

EPA is providing an opportunity, through this notice, for interested parties to provide written comments and input to the Agency on the risk assessments or risk mitigation proposals for the pesticide specified in this notice. Such comments and proposals could address ideas on how to manage potential residential cancer risks from the use of MGK® Repellent 326 as an insect repellent, for example, the feasibility of using a lower percent active ingredient in final products containing MGK® Repellent 326. Comments could also address the availability of additional data to further refine the risk assessments, such as information on the extent and duration of use of products containing MGK® Repellent 326. Last, comments could address the Agency's risk assessment methodologies and assumptions applied to this specific chemical. Comments should be limited to issues raised within the risk assessment and associated documents. All comments should be submitted by *[insert date 60 days after date of publication in the Federal Register]* using the methods in Unit I. of the **SUPPLEMENTARY INFORMATION**. Comments will become part of the Agency record for MGK® Repellent 326.

#### List of Subjects

Environmental protection, Chemicals, MGK® Repellent 326, Pesticides and pest.

Dated: May 14, 2003.

Lois Rossi,

Director, Special Review and Reregistration Division, Office of Pesticide Programs.

[FR Doc. 03-13006 Filed 5-22-03; 8:45 am]

BILLING CODE 6560-50-S

## ENVIRONMENTAL PROTECTION AGENCY

[OPP-2003-0172; FRL-7307-5]

### Flonicamid; 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 ID number OPP-2003-0172, must be received on or before June 23, 2003.

**ADDRESSES:** Comments may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit I. of the **SUPPLEMENTARY INFORMATION**.

**FOR FURTHER INFORMATION CONTACT:** Ann Sibold, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-6502; e-mail address: [sibold.ann@epa.gov](mailto:sibold.ann@epa.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. General Information

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

You may be potentially affected by this action if you are a commercial grower of food or feed crops. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS 111)
- Animal production (NAICS 112)
- Food manufacturing (NAICS 311)
- Pesticide manufacturing (NAICS 32532)

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 this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. 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 Copies of this Document and Other Related Information?

1. *EPA Docket.* EPA has established an official public docket for this action under docket ID number OPP-2003-0172. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although, a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal

holidays. The docket telephone number is (703) 305-5805.

2. *Electronic access.* You may access this **Federal Register** document electronically through the EPA internet under the "**Federal Register**" listings at <http://www.epa.gov/fedrgstr/>.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA dockets. You may use EPA Dockets at <http://www.epa.gov/edocket/> to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although, not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select "search," then key in the appropriate docket ID number.

Certain types of information will not be placed in the EPA dockets. Information claimed as CBI and other information whose disclosure is restricted by statute, which is not included in the official public docket, will not be available for public viewing in EPA's electronic public docket. EPA's policy is that copyrighted material will not be placed in EPA's electronic public docket, but will be available only in printed, paper form in the official public docket. To the extent feasible, publicly available docket materials will be made available in EPA's electronic public docket. When a document is selected from the index list in EPA dockets, the system will identify whether the document is available for viewing in EPA's electronic public docket. Although, not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B. EPA intends to work towards providing electronic access to all of the publicly available docket materials through EPA's electronic public docket.

For public commenters, it is important to note that EPA's policy is that public comments, whether submitted electronically or on paper, will be made available for public viewing in EPA's electronic public docket as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EPA's electronic public docket. The

entire printed comment, including the copyrighted material, will be available in the public docket.

Public comments submitted on computer disks that are mailed or delivered to the docket will be transferred to EPA's electronic public docket. Public comments that are mailed or delivered to the docket will be scanned and placed in EPA's electronic public docket. Where practical, physical objects will be photographed, and the photograph will be placed in EPA's electronic public docket along with a brief description written by the docket staff.

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

You may submit comments electronically, by mail, or through hand delivery/courier. To ensure proper receipt by EPA, identify the appropriate docket ID number in the subject line on the first page of your comment. Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked "late." EPA is not required to consider these late comments. If you wish to submit CBI or information that is otherwise protected by statute, please follow the instructions in Unit I.D. Do not use EPA dockets or e-mail to submit CBI or information protected by statute.

1. *Electronically.* If you submit an electronic comment as prescribed in this unit, EPA recommends that you include your name, mailing address, and an e-mail address or other contact information in the body of your comment. Also, include this contact information on the outside of any disk or CD ROM you submit, and in any cover letter accompanying the disk or CD ROM. This ensures that you can be identified as the submitter of the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties, or needs further information on the substance of your comment. EPA's policy is that EPA will not edit your comment, and any identifying or contact information provided in the body of a comment, will be included, as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

i. *EPA Dockets.* Your use of EPA's electronic public docket to submit comments to EPA electronically is EPA's preferred method for receiving comments. Go directly to EPA Dockets

at <http://www.epa.gov/edocket>, and follow the online instructions for submitting comments. Once in the system, select "search," and then key in docket ID number OPP-2003-0172. The system is an "anonymous access" system, which means EPA will not know your identity, e-mail address, or other contact information unless you provide it in the body of your comment.

ii. *E-mail.* Comments may be sent by e-mail to [opp-docket@epa.gov](mailto:opp-docket@epa.gov), Attention: Docket ID number OPP-2003-0172. In contrast to EPA's electronic public docket, EPA's e-mail system is not an "anonymous access" system. If you send an e-mail comment directly to the docket without going through EPA's electronic public docket, EPA's e-mail system automatically captures your e-mail address. E-mail addresses that are automatically captured by EPA's e-mail system are included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket.

iii. *Disk or CD ROM.* You may submit comments on a disk or CD ROM that you mail to the mailing address identified in Unit I.C.2. These electronic submissions will be accepted in WordPerfect or ASCII file format. Avoid the use of special characters and any form of encryption.

2. *By mail.* Send your comments to: Public Information and Records Integrity Branch (PIRIB) (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001, Attention: Docket ID number OPP-2003-0172.

3. *By hand delivery or courier.* Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, Attention: Docket ID number OPP-2003-0172. Such deliveries are only accepted during the docket's normal hours of operation as identified in Unit I.B.1.

### D. How Should I Submit CBI to the Agency?

Do not submit information that you consider to be CBI electronically through EPA's electronic public docket or by e-mail. You may claim information that you submit to EPA as CBI by marking any part or all of that information as CBI (if you submit CBI on disk or CD ROM, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is 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 docket and EPA's electronic public docket. If you submit the copy that does not contain CBI on disk or CD ROM, mark the outside of the disk or CD ROM clearly that it does not contain CBI. Information not marked as CBI will be included in the public docket and EPA's electronic public docket without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person listed 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 ID 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 FFDCA 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: May 13, 2003.

### Debra Edwards,

Director, Registration Division, Office of Pesticide Programs.

## Summary of Petition

The petitioner's summary of the pesticide petition is printed below as required by FFDCa section 408(d)(3). The summary of the petition was prepared by ISK Bioscience Corporation, and represents the view of the petitioner. 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.

## ISK Biosciences Corporation

PP 3F6552

EPA has received a pesticide petition [3F6552] from ISK Biosciences Corporation, 7470 Auburn Road, Suite A, Concord, Ohio, 44077, 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 by establishing tolerances for the combined residues of the insecticide flonicamid, (N-cyanomethyl-4-trifluoromethylnicotinamide) and its metabolites, TFNA, (4-trifluoromethylnicotinic acid), TFNA-AM, (4-trifluoromethylnicotinamide) and TFNG, (N-(4-trifluoromethylnicotinoyl)-glycine) in or on the raw agricultural commodities: Celery, at 1.2 parts per million (ppm); cotton, at 0.5 ppm; cotton, gin trash, at 6.0 ppm; cotton, hulls, at 1.0 ppm; cotton, meal, at 1.0 ppm; fruit, pome, group 11, at 0.2 ppm; fruit, stone, group 12, except plum and fresh prune plum, at 0.7 ppm; lettuce, head, at 1.0 ppm; lettuce, leaf, at 4.0 ppm; plum, at 0.1 ppm; potato, at 0.2 ppm; potato, flakes, at 0.4 ppm; prune, fresh, at 0.1; spinach, at 9.0 ppm; tomato, paste, at 2.0 ppm; tomato, puree, at 0.5 ppm; vegetable, cucurbit, group 9, at 0.4 ppm; vegetable, fruiting, group 8, at 0.4 ppm; by establishing tolerances for the combined residues of the insecticide flonicamid, (N-cyanomethyl-4-trifluoromethylnicotinamide) and its metabolite TFNA-AM, (4-trifluoromethylnicotinamide) in animal tissues and poultry meat byproducts: Cattle, fat, at 0.01 ppm; cattle, meat, at 0.04 ppm; eggs, at 0.02 ppm; goat, fat,

at 0.01 ppm; goat, meat, at 0.04 ppm; hog, fat, at 0.01; hog, meat, at 0.01 ppm; horse, fat, at 0.01 ppm; horse, meat, at 0.04 ppm; milk, at 0.02 ppm; poultry, fat, at 0.01 ppm; poultry, meat, at 0.01 ppm; poultry, meat byproducts, at 0.01 ppm; sheep, fat, at 0.01 ppm; sheep, meat, at 0.04 ppm; by establishing tolerances for the combined residues of the insecticide flonicamid, (N-cyanomethyl-4-trifluoromethylnicotinamide) and its metabolites TFNA, (4-trifluoromethylnicotinic acid) and TFNA-AM, (4-trifluoromethylnicotinamide) in the animal meat byproducts: cattle, meat byproducts, at 0.06 ppm; goat, meat byproducts, at 0.06 ppm; hog, meat byproducts, at 0.01 ppm; horse, meat byproducts, at 0.06 ppm; and sheep, meat byproducts, at 0.06 ppm.

### A. Residue Chemistry

1. *Plant metabolism.* Wheat, potato and peach metabolism studies were conducted using [<sup>14</sup>C]-pyridyl-flonicamid. The metabolic profile was similar for all three matrices. The major metabolites for the various crops were: TFNA in peach, TFNA and TFNG in potato, and TFNG in wheat. The metabolism of flonicamid in plants shows, the main pathway of metabolism involves hydrolysis of -CN and CONH<sub>2</sub> functional groups in the molecule. The metabolism of flonicamid in plants is well understood.

2. *Analytical method.* Analytical methodology has been developed to determine the residues of flonicamid and its three major plant metabolites, TFNA, TFNG, and TFNA-AM in various crops. The residue analytical method for the majority of crops includes an initial extraction with acetonitrile (ACN)/deionized (DI) water, followed by a liquid-liquid partition with ethyl acetate. The residue method for wheat straw is similar, except that a C<sub>18</sub> solid phase extraction (SPE) is added prior to the liquid-liquid partition. The final sample solution is quantitated using a liquid chromatograph (LC) equipped with a reverse phase column and a triple quadrupole mass spectrometer (MS/MS).

3. *Magnitude of residues.* Residue data were collected on various crops and crop groups during field trials. Maximum total residues for cucurbits (total of 17 field trials) ranged from 0.164 (summer squash) to 0.333 ppm (cucumber). Maximum total residues for stone fruits (total of 21 field trials) ranged from 0.092 (plum) to 0.520 ppm (cherry). Maximum total residues for pome fruits (total of 18 field trials) ranged from 0.054 (pears) to 0.169 ppm

(apples). Maximum total residues for fruiting vegetables (total of 21 field trials) ranged from 0.195 (bell pepper) to 0.290 ppm (non-bell pepper). Maximum total residues for leafy vegetables (total of 24 field trials) ranged from 0.049 (head lettuce without wrappers) to 7.978 ppm (spinach). Maximum total residues for cottonseed with linters (12 field trials) were 0.343 and for gin trash were 5.001 ppm. Maximum total residues for potatoes (total of 17 field trials) were 0.119 ppm.

### B. Toxicological Profile

1. *Acute toxicity.* A battery of acute toxicity studies was conducted which placed flonicamid technical in Toxicity Category III for oral lethal dose (LD)<sub>50</sub>, Category IV for dermal LD<sub>50</sub>, inhalation LC<sub>50</sub>, dermal irritation, and eye irritation. Flonicamid technical is not a dermal sensitizer. In an acute neurotoxicity study, the no observed adverse effect levels (NOAELs) for neurotoxicity were 600 milligrams/kilogram (mg/kg) in males and 1,000 mg/kg in female (highest doses tested). The systemic NOAELs were 600 mg/kg in males and 300 mg/kg in females.

2. *Genotoxicity.* Flonicamid technical did not cause mutations in the bacterial reverse mutation or mouse lymphoma tests with or without metabolic activation, chromosome damage in the mouse micronucleus or cytogenetics tests with and without metabolic activation, an increase in DNA damage in the comet assay or in an *in vivo* rat unscheduled DNA synthesis (UDS) study. Based on the weight of evidence, it is concluded that, flonicamid technical is not genotoxic.

3. *Reproductive and developmental toxicity.* A developmental toxicity study in rats resulted in the maternal and developmental no observed adverse effect levels (NOAELs) of 100 mg/kg/day. The maternal lowest observed adverse effect level (LOAEL) was 500 mg/kg/day based on the treatment-related effects observed on the liver and kidney of the dams in the highest dose group. The developmental LOAEL was 500 mg/kg/day based on the increases in placental weights and incidences of fetal skeletal variations seen only at maternally toxic doses of 500 mg/kg/day.

In the rabbit developmental toxicity study, the maternal and developmental NOAELs were 7.5 mg/kg/day and 25 mg/kg/day highest dose tested (HDT), respectively. The maternal LOAEL was 25 mg/kg/day based on decreased body weights and food consumption. No adverse effects on the fetuses were observed at the highest dose.

In the multi-generation rat reproduction study, the NOAEL was 300 ppm for both parental animals (13.5–32.8 and 16.3–67.0 mg/kg/day, respectively, for males and females) and their offspring. The effects at the highest dose of 1,800 ppm included the following: increased kidney weights and gross and histopathological alterations in the kidney. Findings noted in the top dose females included delayed vaginal opening and increased liver, kidney and spleen weights in the F1 generation and reduced ovary and adrenal weights in the parental generation and decreased uterine weights in the F1 female weanlings. There was an increase in the FSH and LH levels in F1 females tested for these endpoints. These findings did not affect the reproductive performance or survival of offspring in the study.

4. *Subchronic toxicity.* The NOAEL for flonicamid technical in the rat 28-day dermal toxicity study was 1,000 mg/kg/day, which was the highest dose tested.

In a 90-day rat feeding study the NOAEL was established at 200 ppm (12.11 mg/kg/day) for males and 1,000 ppm (72.3 mg/kg/day) for females. The NOAELs were based on effects on hematology, triglycerides, and pathology in the liver and kidney.

In a 13-week mouse study, the NOAEL was 100 ppm (15.25 mg/kg/day in males and 20.1 mg/kg/day in females). The LOAEL is 1,000 ppm (153.9 mg/kg/day in males and 191.5 mg/kg/day in females) based on hematology effects and changes in glucose, creatinine, bilirubin, sodium, chloride and potassium levels, increased liver and spleen weights and histopathology findings in the bone marrow, spleen and kidney.

In a subchronic toxicity study in dogs with capsule administration, the NOAEL was 20 mg/kg/day based on findings of severe toxicity at a dose exceeding the maximum tolerated dose; symptoms included collapse, prostration and convulsions leading to early sacrifice at the LOAEL of 50 mg/kg/day.

In a subchronic neurotoxicity study in rats, the NOAEL for dietary administration was 1,000 ppm (67 mg/kg/day in males and 81 mg/kg/day in females) for systemic toxicity based on body weight and food consumption effects. The NOAEL for neurotoxicity was 10,000 ppm (625 and 722 mg/kg/day in males and females, respectively (highest dose tested).

5. *Chronic toxicity.* In the chronic dog study with administration via using capsules, the NOAEL was 8 mg/kg/day. The LOAEL was 20 mg/kg/day based on

reduced body weights in females and effects on the circulating red blood cells.

In a rat 24-month combined chronic and oncogenicity study, flonicamid technical was not carcinogenic in rats. The NOAEL was 200 ppm (7.32 mg/kg/day) for males and 1,000 ppm (44.1 mg/kg/day) for females. The LOAEL was 1,000 ppm for males and 5,000 ppm for females based on histopathology in the kidney, hematology effects, hepatic effects including changes in biochemical parameters, increased organ weights, and histopathological changes. Atrophy of striated muscle fibers, cataract and retinal atrophy observed in the high dose females were considered to be due to acceleration of spontaneous age-related lesions.

In the 18-month mouse study, effects were observed in the lung, liver, spleen and bone marrow at 250 ppm or higher. Findings included, centrilobular hepatocellular hypertrophy, extramedullary hematopoiesis and pigment deposition in the spleen and decreased cellularity (hypocellularity) in the bone marrow. There were statistically significant increases in the incidence of alveolar/bronchiolar adenomas in both sexes of treated groups with hyperplasia/hypertrophy of epithelial cells in terminal bronchioles. There was a statistically significant increase in the incidence of alveolar/bronchiolar carcinomas in males at 750 ppm and 2,250 ppm and in females at 2,250 ppm only. These effects in the lungs of mice were not life threatening as most of effects were observed at the terminal sacrifice and there was no effect of treatment on mortality in the study. A NOAEL could not be determined from the dose levels administered. Mechanism-of-action studies have indicated that the lung effects are unique to the mouse and are not likely to translate to other species including the rat. Flonicamid technical was not carcinogenic in the rat.

6. *Animal metabolism.* Rat, goat and poultry metabolism studies were conducted using [<sup>14</sup>C]-pyridyl-flonicamid. The majority of the dose was rapidly excreted. Flonicamid was a major component of rat urine 48 hours after dosing. TFNA-AM was the major metabolite found in rats (urine), goats (milk and tissues), and in laying hens (tissues and eggs). TFNG was found between 8–24% of the total radioactive residue (TRR) in the livers of rats sacrificed at intervals between 0.5–6 hours after dosing. The liver samples at these time intervals had <sup>14</sup>C-residues of 2.3%–4.6% of the dose. TFNA was not a major component in animal tissues. The metabolism of flonicamid in animals shows the main pathway of

metabolism involves hydrolysis of -CN and -CONH<sub>2</sub> functional groups in the molecule, identical to plant metabolism. The main metabolic reactions were hydrolysis of cyano to the amide function and ring hydroxylation. In rats, flonicamid was further metabolized by several routes, including nitrile hydrolysis, amide hydrolysis, N-oxidation, and hydroxylation of the pyridine ring, leading to multiple metabolites. The metabolism of flonicamid in animals is well understood.

7. *Metabolite toxicology.* The main metabolites of flonicamid were examined in acute oral toxicity studies in rats and bacterial reverse mutation tests. All the metabolites were less toxic than flonicamid and not mutagenic.

8. *Endocrine disruption.* No special studies investigating potential estrogenic or other endocrine effects of flonicamid have been conducted. Some suggestions of possible endocrine effects were reported at the highest dose tested (1,800 ppm) in the multi-generation reproduction study which showed increased FSH and LH levels, a delay in the time to vaginal opening in the F1 generation, and reduced ovary and adrenal weights in the parental generation. However, there were no effects on reproductive performance or survival of the offspring in the study. At levels that are expected to be found in the environment, flonicamid will not cause any endocrine-related effects.

### C. Aggregate Exposure

1. *Dietary exposure.* Potential dietary exposures from food were estimated using the proposed tolerances for all crops using the Dietary Exposure Evaluation Model (DEEM) for acute and chronic exposure based on U.S. Department of Agriculture's (USDA) Continuing Surveys of Food Intake by Individuals (CSFII) conducted in 1994–1998, and percent crop treated of 100%. The following raw agricultural commodities were included: Leaf lettuce, head lettuce, celery, spinach, cotton, potatoes, fruiting vegetables, cucurbits, stone fruits, pome fruits and resulting secondary residues in meat, milk, poultry and eggs.

i. *Food.* Acute dietary exposure was compared to the acute population adjusted dose (aPAD) of 3.0 mg/kg/day based on the NOAEL of 300 mg/kg from the acute neurotoxicity study in rats and a 100-fold uncertainty factor. The U.S. population exposure is 0.26% of the aPAD and the most highly exposed subpopulation is children 1–2 with 0.56% of the aPAD (95<sup>th</sup> percentile).

Based on the available data, an appropriate cPAD is 0.073 mg/kg/day

based on the NOEL of 7.32 mg/kg/day from the chronic toxicity study in rats and a 100-fold uncertainty factor. The U.S. population exposure is 3.2% of the cPAD and the most highly exposed subpopulation exposure is children 1–6 with 7.4% of the cPAD.

ii. *Drinking water.* A drinking water level of comparison (DWLOC) was calculated by subtracting the chronic/acute food exposures calculated using DEEM™ from the cPAD/aPAD to obtain the acceptable chronic/acute exposure to flonicamid in drinking water. The estimated average and maximum concentration of flonicamid in surface water is 1.20 ppb and 1.64 ppb, respectively. These are both well below the lowest chronic (676 ppb) and acute (29,831 ppb) DWLOC values for flonicamid. Therefore, taking into account all proposed uses, it can be concluded with reasonable certainty that residues of flonicamid in food and drinking water will not result in unacceptable levels of human health risk.

2. *Non-dietary exposure.* There are currently no residential uses of flonicamid registered or pending action that need to be added to the total risk from exposure.

#### D. Cumulative Effects

In consideration of potential cumulative effects of flonicamid and other substances that may have a common mechanism of toxicity, to our knowledge there are currently no available data or other reliable information indicating that any toxic effects produced by flonicamid would be cumulative with those of other chemical compounds; thus only the potential risks of flonicamid have been considered in this assessment of its aggregate exposure. If ISK Biosciences Corporation learns of any other compound with the same mechanism of toxicity they will submit information for EPA to consider concerning potential cumulative effects of flonicamid consistent with the schedule established by EPA in the **Federal Register** of August 4, 1997 (62 FR 42020) (FRL–5734–6), and other EPA publications pursuant to the Food Quality Protection Act (FQPA).

#### E. Safety Determination

1. *U.S. population.* Using conservative exposure assessment analyses, the acute dietary exposure estimates are well below the aPAD of 3 milligrams/kilogram body weight/day (mg/kg bwt/day) for all population subgroups. In addition, the chronic dietary exposure estimates for the various population groups are well below the cPAD of 0.073

mg/kg bwt/day. Based on this information, ISK Biosciences Corporation concludes that there is reasonable certainty that no harm will result from acute or chronic exposure to flonicamid.

2. *Infants and children.* Based on the available developmental and reproductive data on flonicamid, ISK Biosciences Corporation, concludes that, reliable data support use of the standard 100-fold uncertainty factor, and that an additional uncertainty factor is not needed to protect the safety of infants and children under the FQPA. Although, the reproduction study indicated signs of toxicity to some reproductive organs/systems at the high dose of 1,800 ppm in the diet, other signs of toxicity such as effects on the kidney accompanied these; there were no effects observed at a dose level of 300 ppm. There were no effects on reproduction or survival at any dose level. Since acute and chronic aggregate exposure assessments are well below the aPAD and cPAD respectively, there is reasonable certainty that no harm will result to infants and children from aggregate exposure to flonicamid residues.

#### F. International Tolerances

There are no Canadian or Mexican residue limits or codex MRLs for the insecticide flonicamid and its metabolites TFNA, TFNA-AM, and TFNG.

[FR Doc. 03–13005 Filed 5–22–03; 8:45 am]

BILLING CODE 6560–50–S

### ENVIRONMENTAL PROTECTION AGENCY

[FRL–7502–9]

#### Proposed Administrative Settlement Under the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 Regarding the Central Steel Drum Superfund Site, Newark, NJ

**AGENCY:** Environmental Protection Agency.

**ACTION:** Notice of proposed administrative settlement and opportunity for public comment.

**SUMMARY:** The United States Environmental Protection Agency (“EPA”) is proposing to enter into an administrative settlement to resolve claims under the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, as amended (“CERCLA”), 42 U.S.C. 9601 *et seq.* In accordance with EPA guidance, notice is hereby given of

a proposed administrative settlement pursuant to section 122(h)(1) of CERCLA concerning the Central Steel Drum Superfund Site, located in Newark, New Jersey. This notice is being published to inform the public of the proposed settlement and to provide the public with an opportunity to comment on the proposed settlement. This settlement is intended to resolve the civil liability of certain responsible parties for response costs incurred by EPA at the Central Steel Drum Superfund Site. CERCLA provides EPA the authority to settle certain claims for response costs incurred by the United States with the approval of the Attorney General of the United States.

The proposed settlement provides that the potentially responsible parties, Marian Abrams and Jane Mattson, will pay \$18,000.00 in reimbursement of response costs incurred by EPA in performing a removal action to remove the contaminants and hazardous substances from the Central Steel Drum Superfund Site in return for a covenant not to sue under sections 106 and 107 of CERCLA from the United States.

**DATES:** Comments must be provided on or before June 23, 2003.

**ADDRESSES:** Comments should be addressed to the U.S. Environmental Protection Agency, Office of Regional Counsel, 290 Broadway—17th Floor, New York, New York 10007–1866 and should refer to: In the Matter of Central Steel Drum Superfund Site, Marian Abrams and Jane Mattson, Settling Parties, U.S. EPA Region II Docket No. CERCLA–02–2003–2001.

**FOR FURTHER INFORMATION CONTACT:** U.S. Environmental Protection Agency, Office of Regional Counsel, 290 Broadway—17th Floor, New York, New York 10007–1866, Attention: Muthu S. Sundram, Esq. (212) 637–3148.

**SUPPLEMENTARY INFORMATION:** A copy of the proposed administrative settlement agreement, as well as background information relating to the settlement, may be obtained in person or by mail from EPA’s Region II Office of Regional Counsel, 290 Broadway—17th Floor, New York, New York 10007–1866.

Dated: May 14, 2003.

**George Pavlou,**

*Director, Emergency & Remedial Response Division.*

[FR Doc. 03–13002 Filed 5–22–03; 8:45 am]

BILLING CODE 6560–50–P