

The results from an S-phase response study in the rat liver demonstrate that tepraloxydim can induce a selective increase in cell proliferation predominantly in zone 3 after 1, 6, and 13 weeks in females at 4,000 ppm and, to a minor degree, at 600 ppm. In the males, there was an increase in cell proliferation after 1 week treatment at 3,000 ppm and, to a degree, at 600 ppm. The enhanced cell proliferation after 1 week of administration was reversible after 2 weeks of recovery in both sexes and appeared to be reversible in females after 5 weeks of recovery following 13 weeks of administration. The more pronounced S-phase response in female rats also explains why liver neoplasia was predominantly found in the females. These studies indicate that the mode of action, by which an enhancement of liver neoplasia was induced, is a chronic increase in liver cell proliferation. It is emphasized that this mechanism results in an increased incidence of liver tumors only at dose levels at the MTD. It is therefore, concluded that tepraloxydim does not have an oncogenic potential of biological relevance. The result of the carcinogenicity study in mice demonstrates that the HDL of 1,035 mg/kg/day (males) and 1,456 mg/kg/day (females) by far exceeded the criteria of a MTD as evidenced by drastically reduced bwts or bwt changes. A trend towards an increased incidence of liver neoplasia occurred only in females exclusively at that dose level and therefore cannot be extrapolated to dose levels below the MTD. Relative liver weights were distinctly increased at the HDL associated with foci of cellular alteration and hypertrophy of hepatocytes.

In female animals of the HDLs, hyalinization of the uterus was found as well as reduced ovarian activity which may be a consequence of the reduced terminal bwts.

In conclusion, in long-term feeding studies in rats and mice, there was a slight trend towards increased incidences of liver neoplasia at the HDLs. These dose levels were at or exceeded the MTD. As the liver was shown to be the target organ, the increased cell proliferation, resulting in neoplasia is considered to have been due to the toxicity exerted on this organ.

The overall lowest NOAELs obtained in long-term feeding studies were:  
Rats: 6 mg/kg/day  
Mice:

Males: 37 mg/kg/day  
Females: 52 mg/kg/day  
Dogs: 12 mg/kg/day.

These chronic NOAELs demonstrate that the rat is the most sensitive species.

Tepraloxydim does not possess mutagenic or genotoxic properties. As discussed above, it can be concluded that the compound has no biologically relevant oncogenic potential.

Therefore, based on the results of the carcinogenicity study in mice, the results of genotoxicity testing, the results of the 24-month chronic feeding/oncogenicity study in rats, and auxiliary mechanistic data showing that tepraloxydim is not an initiator of the carcinogenic process, BASF believes that the threshold approach to regulating tepraloxydim is appropriate.

ii. *Drinking water.* Based on the available studies, BASF does not anticipate exposure to residues of tepraloxydim in drinking water. There is no established Maximum Concentration Level (MCL) for residues of tepraloxydim in drinking water under the Safe Drinking Water Act (SDWA).

2. *Non-dietary exposure.* Tepraloxydim is not currently registered for any nonagricultural use. The potential for non-occupational exposure to the general population is therefore, not significant.

#### D. Cumulative Effects

BASF has considered the potential for cumulative effects of tepraloxydim and other substances that have a common mechanism of toxicity. No evidence or information exists to suggest that toxic effects produced by tepraloxydim would be cumulative with those of any other chemical compound.

#### E. Safety Determination

1. *U.S. population.* Using the conservative exposure assumptions described above and based on the completeness and the reliability of the toxicity data, BASF has estimated that aggregate exposure to tepraloxydim will utilize less than 4.0% of the RfD for the U.S. population. BASF concludes that there is a reasonable certainty that no harm will result from the aggregate exposure to residues of tepraloxydim, including anticipated dietary exposure and non-occupational exposures.

2. *Infants and children—i. Developmental toxicity.* The teratogenicity studies in rats resulted in a developmental toxicity NOAEL of 40 mg/kg/day and a maternal toxicity NOAEL of 40 mg/kg/day. These NOAEL values are 7x higher than the NOAEL from the 2-year feeding study in rats used to establish the RfD.

The teratogenicity study in rabbits resulted in a developmental toxicity NOAEL of 180 mg/kg/day and a maternal toxicity NOAEL of 60 mg/kg/day. These NOAEL values are 10x higher than the NOAEL from the 2-year

feeding study in rats used to establish the RfD.

ii. *Reproductive toxicity.* The 2-generation reproduction study with rats resulted in a reproductive NOAEL of 268 mg/kg/day ppm and a maternal NOAEL of 53 mg/kg/day. These NOAEL values are significantly higher than the NOAEL from the 2-year feeding study in rats used to establish the RfD.

iii. *Reference dose.* Since developmental and reproductive toxicity occurs at levels at or above the levels shown to exhibit parental toxicity and since these levels are significantly higher than those used to calculate the RfD, BASF believes the RfD of 0.06 mg/kg/day is an appropriate measure of safety for infants and children.

Using the conservative exposure assumptions described above, BASF has concluded that the portion of the RfD that will be utilized by aggregate exposure to residues of tepraloxydim resulting from the proposed tolerances will be less than 15% for all populations of infants and children. The most highly exposed group in the subpopulation groups would be non-nursing infant < 1 year old, which uses 15% of the RfD. Therefore, based on the completeness and reliability of the toxicity data and the conservative exposure assessment, BASF concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the residues of tepraloxydim, including all anticipated dietary exposure and all other non-occupational exposures.

#### F. International Tolerances

A maximum residue level has not been established for tepraloxydim by the Codex Alimentarius Commission. [FR Doc. 99-33036 Filed 12-21-99; 8:45 am]

BILLING CODE 6560-50-F

## ENVIRONMENTAL PROTECTION AGENCY

[PF-907; FRL-6398-7]

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

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces amendment of pesticide petitions (PP 5F4469), and (PP 4F4336), proposing the establishment of regulations for residues of certain pesticide chemicals in or on various food commodities.

**DATES:** Comments, identified by docket control number PF-907, must be received on or before January 21, 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-907 in the subject line on the first page of your response.

**FOR FURTHER INFORMATION CONTACT:** By mail: James Tompkins, Registration Support Branch, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460; telephone number: (703) 305-5697; e-mail address: tompkins.james@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	Examples of poten-tially affected entities
Industry	111	Crop production
	112	Animal production
	311	Food manufacturing
	32532	Pesticide manufac-turing

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" 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-907. 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-907 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, 401 M St., SW., 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-907. 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 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 supports 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: December 7, 1999.

**James Jones,**

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

### Summaries of Petitions

The 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 petitioner and represents the view of the petitioner. EPA is publishing the petition summaries verbatim without editing them in any way. The petition summaries announce 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.

#### Novartis Crop Protection, Inc.

*PP 5F4469 and PP 4F4336*

EPA has received pesticide petitions (PP 4F4336 and PP 5F4469) from Novartis Crop Protection Inc., P.O. Box 18300, Greensboro, NC 27419 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 180.481 by establishing tolerances for residues of prosulfuron, 1-(4-methoxy-6-methyl-triazin-2-yl)-3-[2-(3,3,3-trifluoropropyl)-phenylsulfonyl]-urea in or on the raw agricultural commodities cereal grains group (except rice and wild rice) grain at 0.01 parts per million (ppm); cereal grains group (except rice and wild rice) forage at 0.10 ppm; cereal grains group (except rice and wild rice) fodder at 0.01 ppm;

cereal grains group (except rice and wild rice) straw at 0.02 ppm; cereal grains group (except rice and wild rice) hay at 0.20 ppm; milk at 0.01 ppm; and meat, fat, kidney, liver and meat by-products of cattle, goats, hogs, horses, and sheep at 0.05 ppm. EPA has determined that the petitions contain 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.

This is a revised notice of filing to amend a previous notice of filing published in the **Federal Register** of August 25, 1999 (64 FR 46382) (FRL-6093-7) to propose permanent tolerances, instead of time-limited, for prosulfuron. Refer to the August 25, 1999 notice for a detailed summary of available information to support this action.

[FR Doc. 99-32872 Filed 12-21-99; 8:45 am]

**BILLING CODE 6560-50-F**

## ENVIRONMENTAL PROTECTION AGENCY

**[PB-402404-MN; FRL-6393-2]**

### Lead-Based Paint Activities in Target Housing and Child-Occupied Facilities; State of Minnesota Authorization Application

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

**ACTION:** Notice.

**SUMMARY:** On September 29, 1999, the State of Minnesota submitted an application for EPA approval to administer and enforce training and certification requirements, training program accreditation requirements, and work practice standards for lead-based paint activities in target housing and child-occupied facilities under section 402 of the Toxic Substances Control Act (TSCA). This notice announces the receipt of Minnesota's application, provides a 45-day public comment period, and provides an opportunity to request a public hearing on the application. Minnesota has provided a certification that its program meets the requirements for approval of a State program under section 404 of TSCA. Therefore, pursuant to section 404, the program is deemed authorized as of the date of submission. If EPA finds that the program does not meet the requirements for approval of a State program, EPA will disapprove the program, at which time a notice will be

issued in the **Federal Register** and the Federal program will take effect in Minnesota.

**DATES:** Comments, identified by docket control number PB-402404-MN, must be received on or before February 7, 2000. In addition, a public hearing request may be submitted on or before February 7, 2000.

**ADDRESSES:** Comments and the public hearing request may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I. of the "SUPPLEMENTARY INFORMATION." To ensure proper receipt by EPA, it is imperative that you identify docket control number PB-402404-MN in the subject line on the first page of your response.

**FOR FURTHER INFORMATION CONTACT:** Emma Avant, State of Minnesota Project Officer, Pesticides and Toxic Substances Branch, Environmental Protection Agency, Region V, 77 West Jackson Blvd, DT-8J, Chicago, IL 60601; telephone: (312) 886-7899; e-mail address: avant.emma@epamail.epa.gov.

### SUPPLEMENTARY INFORMATION:

#### I. General Information

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

This action is directed to the public in general. This action may, however, be of interest to firms and individuals engaged in lead-based paint activities in Minnesota. Since other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any 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 or 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" 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 PB-402404-MN. The official record consists of the documents specifically referenced in this action, this notice, the State of