U.S. General Population'' below). For biosolids that meet the most stringent pollutant limits and pathogen controls of part 503, as Granulite does, only minimal additional part 503 requirements need to be met because of the low risk associated with these biosolids, which therefore are allowed to be used as freely as any other soil conditioner. Research indicates that risks associated with the bioavailability of metals in biosolids are low when biosolids are land applied at rates commonly used in agriculture and when good management practices commonly implemented (e.g., soil pH above 5.0) are followed.

1. *Acute toxicity*. EPA initially submitted a list of 200 pollutants potentially found in biosolids for review by a panel of experts; this panel recommended that 50 of these pollutants be studies further, based on avaliable toxicity and exposure data. EPA then developed hazard for each of these 50 pollutants, derived by dividing a pollutant's estimated concentration in soil, plant or animal tissue, or air by the lowest concertration of the pollutants found in the scientific literature to be toxic to the organism being evaluated *via* the most sensetive route of exposure and dassuming maximum toxic effect. A hazard index of less than 1 indicated that the pollutant was not toxic to the organism (*via* that particular exposure pathway), and thus was not analyzed further. EPA further evaluated pollutants with a hazard index value of 1 or greater in the biosolids risk assestment (except for pollutants deferred of deleted due to insufficient or limited data). EPA also evaluated several additional pollutants based in the addition of four exposure pathways. This process resulted in EPA evaluating 23 pollutants in its biosolids risk assestment for land application (see Table 1).

2. *Reproductive and developmental toxicity*. The ingestion of lead by children, which is associated with developmental effects (e.g., learning disabilities), was addressed by the EPA biosolids risk assessment in a conservative manner. EPA evaluated the risk to pica children (children who regularly eat soil) because it is possible that children might ingest soil to which biosolids has been land applied. However, only a small number of children are likely to ingest biosolids in gardens or lawns, especially on a regular basis, and thus this evaluation is more conservative than dietary or drinking water exposures. In addition to lead, limits for arsenic, cadmium, mercury, and selenium are also included in the part 503 rule, based on a child ingesting biosolids that potentially contain these pollutants. Granulite meets all of these limits. For more details, see ''Safety Determination: Infants and Children'' below.

3. *Chronic toxicity*. EPA's risk assessment for the land application of biosolids included the evaluation of chronic effects based on RfDs or RfCs for metals and organic substances potentially found in biosolids. RDAs were used when RfDs were unavailable, or analogous no adverse effect levels were used. Acceptable doses of a substance were estimated for animals, using the most sensitive or most exposed species. The RfDs, RfCs, or analogous levels were combined with other variables to calculate the concentrations of pollutants in biosolids that are reasonably protective against adverse impacts. For the ingestion (dietary) pathways, RfDs were combined with a relative effectiveness RE variable. The RE of exposure accounts for differences in bioavailability depending on the route of exposure (e.g., ingestion or inhalation); because of limited available data, the RE was conservatively set at 1, which assumes 100% bioavailability intake, and thus underestimates the allowable dose of biosolids pollutants and reflects conservative pollutant limits. The pollutant concentrations calculated in the risk assessment were used to develop the most stringent limits in the 40 CFR part 503 rule, which Granulite meets.

4. *Carcinogenicity*. EPA's risk assessment for the land application of biosolids included evaluation of carcinogenicity based on q1*s for metals and organic substances potentially found in biosolids. The q1*s were used with other variables to calculate the concentrations of pollutants in biosolids that are reasonably protective against adverse impacts; these calculated concentrations were used to develop the most stringent pollutant limits in 40 CFR part 503 rule, which Granulite meets. EPA also conducted a population-based risk assessment which indicated that prior to the part 503 rule, biosolids use and disposal practices (including land application, incineration, and surface disposal) could have contributed 0.9 to 5 cancer cases annually; the part 503 rule reduced cancer cases by 0.09 to 0.7 annually. This analysis included exposure to pollutants potentially found in biosolids from all sources, including food, drinking water, residential, and other non-occupational sources.

5. *Endocrine disruption*. The EPA biosolids risk assessment considered all adverse effects identified in the scientific literature, including endocrine effects, if any, and used these to identify no observed adverse effect levels (NOAEL) for the pollutants evaluated. Future research may include additional impacts on wildlife due to limited available field data. Although not specific to endocrine effects, interactive (synergistic) effects observed with biosolids reduce (rather than increase) adverse risks to potential receptors. Interactions between certain elements typically found in biosolids hinder the uptake of metals by plants and the bioavailability of metals to animals and humans. See ''Cumulative Risk'' below for more information on these interactive effects.

C. Aggregate Exposure

The 14 exposure pathways that EPA evaluated in its biosolids risk assessment included: children ingesting biosolids/soil directly (the pica child); adults ingesting plants grown in soils amended with biosolids or drinking ground-water or surface-water containing substances present in biosolids; adults ingesting fish from surface-water containing substances in biosolids; adults ingesting animal products derived from animals that ingested biosolids; animals ingesting biosolids or plants grown in biosolids-amended soils; and plants grown in biosolids-amended soils. Thus, the EPA risk assessment for the land application of biosolids addressed exposures from dietary, drinking water, and non-occupational sources. The most conservative estimate from the 14 exposure pathways was then selected as the limit for each of the pollutants potentially found in biosolids, thus representing protection based on aggregate exposure. Granulite meets these limits.

In addition, the EPA risk assessment calculations for all 14 pathways initially included pollutant exposure from sources other than biosolids (food, air, and water). Exposures from sources other than biosolids were then subtracted from the total allowable dose, yielding a result that represented the allowable dose of a pollutant from biosolids only. This value was then combined with other variables to derive a pollutant limit.

1. *Dietary exposure*. Parameters for human, animal, or plant health (e.g., based on RfDs, q1*s, etc., as described above in ''Chronic Effects'' and (''Carcinogenicity'') were combined with pollutant intake information (e.g., the amount of a particular food type consumed) to derive pollutant limits in the EPA biosolids risk assessment. Several pollutant limits were based on a dietary exposure pathway (for the inorganic chemical molybdenum and for several organic chemicals). However, the limits for molybdenum were re-evaluated and new limits are expected to be less stringent, and limits for organics were not included in the part 503 rule, as discussed in ''Other Considerations'' below. For other pollutants, exposure pathways other than dietary exposure posed more risks, and pollutant limits were based on these higher-risk pathways.

2. *Drinking water*. The part 503 rule requires that biosolids be land applied at the agronomic rate (the rate that provides the amount of nitrogen needed by a crop or vegetation to attain a desired yield while minimizing the amount of nitrogen that will pass below the root zone of the crop or vegetation to ground-water), thus protecting ground-water from biosolids with nitrogen levels in excess of estimated crop needs. In addition, for ground-water, the EPA risk assessment analyzed the pathway involving: the land application of biosolids; the leaching (mobility) of pollutants from soil into ground-water; and the subsequent drinking of well water containing these pollutants by humans. The ground-water pathway evaluation included: a mass balance (between erosion, leaching, volatilization, and degradation persistence); a reference water concentration (based on the q1* or MCL); and use of the VADOFT (from RUSTIC) and the AT123D models. For surface-water exposure, EPA analyzed the pathway involving: the land application of biosolids; the erosion (mobility) of soil containing pollutants in biosolids; the transfer of the pollutants contained in the eroded soil to surface-water; and the ingestion of the surface-water and fish living in the surface-water by humans. The surface-water pathway evaluation included: a mass balance (as described above for ground-water); a reference intake (based on the q1* or RfD); acute or chronic freshwater criteria for aquatic life; a bioconcentration factor; a food chain multiplier; and a dilution factor, among other parameters. No pollutant limit was based on the ground-water pathway because other exposure pathways resulted in more restrictive limits. Only one pollutant limit, for DDT/DDD/DDE, was based on the surface-water pathway; however, organics, including DDT, were deleted from part 503 regulation because they met at least one of three criteria set by EPA (see ''Other Considerations'' below).

While metals potentially present in biosolids may be persistent, they are bound in the biosolids-soil matrix for long periods of time, as discussed in ''Environmental Fate Data Summary'' below. Also, the dry characteristics of Granulite, which is heat-dried, minimize water content and leachability of metals.

3. *Non-dietary exposure*. EPA's biosolids risk assessment evaluated exposure to pollutants potentially found in biosolids that are land applied to gardens, lawns, and other residential and non-occupational settings in non-dietary pathways.

D. Cumulative Effects

Extensive field data used in EPA's risk assessment for biosolids show no adverse effects of low levels of metals in land-applied biosolids. Some metals are not transferred into edible plant parts (even when their concentrations are greatly increased in the biosolids/soil mixture) because these metals (e.g., chromium) are insoluble or strongly bound to the biosolids-soil matrix (by iron or certain other oxides, organic matter, or phosphates in biosolids) or to plant roots (e.g., lead). Or, if other substances commonly found in biosolids, such as zinc, calcium, and iron, are present, these substances will inhibit absorption of some metals (e.g., selenium, molybdenum, and cadmium) from the ingested food into the organism's intestines and blood stream. Also, the EPA biosolids risk assessment included bioavailability and bioaccumulation factors to account for uptake of pollutants by animals (e.g., fish) and subsequently by humans.

E. Safety Determination

1. *U.S. population*. The EPA biosolids risk assessment as well as field data show that certain biosolids that meet low pollutant limits for metals can be considered NOAEL biosolids that have no observed adverse effects on public health and the environment. Granulite meets these limits. Human and animal health protection from pathogens are addressed in the part 503 regulation through technology-based requirements that minimize pathogen densities and reduce vector attraction. Granulite meets the most stringent ''Class A'' part 503 requirements that pathogen densities be reduced to low levels.

2. *Infants and children*. For several of the metals evaluated in EPA's biosolids risk assessment, the pollutant limit identified was based on the exposure pathway for a pica child ingesting biosolids/soil. These limits are conservative because they go beyond expected dietary and drinking water exposures (i.e., a very small percentage of children are expected to consume biosolids in gardens or on lawns). Also, the limit for lead in biosolids in the part 503 regulation is 300 ppm, based on animal data. This number provides an additional margin of safety for growing children because it is lower than the 500 ppm limit for lead derived using EPA's Integrated Exposure Uptake Biokinetic (IEUBK) model. In addition, animal (rat) studies show that the bioavailability of lead in biosolids is 12-fold lower than that assumed in the IEUBK model calculations used; thus the 300 ppm lead limit provides even more of a margin of safety. The limits identified for the other metals (arsenic, cadmium, mercury, and selenium) based on a child ingesting biosolids/soil were calculated in algorithms developed

specifically for the EPA biosolids risk assessment. The most stringent part 503 pollutant limits for metals in biosolids that are land applied are based on these figures; Granulite meets these limits.

F. Other Considerations

Organic chemicals were evaluated in the EPA biosolids risk assessment. However, the part 503 rule did not set limits for organic chemicals because all the organic chemicals analyzed met one or more of the following criteria:

i. The pollutant has been banned or restricted for use in the U.S. or is no longer manufactured in the U.S.

ii. The pollutant is infrequently found in biosolids (e.g., detected less than 5% of the time).

iii. The limit for the pollutant identified in the EPA biosolids risk assessment is not expected to be exceeded in biosolids that are used or disposed.

iv. Nearly all of the organic chemicals evaluated met two or more of these criteria.

G. Practical Analytical Method

Numerous analytical methods were used in the hundreds of research studies on which the EPA risk assessment for the land application of biosolids was based. Examples of analytical methods used for analyzing metals concentrations in plant and animal tissue include atomic absorption, X-ray fluorescence spectroscopy, and autoradiography.

H. List of All Pending Tolerances and Exemptions

The only known exemption from tolerance being proposed for biosolids as an inert ingredient is this application, which is based on the health and environmental protection identified in EPA's part 503 risk assessment for the land application of biosolids, as discussed throughout this application.

I. Environmental Fate Data Summary

Studies have shown that metals are bound in the biosolids-soil matrix over the long-term and that the binding properties of biosolids are environmentally stable. The binding of metals by biosolids renders the metals less bioavailable to plants, animals, and humans, and studies have shown no adverse effects when biosolids containing metals meeting the part 503 pollutant limits, which includes Granulite, are land applied.

The EPA risk assessment for the land application of biosolids included analysis of ecological risks through ground-water, surface-water, plants, livestock, and wildlife (as well as to humans, including children). Low risks were found to be associated with the ground-water pathway and to wildlife, and thus pollutant limits for chemicals of concern for these pathways or endpoints were based on other, more restrictive risk assessment limits for other pathways/endpoints. Granulite meets all of these limits. The one organic pollutant of concern identified for the surface-water pathway was deleted from regulation, as discussed in ''Other Considerations'' above.

J. International Tolerances

None known. Compatibility with any existing MRLs should be possible, based on the low risk of adverse effects identified in EPA's risk assessment for the land application of biosolids. (Bipin Gandhi)

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ENVIRONMENTAL PROTECTION AGENCY

[OPPTS–51894; FRL–5785–8]

Certain Chemicals; Premanufacture Notices

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: Section 5 of the Toxic Substances Control Act (TSCA) requires any person who intends to manufacture or import a new chemical to notify EPA and comply with the statutory provisions pertaining to the manufacture or import of substances not on the TSCA Inventory. Section 5 of TSCA also requires EPA to publish receipt and status information in the **Federal Register** each month reporting premanufacture notices (PMN) and test marketing exemption (TME) application requests received, both pending and expired. The information in this document contains notices received from February 1, 1998 to February 6, 1998.

ADDRESSES: Written comments, identified by the document control number ''[OPPTS–51894]'' and the specific PMN number, if appropriate, should be sent to: Document Control Office (7407), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 401 M St., SW., Rm. ETG–099 Washington, DC 20460.

Comments and data may also be submitted electronically by sending electronic mail (e-mail) to: oppt.ncic@epamail.epa.gov. Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comments and data will also be accepted on disks in WordPerfect in 5.1/6.1 file format or ASCII file format. All comments and data in electronic form must be identified by the docket number [OPPTS–51894]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic comments on this notice may be filed online at many Federal Depository Libraries. Additional information on electronic submissions can be found under ''SUPPLEMENTARY INFORMATION''.

All comments which contain information claimed as CBI must be clearly marked as such. Three sanitized copies of any comments containing information claimed as CBI must also be submitted and will be placed in the public record for this notice. Persons submitting information on any portion of which they believe is entitled to treatment as CBI by EPA must assert a business confidentiality claim in accordance with 40 CFR 2.203(b) for each such portion. This claim must be made at the time that the information is submitted to EPA. If a submitter does not assert a confidentiality claim at the time of submission, EPA will consider this as a waiver of any confidentiality claim and the information may be made available to the public by EPA without further notice to the submitter.

FOR FURTHER INFORMATION CONTACT: Susan B. Hazen, Director, Environmental Assistance Division (7408), Office of Pollution Prevention and Toxics, Environmental Protection Agency, Rm. E–545, 401 M St., SW., Washington, DC, 20460, (202) 554–1404, TDD (202) 554–0551; e-mail: TSCA-Hotline@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: Under the provisions of TSCA, EPA is required to publish notice of receipt and status reports of chemicals subject to section 5 reporting requirements. The notice requirements are provided in TSCA sections 5(d)(2) and 5(d)(3). Specifically, EPA is required to provide notice of receipt of PMNs and TME application requests received. EPA also is required to identify those chemical submissions for which data has been received, the uses or intended uses of such chemicals, and the nature of any test data which may have been developed. Lastly, EPA is required to provide periodic status reports of all chemical substances undergoing review and receipt of notices of commencement.

A record has been established for this notice under docket number ''[OPPTS–51894]'' (including comments and data submitted electronically as described