List of Subjects

Environmental protection.

Dated: October 25, 2001.

Jay S. Ellenberger,

Acting Director, Field and External Affairs Division, Office of Pesticide Programs.

[FR Doc. 01–27597 Filed 11–1–01; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[PF–1047; FRL–6806–1]

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–1047, must be received on or before December 3, 2001.

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–1047 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Sidney Jackson, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305–7610; e-mail address: jackson.sidney@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:

Categories	NAICS	Examples of potentially affected entities
Industry	111 112 311	Crop production Animal production Food manufacturing
	32532	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'' 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–1047. 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–1047 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, 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–1047. 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: October 24, 2001.

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 petitioners. 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.

Interregional Research Project Number 4

6E4703

EPA has received a pesticide petition 6E4703 from the Interregional Research Project Number 4 (IR-4), 681 U.S. Highway #1 South, North Brunswick, NJ 08902-3390 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 combined residues of the herbicide, bentazon (3-isopropyl-1H-2,1,3-benzothiadiazin-4(3H)-one 2,2-dioxide) and its 6- and 8-hydroxy metabolites in or on the raw agricultural commodities clover forage at 1.0 part per million (ppm) and clover hay at 2.0 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. Bentazon is manufactured by the BASF Corporation, Agricultural Products Division.

A. Residue Chemistry

1. *Plant metabolism*. The qualitative nature of the residue in plants is adequately understood. Bentazon is rapidly metabolized, conjugated and incorporated into natural plant constituents. Metabolism involves the hydroxylation of bentazon at the 6- and 8-position. The terminal residues of regulatory concern are bentazon, 6-hydroxy bentazon, and 8-hydroxy bentazon (as specified in 40 CFR 180.355(a)).

2. *Analytical method*. Adequate enforcement methods are available for the determination of residues of bentazon and its 6- and 8-hydroxy metabolites in/on plant commodities. The Pesticide Analytical Manual (PAM) Vol. II lists Method II, a GLC method with flame photometric detection for the determination of bentazon and its hydroxy metabolites in/on corn, rice, and soybeans; the limit of detection for each compound is 0.05 ppm. Method III, modified from Method II, is available for the determination of bentazon and its hydroxy metabolites in/on peanuts and seed and pod vegetables with a limit of detection of 0.05 ppm for each compound.

3. *Magnitude of residues*. A total of 2 field residue trials were conducted on red clover in 1993 in Oregon. A single application of Basagran herbicide was made to clover at a rate of either 1.0 lb. active ingredient per acre (a.i./acre) (0.5X) or 2.0 lb/a.i./acre (1X). The spray volume was 20 gal/acre. An adjuvant (R-11) was included in all treatments at 2 oz./acre. Samples of forage and hay were harvested from each treated plot 36 days after treatment. Samples were analyzed for the combined residues of bentazon and its 6- and 8-hydroxy metabolites. Analysis of the treated samples showed that the maximum total residue was 0.77 ppm in forage and 1.19 ppm in hay.

B. Toxicological Profile

1. *Acute toxicity*. Acute toxicity data for bentazon show that this chemical is not acutely toxic by the oral, inhalation, or dermal routes of exposure (Toxicity Categories III and IV). It is moderately irritating to the eye (Toxicity Category II) and slightly irritating to the skin (Toxicity Category IV). Bentazon is also a dermal sensitizer.

2. *Genotoxicty*. Bentazon was not mutagenic in the tests for gene mutations, which were reverse mutation assays in *S. typhimurium* and in *E. coli* WP2 uvrA as well as forward mutation assays with *in vitro* Chinese hamster ovary cell (HGPRT) cultures. Bentazon was also negative in the mouse micronucleus test for assessing structural chromosomal aberrations and the unscheduled DNA synthesis assay with primary mouse hepatocytes for detecting DNA damage.

3. *Reproductive and developmental toxicity*. A developmental study in rats was conducted at doses of 0, 40, 100, or 250 milligrams per kilogram per day (mg/kg/day). The maternal NOAEL (no observed adverse effect level) is 250 mg/kg/day, HDT (highest dose tested). The maternal LOAEL (lowest observed adverse effect level) is greater than 250 mg/kg/day. The developmental NOAEL is 100 mg/kg/day. The developmental LOAEL is 250 mg/kg/day, based on increased postimplantation loss, skeletal variations (incomplete or absent ossification in the phalangeal nucleii of the extremities, the sternebrae and cervical vertebrae), and reduced body weights or fetuses surviving to day 21.

A developmental study in rabbits was conducted at doses of 0, 75, 150, or 375 mg/kg/day. The maternal/developmental NOAEL is 150 mg/kg/day. The maternal/developmental LOAEL is 375 mg/kg/day (HDT), based

on doe with partial abortion, embryonic resorptions, and no living fetuses. A 2–generation reproduction toxicity study in rats was conducted at doses of 0, 200, 800, or 3,200 ppm; equivalent to 0, 15, 62, or 249 mg/kg/day. The parental systemic NOAEL is 62 mg/kg/day. The parental systemic LOAEL is 249 mg/kg/day, based on increased incidences of kidney mineralization and liver microgranuloma. The reproductive NOAEL is 15 mg/kg/day. The reproductive LOAEL is 62 mg/kg/day, based on reduced pup growth (body weight gain) during lactation.

4. *Subchronic toxicity.* A 21–day dermal toxicity study in rabbits was conducted at doses of 0, 250, 500, or 1,000 mg/kg/day. The NOAEL is 1,000 mg/kg/day (HDT). The LOAEL is greater than 1,000 mg/kg/day. A 13–week feeding study in rats was conducted at doses of 0, 400, 1,200, or 3,600 ppm; equivalent to 0, 25.3, 77.8, or 243.3 mg/kg/day for males and 0, 28.9, 86.1, or 258.3 mg/kg/day for females. The NOAEL is 77.8 mg/kg/day. The LOAEL is 243.3 mg/kg/day for males and 258.3 mg/kg/day for females based on depressed mean body weights in females, a slight increase in food consumption in males, increased thromboplastin and prothrombin times (males only), and increased kidney and liver weights.

5. *Chronic toxicity.* A chronic feeding study in dogs was conducted at doses of 0, 100, 400, or 1,600 ppm; equivalent to 0, 3.2, 13.1, or 52.3 mg/kg/day. The NOAEL is 3.2 mg/kg/day. The LOAEL is 13.1 mg/kg/day based on a dose-dependent presence of feces with red areas in dogs at 13.1 mg/kg/day (400 ppm) and 52.3 mg/kg/day (1,600 ppm) and slight to severe anemia at the high dose. A chronic feeding/carcinogenicity study in rats was conducted at doses of 0, 200, 800, or 4,000 ppm; equivalent to 0, 9, 35, or 180 mg/kg/day in males and 0, 11, 45, or 244 mg/kg/day in females. The NOAEL is 9/11 mg/kg/day, in males/females. The LOAEL is 35/45 mg/kg/day, in males/females, based on increased water consumption, changes in urinalysis and hematology/coagulation parameters, and decreased absolute and relative thyroid weight. No evidence of carcinogenicity was observed. An oncogenicity study in mice was conducted at doses of 0, 100, 400, or 2,000 ppm; equivalent to 0, 12, 47, or 242 mg/kg/day in males and 0, 12, 48, or 275 mg/kg/day in females. The NOAEL is 12 mg/kg/day. The LOAEL is 47/48 mg/kg/day in males/females, based on increased prothrombin time, increased liver and kidney weights, calcification of the tunica albuginea, and islet cell hyperplasia of the pancreas. No evidence of carcinogenicity was observed.

6. *Animal metabolism.* A rat metabolism study with oral dosing showed that parent bentazon was the major metabolite found in urine, amounting to 77.37–91.02% of the dose. Another metabolism study demonstrated that the absorption and excretion of bentazon or its sodium salt in male rats after oral administration is rapid and essentially equivalent. No sex differences in the absorption, metabolism or excretion of sodium bentazon are apparent based on equivalent excretion half-lives (4 hours), pattern of excretion greater than 90% in urine or urinary metabolite identification greater than 80% as free acid. A dermal penetration study in rats was conducted at doses of 0.12, 1.2, 12, or 120 mg/kg. Single topical application of radioactive sodium bentazon did not appear to significantly penetrate the skin since a maximum of only 1-2% of the radioactivity was recovered primarily in the urine at 72 hours. Negligible amounts of dermally applied radioactivity were retained in the liver, kidneys, G.I. tract and carcass. For risk assessment purposes, dermal penetration is estimated to be 1-2%.

7. *Metabolite toxicology.* There are no metabolites of toxicological significance to mammals.

8. *Endocrine disruption.* No special studies investigating potential estrogenic or endocrine effects of bentazon have been conducted. However, the standard battery of required studies has been completed. These studies include an evaluation of the potential effects on reproduction and development, and an evaluation of the pathology exposure. These studies are generally considered to be sufficient to detect any endocrine effects but no such effects of the endocrine organs following repeated or long-term were noted in any of the studies.

C. Aggregate Exposure

1. *Dietary exposure*—i. *Food.* In 1999, EPA evaluated the hazard and exposure data for bentazon and recommended that the FQPA safety factor be retained at 10X in assessing the risk posed by this chemical because there was evidence of increased susceptibility in the developmental toxicity study in rats and in the 2-generation reproduction toxicity study in rats. The 10X FQPA Safety Factor is applicable to females 13–50 years old for acute dietary and residential exposure assessments and to all population subgroups for chronic dietary and residential exposure assessments. The acute and chronic Population Adjusted Doses (aPAD and cPAD, respectively) are modification of the acute and chronic Reference Doses (RfDs) to include the FQPA safety factor. The acute or chronic PAD is equal to the acute or chronic RfD divided by the FQPA safety factor.

Acute and chronic dietary exposure analyses for bentazon were performed using the Dietary Exposure Evaluation Model (DEEM) which incorporates data generated in the USDA 1989-1992 nationwide Continuing Surveys of Food Intake by Individuals (CSFII). For the acute analysis, tolerance level residues were used and 100% crop treated (CT) was assumed for all commodities (Tier I) for the females 13–50 years old subgroup (the subpopulation of concern). For all the females 13–50 years old subgroup, 5% or less of the aPAD is occupied by dietary exposure from food. Results of the acute analysis indicate that the acute dietary risk residues in food associated with existing and proposed uses of bentazon do not exceed EPA's level of concern.

A refined chronic dietary exposure analysis (Tier 3) was performed using anticipated and tolerance level residues for commodities for the general U.S. population and all population subgroups. For the chronic analysis, percent crop treated information was used for several commodities. The percent chronic population adjusted dose (%cPADs) for all subgroups were less than 100%, with the highest being 28% for the children 1–6 years subgroup. Results of the chronic analysis indicate that the chronic dietary risk from residues in food associated with the existing and proposed uses of bentazon do not exceed EPA's level of concern.

ii. *Drinking water.* SCI-GROW (Screening Concentration in Ground Water) modeling indicates that bentazon residue (bentazon + its metabolite, 2-amino-N-isopropyl benzamide (AIBA) concentrations in ground water used as drinking water are not likely to exceed 4.25 parts per billion (ppb). The other regulated bentazon metabolites (6-hydroxy and 8-hydroxy bentazon) have not been found in environmental fate studies. Limited monitoring data indicated a range of bentazon concentrations (excluding degradation products) in ground water of 20 to 120 ppb. Because monitoring data indicate a higher concentration than the SCI-GROW screening model, EPA used the 20 ppb as the environmental exposure concentration (EEC) for both acute and chronic scenarios. The EEC for surface water (from EPA's Pesticide Root Zone Model-EXAMS modeling) is 41 ppb for the peak (acute) and 8 ppb for the 36-year annual mean (chronic). The surface

and ground water estimates were used to compare against back-calculated drinking water levels of comparison (DWLOCs) for aggregate risk assessments. For the acute exposure scenario, the DWLOC is 2800 ppb for females (13+/nursing). For the chronic exposure scenario, the DWLOCs are 95, 82, 22, 94, and 95 ppb for the U.S. population, females (13+/nursing), children (1–6 years), Hispanics and males (13–19 years), respectively.

2. *Non-dietary exposure.* Because bentazon is registered for consumer use on turf and ornamentals, there is potential for residential exposure to adult applicators and adults and children entering recreational and residential areas treated with bentazon.

The handler exposure is expected to be short-term while the post-application exposure is expected for both the short- and intermediate-term. However, since there is no short-term dermal endpoint, the residential post-application exposure cannot be aggregated with the handler exposure. Short-term, non-dietary ingestion exposure for toddlers is not a concern because it was determined that there is no acute dietary or oral endpoint applicable to infants and children. However, intermediate-term, non-dietary ingestion exposure to toddlers playing on treated turf is possible and was assessed using the intermediate-term endpoint identified from the 1 year dog feeding study. Intermediate-term exposure is not expected for the ornamental use. The level of concern for residential exposures to bentazon is for MOE's less than 1,000.

There are no chemical-specific or site-specific data available to determine the potential risks associated with residential exposures from handling bentazon. Therefore, the exposure estimates are based on assumptions and generic data as specified by the December 18, 1997 Draft HED Standard Operating Procedures (SOPs) for Residential Exposure Assessments. Because bentazon is applied no more than twice per year, only short-term exposure is expected for the residential handler. Because a dermal endpoint of concern for the short-term duration was not identified, only inhalation exposure estimates are relevant. Assuming that a homeowner treats his lawn and ornamental plants on the same day, the aggregate inhalation short-term MOE is 500,000 for the residential handler. This estimate indicates that the potential handler risks from residential uses of bentazon do not exceed EPA's level of concern.

Environmental fate data indicate that bentazon is moderately resistant to degradation (t1/2 = 24–65 days). Due to the length of time bentazon is expected to remain in the environment, both short- and intermediate-term residential post-application exposures are expected. For toddlers playing on treated turf, the oral intermediate-term endpoint was used to assess toddler incidental ingestion exposures. Based on the residential use pattern, no long-term post-application residential exposure is expected. Short-term, non-dietary oral exposures to the toddler were not assessed because the subgroup of concern was identified as females 13–50 years old. This endpoint is not applicable to the infant and children population subgroups. Intermediate-term, post-application exposure is not expected from the ornamental use of bentazon.

Changes to the residential SOPs have been proposed that alter the residential post-application scenario assumptions. The proposed assumptions are expected to better represent residential exposure and are still considered to be high-end, screening level assumptions. Therefore, the proposed assumptions are used to calculate exposure estimates.

The dermal post-application exposure from the turfgrass use for the adult results in an MOE of 9,100. The MOEs for post-application exposures for the toddler are calculated as 6,400 and 3,500 for dermal and hand-to-mouth exposures, respectively. The aggregate intermediate MOE for post-application residential exposure to toddlers is 2,200. Therefore, all residential post-application exposure estimates are well below EPA's level of concern. Because these estimates were calculated using screening-level assumptions, it is believed that the actual risks will be lower. For the intermediate-term, typical lawn maintenance practices such as mowing and watering are expected to expedite the dissipation of bentazon on turfgrass. Therefore, with less residue available, potential incidental hand-to-mouth exposures are expected to be substantially lower.

D. Cumulative Effects

There is no available data to determine whether bentazon has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, bentazon does not appear to produce a toxic metabolite produced by other substances. For the purposes of this notice of filing, therefore, it is assumed that bentazon does not have a common mechanism of toxicity with other substances.

E. Safety Determination

1. *U.S. population.* Acute risk estimates from aggregate exposure to bentazon in food and water are below EPA's level of concern. For Tier 1 acute dietary exposure analysis, it was assumed that 100% of the crops treated with bentazon and that residues equaled the tolerance level. For all females 13–50 years old subgroups, less than or equal to 5% of the aPAD is occupied by dietary exposure from food. The acute dietary risk from food associated with the existing and proposed uses of bentazon is below EPA's level of concern. The estimated average concentrations of bentazon in surface and ground water are less than EPA's levels of comparison for bentazon in drinking water as a contribution to acute aggregate exposure.

Chronic (non-cancer) aggregate risk estimates are below EPA's level of concern. The chronic dietary exposure analysis for residues in food incorporated anticipated and tolerance level residues for commodities. Percent crop treated information was used for several commodities. The %cPADs for all subgroups were less than 100%, with the highest being 28% for the children 1–6 years old subgroup. Thus, the chronic dietary risk estimates from food associated with existing and proposed uses of bentazon do not exceed EPA's level of concern. For ground and surface water, the estimated average concentrations of bentazon are less than EPA's levels of comparison for bentazon in drinking water as a contribution to chronic aggregate exposure.

Aggregate short-term risk estimates are below EPA's level of concern. In aggregating short-term risk, the background chronic dietary exposure (food + drinking water) and short-term inhalation exposures from residential uses are considered. Because a dermal endpoint of concern for the short-term duration was not identified, only inhalation exposure estimates are relevant for the adult handler. Short-term inhalation exposure may occur for a homeowner treating turf and ornamentals on the same day. The total short-term food and residential aggregate MOE value is 220,000. As this MOE is greater than 1,000, the short-term food and residential aggregate risk estimate is below EPA's level of concern. For surface and ground water, the estimated average concentrations of bentazon are less than EPA's levels of comparison for bentazon in drinking water contribution to short-term aggregate exposure.

Aggregate intermediate-term risk estimates are below EPA's level of concern for adults. In aggregating intermediate-term risk, the background chronic dietary exposure (food + drinking water) and intermediate-term dermal exposures from residential uses are considered. For adults, dermal post-application exposures may result from dermal contact with treated turf. For adults, the total food and residential intermediate-term aggregate MOE is 7,600. As this value is greater than 1,000, the intermediate-term aggregate risk estimate is below EPA's level of concern. For surface and ground water, the estimated average concentrations of bentazon are less than EPA's levels of comparison for bentazon in drinking water as a contribution to intermediate-term aggregate exposure.

A cancer risk assessment was not done. Bentazon is classified as a Group E chemical (evidence of non-carcinogenicity for humans) based upon lack of evidence of carcinogenicity in rats and mice. Based on these risk assessments, it is concluded that there is a reasonable certainty that no harm will result from aggregate exposure to bentazon residues.

2. *Infants and children.* In assessing the potential for additional sensitivity of infants and children to residues of bentazon, data from developmental toxicity studies in the rat and rabbit and a 2-generation reproduction study in the rat are considered. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from maternal pesticide exposure during gestation. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base unless EPA determines that a different margin of safety will be safe for infants and children.

Margins of safety are incorporated into EPA risk assessments either directly through use of a margin of exposure (MOE) analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. EPA believes that reliable data support using the standard uncertainty factor (usually 100 for combined interspecies and intraspecies variability) and not the additional tenfold MOE/uncertainty factor when EPA has a complete data base under existing guidelines and when the severity of the effect in infants or children or the potency or unusual toxic properties of a compound do not raise concerns regarding the adequacy of the standard MOE/safety factor.

The toxicological data base for evaluating prenatal and postnatal toxicity of bentazon is complete with respect to current data requirements. There was evidence of increased susceptibility following *in utero* exposure to bentazon in the prenatal developmental toxicity study in rats and there was quantitative evidence of increased susceptibility following prenatal/postnatal exposure to bentazon in the 2-generation reproduction study in rats.

There is a complete toxicity data base for bentazon and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. The FQPA Safety Factor for protection of infants and children will be retained at 10x for bentazon due to the increased prenatal/postnatal susceptibility. The FQPA Safety Factor for bentazon is applicable to females 13–50 years old only for acute dietary and residential exposure assessments because increased susceptibility was demonstrated in the developmental study in rats which is designed to evaluate chemical effects on the mother and fetus from the time of implantation of the fertilized egg in the uterus through the end of gestation. The safety factor is also applicable to all population subgroups for chronic dietary and residential exposure assessments because increased susceptibility was demonstrated in the 2-generation reproduction study (which is designed to assess the effects of the pesticide on male and female reproductive processes, from egg and sperm production and mating through pregnancy, birth, nursing, growth and development, and maturation). An acute endpoint was not identified and this risk assessment was not required.

Using the exposure assumptions described in this unit, it was concluded that aggregate exposure to bentazon from food will utilize 28% of the chronic PAD for children 1–6 years old. EPA generally has no concern for exposures below 100% of the chronic PAD because the chronic PAD 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 bentazon in drinking water and from non-dietary, non-occupational exposure, the aggregate exposure is not expected to exceed 100% of the chronic PAD.

Although bentazon is a registered herbicide for use on turf and ornamentals, short-term non-dietary ingestion exposure for toddlers is not assessed because EPA determined that there is no acute dietary or oral endpoint applicable to infants and children. Aggregate intermediate-term risk estimates are below EPA's level of concern for infants and children. In aggregating intermediate-term risk, background chronic dietary exposure (food + drinking water) and intermediate-term, non-dietary oral and dermal exposures from residential uses are considered. For toddlers, dermal and non-dietary oral postapplication exposures may result from dermal contact with treated turf as well as hand-to-mouth transfer of residues from turfgrass. For infants and children, the total food and residential intermediate-term aggregate MOE is 2,000. As this value is greater than 1,000, the intermediate-term aggregate risk estimate is below EPA's level of concern. For surface and ground water, the estimated average concentrations of bentazon are less than EPA's levels of comparison for bentazon in drinking water as a contribution to intermediate-term aggregate exposure.

Based on these risk assessments, BASF concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to bentazon residues.

F. International Tolerances

There is neither a Codex proposal, nor Canadian or Mexican limits for residues of bentazon in clover. Therefore, a compatibility issue is not relevant to the proposed tolerance.

[FR Doc. 01–27600 Filed 11–1–01; 8:45 am]
BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[FRL–7097–9]

Proposed CERCLA Administrative Cost Recovery Settlement; Cliff/Dow Dump, Marquette, MI

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice; request for public comment.

SUMMARY: In accordance with section 122(i) the Comprehensive Environmental Response, Compensation, and Liability Act, as amended (''CERCLA''), 42 U.S.C. 9622(i), notice is hereby given of a proposed administrative settlement for recovery of past response costs