ALLEATO®

INFORMACIÓN TÉCNICA

(FOSETIL-AL = FOSETYL-ALUMINUM)

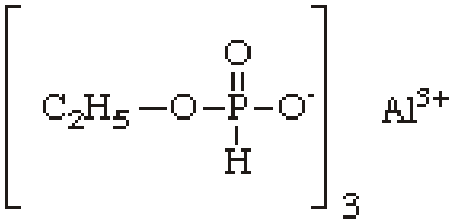
Fungicida Bactericida Agricola

TIPO DE PLAGUICIDA E IDENTIFICACIÓN

ALLEATO®, tiene acción fungicida y bactericida sistémico con capacidad de traslocación ascendente y descendente.
Nombre químico : CA, IUPAC: Tris (O-etil fosfonato) de aluminio
CAS 39148-24-8.
LS 74783. 32545 RP.
SHA 123301.
Nombre común : FOSETIL ALUMINIO
Sinonimia : Fosetil-al

CARACTERÍSTICAS FÍSICO-QUÍMICAS

Grupo químico: Este producto es un fungicida que pertenece al grupo de los alcoil fosfonatos.
Clasificación : FOSFONATO
Fórmula estructural :



Fórmula empírica : $_{Al}(C_2\ H_6\ O_3\ P)_3$.
Peso molecular : 354,1.
Estado físico : polvo cristalino.
Color : blanco.

HELM DE MÉXICO, S.A.

Olor : inodoro.
Punto de fusión : se descompone sin fundirse a > 200 ºC.
Punto de inflamación : no inflamable.
Tensión de vapor a 25 ºCentigrados : $< 0{,}098 \times 10^{-6}$ mm Hg.
< 13 µPa.
Coeficiente de partición (n-octanol/agua) : log P -2,523 a pH 4.
Solubilidad a 20 ºCentígrados : en agua 120 g/l.
Solubilidad a 20 ºCentígrados : en solventes en mg/l: metanol 920, acetona 13, acetonitrilo, acetato de etilo y hexano 5. Prácticamente insoluble (< 5 mg/l) en otros disolventes orgánicos.
Estabilidad: el Producto técnico es estable en las condiciones normales de almacenamiento. Su vida media en solución a 1 g/l en agua a 20 ºCentígrados es superior a 100 días. Se descompone con álcalis y ácidos fuertes. Se oxida con agentes oxidantes fuertes. Se hidroliza el 50% en 6 horas a 70 ºCentígrados y **pH** 1,2 y en 12 horas a pH 12,8.
Corrosivo: no corroe los metales.
Clasificación Toxicológica : IV

TOXICOLOGÍA

Mamíferos :
Toxicidad aguda :
DL_{50} Oral en rata : 5000 mg/kg.
DL_{50} Oral en cobaya : 2780 mg/kg.
DL_{50} Oral en conejo : 2680 mg/kg.
DL_{50} Oral en ratón : 3700 mg/kg.
DL_{50} Dérmica en rata : > 3200 mg/kg.
DL_{50} Dérmica en conejo : > 2000 mg/kg.
DL_{50} Intraper. en rata : 550 mg/kg.
Irritación :
Dérmica en conejo : no irritante.
Ocular en conejo : irritante (EPA).
Sensibilidad :
No sensibiliza la piel de los cobayas.
Inhalación :
CL_{50} en rata : > 1,73 mg/l.
Subcrónica :
En rata, dieta 90 días, NSE : 5000 mg/kg dieta.
En perro, dieta 90 días, NSE : 50000 mg/kg dieta.
Crónica :
En perro, dieta 2 años, NSE : 10000 mg/kg dieta.
En rata, dieta 2 años, NSE : 8000 mg/kg.
Teratogénesis :
En rata, NSE : > 1000 mg/kg/día.

En conejo, NSE : > 500 mg/kg/día.
No teratógeno ni mutágeno.
Reproducción :
En rata, NSE : 6000 mg/kg dieta.
Carcinogénesis:
En rata, NSE: 8000 mg/kg dieta.

Exposición crónica : No se han encontrado efectos en los estudios realizados en los animales.

EFECTOS EN EL MEDIO AMBIENTE

Aves:
DL_{50} Oral aguda en *Colinus virginianus* : > 8000 mg/kg.
DL_{50} Oral aguda en *Coturnix japonica* : 4997 mg/kg.
CL_{50}, dieta, en varios : > 20000 mg/kg dieta.
Peces y organismos acuáticos:
CL_{50}, 96 h, en cangrejo violinista: 145 mg/l.
CL_{50}, 96 h, en *Lepomis macrochirus*: 161 mg/l.
CL_{50}, 96 h, en *Salmo gairdneri* : 428 mg/l.
CL_{50}, 48 h, en *Daphnia magna* : 189 mg/l.
Abejas:
Sin mortalidad por contacto a 200 µg/abeja.
IDA:
3.0 mg/kg.

ALLEATO®, no es tóxico a aves, abejas, peces ni otros organismos acuáticos.

ACTIVIDAD

Fungicida con actividad sistémica, especialmente contra oomicetos; penetra en menos de 1 h en la planta y se trasloca siguiendo las corrientes de savia. El efecto sistémico se manifiesta a la vez en sentido ascendente por el xilema y descendente en el floema.

Ejerce su acción por 2 vías :

a) vía directa, por bloqueo de la esporulación del hongo, así, se ha comprobado que impide la formación de esporangios, esporocistos, oósporas y clamidosporas.

b) vía indirecta, por estimulación de las defensas naturales de la planta que hace intervenir mecanismos fisiológicos complejos y múltiples, como prueban las observaciones microscópicas que muestran mecanismos de hipersensibilidad y de micronecrosis celulares idénticos a los de las variedades genéticamente resistentes. Tiene una protección preventiva de larga duración; está igualmente, su acción curativa durante los 2 a 3 días siguientes a la infección. Es eficaz sobre

ficomicetos y, en especial, para los peronosporales (cenicillas o mildius). Junto a la actividad fungicida, se ha mostrado eficaz como bactericida, combatiendo con éxito bacteriosis producidas por *Xanthomonas spp., Erwinia spp. y Pseudomonas spp.*

APLICACIONES

Recomendado en el control preventivo y, aplicado a tiempo, curativo de oomicosis, incluso las que se presentan a nivel de cuello-tronco; entre ellas cabe destacar *Bremia lactuce*, *Phytophthora citrophthora*, *Peronospora tabacina*, *Plasmopara viticola*, *Pseudoperonospora spp.*, *Pythium spp. Rhizoctonia spp.*, etc. en cultivos de aguacate, algodonero, cacao, caucho, cebolla, césped, cítricos, cucurbitáceas (melón, pepino, etc.), cupresáceas (viveros), fresa, frutales de hueso, frutales de pepita, lechuga, lúpulo, ornamentales, pimiento, piña tropical, tabaco y vid. También ha sido utilizado en el control del fuego bacteriano en peral y manzano y en la prevención de podredumbres de almacén ("aguado") en frutos cítricos. Dosis: 200-240 g s.a./hl; en césped pueden utilizarse 9,6-19,2 kg s.a./ha.

HONGOS Y BACTERIAS QUE COMBATE EL FOSETIL ALUMINIO:

ALLEATO®, junto a la actividad fungicida, se ha mostrado eficaz como **fungicida**, combatiendo con éxito a los hongos que producen las siguientes enfermedades :

NOMBRE CIENTÍFICO	NOMBRE COMÚN
Alternaria longipes	MANCHA CAFÉ DE LA HOJA
Alternaria spp	MANCHA DE LA HOJA
Ceratocystis paradoxa	PUDRICIÓN NEGRA
Fusarium spp	PUDRICIÓN
Guignardia bidwellii	PUDRICIÓN NEGRA
Penicillium spp	PUDRICIÓN
Peronospora cubensis	CENICILLA VELLOSA
Peronospora spp	CENICILLA VELLOSA
Peronospora tabacina	MOHO AZUL
Phomopsis viticola	BRAZO MUERTO
Phytophthora cactorum	CÁNCER DEL TRONCO
Phytophthora cinnamomi	CÁNCER DEL TRONCO
Phytophthora fragariae	CORAZÓN ROJO
Phytophthora infestans	TIZÓN TARDÍO
Phytophthora parasitica	GOMOSIS
Phytophthora parasitica var nicotianae	PIERNA NEGRA
Phytophthora spp	MARCHITAMIENTO DE LA HOJA
Podosphaera leucotricha	CENICILLA POLVORIENTA
Pseudoperonospora cubensis	CENICILLA VELLOSA

Pseudopeziza traecheiphila	MANCHA DE LA HOJA
Stemphylium solani	MANCHA GRIS
Uncinula necator	CENICILLA POLVORIENTA
Venturia spp	MANCHA DE LA HOJA

ALLEATO®, está recomendado en el control preventivo y, aplicado a tiempo, curativo de oomicosis, incluso las que se presentan a nivel de cuello-tronco; entre ellas cabe destacar:

NOMBRE CIENTÍFICO	NOMBRE COMÚN
Bremia lactuce	CENICILLA VELLOSA
Phytophthora citrophthora	GOMOSIS
Peronospora tabacina	MOHO AZUL
Plasmopara viticola	CENICILLA VELLOSA
Pseudoperonospora spp	CENICILLA VELLOSA
Pythium spp	PUDRICIÓN
Rhizoctonia spp	PUDRICIÓN

ALLEATO®, junto a la actividad fungicida, se ha mostrado eficaz como **bactericida**, combatiendo con éxito bacteriosis que producen las siguientes enfermedades :

NOMBRE CIENTÍFICO	NOMBRE COMÚN
Xanthomonas spp	TIZÓN BACTERIANO
Erwinia spp	PUDRICIÓN SUAVE
Pseudomonas spp	MANCHA BACTERIAL

FITOTOXICIDAD :

No es fitotóxico si se usa en los cultivos y a las dosis recomendadas. Hacer ensayos previos sobre cultivos de lechuga y ornamentales con tolerancia desconocida, en especial, en geranio, petunia y saintpaulia.

CONTRAINDICACIONES :

Evite el contacto con piel y ojos. No hacer más de 3 a 4 aplicaciones por temporada. Alternese las aplicaciones de **ALLEATO®** con fungicidas de contacto para evitar resistencia de las enfermedades al producto. No afecta a la fermentación ni a las cualidades organolépticas de los vinos. Si se usa en fresa, no mezclar con ningún otro producto. Los inhibidores de la biosíntesis de los compuestos fenólicos (glifosato, ácido a-aminooxiacético) anulan el efecto del **ALLEATO®** . No aplique en horas de calor intenso, ni cuando la velocidad del viento sea alta. Esperar de 7 a 10 días después de la última aplicación de aceite para aplicar

ALLEATO®. Un cubrimiento uniforme y completo es esencial para el control de las enfermedades.

PERSISTENCIA

Ligeramente Persistente

TIEMPO DE REINGRESO AL CAMPO

Puede entrarse al campo ó zonas tratadas de 24 horas después de su aplicación.

ANOTACIONES

No afecta a la fermentación ni a las cualidades organolépticas de los vinos. Si se usa en fresa, no mezclar con ningún otro producto. Hacer ensayos previos sobre cultivos de lechuga y ornamentales con tolerancia desconocida, en especial, en geranio, petunia y saintpaulia. Los inhibidores de la biosíntesis de los compuestos fenólicos (glifosato, ácido a-aminooxiacético) anulan el efecto del fosetil-al. La asociación con cimoxanilo + folpet es muy eficaz contra mildiu de la vid; su asociación con oxicloruro de cobre se destina al control de peronosporales en lúpulo y vid; su formulación con mancozeb es eficaz en el control de *Phytophthora infestans*.

INCOMPATIBILIDAD

ALLEATO® no es compatible con productos de reacción alcalina. No mezclarlo con productos a base de cobre o con fertilizantes foliares nitrogenados; si requiere hacer mezcla esta solo se podrá hacer con productos registrados y autorizado en los cultivos aquí indicados, no aplicar a ornamentales en mezcla con soluciones nutricionales. Se puede formular con bendiocarb, captan, cimoxanilo, estreptomicina, folpet, mancozeb y tiabendazol.

DEGRADACIÓN

Se degrada rápidamente tanto en suelos húmedos como en secos en condiciones aerobias siendo su vida media de 1 a 1,5 horas en suelos limosos y arcillosos y de 20 minutos en arenosos. No contamina las aguas subterráneas. No se bioacumula. La degradación se produce por hidrólisis del enlace éster dando ácido fosforoso y etanol. El etanol se degrada después a CO_2. El ácido fosforoso forma precipitados con Ca, Al y Fe en el suelo. En las ratas se elimina casi en su totalidad en 24 horas, en la orina y en forma inalterada o como ácido fosfórico.

PRECAUCIONES Y ADVERTENCIAS DE USO

Use el equipo de protección adecuado durante su manejo: overol de mangas largas, guantes impermeables, lentes de seguridad, botas, gorra y mascarilla provista de filtro. Lávese las manos

antes de comer, beber o fumar. Al terminar las labores diarias, báñese con abundante agua y jabón y póngase ropa limpia. Lave bien con agua y jabón su ropa protectora contaminada, antes de volver a usarla. Es un producto ligeramente tóxico, por lo que deberá evitarse su ingestión y contacto con la piel y ojos. No se transporte, ni almacene junto a productos alimenticios, ropa o forrajes. Manténgase fuera del alcance de los niños y animales domésticos. No almacenar en casas habitación. No deben exponerse ni manejar este producto las mujeres embarazadas, en lactación y personas menores de 18 años. No se reutilice el envase, destrúyase.

PRIMEROS AUXILIOS

En caso de intoxicación, consiga inmediatamente atención médica, mientras tanto se deben aplicar los siguientes primeros auxilios :

Retire al paciente a un lugar fresco y ventilado. Si ha habido contacto con la piel, quítese de inmediato la ropa contaminada y lávese la piel con abundante agua y jabón. Consiga inmediatamente atención médica. Si ha habido contacto con los ojos, éstos deben lavarse de inmediato con abundante agua limpia durante 15 minutos. Si el material ha sido ingerido, no provoque el vómito. El vómito debe ser supervisado por un médico debido al posible daño pulmonar que puede resultar por la aspiración del solvente.

RECOMENDACIONES AL MÉDICO

Grupo químico : Este producto es un insecticida del grupo de los alcoil fosfonatos.

Síntomas de intoxicación: Dolor de cabeza, mareos, nerviosismo, debilidad, náuseas, calambres, diarrea y molestias de pecho. Altamente irritante a los ojos. Ligeramente irritante a la piel.

Tratamiento: No existe antídoto específico, por lo que en caso de intoxicación, aplicar tratamiento sintomático. Los signos comprenden: sudoración, miosis, lagrimeo, salivación y otras secreciones del aparato respiratorio.

MEDIDAS DE PROTECCIÓN AL AMBIENTE

Este producto no es tóxico a abejas, peces y organismos acuáticos. Evite la contaminación de lagos, ríos, arroyos, estanques y cualquier fuente o depósito de agua, ya sea por viento o eliminación de sobrantes. Disponga los envases vacíos de acuerdo al Reglamento de la Ley General de Equilibrio Ecológico y Protección al Ambiente en materia de residuos peligrosos.

CONDICIONES DE ALMACENAMIENTO Y TRANSPORTE

Almacene bajo condiciones normales de almacenamiento. No lo almacene ni transporte junto con productos alimenticios, ropa o forrajes. Almacénese en lugar fresco, seco y bien ventilado. No es corrosivo ni inflamable. Si el transporte sufriese algún accidente, siga las indicaciones específicas en las hojas de transportación y avise a la autoridad más cercana; deslinde el área en cuestión, colocando los residuos por derrame en un lugar seguro.

USOS

- AGRÍCOLA
- INDUSTRIAL
- URBANO

CONCENTRACIÓN DEL MATERIAL TÉCNICO Y FORMULACIONES

CONCENTRACIÓN DEL PRODUCTO TÉCNICO

MATERIAL TÉCNICO SÓLIDO 950 g. I.A./KG.

FORMULACIONES COMERCIALIZALES AGRÍCOLAS

GRANULO DISPERSABLE	800 g. I.A./KG.
POLVO HUMECTABLE	800 g. I.A./KG.

FORMULACIONES COMERCIALIZALES URBANAS

POLVO HUMECTABLE	800 g. I.A./KG.

PLAGUICIDAS CON QUE SE PUEDA MEZCLAR EL FOSETIL ALUMINIO

FOSETIL ALUMINIO + CYMOXANIL
FOSETIL ALUMINIO + CYMOXANIL + FOLPET
FOSETIL ALUMINIO + FOLPET
FOSETIL ALUMINIO + MANCOZEB
FOSETIL ALUMINIO + METALAXIL
FOSETIL ALUMINIO + MENFENOXAM
FOSETIL ALUMINIO + SULFATO DE ESTREPTOMICINA
FOSETIL ALUMINIO + TIABENDAZOL.

ALLEATO® esta autorizado en México en los siguientes cultivos para prevención y control de las enfermedades que a continuación se indican.

CULTIVO	ENFERMEDAD	DOSIS kg/ha	OBSERVACIONES
Limón Toronjo (1) Naranjo Mandarino	Gomosis de los cítricos *(Phytophtora parasítica)*	2.0-2.5	Aplique al follaje de manera preventiva o cuando observe los primeros síntomas de la enfermedad. Realice 3 aplicaciones a intervalos de 30 días.
Aguacatero (30)	Tristeza del aguacatero *(Phytophthora cinnamomi)*	0.2-0.4 kg/100 L de agua	Empiece las aplicaciones cuando las condiciones climáticas sean favorables para la aparición y desarrollo de la enfermedad, aunque no se observen los síntomas, realice tres aplicaciones a intervalos de 30 días según la necesidad para mantener el control.
Papa (14) Jitomate (14)	Tizón tardío *(Phytophthora infestans)*	2.5-3.0	Empiece las aplicaciones cuando las condiciones climáticas sean favorables para la aparición y desarrollo de la enfermedad y repita semanalmente según la necesidad para mantener el control.
Pepino Melón Calabaza (SL) Calabacita Sandía	Mildiu del pepino *(Pseudoperonospora cubensis)*	2.0-3.0	Empiece las aplicaciones cuando las condiciones climáticas sean favorables para la aparición y desarrollo de la enfermedad y repita semanalmente según la necesidad para mantener el control.
( )= Intervalo de seguridad en días SL= Sin Límite			

ALLEATO® ESTÁ REGISTRADO EN ESTADOS UNIDOS Y SUS TOLERANCIAS CON EL LÍMITE MÁXIMO DE RESIDUOS (LMR) EN EPA, SON :

Federal Register Environmental Documents

Fosetyl-Al; Pesticide Tolerance for Emergency Exemptions

Related Material

* Other Related Documents

[**Federal Register: July 14, 1999 (Volume 64, Number 134)**]
[Rules and Regulations]
[Page 37870-37875]
From the Federal Register Online via GPO Access [wais.access.gpo.gov]
[DOCID:fr14jy99-10]

ENVIRONMENTAL PROTECTION AGENCY
40 CFR Part 180
[OPP-300889; FRL-6089-8]
RIN 2070-AB78

Fosetyl-Al; Pesticide Tolerance for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).
ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for residues of fosetyl-Al [Aluminum tris (O-ethylphosphonate)] in or on succulent peas. This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing seed treatment use of the pesticide on peas. This regulation establishes a maximum permissible level for residues of fosetyl-Al in this food commodity pursuant to section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996. The tolerance will expire and is revoked on September 31, 2000.

DATES: This regulation is effective July 14, 1999. Objections and requests for hearings must be received by EPA on or before September 13, 1999.

ADDRESSES: Written objections and hearing requests, identified by the docket control number [OPP-300889], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ``Tolerance Petition Fees" and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, [OPP-300889], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 119, Crystal Mall 2 (CM #2), 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epa.gov. Copies of electronic objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1/6.1 or ASCII file format. All copies of electronic objections and hearing requests must be identified by the docket control number [OPP-300889]. No Confidential Business Information (CBI) should be submitted through e-mail. Copies of electronic objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Stephen Schaible, 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. 271, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703)308-9362, schaible.stephen@epa.gov.

SUPPLEMENTARY INFORMATION: EPA, on its own initiative, pursuant to sections 408(l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, is establishing a tolerance for residues of the fungicide fosetyl-Al, in or on peas, succulent at 1.0 parts per million (ppm). This tolerance will expire and is revoked on September 31, 2000. EPA will publish a document in the Federal Register to remove the revoked tolerance from the Code of Federal Regulations.

I. Background and Statutory Findings

The Food Quality Protection Act of 1996 (FQPA) (Public Law 104-170) was signed into law August 3, 1996. FQPA amends both the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 301 et seq., and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 et seq. The FQPA amendments went into effect immediately. Among other things, FQPA amends FFDCA to bring all EPA pesticide tolerance-setting activities under a new section

408 with a new safety standard and new procedures. These activities are described in this preamble and discussed in greater detail in the final rule establishing the time-limited tolerance associated with the emergency exemption for use of propiconazole on sorghum (61 FR 58135, November 13, 1996) (FRL-5572-9).

New section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is [[Page 37871]] ``safe.'' Section 408(b)(2)(A)(ii) defines ``safe'' to mean that ``there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ``ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .''

Section 18 of FIFRA authorizes EPA to exempt any Federal or State agency from any provision of FIFRA, if EPA determines that ``emergency conditions exist which require such exemption.'' This provision was not amended by FQPA. EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

Section 408(l)(6) of the FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of FIFRA. Such tolerances can be established without providing notice or period for public comment. Because decisions on section 18-related tolerances must proceed before EPA reaches closure on several policy issues relating to interpretation and implementation of the FQPA, EPA does not intend for its actions on such tolerances to set binding precedents for the application of section 408 and the new safety standard to other tolerances and exemptions.

II. Emergency Exemption for Fosetyl-Al on Peas, Succulent and FFDCA Tolerances

According to the Applicant, wet conditions in 1998 contributed to severe outbreak of downy mildew in many pea fields in Washington and Idaho. There is concern that a significant outbreak of downy mildew will occur in 1999 because oospores have the ability to survive for 10-15 years. Because of a lack of resistance to the pathogen in commercially grown pea varieties and development of resistance in the pest population to the commercially used fungicides metalaxyl and menfenoxam, an emergency situation has arisen. EPA has authorized under FIFRA section 18 the seed treatment use of fosetyl-Al on peas for control of downy mildew in Washington and Idaho. After having reviewed the submission, EPA concurs that emergency conditions exist for these States.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of fosetyl-Al in or on peas. In doing so, EPA considered the safety

standard in FFDCA section 408(b)(2), and EPA decided that the necessary tolerance under FFDCA section 408(l)(6) would be consistent with the safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption in order to address an urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing this tolerance without notice and opportunity for public comment under section 408(e), as provided in section 408(l)(6). Although this tolerance will expire and is revoked on September 31, 2000, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on peas, succulent after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA, and the residues do not exceed a level that was authorized by this tolerance at the time of that application. EPA will take action to revoke this tolerance earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because this tolerance is being approved under emergency conditions, EPA has not made any decisions about whether fosetyl-Al meets EPA's registration requirements for use on peas or whether a permanent tolerance for this use would be appropriate. Under these circumstances, EPA does not believe that this tolerance serves as a basis for registration of fosetyl-Al by a State for special local needs under FIFRA section 24(c). Nor does this tolerance serve as the basis for any State other than Washington and Idaho to use this pesticide on this crop under section 18 of FIFRA without following all provisions of EPA's regulations implementing section 18 as identified in 40 CFR part 166. For additional information regarding the emergency exemption for fosetyl-Al, contact the Agency's Registration Division at the address provided under the ``ADDRESSES'' section.

III. Aggregate Risk Assessment and Determination of Safety

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL-5754-7).

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of fosetyl-Al and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a time-limited tolerance for residues of fosetyl-Al on peas, succulent at 1.0 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by fosetyl-Al are discussed in this unit.

B. Toxicological Endpoint

1. Acute toxicity. No appropriate endpoint attributable to a single dose exposure was identified in acute oral toxicity studies. Therefore, risk assessments for these exposure scenarios were not conducted.

2. Short- and intermediate-term toxicity. No toxicological endpoints of concern were identified for short-term and intermediate-term dermal exposure or inhalation exposure for all time periods. Risk assessments for these exposure scenarios were not conducted.

3. Chronic toxicity. EPA has established the Reference Dose (RfD) for fosetyl-Al at 2.5 milligrams/kilograms/day (mg/kg/day). This RfD is based on a no observed adverse effect level (NOAEL) of 250 mg/kg/day, taken from a 2-year chronic study in dogs in which testicular degeneration was observed at the lowest observed adverse effect level (LOAEL) of 500 mg/kg/day. An uncertainty factor (UF) of 100 was employed to account for inter- and intraspecies variability. As the 10x safety factor was removed, the chronic population adjusted dose (cPAD) is equal to the RfD. The cPAD is calculated by dividing the RfD by the appropriate safety factor in situations where it is decided an additional safety factor should be retained. The cPAD will differ from the RfD in situations where the decision is made to retain either a 10x or 3x safety factor.

4. Carcinogenicity. Fosetyl-Al is unlikely to pose a carcinogenic hazard to humans. Effects observed in rats occurred under extremely high doses, under conditions not anticipated to occur outside of the laboratory.

C. Exposures and Risks

1. From food and feed uses. Tolerances have been established (40 CFR 180.415) for the residues of fosetyl-Al, in or on a variety of raw agricultural commodities. Risk assessments were conducted by EPA to assess dietary exposures and risks from fosetyl-Al as follows:

i. Acute exposure and risk. Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. No toxicological endpoints were identified which could be attributable to a single dietary exposure. Therefore, a risk assessment for this exposure scenario was not conducted.

ii. Chronic exposure and risk. Tolerance level residues and 100% crop treated were assumed to calculate theoretical maximum residue contributions (TMRCs) from published and proposed uses for the United States (U.S.) population and population subgroups. Chronic exposure for the U.S. population represents 3% of the Cpad.

2. From drinking water. Fosetyl-Al is not expected to reach ground or surface water under most conditions. The residues that do reach surface water will likely be rapidly degraded by microbial metabolism. There is no established Maximum Contaminant Level (MCL) for residues of fosetyl-Al in drinking water.

The Agency has calculated drinking water levels of comparison (DWLOCs) for chronic exposure to fosetyl-Al residues in surface and ground water. These DWLOCs are calculated by subtracting from the cPAD the respective chronic dietary exposure attributable to food to obtain the acceptable exposure to fosetyl-Al in drinking water. Default body weights (70 kg for males, 60 kg for females, and 10 kg for infants and children) and default drinking water consumption estimates (2 L/day for adults, 1 L/day for infants and children) are then used to calculate the actual DWLOCs. The DWLOC represents the concentration level in surface water or ground water at which aggregate exposure to the chemical is not of concern.

Using Generic Expected Environmental Concentration (GENEEC) and Screening Concentration in Ground Water (SCI-GROW) models (for surface and ground water, respectively), the Agency has calculated chronic Tier I Estimated Environmental Concentrations (EECs) for fosetyl-Al for use in human health risk assessments. These values represent the upper bound estimates of the concentrations of fosetyl-Al that might be found in surface water and ground water assuming the maximum application rate allowed on the label of the highest use pattern. The EECs from these models are compared to the DWLOCs to make the safety determination.

i. Acute exposure and risk. No toxicological endpoints were identified which could be attributable to a single dietary exposure. Therefore, a risk assessment for this exposure scenario was not conducted.

ii. Chronic exposure and risk. Using the SCI-GROW model, the maximum long-term EEC in ground water is not expected to exceed 0.0046 parts per billion (ppb). The chronic EEC in surface water is 9 ppb. The DWLOC for the U.S. population was calculated to be 85,000 ppb. As even the upper bound concentrations of fosetyl-Al in ground water and surface water are not expected to exceed the DWLOC, the Agency concludes with reasonable certainty that chronic exposure to fosetyl-Al in drinking water is not of concern.

3. From non-dietary exposure. Fosetyl-Al is currently registered for use on the following residential non-food sites: lawn, turf, and ornamental plants. However, no toxicological endpoints of concern were identified for short-term and intermediate-term dermal exposure or inhalation exposure for all time periods, and risk assessments for these exposure scenarios were not conducted. Long-term (chronic) exposure is not expected for residential uses.

4. Cumulative exposure to substances with a common mechanism of toxicity. Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ``available information'' concerning the cumulative effects of a particular pesticide's residues and ``other substances that have a common mechanism of toxicity." EPA does not have, at this time, available data to determine whether fosetyl-Al has a

common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, fosetyl-Al does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that fosetyl-Al has a common mechanism of toxicity with other substances. For more information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

D. Aggregate Risks and Determination of Safety for U.S. Population

1. Acute risk. No toxicological endpoints were identified which could be attributable to a single dose exposure. Therefore, a risk assessment for this exposure scenario was not conducted.

2. Chronic risk. Using the TMRC exposure assumptions described in this unit, EPA has concluded that aggregate exposure to fosetyl-Al from food will utilize 3% of the cPAD for the U.S. population. The major identifiable subgroup with the highest aggregate exposure is children, 1-6 years (discussed below). EPA generally has no concern for exposures below 100% of the RfD (cPAD) because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Estimated chronic environmental concentrations of fosetyl-Al in surface water and ground water do not exceed chronic DWLOCs calculated by the Agency. EPA does not expect the aggregate exposure to exceed 100% of the cPAD.

3. Short- and intermediate-term risk. Short- and intermediate-term aggregate exposure takes into account chronic dietary food and water (considered to be a background exposure level) plus indoor and outdoor residential exposure. No toxicological endpoints of concern were identified for short-term and intermediate-term dermal exposure or inhalation exposure for all time periods. Risk assessments for these exposure scenarios were not conducted.

4. Aggregate cancer risk for U.S. population. Fosetyl-Al is unlikely to pose a carcinogenic hazard to humans. Effects observed in rats occurred under extremely high doses, under conditions not anticipated to occur outside of the laboratory.

5. Determination of safety. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to fosetyl-Al residues.

E. Aggregate Risks and Determination of Safety for Infants and Children

1. Safety factor for infants and children --

i. In general. In assessing the potential for additional sensitivity of infants and children to residues of fosetyl-Al, EPA considered data from developmental toxicity studies in the rat and rabbit and a

2-generation reproduction study in the rat. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from maternal pesticide exposure during gestation. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for pre- and postnatal toxicity and the completeness of the database unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a margin of exposure (MOE) analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. EPA believes that reliable data support using the standard MOE and uncertainty factor (usually 100 for combined inter- and intraspecies variability) and not the additional tenfold MOE/uncertainty factor when EPA has a complete data base under existing guidelines and when the severity of the effect in infants or children or the potency or unusual toxic properties of a compound do not raise concerns regarding the adequacy of the standard MOE/safety factor.

ii. Developmental toxicity studies. In the developmental toxicity study in rats, developmental effects in pups occurred only in the presence of maternal toxicity and at four times the limit dose (developmental LOAEL = 4,000 mg/kg/day). In the prenatal developmental toxicity study in rabbits, no evidence of developmental toxicity was seen at the limit dose.

iii. Reproductive toxicity study. In the multi-generation reproduction study in rats, offspring effects occurred only at parentally toxic dose levels.

iv. Pre- and postnatal sensitivity. The available studies showed no evidence of increased susceptibility of fetus/pups in the developmental or reproductive toxicity studies. The Agency supports removal of the 10x safety factor for aggregate risk assessment.

v. Conclusion. There is a complete toxicity database for fosetyl-Al and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures.

2. Acute risk. No toxicological endpoints were identified which could be attributable to a single dietary exposure. Therefore, a risk assessment for this exposure scenario was not conducted.

3. Chronic risk. Using the exposure assumptions described in this unit, EPA has concluded that aggregate exposure to fosetyl-Al from food will utilize 6% of the cPAD/RfD for infants and children. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Estimated chronic environmental concentrations of fosetyl-Al in surface water and ground water do not exceed chronic DWLOCs calculated by the Agency. EPA does not expect the aggregate exposure to exceed 100% of the RfD.

4. Short- or intermediate-term risk. No toxicological endpoints of concern were identified for short-term and intermediate-term dermal exposure or inhalation exposure for all time periods. Risk assessments for these exposure scenarios were not conducted.

5. Determination of safety. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to fosetyl-Al residues.

IV. Other Considerations

A. Metabolism in Plants and Animals

The nature of the residue in plants is adequately understood. The residue of concern is parent fosetyl-Al. There are no livestock feed items associated with the proposed seed treatment use on peas.

B. Analytical Enforcement Methodology

Adequate enforcement methodology is available to enforce the tolerance expression (associated with petition number 5F3251). The method may be requested from: Calvin Furlow, PRRIB, IRSD (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm 101FF, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305-5229.

C. Magnitude of Residues

Residues of fosetyl-Al are not expected to exceed 1.0 ppm in/on succulent peas as a result of the proposed seed treatment use on peas. Secondary residues are not expected in animal commodities as there are no feed items associated with succulent peas.

D. International Residue Limits

There are no Codex, Canadian or Mexican Maximum Residue Limits (MRLs) for fosetyl-Al on peas.

E. Rotational Crop Restrictions

No rotational crop restrictions are required for this chemical, due to its extremely short half-life in soil.

V. Conclusion

Therefore, the tolerance is established for residues of fosetyl-Al in peas, succulent at 1.0 ppm.

VI. Objections and Hearing Requests

The new FFDCA section 408(g) provides essentially the same process for persons to ``object'' to a tolerance regulation as was provided in the old section 408 and in section 409. However, the period for filing objections is 60 days, rather than 30 days. EPA currently has procedural regulations which govern the submission of objections and hearing requests. These regulations will require some modification to reflect the new law. However, until those modifications can be made, EPA will continue to use those procedural regulations with appropriate adjustments to reflect the new law.

Any person may, by September 13, 1999, file written objections to any aspect of this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given under the ``ADDRESSES'' section (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). EPA is authorized to waive any fee requirement ``when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.'' For additional information regarding tolerance objection fee waivers, contact James Tompkins, 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. 239, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305-5697, tompkins.jim@epa.gov. Requests for waiver of tolerance objection fees should be sent to James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

If a hearing is requested, the objections must include a statement of the factual issues on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the requestor (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). Information submitted in connection with an objection or hearing request 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 information 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. VII. Public Record and Electronic Submissions

EPA has established a record for this regulation under docket control number [OPP-300889] (including any comments and data submitted electronically). 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 public record is located in Rm. 119 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA.

Objections and hearing requests may be sent by e-mail directly to EPA at:

opp-docket@epa.gov

E-mailed objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this regulation, as well as the public version, as described in this unit will be kept in paper form. Accordingly, EPA will transfer any copies of objections and hearing requests received electronically into printed, paper form as they are received and will place the paper copies in the official record which will also include all comments submitted directly in writing. The official record is the paper record maintained at the Virginia address in ``ADDRESSES'' at the beginning of this document.

VIII. Regulatory Assessment Requirements

A. Certain Acts and Executive Orders

This final rule establishes a tolerance under section 408 of the FFDCA. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled Regulatory Planning and Review (58 FR 51735, October 4, 1993). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 et seq., or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4). Nor does it require any special considerations as required by Executive Order 12898, entitled Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations (59 FR 7629, February 16, 1994), or require OMB review in accordance with Executive Order 13045, entitled Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997).

In addition, since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(l)(6), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 et seq.) do not apply. Nevertheless, the Agency previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on

May 4, 1981 (46 FR 24950), and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

B. Executive Order 12875

Under Executive Order 12875, entitled Enhancing the Intergovernmental Partnership (58 FR 58093, October 28, 1993), EPA may not issue a regulation that is not required by statute and that creates a mandate upon a State, local or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments. If the mandate is unfunded, EPA must provide to OMB a description of the extent of EPA's prior consultation with representatives of affected State, local, and tribal governments, the nature of their concerns, copies of any written communications from the governments, and a statement supporting the need to issue the regulation. In addition, Executive Order 12875 requires EPA to develop an effective process permitting elected officials and other representatives of State, local, and tribal governments ``to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates."

Today's rule does not create an unfunded Federal mandate on State, local, or tribal governments. The rule does not impose any enforceable duties on these entities. Accordingly, the requirements of section 1(a) of Executive Order 12875 do not apply to this rule.

C. Executive Order 13084

Under Executive Order 13084, entitled Consultation and Coordination with Indian Tribal Governments (63 FR 27655, May 19, 1998), EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments. If the mandate is unfunded, EPA must provide OMB, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments ``to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities."

Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. This action does not involve or impose any requirements that affect Indian tribes. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

IX. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 et seq., as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the Agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives and the Comptroller General of the United States prior to publication of the rule in the Federal Register. This rule is not a ``major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: June 28, 1999.

James Jones,
Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346(a) and 371.

2. In Sec. 180.415, by revising paragraph (b) to read as follows:

Sec. 180.415 Aluminum tris (O-ethylphosphonate); tolerances for residues.

* * * * *

(b) Section 18 emergency exemptions. A time-limited tolerance is established for residues of the fungicide aluminum tris (O-ethylphosphonate) in connection with use of the pesticide under section
18 emergency exemptions granted by EPA. This tolerance will expire and is revoked on the dates specified in the following table.

Commodity	Parts per million	Expiration/ revocation date
Peas, succulent	1.0	9/31/00

ALLEATO® ESTÁ REGISTRADO EN CANADA Y SUS TOLERANCIAS CON EL LÍMITE MÁXIMO DE RESIDUOS (LMR), SON:

FOOD AND DRUGS ACT
Regulations Amending the Food and Drug Regulations
(1315 — Fosetyl-aluminum)

P.C. 2003-1830 19 November, 2003

Her Excellency the Governor General in Council, on the recommendation of the Minister of Health, pursuant to subsection 30(1) (see footnote a) of the Food and Drugs Act, hereby makes the annexed Regulations Amending the Food and Drug Regulations (1315 — Fosetyl-aluminum).

REGULATIONS AMENDING THE FOOD AND DRUG REGULATIONS (1315 — FOSETYL-ALUMINUM)

AMENDMENT

1. The portion of item F.5 of Table II to Division 15 of Part B of the Food and Drug Regulations (see footnote 1) in column IV is replaced by the following:

No.	III	
Maximum Residue Limit p.p.m.	IV	
Foods		
F.5	100	Celery, lettuce, spinach
	75	Strawberries
	60	Bok choy cabbage, broccoli, cabbage, cauliflower, Chinese broccoli, mustard greens
	15	Cantaloupes, cucumbers, squash
	10	Avocados
	3	Tomatoes
	1	Apples
	0.5	Onions (dry)

COMING INTO FORCE

2. These Regulations come into force on the day on which they are registered.

HELM DE MÉXICO, S.A.

REGULATORY IMPACT
ANALYSIS STATEMENT

(This statement is not part of the Regulations.)

Description

Fosetyl-aluminum is registered under the Pest Control Products Act as a systemic fungicide with protective and curative action for use on apples and lettuce. Maximum Residue Limits (MRLs) have been established under the Food and Drugs Act for residues of fosetyl-aluminum resulting from its use in Canada and other countries at 100 parts per million (ppm) in celery, lettuce and spinach; 75 ppm in strawberries; 60 ppm in broccoli, cabbage, cauliflower and mustard greens; 15 ppm in cantaloupes, cucumbers, and squash; 10 ppm in avocados; 3 ppm in tomatoes; 1 ppm in apples and 0.5 ppm in onions (dry). By virtue of subsection B.15.002(1) of the Food and Drug Regulations, the MRL for other foods is 0.1 ppm.

The Pest Management Regulatory Agency (PMRA), of Health Canada, has recently approved an application to amend the registration of fosetyl- aluminum in order to allow its use for the control of downy mildew on bok choy cabbage and Chinese broccoli. This regulatory amendment will establish an MRL for residues of fosetyl-aluminum resulting from this use in bok choy cabbage and Chinese broccoli, in order to permit the sale of food containing these residues.

Before making a registration decision regarding a new use of a pest control product, the PMRA conducts the appropriate assessment of the risks and value of the product specific to its proposed use. The registration of the pest control product will be amended if: the data requirements for assessing value and safety have been adequately addressed; the evaluation indicates that the product has merit and value; and the human health and environmental risks associated with its proposed use are acceptable.

The human health risk assessment includes an assessment of dietary risks posed by expected residues of the pest control product, as determined through extensive toxicological studies. An acceptable daily intake (ADI) and/or acute reference dose (ARD) is calculated by applying a safety factor to a no observable adverse effect level or, in appropriate cases, by applying a risk factor which is calculated based on a linear low-dose extrapolation. The potential daily intake (PDI) is calculated from the amount of residue that remains on each food when the pest control product is used according to the proposed label and the intake of that food from both domestic and imported sources in the diet. PDIs are established for various Canadian subpopulations and age groups, including infants, toddlers, children, adolescents and adults. Provided the PDI does not exceed the ADI or ARD for any subpopulation or age group, and the lifetime risk is acceptable, the expected residue levels are established as MRLs under the Food and Drugs Act to prevent the sale of food with higher residue levels. Since, in most cases, the PDI is well below the ADI and lifetime risks are very low when MRLs are originally established, additional MRLs for the pest control product may be added in the future.

After the review of all available data, the PMRA has determined that an MRL for fosetyl-aluminum of 60 ppm in bok choy cabbage and Chinese broccoli would not pose an unacceptable health risk to the public.

Alternatives

Under the Food and Drugs Act, it is prohibited to sell food containing residues of pest control products at a level greater than 0.1 ppm unless a higher MRL has been established in Table II, Division 15, of the Food and Drug Regulations. In the case of fosetyl-aluminum, establishment of an MRL for bok choy cabbage and Chinese broccoli is necessary to support the additional use of a pest control product which has been shown to be both safe and effective, while at the same time preventing the sale of food with unacceptable residues.

As a means to improve the responsiveness of the regulatory system, an Interim Marketing Authorization (IMA) was issued on November 9, 2002, to permit the immediate sale of Chinese broccoli and bokchoy cabbage containing residues of fosetyl-aluminum with an MRL of 60 ppm while the regulatory process to formally amend the Regulation is undertaken.

Benefits and Costs

The use of fosetyl-aluminum on bok choy cabbage and Chinese broccoli will provide joint benefits to consumers and the agricultural industry as a result of improved management of pests. In addition, this regulatory amendment will contribute to a safe, abundant and affordable food supply by allowing the importation and sale of food commodities containing acceptable levels of pesticide residues.

Some costs may be incurred related to the implementation of analytical methods for analysis of fosetyl-aluminum in the foods mentioned above. Resources required are not expected to result in significant costs to the government.

Consultation

Registration decisions, including dietary risk assessments, made by the PMRA are based on internationally recognized risk management principles, which are largely harmonized among member countries of the Organization for Economic Cooperation and Development. Individual safety evaluations conducted by the PMRA include a review of the assessments conducted at the international level as part of the Joint Food and Agriculture Organization of the United Nations/World Health Organization Food Standards Programme in support of the Codex Alimentarius Commission, as well as MRLs adopted by other national health/regulatory agencies.

This schedule of amendment was pre-published in the Canada Gazette, Part I, on May 10, 2003. Interested parties were invited to make representations concerning the proposed amendment. No responses were received.

ALLEATO® ESTÁ REGISTRADO EN ESPAÑA Y SUS TOLERANCIAS CON EL LÍMITE MÁXIMO DE RESIDUOS (LMR), SON:

Fosetil-Al

CODIGO	PRODUCTO	LIMITE (mg/Kg)
0101	Citricos	6
0102	Frutos con o sin cascara	0,2
0103	Frutos de pepita	1
0104	Frutos de hueso	0,2
010501	Uvas de mesa y vinificacion	2
010502	Fresas (distintas de silvestres)	0,5
010503	Frutas de caña(distintas de las silvestres)	0,2
010504	Otras bayas y frutas pequeñas(distintas de silves)	0,2
010505	Bayas y frutas silvestres	0,2
010601	Aguacates	1
010602	Platanos	0,2
010603	Datiles	0,2
010604	Higos	0,2
010605	Kiwis	0,2
010606	Kumquats	0,2
010607	Lichis	0,2
010608	Mangos	0,2
010609	Aceitunas	0,2
010610	Frutos de la pasion	0,2
010611	Piñas	0,2
010612	Granadas	0,2
010613	Chirimoyas	0,2
010614	Otras frutas.otros	0,2
0201	Raices y tuberculos	0,2
0202	Bulbos	0,2
0203	Frutos y peponides	1
0204	Hortalizas del genero brassica	0,2
02050101	Berros	0,2
02050102	Canonigos	0,2
02050103	Lechugas	2
02050104	Escarolas	0,2
02050105	Otras lechugas y similares	0,2
020502	Espinacas y similares	2
020503	Berros de agua	0,2
020504	Endibias	0,5

020505	Hierbas aromaticas	0,2
020601	Judias (con vaina)	1
020602	Judias (sin vaina) incluye habas	1
020603	Guisantes (sin vaina)	2
020604	Guisante con vaina	1
020605	Otras leguminosas verdes	1
0207	Tallos jovenes	0,2
0208	Hongos y setas	0,2
03	Legumbres secas	0,2
04	Semillas oleaginosas y otras	0,2
05	Patatas	1
06	Te y otras infusiones	0,2
07	Lupulos (desecados)incl.los granulados y polvo	100
08	Especias	0,2
09	Cereales	0,2
10	Otros productos de consumo	0,2
11	Forrajes y pajas	0,2

ALLEATO® ESTÁ REGISTRADO EN JAPON Y SUS TOLERANCIAS CON EL LÍMITE MÁXIMO DE RESIDUOS (LMR), SON:

MRLs for Agricultural Chemicals in JAPAN

FOSETYL

Foods	MRLs (ppm)
Potato	35
Watercress	60
Chinese cabbage	100
Cabbage	100
Brussels sprouts	100
Kale	60

Cauliflower	60
Broccoli	60
Other Cruciferous vegetables	100
Artichoke	100
Chicory	100
Endive	100
SHUNGIKU	100
Lettuce (Cos lettuce, Leaf lettuce)	100
Other Composite vegetables	100
Onion	50
Welsh (including Leek)	100
Garlic	50
Asparagus	100
Multiplying onion (including Shallot)	100
Other Liliaceous vegetables	100
Parsley	100
Celery	100
Other Umbelliferous vegetables	100
Tomato	100

Cucumber (including Gherkin)	100
Pumpkin (including Squash)	100
Water melon Melons Other cucurbitaceous vegetables	15 70 15
Spinach Other Vegetables	100 100
UNSHU orange	20
NATSUDAIDAI (whole) Lemon Orange (including Navel)	150 150 150
Grapefruit	150
Lime	150
Other Citrus fruits	150
Apple	75
Japanese pear	50
Pear	50
Quince Loquat Peach	10 10 150

Strawberry	75
Raspberry	70
Blackberry	70
Blueberry	70
Other berries	70
Grape	70
Kiwifruit	70
Avocado	150
Pineapple	80
Cotton seeds	3
Hop	1440

[Note] N.D.: Not detected.

LIGERAMENTE TÓXICO

M.R.
MARCA REGISTRADA