

conclusion that there is a "reasonable certainty of no harm" from the proposed use of imazapic on grasses and the currently registered crop, peanuts.

2. *Infants and children.* The conservative dietary exposure estimates previously presented will utilize 0.3% of the RfD for all infants, for the non-nursing infant group, and for children ages 7 to 12. The chronic dietary exposures for children 1 to 6 years of age, the most highly exposed subgroup, will utilize only 0.6% of the RfD. Results from the two-generation reproduction study in rats and the developmental toxicity studies in rabbits and rats indicate no increased sensitivity to developing offspring when compared to parental toxicity. These results also indicate that imazapic is neither a developmental toxicant nor a teratogen in either the rat or rabbit. Therefore, an additional safety factor is not warranted, and the RfD of 0.5 mg/kg bwt/day, which utilizes a 300-fold safety factor is appropriate to ensure a reasonable certainty of no harm to infants and children.

#### F. International Tolerances

There are no Codex maximum residue levels established or proposed for residues of imazapic from use on grasses.

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BILLING CODE 6560-50-F

## ENVIRONMENTAL PROTECTION AGENCY

[PF-964; FRL-6739-1]

### Notice of Filing a Pesticide Petition to Establish a Tolerance for a Certain Pesticide Chemical in or on Food

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

**ACTION:** Notice.

**SUMMARY:** This notice announces the initial filing of a pesticide petition proposing the establishment of regulations for residues of a certain pesticide chemical in or on various food commodities.

**DATES:** Comments, identified by docket control number PF-964, must be received on or before September 25, 2000.

**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.** To ensure proper receipt by EPA, it is imperative that you identify docket control number

PF-964 in the subject line on the first page of your response.

**FOR FURTHER INFORMATION CONTACT:** By mail: Daniel C. Kenny, Fungicides Branch, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305-7546; e-mail address: kenny.dan@epa.gov.

#### SUPPLEMENTARY INFORMATION:

##### I. General Information

###### A. Does this Action Apply to Me?

You may be affected by this action if you are an agricultural producer, food manufacturer or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

Cat-egories	NAICS codes	Examples of potentially affected entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

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 in the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT.**

###### B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at <http://www.epa.gov/>. To access this document, on the Home Page select "Laws and Regulations," "Regulations and Proposed Rules," and then look up the entry for this document under the "Federal Register—Environmental Documents." You can also go directly to the **Federal Register** listings at <http://www.epa.gov/fedrgstr/>.

2. *In person.* The Agency has established an official record for this

action under docket control number PF-964. The official record consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, and other information related to this action, including any information claimed as confidential business information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period, is available for inspection in the Public Information and Records Integrity Branch (PIRIB), 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 PIRIB 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 PF-964 in the subject line on the first page of your response.

1. *By mail.* Submit your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

2. *In person or by courier.* Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA. The PIRIB is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305-5805.

3. *Electronically.* You may submit your comments electronically by e-mail to: "[opp-docket@epa.gov](mailto:opp-docket@epa.gov)," or you can submit a computer disk as described above. Do not submit any information electronically that you consider to be CBI. Avoid the use of special characters and any form of encryption. Electronic submissions will be accepted in Wordperfect 6.1/8.0 or ASCII file format. All comments in electronic form must be identified by docket control

number PF-964. Electronic comments may also be filed online at many Federal Depository Libraries.

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

Do not submit any information electronically that you consider to be CBI. You may claim information that you submit to EPA 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 accordance with procedures set forth in 40 CFR part 2. In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public version of the official record. Information not marked confidential will be included in the public version of the official record without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person identified under **FOR FURTHER INFORMATION CONTACT**.

#### *E. What Should I Consider as I Prepare My Comments for EPA?*

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.
2. Describe any assumptions that you used.
3. Provide copies of any technical information and/or data you used that support your views.
4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.
5. Provide specific examples to illustrate your concerns.
6. Make sure to submit your comments by the deadline in this notice.
7. To ensure proper receipt by EPA, be sure to identify the docket control number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

## **II. What Action is the Agency Taking?**

EPA has received a pesticide petition as follows proposing the establishment and/or amendment of regulations for residues of a certain pesticide chemical 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 this petition contains 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 support granting of the petition. Additional data may be needed before EPA rules on the petition.

### **List of Subjects**

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

Dated: August 15, 2000.

**Peter Caulkins,**

*Acting Director, Registration Division, Office of Pesticide Programs.*

### **Summary of Petition**

The petitioner summary of the pesticide petition is printed below as required by section 408(d)(3) of the FFDCA. The summary of the petition was prepared by the petitioner and represents the view of the petitioner. EPA is publishing the petition summary verbatim without editing it 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.

### **Rohm and Haas Company**

*PP 9F5058*

EPA has received a pesticide petition (PP 9F5058) from Rohm and Haas Company, 100 Independence Mall West, Philadelphia, PA proposing, pursuant to section 408(d) of the FFDCA, 21 U.S.C. 346a(d), to amend 40 CFR part 180 by establishing a tolerance for residues of zoxamide (RH-117281 Technical) benzamide-3,5-dichloro-N-(3-chloro-1-ethyl-1-methyl-2-oxopropyl)-4-methyl in or on the raw agricultural commodity tomatoes and cucurbits at 2 parts per million (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 support granting of the petition. Additional data may be needed before EPA rules on the petition.

#### *A. Residue Chemistry*

1. *Plant metabolism.* The metabolism of zoxamide in plants (tomatoes and cucurbits) is adequately understood for the purposes of these tolerances. There were no significant metabolites other than the parent compound in either

crop. Residues were surface residues of parent zoxamide and minor amounts of hydrolysis or photolysis degradates and a fairly large number of polar materials, each less than 2% of the total radioactive residue (TRR). No metabolites were present in excess of 5% of the total dosage. This is the same pattern seen in grapes, filed earlier.

2. *Analytical method.* Tolerance enforcement methods using gas chromatography/electron capture detection (GC/ECD) with confirmation by gas chromatography/mass selective detection (GC/MSD), have been developed for zoxamide in cucurbits (cucumber, cantaloupe, zucchini), tomatoes, tomato paste, and tomato puree. The limit of quantitation is 0.01 ppm for all matrices. Average recoveries are  $89.3 \pm 9.71\%$  for cucurbits,  $93.8 \pm 10.1\%$  for tomatoes,  $94.1 \pm 9.3\%$  for tomato paste, and  $90.7 \pm 13.7\%$  for tomato puree, over the range of fortifications. The methods involve extraction with solvent, filtration, liquid-liquid partition, and final purification of the residues using solid phase column chromatography. The methods have been radiovalidated and an independent laboratory validation has been completed.

3. *Magnitude of residues—Cucurbits.* Seventeen cucurbit field residue trials were conducted in nine states. There were 6 trials for cucumbers, 6 trials for cantaloupe, and 5 trials for zucchini. These trials will cover a cucurbit crop group tolerance. All studies were done with eight applications of 0.2 lb. active ingredient/acre (ai/acre) (0.224 kg ai/ha) for a total seasonal use rate of 1.6 lb. ai/acre (1.8 kg ai/ha). In all trials, fruit was harvested on the day of the final application (0 day Pre-harvest interval (PHI)). This is the proposed maximum seasonal use rate and proposed PHI. In three trials, residue decline samples were taken over 6 or 7 days.

Samples were analyzed for RH-117281. The average residue over all trials was 0.11 ppm (0.245 ppm for cantaloupe, 0.053 ppm for cucumbers and 0.115 ppm for zucchini). This single highest residue in any trial was 0.73 ppm. Residue declined from 0.12 to 0.04 ppm over 7 days in one trial and remained fairly constant at about 0.04 ppm in the other two residue decline trials.

These data support the establishment of a permanent tolerance of 2.0 ppm on cucurbits.

*Tomatoes.* Sixteen field residue trials, including 2 decline experiments, 2 bridging trials, and one processing study were conducted in six states. The trials each consisted of eight applications of the 80 W formulation of RH-117281 at

0.02 lb. ai/acre (0.224 kg ai/ha), for a total seasonal rate of 1.6 lb ai/acre (1.8 kg ai/ha). The bridging trials had a separate treated plot which received 10 applications of the 2F formulation at the same rate. Three of the trials, including the processing study trial, had 1 to 3 additional applications in order to ensure that the commercial quality fruit could be harvested at the appropriate preharvest interval. In all of the trials, fruit was harvested 5 days after the final application. In two of the trials, samples were taken at 0, 3, 5, and 7 days after the final application to determine residue decline.

Samples were analyzed for residues of RH-117281. The average residue over all trials was 0.21 ppm. This single highest residue in any trial was 1.18 ppm.

Tomato puree and tomato paste were generated from one residue trial. Washing removed about 80% of the residue from the tomato RAC. There was no concentration of residue in either tomato puree or tomato paste.

These data support the establishment of a permanent tolerance of 2.0 ppm on tomatoes and tomato processed fractions.

#### B. Toxicological Profile

1. *Acute toxicity.* Zoxamide has low acute toxicity. Zoxamide was practically non-toxic by ingestion of a single oral dose in rats and mice ( $LD_{50} > 5,000$  milligrams/kilograms (mg/kg), practically non-toxic by dermal application to rats ( $LD_{50} > 2,000$  mg/kg), and practically non-toxic to rats after a 4-hr inhalation exposure with an  $LC_{50}$  value of  $> 5.3$  mg/L (highest attainable concentration), is not considered to be a primary eye irritant or a skin irritant and is not a dermal sensitizer. The technical material was nonirritating to skin after single applications and moderately irritating to eyes. Zoxamide produced delayed contact hypersensitivity in the guinea pig at concentrations of 2,500 ppm and higher. An acute neurotoxicity study in rats did not produce any neurotoxic or neuropathologic effects with a NOAEL  $> 2,000$  mg/kg.

2. *Genotoxicity.* Zoxamide was nonmutagenic in a standard battery of tests. In *in vitro* assays, zoxamide showed no evidence of mutagenic activity in an Ames and CHO/HGPRT assays for gene mutation, and no evidence of structural chromosomal aberrations in the CHO *in vitro* cytogenetic study. As predicted by its antitubulin mode of action, mitotic accumulation and polyploidy were noted at cytotoxic doses in the *in vitro* chromosomal assay. However, there was no evidence of structural or numerical

chromosomal aberrations when zoxamide was tested *in vivo* in the mouse micronucleus test.

3. *Reproductive and developmental toxicity*— i. No observable adverse effects levels (NOAELs) for developmental and maternal toxicity to zoxamide were established at 1,000 mg/kg/day highest dose tested (HDT) in both the rat and rabbit. No signs of developmental toxicity were exhibited.

ii. In a 2-generation reproduction study in the rat, zoxamide had a no adverse effect on reproductive performance or pup development at doses up to an exceeding 1,471 mg/kg/day, the limit dose tested. This NOAEL was 20-fold higher than the NOAEL for adult toxicity of 71 mg/kg/day. A delay in periweaning weight gain and associated spleen effects in the F1 and F2a litters were shown in the F2b litters to be a secondary effect related to feed refusal due to palatability of the treated diets, and not to a systemic toxic effect. The consequences of feed refusal due to palatability do not constitute an adverse effect relevant to human health risk assessment.

4. *Subchronic toxicity.* The NOAEL in a 90-day rat subchronic feeding and neurotoxicity study was 1,500 mg/kg/day in males and 1,622 mg/kg/day in females HDT. Zoxamide did not produce neurotoxic or neuropathologic effects.

A 90-day feeding study with mice, the NOAEL was 436 mg/kg/day in males and 574 mg/kg/day in females based on a slight decrease in weight gain among the females only at the LOAEL of 1,666 mg/kg/day.

A 90-day dog feed study gave a NOAEL of 55 mg/kg in males and 62 mg/kg/day in females based on increased liver weights without a corresponding clinical or histopathologic change in females only at 322 mg/kg/day.

No signs of systemic toxicity were observed when zoxamide was administered dermally to rats for 28 days at a limit dose of 1,000 mg/kg/day. This occurred despite skin irritation at all doses tested (150, 400, and 1,000 mg/kg/day). Similarly, *in vivo* dermal absorption was shown to be low regardless of concentration or formulation type (i.e.,  $< 1-6\%$  of the administered dose was systemically absorbed after 24 hrs.)

5. *Chronic toxicity.* In a combined rat chronic/oncogenicity study, the NOAEL for chronic toxicity was 51 mg/kg/day in males and 65 mg/kg/day in females based on an equivocal increase in relative liver weight at a LOAEL of 328 mg/kg/day in females at the interim sacrifice only. The NOAEL was considered to be 1,058

mg/kg/day in males and 1331 mg/kg/day in females (HDT, limit dose). No carcinogenicity was observed.

An 18-month mouse carcinogenicity study showed no signs of carcinogenicity or of any other compound-related effect at dosage levels up to 1021 mg/kg/day in males and 1,289 mg/kg/day in females (HDT, limit dose).

The NOAEL in a 1-year feeding study in dogs was 255 mg/kg/day in males and 48 mg/kg/day in females based on minimal effects on body weight and body weight gain and increased liver weights in females only at a LOAEL of 278 mg/kg/day.

6. *Animal metabolism.* In pharmacokinetic and metabolism studies in the rat, zoxamide was rapidly and extensively absorbed, metabolized and excreted following oral exposure. A total of approximately 60% of the administered dose was systemically absorbed. Plasma levels peaked within 8 hours of dosing, and declined with a half-life of 12–14 hours, consistent with the nearly complete excretion within 48 hours. No evidence of accumulation of the parent compound or its metabolites was observed. The predominant route of excretion was hepatobiliary. Metabolism was found to occur through multiple pathways involving primary hydrolysis, glutathione-mediated reactions, and reductive dehalogenation; secondary oxidation on both the aromatic methyl and the aliphatic side-chain; and terminal glucuronic acid and ammo acid conjugation. Altogether, 32 separate metabolites were identified; no single metabolite other than parent zoxamide accounted for more than 10% of the administered dose. The rapid metabolism and excretion of zoxamide is a major factor explaining the compound's overall remarkably low toxicity profile in animals.

7. *Metabolite toxicology.* There were no significant metabolites other than the parent zoxamide in tomatoes or cucurbits.

8. *Endocrine disruption.* Based on structure-activity and mode of action information as well as the lack of developmental and reproductive toxicity, zoxamide is unlikely to exhibit endocrine activity. There was no evidence of a functional or histopathologic change in the male or female reproductive tract, and no indicators of an endocrine effect of any kind below limit doses in mammalian subchronic or chronic studies or in mammalian and avian reproduction studies. A slight thyroid effect at the limit dose (994–1139 mg/kg/day) in the subchronic and chronic dog studies was secondary to liver hypertrophy and

enlargement at that dose. Collectively, the weight of evidence provides no indication of an endocrine effect of zoxamide.

**C. Aggregate Exposure**

**1. Dietary exposure— i. Food.**

Tolerances are proposed in the present or preceding summaries for the residues of zoxamide in or on tomatoes (2 ppm), cucurbits (2 ppm), potatoes (0.1 ppm), grapes (5 ppm), and raisins (15 ppm). There is no reasonable expectation of transfer of residues of zoxamide into meat or milk from potatoes. There are no tomato, cucurbit or grape feed commodities fed to livestock, and none of these commodities is fed to poultry. There are no other established or proposed U.S. tolerances for zoxamide, and no currently registered uses in the United States. Risk assessments were conducted by Rohm and Haas to assess dietary exposures and risks from zoxamide as follows:

*Acute exposure and risk.* No acute endpoint was identified for zoxamide, and no acute risk assessment is required.

*ii. Chronic exposure and risk.* For chronic dietary risk assessment, the proposed tolerance values, as well as anticipated (average) residues and processing factors were used and the assumption that 100% of all tomatoes, cucurbits, potatoes, and grapes will contain residues of zoxamide at the tolerance or anticipated residue levels. Potential chronic exposures were estimated using USDA food consumption data from the 1989-1992 survey. With the proposed tolerances and anticipated residue levels for zoxamide, the percentage of the 0.5 mg/kg/day RfD utilized is as follows:

	Tolerance Levels Total % RfD	Anticipated Residues Total % RfD
U.S. Population—48 States .....	1.3	0.1
Nursing Infants < 1 year old ...	1.3	0.2
Non-Nursing Infants < 1 year old .....	2.4	0.1
Children 1-6 years old .....	3.5	0.2
Children 7-12 years old .....	1.8	0.1

The chronic dietary risks from these uses do not exceed EPA's level of concern.

*iii. Drinking water.* No direct information is available on potential for exposure to zoxamide from drinking water. However, exposure from drinking water is unlikely to occur as a result of

the uses on treated crops. Submitted environmental fate studies indicate that zoxamide dissipates rapidly from the environment under all conditions tested, and it is not mobile and poses no threat to groundwater. Furthermore, its environmental metabolites are very short-lived and also have no potential to leach.

There is no established Maximum Concentration Level (MCL) for residues of zoxamide in drinking water, and no drinking water health advisory levels have been established. There is no entry for zoxamide in the "Pesticides in Groundwater Database" (EPA 734-122-92-001, September 1992).

**2. Chronic exposure and risk.** Nevertheless, to assess an upper bound on the potential for exposure from drinking water, chronic exposure to zoxamide in drinking water was estimated using the generic expected environmental concentration (GENEEC) V1.2 model, as directed in OPP's Interim Approach for Addressing Drinking Water Exposure. GENEEC is a highly conservative model used to estimate residue concentrations in surface water. As indicated in EPA's drinking water exposure guidance, a very small percentage of people in the U.S. would derive their drinking water from such sources. GENEEC (56 Day average) water exposure values utilize substantially less than 1% of the RfD for adults and children.

**3. Non-dietary exposure.** Zoxamide is not currently registered for any indoor or outdoor residential or structural uses and no application is pending; therefore, no non-dietary non-occupational exposure is anticipated.

**4. Aggregate exposure and risk.** The anticipated aggregate exposure from food and drinking water combined is <4% of the RfD, and there is no expectation of other non-occupational exposure. Thus, aggregate exposure to zoxamide does not exceed EPA's level of concern.

**D. Cumulative Effects**

At this time, no data are available to determine whether zoxamide has a common mechanism of toxicity with other substances. Thus, it is not appropriate to include this fungicide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, zoxamide does not appear to produce a toxic metabolite produced by other substances. In addition, the toxicity studies submitted to support this petition indicate that zoxamide has only limited toxic potential. No toxic endpoints of potential concern were

identified. For the purposes of this tolerance action, therefore, zoxamide [benzamide-3,5-dichloro-N-(3-chloro-1-ethyl-1-methyl-2-oxopropyl)-4-methyl] is assumed not to have a common mechanism of toxicity with other substances.

**E. Safety Determination**

**1. U.S. population— i. Acute exposure and risk.** Since no acute endpoint was identified for zoxamide, no acute risk assessment is required.

*ii. Chronic exposure and risk.* Using the conservative exposure assumptions described above and taking into account the completeness and reliability of the toxicity data, the percentage of the RfD that will be utilized by dietary (food only) exposure to residues of zoxamide from the proposed tolerances is 1.3% (tolerance levels) and 0.1% (anticipated residues) for the U.S. population. Aggregate exposure (food and water) are expected to be 1.37% RfD. 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. Rohm and Haas concludes that there is a reasonable certainty that no harm will result from aggregate exposure to zoxamide residues to the U.S. population.

**2. Infants and children— i. In general.** The potential for additional sensitivity of infants and children to residues of zoxamide is assessed using data from developmental toxicity studies in the rat and rabbit and 2-generation reproduction studies 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.

*ii. Developmental toxicity studies— Rats.* In a developmental toxicity study in rats, the maternal NOAEL was 1,000 mg/kg/day (highest dose tested, HDT), and the developmental (pup) NOAEL was 1,000 mg/kg/day HDT.

*iii. Rabbits.* In a developmental toxicity study in rats, the maternal NOAEL was 1,000 mg/kg/day HDT, and the developmental (pup) NOAEL was 1,000 mg/kg/day HDT.

*iv. Reproductive toxicity study—Rats.* In a multigeneration reproductive toxicity study in rats, the parental (systemic) NOAEL was 71 mg/kg/day, based on an equivocal liver effect at the LOAEL of 360 mg/kg/day. The NOAEL for reproductive and developmental

effects was 1,471 mg/kg/day HDT. No adverse reproductive or developmental effects were observed.

3. *Prenatal and postnatal sensitivity.* No developmental or reproductive effects were demonstrated for zoxamide as a result of systemic exposures at up to limit doses of 1,000 and 1,471 mg/kg/day. Additionally, these NOAELs are greater than 20-fold higher than the NOAELs of 48-51 mg/kg/day from the dog and rat chronic studies which are the basis of the RfD. These developmental and reproductive studies indicate that developing and maturing animals are not more sensitive either pre or postnatally than other age groups to zoxamide; i.e., zoxamide does not exhibit additional prenatal or postnatal sensitivity. Thus, reliable data indicate that an additional Food Quality Protection Act uncertainty factor is not necessary to insure an adequate margin of safety for protection of infants and children.

4. *Acute exposure and risk.* No acute endpoint was identified for zoxamide, and therefore no acute risk assessment is required.

5. *Chronic exposure and risk.* Using the conservative exposure assumptions described above and taking into account the completeness and reliability of the toxicity data, the percentage of the RfD that will be utilized by dietary (food only) exposure to residues of zoxamide from the proposed tolerances is 2.4% (tolerance levels) and 0.2% (anticipated residues) for children, 1-6 years old, the most highly exposed subgroups. Aggregate exposure (food and water) are expected to be <4% RfD. 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. Rohm and Haas concludes that there is a reasonable certainty that no harm will result from aggregate exposure to zoxamide residues to the U.S. population.

#### F. International Tolerances

There are currently no CODEX, Canadian or Mexican maximum residue levels established for zoxamide in tomatoes, processed tomato products, or cucurbits. Thus, no harmonization issues are required to be resolved for this action.

[FR Doc. 00-21674 Filed 8-23-00; 8:45 am]

BILLING CODE 6560-50-F

## ENVIRONMENTAL PROTECTION AGENCY

[FRL-6857-4]

### John P. Saad Superfund Site; Notice of Proposed Settlement

**AGENCY:** Environmental Protection Agency.

**ACTION:** Notice of proposed settlements.

**SUMMARY:** The United States Environmental Protection Agency (EPA) proposed to enter into three (2) cost recovery settlements, one (1) pursuant to section 122(g) and one(1) pursuant to section 122(h) of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), 42 U.S.C. 9622(g). These administrative settlements will resolve the settling party's liability for past response costs incurred by EPA at the John P. Saad Superfund Site located in Nashville, Tennessee. EPA will consider public comments on the proposed settlements for thirty (30) days. EPA may withdraw from or modify the proposed settlements should such comments disclose facts or considerations which indicate that the proposed settlements are inappropriate, improper, or inadequate.

Copies of the proposed settlements are available from: Ms. Paula V. Batchelor, Waste Management Division, U.S. EPA Region 4, 61 Forsyth Street, Atlanta, Georgia 30303, 404/562-8887.

Written comments may be submitted to Ms. Batchelor within 30 calendar days of the date of publication.

Dated: June 22, 2000.

**Anita Davis,**

*Acting Chief, Program Services Branch, Waste Management Division.*

[FR Doc. 00-21670 Filed 8-23-00; 8:45 am]

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## ENVIRONMENTAL PROTECTION AGENCY

[FRL-6857-3]

### Proposed Settlement Under Section 122(g) of the Comprehensive Environmental Response, Compensation, and Liability Act; In the Matter of Lakeland Disposal Service, Inc., Claypool, Indiana

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

**ACTION:** Notice; request for public comment.

**SUMMARY:** Notice of *De Minimis* Settlement: In accordance with section 122(i)(1) of the Comprehensive

Environmental Response, Compensation, and Liability Act of 1980, as amended (CERCLA), U.S. EPA gives notice of a proposed administrative settlement concerning the remedial action at the Lakeland Disposal Service, Inc., Superfund Site, Claypool, County of Kosciusko, Indiana (the Site). The proposed agreement will resolve issues concerning one individual *De Minimis* landowner at the Site. U.S. EPA has previously submitted the proposed agreement to the U.S. Department of Justice for review and has received its approval for the proposed agreement via letter dated March 7, 2000.

**DATES:** Comments must be provided on or before September 25, 2000.

**ADDRESSES:** Barbara Wester (C-14J), Office of Regional Counsel, U.S. Environmental Protection Agency, Region 5, 77 W. Jackson Boulevard, Chicago, Illinois 60605-3590. Include the following name of the matter in the comment: In the Matter of Lakeland Disposal Service, Inc., Claypool, Indiana, U.S. EPA Docket No. V-W-99-C-561.

**FOR FURTHER INFORMATION CONTACT:** Barbara Wester (C-14J), Office of Regional Counsel, U.S. Environmental Protection Agency, Region 5, 77 W. Jackson Boulevard, Chicago, Illinois 60604-3590.

**SUPPLEMENTARY INFORMATION:** Homer Dove owns approximately five (5) acres of property located adjacent to and within the boundaries of the Site and did not himself contribute any wastes to the Site. The Record of Decision (ROD) for the Site, issued on September 28, 1993, contemplated that deed restrictions and institutional controls would be an important part of the remedy. The Settlement provides: That Dana Corporation; Eaton Corporation; General Motors Corporation; United Technologies Automotive, Inc.; and Warsaw Black Oxide, Inc. (collectively, the UAO Group) will compensate Mr. Dove for the loss of use of his property; that Mr. Dove will establish the contractual access provisions and deed restrictions necessary to effect the ongoing remediation of the Site proscribed by the ROD; and that Mr. Dove will convert these contractual promises to the form of an environmental easement, if U.S. EPA request that he do so. U.S. EPA will receive written comments relating to this settlement agreement for a period of thirty (30) days from the date of publication of this notice. Under CERCLA section 122(i)(3), U.S. EPA will consider any comments filed during this public comment period in "determining whether or not to consent to the