Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA, Attention: Docket ID Number OPP–2005–0167. 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. Offer alternative ways to improve the registration activity.
7. Make sure to submit your comments by the deadline in this notice.
8. 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. Registration Applications

EPA received applications as follows to register pesticide products containing active ingredients not included in any previously registered products pursuant to the provision of section 3(c)(4) of FIFRA. Notice of receipt of these applications does not imply a decision by the Agency on the applications.

Products Containing Active Ingredients not Included in any Previously Registered Products

1. *File symbol:* 82100–R. *Applicant:* PQ Corporation, P.O. Box 840, Valley Forge, PA 19482–0840. *Product name:* AgSilr 25. *Type of product:* Biochemical pesticide. *Active ingredient:* Potassium silicate at 29.1%. *Proposed classification/Use:* Fungicide, miticide and insecticide.

2. *File symbol:* 82100–E. *Applicant:* PQ Corporation, P.O. Box 840, Valley Forge, PA 19482–0840. *Product name:* Technical Potassium Silicate. *Type of product:* Biochemical pesticide. *Active ingredient:* Potassium silicate at 100%. *Proposed classification/Use:* Fungicide, miticide and insecticide.

List of Subjects

Environmental protection, Pesticides and pests.

Dated: July 11, 2005.

Janet L. Andersen,

Director, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs.

[FR Doc. 05–14881 Filed 7–26–05; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2005–0139; FRL–7727–2]

Flucarbazone-sodium; 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 identification (ID) number OPP–2005–0139, must be received on or before August 26, 2005.

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: Jim Tompkins, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–5697; e-mail address: *tompkins.jim@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 an agricultural producer, food manufacturer, or pesticide manufacturer. 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. *Docket.* EPA has established an official public docket for this action under docket ID number OPP–2005–0139. 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, 1801 S. Bell St., 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.1. 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 in 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–2005–0139. 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*, Attention: Docket ID Number OPP–2005–0139. 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–2005–0139.

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, 1801 S. Bell St., Arlington, VA, Attention: Docket ID Number OPP–2005–0139. 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?

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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**.

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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: July 18, 2005.

Donald R. Stubbs,

Acting Director, Registration Division, Office of Pesticide Programs.

Summary of Petition

The petitioner summary of the pesticide petition is printed below as required by FFDCA section 408(d)(3). The summary of the petition was prepared by the petitioner 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.

Arvesta Corporation

PP 5F6949

EPA has received a pesticide petition (PP 5F6949) from Arvesta Corporation, 100 First Street, Suite 1700, San Francisco, CA 94105, 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 flucarbazone-sodium: 4,5-dihydro-3-methoxy-4-methyl-5-oxo-N-[[2-(trifluoromethoxy)phenyl]sulfonyl]-1H-1,2,4-triazole 1-carboxamide, sodium salt; and its N-desmethyl metabolite in or on the raw agricultural commodities (RACs):

Commodity	Parts per million
Wheat, forage	0.30
Wheat, grain	0.01
Wheat, hay	0.10
Wheat, straw	0.05

And combined residues of flucarbazone-sodium and its metabolites converted to 2-(trifluoromethoxy)benzene sulfonamide and calculated as flucarbazone-sodium in or on the raw agricultural commodities:

Commodity	Parts per million
Milk	0.005
Meat and meat by-products except liver (cattle, goats, sheep, horses, hogs)	0.01
Liver (cattle, goats, sheep, horses, hogs)	1.50

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

A. Residue Chemistry

1. *Plant metabolism*. The metabolism of flucarbazone-sodium in wheat was rapid and extensive. Little or no parent flucarbazone-sodium was found in the RACs. A primary metabolic pathway in wheat involved the N-demethylation of flucarbazone-sodium to give N-desmethyl flucarbazone-sodium. N-desmethyl flucarbazone-sodium was found in all of the wheat RACs. The N-desmethyl flucarbazone-sodium was then either hydrolyzed or conjugated with glucose. Another primary metabolic pathway was hydrolysis of flucarbazone-sodium yielding sulfonic acid and sulfonamide which were isolated, and N,O-dimethyl triazolinone which was not isolated. Other metabolites were then subsequently formed by oxidative reactions, hydrolytic reactions, and conjugation.

2. *Analytical method*—i. *Plants*. The proposed tolerance expression is parent flucarbazone-sodium and N-desmethyl flucarbazone-sodium. An analytical method was developed to measure these two analytes in plant matrices. This method was validated in wheat tissues. The flucarbazone-sodium and N-desmethyl flucarbazone-sodium residues are extracted from the wheat samples with 0.05 M NH_4OH by accelerated solvent extraction (ASE). The extracts are purified by a combination of C-18 solid phase extraction (SPE) and ethylene diamine-N-propyl (PSA) spe. The resultant analytes are detected by liquid chromatography/tandem mass spectroscopy (lc/ms/ms) and quantified against known amounts of deuterated internal standards. The method limit of quantitation (LOQ) is 0.01 milligram/kilogram (mg/kg) of either analyte in all wheat matrices. The method limit of detection (LOD) is 0.005 mg/kg of either analyte in all wheat matrices.

ii. *Animals*. An analytical method was developed to measure the residues of flucarbazone-sodium in animal tissues and milk. Since the flucarbazone-sodium-related residues were present in ruminant tissues as a mixture of bound, conjugated, and unconjugated residues, a method was developed that simultaneously extracted and hydrolyzed the majority of the flucarbazone-sodium-related residues to flucarbazone-sodium sulfonamide. The flucarbazone-sodium residues are simultaneously hydrolyzed to flucarbazone-sodium sulfonamide and extracted from the animal tissues and milk by heating with 8% trifluoroacetic acid (TFA) in water. The analysis of fat was complicated by the large quantities of lipids that were released during hydrolysis and extraction. Therefore, the flucarbazone-sodium residues are extracted into acetonitrile/water (9:1) before they are hydrolyzed to flucarbazone-sodium sulfonamide. After conversion to flucarbazone-sodium sulfonamide, the residues are purified and partitioned. The residues are detected by lc/ms/ms and quantified against known amounts of deuterated internal standards. The LOQ in the tissues and milk is 0.020 and 0.005 mg/kg, respectively. The estimated LOD (3x highest background response) in the liver, muscle, and milk is 0.014, 0.002, and 0.004 mg/kg, respectively. The recoveries of flucarbazone-sodium were determined in all tissues and milk after fortification with flucarbazone-sodium. The average recoveries of flucarbazone-sodium from liver fortified at 0.020 and 0.100 mg/kg were 104 and 100%, respectively. The average recoveries of flucarbazone-sodium from muscle fortified at 0.020 and 0.100 mg/kg were 97 and 102%, respectively. In milk, the average recoveries of flucarbazone-sodium at fortifications of 0.005, 0.010, and 0.050 mg/kg were 111 (after correction for background in the control samples, the average recovery was 92%), 97 and 91%, respectively. An independent laboratory validation of the analytical method was performed. The method was successfully validated indicating that the method could be satisfactorily run by following the written procedure.

3. *Magnitude of residues*. Field trials were conducted with wheat at 36 locations to evaluate the quantity of flucarbazone-sodium residues in wheat forage, hay, straw, and grain following treatment with flucarbazone-sodium 70WG at a rate of 30 grams active ingredient/hectacre (g ai/ha). The highest average field trial (HAFT) residue detected in forage, hay, and straw were 0.27, 0.08, and 0.04 mg/kg, respectively. Residues of flucarbazone-sodium were <0.01 mg/kg in wheat grain.

B. Toxicological Profile

1. *Acute toxicity*—i. Flucarbazone-sodium is not toxic to fasted rats following a single oral administration. The oral lethal dose (LD_{50}) is >5,000 mg/kg body weight (bwt) for males and females.

ii. Flucarbazone-sodium is not toxic to rats following a single dermal application. The dermal LD_{50} is >5,000 milligrams/kilogram/body weight (mg/kg/bwt) for males and females.

iii. An acute inhalation study with rats showed low toxicity with a 4–hour dust aerosol lethal concentration (LC_{50}) >5,130 mg/m^3 air for males and females.

iv. An eye irritation study in rabbits showed only very slight, reversible irritation.

v. A dermal irritation study in rabbits showed flucarbazone-sodium is not irritating to skin.

vi. Flucarbazone-sodium has no skin sensitizing potential under the conditions of the maximization test in guinea pigs.

2. *Genotoxicity*. The genotoxic action of flucarbazone-sodium was studied in bacteria and mammalian cells with the aid of various *in vitro* test systems (*Salmonella* microsome test, hypoxanthine guanine phophoribosyl transferase (HGPRT) test with Chinese hamster V79 cells, cytogenetic study with Chinese hamster V79 cells, and unscheduled DNA synthesis test) and in one *in vivo* test (micronucleus test). None of the tests revealed any evidence of a mutagenic or genotoxic potential of flucarbazone-sodium. The compound did not induce point mutation, DNA damage, or chromosome aberration.

3. *Reproductive and developmental toxicity*. In a 2–generation reproduction study, Wistar rats were administered dietary levels of flucarbazone-sodium at levels of 0, 50, 4,000, and 20,000/12,000 parts per million (ppm) (dose reduction week 6). The no observed adverse effect levels (NOAELs) for reproductive parameters was established at 4,000 ppm, based on slight reduction in pup weight development at 12,000 ppm. The NOAELs established for parental males and females were 4,000 and 50 ppm, respectively.

i. A developmental toxicity study was conducted with Sprague-Dawley rats via oral gavage of flucarbazone-sodium at levels of 0, 100, 300, and 1,000 milligrams/kilogram body weight/day (mg/kg bwt/day) on days 6 through 19 of gestation. There were no signs of maternal toxicity, embryotoxicity, fetotoxicity, or teratogenicity at the level of 1,000 mg/kg bwt/day. Therefore, the maternal and developmental NOAELs for rats were established at >1,000 mg/kg bwt/day, the limit dose for this study type.

ii. Himalayan rabbits were administered flucarbazone-sodium at levels of 0, 100, 300, 500, or 1,000 mg/kg/bwt by oral gavage days 6 through 28 post coitum in a test for developmental toxicity. A maternal NOAEL of 100 mg/kg bwt/day was established based on clinical findings, body weight loss, decreased feed consumption, gastrointestinal changes, increased liver weights, and fatty liver changes at 300 mg/kg bwt/day. The gestation rate NOAEL of 100 mg/kg bwt/day was based on one abortion (assessed as secondary due to maternal toxicity) at 300 mg/kg bwt/day. The NOAEL for fetal parameters of 300 mg/kg bwt/day was based on decreased fetal weights and delayed ossification at 500 mg/kg bwt/day. No teratogenic potential of flucarbazone-sodium was evident in rabbits.

4. *Subchronic toxicity*—i. A 28–day dermal rabbit study established a systemic NOAEL of >1,000 mg/kg bwt/day (the dermal limit dose) for males and females. The local dermal effects, skin thickening, seen at 1,000 mg/kg were regarded as a result of mechanical friction and of no toxicological relevance.

ii. A 90–day rat feeding study defined a NOAEL at 250 ppm (17.6 mg/kg bwt/day) for males and 1,000 ppm (101.7 mg/kg bwt/day) for females based on a decreased spleen weight in males at 1,000 ppm and on immunologic changes at 4,000 ppm in females.

iii. A 90–day feeding study with male and female B6C3F1 mice established a NOAEL of 7,000 ppm (equivalent to >2,083, and 3,051 mg/kg bwt/day for males and females, respectively). The dose of 7,000 ppm was the HDT.

iv. A 90–day dog feeding study at levels of 0, 1,000, 5,000, and 50,000 ppm established a NOAEL of 1,000 ppm (equivalent to 33.8 mg/kg bwt/day in males and 35.2 mg/kg bwt/day in females) based on decreased thyroxine levels and increased thyroxine-binding capacity, macroscopic and microscopic effects on the gastric mucosa and an eosinophilic hepatocellular cytoplasm occurring at 5,000 ppm and above. The liver enzyme induction at 1,000 ppm was assessed as a slight adaptive response in the detoxification process of flucarbazone-sodium but not as an adverse effect, due to the absence of clinical chemical changes that would indicate liver damage and due to the

absence of any histopathologic liver changes at this dietary level.

v. A 28–day (6 hours/day; 5 days/week) subacute inhalation toxicity study was conducted with male and female Wistar rats exposed to mean actual concentrations of 5.2, 30.0, 180.1 and 513.3 mg/m^3 air. A NOAEL of 5.2 mg/m^3 air was established based on histopathological changes observed at 30 mg/m^3 air and above.

5. *Chronic toxicity*—i. A 2–year chronic toxicity/oncogenicity study was conducted with male and female Wistar rats at dietary levels of 0, 2.5, 7.5, 125, and 1,000 mg/kg bwt. A NOAEL of 125 mg/kg was established based on increased food consumption (both sexes) and lower body weights (females) at 1,000 mg/kg. No carcinogenic potential was indicated.

ii. B6C3F1 mice were administered flucarbazone-sodium via the diet at levels of 0, 50, 1,000, and 7,000 ppm in a 2–year carcinogenicity study. The NOAEL was established in males and females at 1,000 ppm (equivalent to 275 and 459 mg/kg bwt/day, respectively) based on reduced body weight gain in both sexes and on increased feed consumption in males at the 7,000 ppm level. No carcinogenic potential was indicated.

iii. A 1–year feeding study in dogs at levels of 0, 200, 1,000, and 5,000 ppm established a NOAEL of 1,000 ppm for males (equal to 35.9 mg/kg bwt/day) based on decreased body weight development, increased ALAT- and ASAT-levels and slightly increased N-demethylase levels. The NOAEL of 1,000 ppm for females (equal to 37.1 mg/kg bwt/day) was based on body weight gain depression, increased N-demethylase levels, decreased T4 levels, and marginally increased liver weight.

6. *Animal metabolism*. Flucarbazone-sodium was metabolized via two pathways. The major pathway involved the hydrolysis of the urea linkage forming sulfonamide and N,O-dimethyltriazolinone. The sulfonamide was shown to be the major metabolite in the blood, fat, liver, and muscle at 4 to 6 hours following oral administration of phenyl-UL-14C flucarbazone-sodium. The sulfonamide was conjugated with glucuronic acid or acetate sulfonamide N-glucuronide or N-acetyl sulfonamide or hydroxylated and then conjugated with glucuronic acid to form hydroxysulfonamide-O-glucuronide prior to elimination in the urine. A minor pathway involved N-demethylation of flucarbazone-sodium to form N-desmethyl flucarbazone-sodium followed by hydrolysis to form the sulfonamide and O-methyltriazolinone. Demethylation of N,Odimethyltriazolinone led to the formation of N-methyltriazolinone, O-methyltriazolinone, and ultimately, urazole; methyl urethane was probably formed from the cleavage of O-methyltriazolinone.

7. *Metabolite toxicology*—i. The animal and plant metabolite flucarbazone-sodium sulfonamide (trifluoromethoxysulfonamide) has a low acute oral toxicity (LD_{50} >2,000 mg/kg/bwt) in fasted rats.

ii. The plant metabolite flucarbazone-sodium sulfonamide lactate conjugate has no acute oral toxicity (NOAEL: 5,000 mg/kg/bwt) in fasted rats.

iii. The plant metabolite flucarbazone-sodium sulfonamide alanine has no acute oral toxicity (NOAEL: 5,000 mg/kg/bwt) in fasted rats.

iv. The soil metabolite O-desmethyl flucarbazone-sodium has an acute oral LD_{50} value in fasted male and female rats of >2,500 - <5,000 mg/kg bwt.

v. The plant, animal, and soil metabolite, MKH 10868 (flucarbazone-sodium sulfonic acid Na-salt), has no acute oral toxicity (LD_{50} >5,000 mg/kg bwt) in fasted male and female rats.

vi. MKH 10868 was considered non-mutagenic with and without S9 mix in the plate incorporation as well as in the preincubation modification of the Salmonella/microsome test.

8. *Endocrine disruption*. There is no evidence to suggest that flucarbazone-sodium has an effect on the endocrine system. Studies in this data base include evaluation of the potential effects on reproduction and development, and an evaluation of the pathology of the endocrine organs following short- and long-term exposure. These studies revealed no endocrine effects due to flucarbazone-sodium.

9. *Other studies*—i. An acute neurotoxicity screening study in rats established an overall NOAEL for males and females of 500 mg/kg based on transient neurobehavioral effects. Evidence of toxicity was only slight at a limit dose of 2,000 mg/kg and complete recovery occurred within 7 days following treatment.

ii. A subchronic neurotoxicity screening study in rats established an overall NOAEL of 2,000 ppm for males (equal to 147 mg/kg bwt/day) and 20,000 ppm (equal to 1,736 mg/kg bwt/day) for females based on a slight decrease in body weight and food consumption. The NOAEL for microscopic lesions was 20,000 ppm for males and females, the highest dose tested (HDT). There was no evidence of neurotoxicity at any dietary level.

iii. A plaque-forming-cell assay (to investigate immunotoxicological potential) was performed on rats after a 4–week dietary exposure. The NOAEL of 20,000 ppm (equivalent to 2,205 and 2,556mg/kg bwt/day in males and females, respectively) was based on the lack of specific effects in the HGT.

iv. The immunotoxicity potential of flucarbazone-sodium was additionally investigated in antibody plaque-cell forming assays and in assays examining splenic T-cells, B-cells, and NK-cells after 4–week dietary administrations in male and female rats at levels up to and including 1,000 mg/kg bwt/day. There was no statistically significant effect on the humoral immune system and no effects on splenic cell populations, cell-mediated immune response, or the innate immune response in males or females. The NOAEL for immunotoxicity from these studies was 1,000 mg/kg bwt/day, the immunotoxicity limit dose.

C. Aggregate Exposure

1. *Dietary exposure*—i. *Food*. Estimates of chronic dietary exposure to residues of flucarbazone-sodium utilized the proposed tolerance-level residues for wheat forage, wheat hay, wheat straw, wheat grain, meat, liver, and milk of 0.30, 0.10, 0.05, 0.01, 0.01, 1.50, and 0.005 ppm, respectively. Other assumptions were that 100% of the target crop would be treated with flucarbazone-sodium and that no loss of residue would occur due to processing and/or cooking. A chronic reference dose (RfD) of 0.36 milligrams/kilogram/day (mg/kg/day) was assumed based on the NOAEL of 35.9 mg/kg/day from the one year dog feeding study. A safety factor of 100 was used based on interspecies extrapolation (10x) and intraspecies variability (10x). Using these conservative assumptions, dietary residues of flucarbazone-sodium contribute 0.006659 mg/kg/day (2% of the RfD) for children 1-6 years, the most sensitive sub-population. For the U.S. population, the exposure was 0.002891 mg/kg/day (1% of the RfD). For acute dietary exposure, the same conservative assumptions were made. Based on the NOAEL of 300 mg/kg/day from the rabbit developmental toxicity study, an acute RfD of 3.0 mg/kg/day was used to calculate the acute dietary risk to the most exposed subgroup: females, 13 to 50 years old. The acute dietary exposure from food to flucarbazone-sodium will occupy <1% of the RfD for females, 13 to 50 years old.

ii. *Drinking water*. Given the post-emergence application pattern, low use rates and rapid soil degradation of flucarbazone-sodium, the risk of ground and surface water contamination and exposure via drinking water is negligible. The surface water model

generic expected environment concentration (GENEEC) and the ground water model (SCI-GROW) were used to determine whether drinking water from surface or ground water sources represented a worst-case exposure scenario. These models predict residues of flucarbazone-sodium would be higher in surface water. Assuming a worst-case GENEEC scenario where residues of flucarbazone-sodium occur in surface water used for drinking water at the highest predicted acute and chronic concentrations, the risk from exposure to residues of flucarbazone-sodium are well within EPA's acceptable limits.

The GENEEC model predicted an acute surface water concentration of flucarbazone-sodium of 1.45 µg/L. Assuming a 70 kilogram (kg) adult drinks 2 liters/day containing 1.45 µg/L, the acute exposure would be 0.0000414 mg/kg/day for adults. Assuming a 10 kg child drinks 1 liter/day containing 1.45 µg/L, the exposure would be 0.000145 mg/kg/day. Based on the NOAEL of 300 mg/kg/day from the rabbit developmental toxicity study and assuming a safety of 100 (10x for interaspecies variability and 10x for interspecies extrapolation), the MOE for adults of 72,500 and for children of 20,700 do not exceed EPA's level of concern for adults or children. This assessment is based on the GENEEC highest predicted acute concentration of flucarbazone-sodium in drinking water using worst-case assumptions.

Using GENEEC, the highest predicted chronic (60–day exposure) concentration of flucarbazone-sodium was 1.44 µg/L. EPA interim policy recommends that the 60–day GENEEC value to be divided by an adjustment factor of 3 to obtain a value for chronic risk assessment calculations. Therefore, a surface water value of 0.48 µg/L was used for chronic risk assessment. Assuming a 70 kg adult consumes 2 liters (L) of water per day containing 0.48 µg/L of flucarbazone-sodium residues for a period of 70 years, less than 0.004% of the RfD was consumed from residues of flucarbazone-sodium in surface water used for drinking water (worst-case scenario). For a 10 kg child drinking 1 L of water per day containing 0.48 µg/L of flucarbazone-sodium residues, only 0.01% of the RfD was consumed by drinking water.

2. *Non-dietary exposure*. There are no current non-food uses for flucarbazone-sodium registered under the Federal Insecticide,Fungicide, and Rodenticide Act (FIFRA), as amended. No non-food uses are proposed for flucarbazone-sodium. No non-dietary exposures are expected for the general population.

D. Cumulative Effects

Flucarbazone-sodium falls into the category of sulfonamide herbicides. There is no information to suggest that any of this class of herbicides has a common mechanism of mammalian toxicity or even produce similar effects so it is not appropriate to combine exposures of flucarbazone-sodium with other herbicides. Arvesta Corporation is considering only the potential risk of flucarbazone-sodium.

E. Safety Determination

1. *U.S. population*. As presented previously, the exposure of the U.S. general population to flucarbazone-sodium is low, and the risks, based on comparisons to the reference dose, are minimal. The margins of safety from the use of flucarbazone-sodium are well within EPA's acceptable limits. Arvesta Corporation concludes that there is a reasonable certainty that no harm will result to the U.S. population from aggregate exposure to flucarbazone-sodium residues.

2. *Infants and children*. The complete toxicological data base including the developmental toxicity and 2–generation reproduction studies were considered in assessing the potential for additional sensitivity of infants and children to residues of flucarbazone-sodium. The developmental toxicity studies in rats and rabbits revealed no increased sensitivity of rats or rabbits to in-utero exposure to flucarbazone-sodium. The 2–generation reproduction study did not reveal any increased sensitivity of rats to in-utero or postnatal exposure to flucarbazone-sodium. Furthermore, none of the other toxicology studies revealed any data demonstrating that young animals were more sensitive to flucarbazone-sodium than adult animals. The data taken collectively clearly demonstrate that application of a Food Quality Protection Act (FQPA) uncertainty factor for increased sensitivity of infants and children is not necessary for flucarbazone-sodium.

F. International Tolerances

A default Maximum Residue Limit (MRL) of 0.01 ppm has been established in Canada for residues of flucarbazone-sodium and its N-desmethyl metabolite on wheat grain. This value is consistent with the tolerance being proposed in the United States on wheat grain. There are no harmonized MRLs at the European Union level and no Codex MRLs for this compound on wheat at present. Therefore, no compatibility issues exist with Codex in regard to the proposed U.S. tolerances.

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ENVIRONMENTAL PROTECTION AGENCY

[OPP–2005–0166; FRL–7719–5]

Potassium Silicate; 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 identification (ID) number OPP–2005–0166, must be received on or before August 26, 2005.

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: Carol E. Frazer, Biopesticides and Pollution Prevention Division (7511C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–8810; e-mail address:*frazer.carol@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

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