

### III. Procedures for Withdrawal of Request

Registrants who choose to withdraw a request for cancellation must submit such withdrawal in writing to James A. Hollins, at the address given above, postmarked before November 22, 1999. This written withdrawal of the request for cancellation will apply only to the applicable 6(f)(1) request listed in this notice. If the product(s) have been subject to a previous cancellation action, the effective date of cancellation and all other provisions of any earlier cancellation action are controlling. The withdrawal request must also include a commitment to pay any reregistration fees due, and to fulfill any applicable unsatisfied data requirements.

### IV. Provisions for Disposition of Existing Stocks

The effective date of cancellation will be the date of the cancellation order. The orders effecting these requested cancellations will generally permit a registrant to sell or distribute existing stocks for 1 year after the date the cancellation request was received. This policy is in accordance with the Agency's statement of policy as prescribed in **Federal Register** (56 FR 29362) June 26, 1991; [FRL 3846-4]. Exceptions to this general rule will be made if a product poses a risk concern, or is in noncompliance with reregistration requirements, or is subject to a data call-in. In all cases, product-specific disposition dates will be given in the cancellation orders.

Existing stocks are those stocks of registered pesticide products which are currently in the United States and which have been packaged, labeled, and released for shipment prior to the

effective date of the cancellation action. Unless the provisions of an earlier order apply, existing stocks already in the hands of dealers or users can be distributed, sold or used legally until they are exhausted, provided that such further sale and use comply with the EPA-approved label and labeling of the affected product(s). Exceptions to these general rules will be made in specific cases when more stringent restrictions on sale, distribution, or use of the products or their ingredients have already been imposed, as in Special Review actions, or where the Agency has identified significant potential risk concerns associated with a particular chemical.

#### List of Subjects

Environmental protection, Pesticides and pests, Product registrations.

Dated: May 13, 1999.

**Richard D. Schmitt,**

*Acting Director, Information Resources and Services Division, Office of Pesticide Programs.*

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### ENVIRONMENTAL PROTECTION AGENCY

[PF-874; FRL-6081-3]

#### 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-874, must be received on or before June 25, 1999.

**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. 119, CM #2, 1921 Jefferson Davis Highway, 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 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. 119 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
JoAnne Miller .....	Rm. 237, CM #2, 703-305-6224, e-mail: miller.joanne@epamail.epa.gov.	1921 Jefferson Davis Hwy, Arlington, VA Do.
Bipin C. Gandhi .....	Rm. 707A, CM #2, 703-305-7740, e-mail: gandhi.bipin@epamail.epa.gov.	

**SUPPLEMENTARY INFORMATION:** EPA has received pesticide petitions as follows proposing the establishment and/or amendment of regulations for residues of certain pesticide chemicals in or on various food commodities under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that these petitions contain data or information regarding the elements set forth in section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data supports granting of the

petition. Additional data may be needed before EPA rules on the petition.

The official record for this notice of filing, as well as the public version, has been established for this notice of filing under docket control number [PF-874] (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. Comments 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 control number [PF-874] and appropriate petition number. Electronic comments this 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: May 13, 1999.

**James Jones,**

*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. Novartis Crop Protection, Inc.

PP 7F4897

EPA has received an amended pesticide petition (7F4897) from Novartis Crop Protection, Inc., P.O. Box 18300, Greensboro, NC 27419 proposing, pursuant to section 408(d) of the FFDCA, 21 U.S.C. 346a(d), to amend 40 CFR part 180.368 by establishing and amending current tolerances for residues of metolachlor (2-chloro-N-(2-ethyl-6-methylphenyl)-N-(2-methoxy-1-methylethyl)acetamide and its metabolites, determined as the derivatives, 2-[(2-ethyl-6-methylphenyl)amino]-1-propanol and 4-(2-ethyl-6-methylphenyl)-2-hydroxy-5-methyl-3-morpholinone, each expressed as the parent compound, in or on the raw agricultural commodities sunflower seed at 0.5 parts per million (ppm); sunflower meal at 1.0 ppm; sugar beet tops at 15.0 ppm; sugar beet roots at 0.5 ppm; sugar beet dried pulp at 1.0 ppm; sugar beet molasses at 3.0 ppm; cotton gin trash at 5.0 ppm; liver (of goats, hogs, horses, sheep, cattle) at 0.1 ppm and kidney (of goats, hogs, horses, sheep, cattle) at 0.5 ppm. EPA has determined that the petition contains data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; however, EPA has not fully

evaluated the sufficiency of the submitted data at this time or whether the data supports granting of the petition. Additional data may be needed before EPA rules on the petition.

#### A. Residue Chemistry

1. *Plant metabolism.* The qualitative nature of the metabolism of metolachlor in plants is well understood. Metabolism in plants involves conjugation of the chloroacetyl side chain with glutathione, with subsequent conversion to the cysteine and thiolactic acid conjugates. Oxidation to the corresponding sulfoxide derivatives occurs and cleavage of the side chain ether group, followed by conjugation with glucose.

2. *Analytical method.* Novartis has submitted a practical analytical method involving extraction by acid reflux, filtration, partition and cleanup with analysis by gas chromatography using Nitrogen/Phosphorous (N/P) detection. The methodology converts residues of metolachlor into a mixture of CGA-37913 and CGA-49751. The limit of quantitation (LOQ) for the method is 0.03 ppm for CGA-37913 and 0.05 ppm for CGA-49751.

3. *Magnitude of residues—i. Sunflower.* A total of 15 residue trials were conducted in major sunflower growing areas of the United States. Applications were made at 1- and 2x the maximum labeled rate of 3.0 lbs. ai/A (metolachlor). Processing was also conducted with seeds processed into meal, hulls, crude oil, refined oil and soapstock. Based on these studies, tolerances are proposed in sunflower seed at 0.5 ppm and in sunflower meal at 1.0 ppm.

ii. *Sugarbeets.* Eleven sugar beet trials were conducted using six different treatment scenarios. The maximum 1x use rate was 4.0 lbs. active ingredient (ai)/A of S-metolachlor applied preplant surface or preplant incorporated (1.33 lbs. ai/A) plus a post foliar spray (2.66 lbs. ai/A). 3x and 5x treatments were also conducted. Maximum residues at the 1x rate were 14 ppm in sugar beet tops and 0.32 ppm in sugar beet roots. Using theoretical animal diets, Novartis determined that current tolerances for metolachlor in kidney and liver may not be adequate to cover residues resulting from the feeding of sugar beet tops in combination with peanut hay and sorghum grain. In the processing study, it was determined that tolerances would be required in dried pulp and molasses, but not in refined sugar.

iii. *Cotton.* Results of data submitted September 1998, to address an EPA request for residue data to determine residues of metolachlor in cotton gin

trash indicated a tolerance of 5.0 ppm needed to be established for metolachlor in this raw agricultural commodity (RAC).

#### B. Toxicological Profile

1. *Acute toxicity.* Metolachlor has a low order of acute toxicity. The combined rat oral LD<sub>50</sub> is 2,877 milligrams/kilograms (mg/kg). The acute rabbit dermal LD<sub>50</sub> is > 2,000 mg/kg and the rat inhalations LC<sub>50</sub> is > 4.33 milligrams per liter (mg/L). Metolachlor is not irritating to the skin and eye. It was shown to be positive in guinea pigs for skin sensitization. End use formulations of metolachlor also have a low order of acute toxicity and cause slight skin and eye irritation.

2. *Genotoxicity.* Assays for genotoxicity were comprised of tests evaluating metolachlor's potential to induce point mutations (*Salmonella* assay and an L5178/TK+/- mouse lymphoma assay), chromosome aberrations (mouse micronucleus and a dominant lethal assay) and the ability to induce either unscheduled or scheduled DNA synthesis in rat hepatocytes or DNA damage or repair in human fibroblasts. The results indicate that metolachlor is not mutagenic or clastogenic and does not provoke unscheduled DNA synthesis.

3. *Reproductive and developmental toxicity.* The developmental and teratogenic potential of metolachlor was investigated in rats and rabbits. The results indicate that metolachlor is not embryotoxic or teratogenic in either species at maternally toxic doses. The no-observed adverse effect level (NOAEL) for developmental toxicity for metolachlor was 360 mg/kg/day for both the rat and rabbit, while the NOAEL for maternal toxicity was established at 120 mg/kg/day in the rabbit and 360 mg/kg/day in the rat. A 2-generation reproduction study was conducted with metolachlor in rats at feeding levels of 0, 30, 300 and 1,000 ppm. The reproductive NOAEL of 300 ppm (equivalent to 23.5 to 26 mg/kg/day) was based upon reduced pup weights in the F1a and F2a litters at the 1,000 ppm dose level (equivalent to 75.8 to 85.7 mg/kg/day). The NOAEL for parental toxicity was equal to or greater than the 1,000 ppm dose level.

4. *Subchronic toxicity.* Metolachlor was evaluated in a 21-day dermal toxicity study in the rabbit and a 6-month dietary study in dogs; NOAELs of 100 mg/kg/day and 7.5 mg/kg/day were established in the rabbit and dog, respectively. The liver was identified as the main target organ. Metolachlor was also recently evaluated in a new 90-day subchronic feeding study in rats. The

NOAEL was defined as 300 ppm, corresponding to average daily intakes of 20.2 mg/kg body weight (bwt) in males and 23.4 mg/kg bwt in females.

5. *Chronic toxicity.* A 1 year dog study was conducted at dose levels of 0, 3.3, 9.7, or 32.7 mg/kg/day. The reference dose (RfD) for metolachlor is based on the 1 year dog study with a NOAEL of 9.7 mg/kg/day. The RfD for metolachlor is established at 0.1 mg/kg/day using a 100-fold uncertainty factor. A combined chronic toxicity/oncogenicity study was also conducted in rats at dose levels of 0, 1.5, 15 or 150 mg/kg/day. The NOAEL for systemic toxicity was 15 mg/kg/day.

6. *Animal metabolism.* In animals, metolachlor is rapidly metabolized and almost totally eliminated in the excreta of rats, goats, and poultry. Metabolism in animals proceeds through common Phase 1 intermediates and glutathione conjugation.

7. *Metabolite toxicology.* The metabolism of metolachlor has been well characterized in standard Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) rat metabolism studies. The metabolites found are considered to be toxicologically similar to parent. Metolachlor does not readily undergo dealkylation to form an aniline or quinone imine as has been reported for other members of the chloroacetanilide class of chemicals. Therefore, it is not appropriate to include metolachlor with the group of chloroacetanilides that readily undergo dealkylation, producing a common toxic metabolite (quinone imine).

8. *Endocrine disruption.* Metolachlor does not belong to a class of chemicals known or suspected of having adverse effects on the endocrine system. There is no evidence that metolachlor has any effect on endocrine function in developmental or reproduction studies. Furthermore, histological investigation of endocrine organs in the chronic dog, rat and mouse studies conducted with metolachlor did not indicate that the endocrine system is targeted by metolachlor, even at maximally tolerated doses administered for a lifetime. Although residues of metolachlor have been found in RAC, there is no evidence that metolachlor bioaccumulates in the environment.

### C. Aggregate Exposure

1. *Dietary exposure.* For purposes of assessing the potential dietary exposure to metolachlor, aggregate exposure has been estimated based on the theoretical maximum residue contribution (TMRC) from the use of metolachlor in or on RAC for which tolerances have been previously established (40 FR 180.368). The incremental effect on dietary risk

resulting from the addition of the uses on sunflowers and sugarbeets was also included by conservatively assuming that exposure would occur at the proposed tolerance levels with 100% of the crop treated.

i. *Food.* The TMRC is obtained by multiplying the tolerance level residue for all these RAC by the consumption data which estimates the amount of these products consumed by various population subgroups. Some of these RAC (e.g. corn forage and fodder, peanut hay, sunflower meal, sugarbeet tops) are fed to animals; thus exposure of humans to residues in these fed commodities might result if such residues are transferred to meat, milk, poultry, or eggs. Therefore, tolerances of 0.02 ppm for milk, meat and eggs and 0.2 ppm for kidney and 0.05 ppm for liver have been previously established for metolachlor. Based upon theoretical diets constructed from the sugar beet residue data, Novartis is proposing raising the tolerances in kidney (0.5 ppm) and liver (0.1 ppm) to cover any transfer of residues to animals that may occur from the feeding of treated sugar beet tops. In conducting this exposure assessment, it has been conservatively assumed that 100% of all RAC for which tolerances have been established or proposed in this petition for metolachlor will contain metolachlor residues and those residues would be at the level of the tolerance, which results in an over estimation of human exposure.

ii. *Drinking water.* Another potential source of exposure of the general population to residues of pesticides are residues in drinking water. Environmental fate studies show that metolachlor appears to be moderately persistent and ranges from being mobile to highly mobile in different soils. Based on experience with metolachlor, it is believed metolachlor will be infrequently found in drinking water sources, and when found, will be in the low parts per billion (ppb) range. Metolachlor is not yet regulated under the Safe Drinking Water Act; therefore, no maximum contaminant level (MCL) has been established for it. A 1-10 day Health Advisory Level has been established at 2,000 ppb and a Lifetime Health Advisory Level has been established at 100 ppb. It is not likely that maximum or average concentrations of metolachlor will exceed the 1-10 day HA levels or that annual average metolachlor concentrations will exceed the lifetime HA of 100 ppb. In addition, through the reregistration process, Novartis has amended its labels to include further protections to minimize ground and surface water contamination.

2. *Non-dietary exposure.* Although metolachlor may be used on turf and ornamentals in a residential setting, that use represents less than 0.1% of the total herbicide market for residential turf and landscape uses. No indoor uses of metolachlor are registered. Currently, there are no acceptable, reliable exposure data available to assess any potential risks. However, given the small amount of material that is used, it is concluded that the potential for non-occupational exposure to the general population is unlikely. EPA has identified a toxicity endpoint for intermediate-term residential risks. Based on the high level of this endpoint (NOAEL of 100 mg/kg/day and lowest-observed adverse effect level (LOAEL) of 1,000 mg/kg/day from the 21-day dermal toxicity study in rabbits), EPA has said it does not expect the intermediate-term aggregate risk to exceed the level of concern.

### D. Cumulative Effects

The potential for cumulative effects of metolachlor and other substances that have a common mechanism of toxicity has also been considered. It is concluded that consideration of a common mechanism of toxicity with other registered pesticides in this chemical class (chloroacetamides) is not appropriate. Since EPA itself has stated that the carcinogenic potential of metolachlor is not the same as other registered chloroacetamide herbicides, based on differences in rodent metabolism (EPA Peer Review of metolachlor, 1994), it is believed that metolachlor should only be considered in an aggregate exposure assessment and not a cumulative assessment.

### E. Safety Determination

1. *U.S. population.* Using the conservative exposure assumptions described above, based on the completeness and reliability of the toxicity data, it is concluded that aggregate exposure to metolachlor (including the proposed uses) in food will utilize 2.06% of the RfD for the U.S. population. 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. Despite the potential for exposure to metolachlor in drinking water and from non-dietary, non-occupational exposures, it is not expected that aggregate exposure from all sources will exceed 100% of the RfD. Therefore, one can conclude there is a reasonable certainty that no harm will result from aggregate exposure to metolachlor.

2. *Infants and children.* In assessing the potential for additional sensitivity of infants and children to residues of metolachlor, data from developmental toxicity studies in the rat and rabbit and a 2-generation reproduction study in the rat have been considered. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from chemical exposure during prenatal development to one or both parents. Reproduction studies provide information relating to effects from exposure to a chemical on the reproductive capability of mating animals and data on systemic toxicity.

Developmental toxicity (reduced mean fetal bwt, reduced number of implantations/dam with resulting decreased litter size, and a slight increase in resorptions/dam with a resulting increase in post-implantation loss) was observed in studies conducted with metolachlor in rats and rabbits. The NOAEL's for developmental effects in both rats and rabbits were established at 360 mg/kg/day. The developmental effect observed in the metolachlor rat study is believed to be a secondary effect resulting from maternal stress (lacrimation, salivation, decreased bwt gain and food consumption and death) observed at the limit dose of 1,000 mg/kg/day.

A 2-generation reproduction study was conducted with metolachlor at feeding levels of 0, 30, 300 and 1,000 ppm. The reproductive NOAEL of 300 ppm (equivalent to 23.5 to 26 mg/kg/day) was based upon reduced pup weights in the F1a and F2a litters at the 1,000 ppm dose level (equivalent to 75.8 to 85.7 mg/kg/day). The NOAEL for parental toxicity was equal to or greater than the 1,000 ppm dose level.

FFDCA section 408 provides that EPA may apply an additional safety factor for infants and children in the case of threshold effects to account for pre- and postnatal toxicity and the completeness of the data base. Based on the current toxicological data requirements, the data base relative to pre- and postnatal effects for children is complete. Further, for the chemical metolachlor, the NOAEL of 9.7 mg/kg/day from the metolachlor chronic dog study, which was used to calculate the RfD (discussed above), is already lower than the developmental NOAELs of 360 mg/kg/day from the metolachlor teratogenicity studies in rats and rabbits. With regard to the metolachlor reproduction study, the lack of severity of the pup effects observed (decreased bwt) in the reproduction study at the systemic LOAEL (equivalent to 75.8 to 85.7 mg/kg/day) and the fact that the effects were

observed at a dose that is nearly 10 times greater than the NOAEL in the chronic dog study (9.7 mg/kg/day), suggest there is no additional sensitivity for infants and children. Therefore, it is concluded that an additional uncertainty factor is not warranted to protect the health of infants and children and that the RfD at 0.1 mg/kg/day based on the chronic dog study is appropriate for assessing aggregate risk to infants and children from use of metolachlor.

Using the conservative exposure assumptions described above, the percent of the RfD that will be utilized by aggregate exposure to residues of metolachlor is 1.27% for nursing infants less than 1 year old, 4.13% for non-nursing infants, 4.42% for children 1-6 years old and 3.26% for children 7-12 years old. 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. Despite the potential for exposure to metolachlor in drinking water and from non-dietary, non-occupational exposure, it is not expected that aggregate exposure from all sources will exceed 100% of the RfD. Therefore, based on the completeness and reliability of the toxicity data and the conservative exposure assessment, it is concluded there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to metolachlor residues.

#### *F. International Tolerances*

There are no Codex Alimentarius Commission (CODEX) maximum residue levels (MRL's) established for residues of metolachlor in or on RAC.

#### **2. Omnicem S.A., Industrial Research Park, 1348 Louvain-La-Neuve, Belgium**

PP 8E4950

EPA has received a pesticide petition (8E4950) from Omnicem S.A., Industrial Research Park, 1348 Louvain-La-Neuve, Belgium proposing, pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), to amend 40 CFR part 180 to establish an exemption from the requirement of a tolerance for a range of  $\alpha$ -alkyl ( $C_{12}$  -  $C_{18}$ )- $\omega$ -hydroxypoly(oxypropylene) poly(oxyethylene) copolymers (where the poly(oxypropylene) content is 3-60 moles and the poly(oxyethylene) content is 5-80 moles) when used in accordance with good agricultural practices as an inert ingredient in pesticide formulations applied to

growing agricultural crops in or on the RAC after harvest or to animals at ppm. EPA has determined that the petition contains data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data supports granting of the petition. Additional data may be needed before EPA rules on the petition.

#### *A. Toxicological Profile*

In the case of certain chemical substances that are defined as "polymers," the Agency has established a set of criteria which identify categories of polymers that present low risk. These criteria (described in 40 CFR 723.250) identify polymers that are relatively unreactive and stable compounds compared to other chemical substances as well as polymers that typically are not readily absorbed. These properties generally limit a polymer's ability to cause adverse effects. In addition, these criteria exclude polymers about which little is known. The Agency believes that polymers meeting the criteria noted above will present minimal or no risk. Alpha-alkyl ( $C_{12}$  -  $C_{18}$ )- $\omega$ -hydroxypoly(oxypropylene) poly(oxyethylene) copolymers (where the poly(oxypropylene) content is 3-60 moles and the poly(oxyethylene) content is 5-80 moles) conform to the definition of a polymer given in 40 CFR 723.250(b) and meet the following criteria that are used to identify low risk polymers.

1. Alpha-alkyl ( $C_{12}$  -  $C_{18}$ )- $\omega$ -hydroxypoly(oxypropylene) poly(oxyethylene) copolymers (where the poly(oxypropylene) content is 3-60 moles and the poly(oxyethylene) content is 5-80 moles) are not cationic polymers, nor are they capable of becoming a cationic polymer in the natural aquatic environment.

2. Alpha-alkyl ( $C_{12}$  -  $C_{18}$ )- $\omega$ -hydroxypoly(oxypropylene) poly(oxyethylene) copolymers (where the poly(oxypropylene) content is 3-60 moles and the poly(oxyethylene) content is 5-80 moles) contains as an integral part of their composition the atomic elements carbon, hydrogen, and oxygen.

3. Alpha-alkyl ( $C_{12}$  -  $C_{18}$ )- $\omega$ -hydroxypoly(oxypropylene) poly(oxyethylene) copolymers (where the poly(oxypropylene) content is 3-60 moles and the poly(oxyethylene) content is 5-80 moles) do not contain as an integral part of their composition, except as impurities, any element other than those listed in 40 CFR 723.250(d)(2)(iii).

4. Alpha-alkyl ( $C_{12}$  -  $C_{18}$ )- $\omega$ -hydroxypoly(oxypropylene) poly(oxyethylene) copolymers (where the poly(oxypropylene) content is 3-60 moles and the poly(oxyethylene) content is 5-80 moles) are not designed, nor are they reasonably anticipated to substantially degrade, decompose or depolymerize.

5. Alpha-alkyl ( $C_{12}$  -  $C_{18}$ )- $\omega$ -hydroxypoly(oxypropylene) poly(oxyethylene) copolymers (where the poly(oxypropylene) content is 3-60 moles and the poly(oxyethylene) content is 5-80 moles) are not manufactured or imported from monomers and/or other reactants that are not already included on the TSCA Chemical Substance Inventory or manufactured under an applicable TSCA section 5 exemption.

6. Alpha-alkyl ( $C_{12}$  -  $C_{18}$ )- $\omega$ -hydroxypoly(oxypropylene) poly(oxyethylene) copolymers (where the poly(oxypropylene) content is 3-60 moles and the poly(oxyethylene) content is 5-80 moles) are not a water absorbing polymer with a number average molecular weight greater than or equal to 10,000 daltons.

7. The minimum number-average molecular weight of  $\alpha$ -alkyl ( $C_{12}$  -  $C_{18}$ )- $\omega$ -hydroxypoly(oxypropylene) poly(oxyethylene) copolymers (where the poly(oxypropylene) content is 3-60 moles and the poly(oxyethylene) content is 5-80 moles) is 1,517 daltons. Substances with molecular weights greater than 400 generally are not absorbed through the intact skin, and substances with molecular weights greater than 1,000 normally are not absorbed through the intact gastrointestinal (GI) tract. Chemicals not absorbed through the skin or GI tract usually are incapable of eliciting a toxic response.

8. Alpha-alkyl ( $C_{12}$  -  $C_{18}$ )- $\omega$ -hydroxypoly(oxypropylene) poly(oxyethylene) copolymers (where the poly(oxypropylene) content is 3-60 moles and the poly(oxyethylene) content is 5-80 moles) has a range of molecular weights from a minimum of 1,517 to a maximum of 4,540 and contains less than 2% oligomeric material below molecular weight 500 and less than 5% oligomeric material below 1,000 molecular weight.

9. Alpha-alkyl ( $C_{12}$  -  $C_{18}$ )- $\omega$ -hydroxypoly(oxypropylene) poly(oxyethylene) copolymers (where the poly(oxypropylene) content is 3-60 moles and the poly(oxyethylene) content is 5-80 moles) does not contain reactive functional groups.

10. There is no evidence that  $\alpha$ -alkyl ( $C_{12}$  -  $C_{18}$ )- $\omega$ -

hydroxypoly(oxypropylene) poly(oxyethylene) copolymers (where the poly(oxypropylene) content is 3-60 moles and the poly(oxyethylene) content is 5-80 moles) are endocrine disruptors, whereas substances with molecular weights greater than 400 generally are not absorbed through the intact skin, and substances with molecular weights greater than 1,000 normally are not absorbed through the intact gastrointestinal tract (GI). Chemicals not absorbed through the skin or GI tract usually are incapable of eliciting a toxic response.

#### B. Aggregate Exposure

1. *Dietary exposure.* Alpha-alkyl ( $C_{12}$  -  $C_{18}$ )- $\omega$ -hydroxypoly(oxypropylene) poly(oxyethylene) copolymers (where the poly(oxypropylene) content is 3-60 moles and the poly(oxyethylene) content is 5-80 moles) are not absorbed through the intact GI tract and are considered incapable of eliciting a toxic response.

i. *Food.* Alpha-alkyl ( $C_{12}$  -  $C_{18}$ )- $\omega$ -hydroxypoly(oxypropylene) poly(oxyethylene) copolymers (where the poly(oxypropylene) content is 3-60 moles and the poly(oxyethylene) content is 5-80 moles) are not absorbed through the intact GI tract and are considered incapable of eliciting a toxic response.

ii. *Drinking water.* Even though some members of this family of polymers are water soluble, the high binding capacity to clay particles renders them immobile. Based upon the high binding to clay of  $\alpha$ -alkyl ( $C_{12}$  -  $C_{18}$ )- $\omega$ -hydroxypoly(oxypropylene) poly(oxyethylene) copolymers (where the poly(oxypropylene) content is 3-60 moles and the poly(oxyethylene) content is 5-80 moles,) there is no reason to expect human exposure to residues in drinking water. The copolymers are biodegraded in the environment over time into small molecular units that are easily mineralized into the soil matrix or utilized by the microbial populations. These small molecular units are considered to be toxicologically safe.

2. *Non-dietary exposure.* Typical use of this type of polymer is in the detergent formulations.

#### C. Cumulative Effects

There are data that support cumulative risk from  $\alpha$ -alkyl ( $C_{12}$  -  $C_{18}$ )- $\omega$ -hydroxypoly(oxypropylene) poly(oxyethylene) copolymers (where the poly(oxypropylene) content is 3-60 moles and the poly(oxyethylene) content is 5-80 moles), since polymers with molecular weights greater than 400 are not readily absorbed through the

intact skin and substances with molecular weights greater than 1,000 are not normally absorbed through the intact GI tract. Chemicals not absorbed through the skin or GI tract generally are incapable of eliciting a toxic response. Therefore, there are no reasonable expectations of increased risk due to cumulative exposure.

#### D. Safety Determination

1. *U.S. population.* Alpha-alkyl ( $C_{12}$  -  $C_{18}$ )- $\omega$ -hydroxypoly(oxypropylene) poly(oxyethylene) copolymers (where the poly(oxypropylene) content is 3-60 moles and the poly(oxyethylene) content is 5-80 moles) cause no safety concerns because they conform to the definition of a low risk polymer given in 40 CFR 723.250(b) and as such are considered incapable of eliciting a toxic response. Also, there are no additional pathways of exposure (non-occupational, drinking water, etc.) where there would be additional risk.

2. *Infants and children.* Alpha-alkyl ( $C_{12}$  -  $C_{18}$ )- $\omega$ -hydroxypoly(oxypropylene) poly(oxyethylene) copolymers (where the poly(oxypropylene) content is 3-60 moles and the poly(oxyethylene) content is 5-80 moles) cause no additional concern to infants and children because the polymers conform to the definition of a low risk polymer given in 40 FR 723.250(b) and as such are considered incapable of eliciting a toxic response. Also, there are no additional pathways of exposure (non-occupational, drinking water, etc.) where infants and children would be additional risk.

#### E. International Tolerances

We are not aware of any country requiring a tolerance for  $\alpha$ -alkyl ( $C_{12}$  -  $C_{18}$ )- $\omega$ -hydroxypoly(oxypropylene) poly(oxyethylene) copolymers (where the poly(oxypropylene) content is 3-60 moles and the poly(oxyethylene) content is 5-80 moles). Nor have there been any CODEX Maximum Residue Levels (MRLs) established for any food crops at this time.

Omnichem SA is petitioning that  $\alpha$ -alkyl ( $C_{12}$  -  $C_{18}$ )- $\omega$ -hydroxypoly(oxypropylene) poly(oxyethylene) copolymers (where the Poly(oxypropylene) content is 3-60 moles and the poly(oxyethylene) content is 5-80 moles) be exempt from the requirement of a tolerance based upon the low risk polymer definition as per 40 CFR 723.250. Therefore, an analytical method to determine residues of  $\alpha$ -alkyl ( $C_{12}$  -  $C_{18}$ )- $\omega$ -hydroxypoly(oxypropylene)

poly(oxyethylene) copolymers in RAC has not been proposed.

[FR Doc. 99-13035 Filed 5-25-99; 8:45 am]

BILLING CODE 6560-50-F

## ENVIRONMENTAL PROTECTION AGENCY

[OPP-00600; FRL-6081-6]

### Pesticides; Policy Issues Related to the Food Quality Protection Act

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice of availability.

**SUMMARY:** To assure that EPA's policies related to implementing the Food Quality Protection Act are transparent and open to public participation, EPA is soliciting comments on a draft policy paper entitled "Use of the Pesticide Data Program in Acute Dietary Assessment." This notice is the eighth in a series concerning science policy documents related to the Food Quality Protection Act and developed through the Tolerance Reassessment Advisory Committee.

**DATES:** Comments for this policy paper, identified by docket control number OPP-00600, must be received on or before July 26, 1999.

**ADDRESSES:** Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I.C. of the "SUPPLEMENTARY INFORMATION" section of this document. To ensure proper receipt by EPA, it is imperative that you identify docket control number OPP-00600 in the subject line on the first page of your response.

**FOR FURTHER INFORMATION CONTACT:** Kathleen Martin, Environmental Protection Agency (7509C), 401 M St., SW., Washington, DC 20460. Office location and telephone number: 1921 Jefferson Davis Highway (7509C), Arlington, VA, 22207; (703) 308-2857; fax: (703) 305-5147; e-mail address: martin.kathleen@epa.gov.

#### SUPPLEMENTARY INFORMATION:

##### I. General Information

###### A. Does This Notice Apply to Me?

You may be potentially affected by this notice if you manufacture or formulate pesticides. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS	Examples of potentially affected entities
Pesticide producers	32532	Pesticide manufacturers Pesticide formulators

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed could also be affected. If available, the North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this notice affects certain entities. If you have any questions regarding the applicability of this announcement to you, consult the person listed in the "FOR FURTHER INFORMATION CONTACT" section of this document.

##### B. How Can I Get Additional Information or Copies of This Document or Other Documents?

1. *Electronically.* You may obtain electronic copies of this document and the science policy paper from the EPA Home Page under the Office of Pesticide Programs at <http://www.epa.gov/pesticides/>. On the Office of Pesticide Program Home Page select "TRAC" and then look up the entry for this document. You can also go directly to the listings at the EPA Home Page at the **Federal Register**—Environmental Documents entry for this document under "Laws and Regulations" (<http://www.epa.gov/fedrgstr/>) to obtain this notice and the science policy paper.

2. *Fax on Demand.* You may request to receive a faxed copy of this document, as well as supporting information, by using a faxphone to call (202) 401-0527 and selecting item 6035. You may also follow the automated menu.

3. *In person or by phone.* If you have any questions or need additional information about this action, you may contact the person identified in the "FOR FURTHER INFORMATION CONTACT" at the beginning of this document. In addition, the official record for the science policy paper listed in the "SUMMARY" at the beginning of this document, including the public version, has been established under docket control number OPP-00600 (including comments and data

submitted electronically as described below). This record not only includes the documents that are physically located in the docket, but also includes all the documents that are referenced in those documents. Public versions of these records, including printed, paper versions of any electronic comments, which do not include any information claimed as Confidential Business Information (CBI), are available for inspection in Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Public Information and Records Integrity Branch telephone number is (703) 305-5805.

##### C. How and to Whom Do I Submit Comments?

You may submit comments through the mail, in person, or electronically. To ensure proper receipt by EPA, it is imperative that you identify docket control number OPP-00600 in the subject line on the first page of your response.

1. *By mail.* Submit written comments 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.

2. *In person or by courier.* Deliver written comments to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

3. *Electronically.* Submit your comments and/or data electronically by e-mail to: [opp-docket@epa.gov](mailto:opp-docket@epa.gov). Do not submit any information electronically that you consider to be CBI. Submit electronic comments as an ASCII file, avoiding the use of special characters and any form of encryption. Comments and data will also be accepted on standard computer disks in WordPerfect 5.1/6.1 or ASCII file format. All comments and data in electronic form must be identified by the docket control number. Electronic comments on this notice may also be filed online at many Federal Depository Libraries.

##### D. How Should I Handle CBI Information That I Want to Submit to the Agency?

You may claim information that you submit in response to this document as CBI by marking any part or all of that information as CBI. Information so marked will not be disclosed except in