

Transmission Service Tariff, FERC Original Volume No. 11.

*Comment date:* August 14, 1997, in accordance with Standard Paragraph E at the end of this notice.

## 21. Black Hills Corporation

[Docket No. ER97-3711-000]

Take notice that on July 14, 1997, Black Hills Corporation, which operates its electric utility business under the assumed name of Black Hills Power and Light Company (Black Hills), tendered for filing an executed Form Service Agreement with Rainbow Energy Marketing Corporation.

Copies of the filing were provided to the regulatory commission of each of the states of Montana, South Dakota, and Wyoming.

Black Hills has requested that further notice requirement be waived and the tariff and executed service agreements be allowed to become effective June 23, 1997.

*Comment date:* August 14, 1997, in accordance with Standard Paragraph E at the end of this notice.

## 22. Central Hudson Gas and Electric Corporation

[Docket No. ER97-3712-000]

Take notice that on July 14, 1997, Central Hudson Gas and Electric Corporation (CHG&E), tendered for filing pursuant to 35.12 of the Federal Energy Regulatory Commission's (Commission) Regulations in 18 CFR a Service Agreement between CHG&E and Entergy Power Marketing Corporation. The terms and conditions of service under this Agreement are made pursuant to CHG&E's FERC Electric Rate Schedule, Original Volume No. 1 (Power Sales Tariff) accepted by the Commission in Docket No. ER97-890-000. CHG&E also has requested waiver of the 60-day notice provision pursuant to 18 CFR 35.11.

A copy of this filing has been served on the Public Service Commission of the State of New York.

*Comment date:* August 14, 1997, in accordance with Standard Paragraph E at the end of this notice.

## 23. Central Hudson Gas & Electric Corporation

[Docket No. ER97-3713-000]

Take notice that on July 14, 1997, Central Hudson Gas & Electric Corporation (CHG&E), tendered for filing pursuant to 35.12 of the Federal Energy Regulatory Commission's (Commission) Regulations in 18 CFR a Service Agreement between CHG&E and Delmarva Power & Light Company. The terms and conditions of service under

this Agreement are made pursuant to CHG&E's FERC Open Access Schedule, Original Volume No. 1 (Transmission Tariff) filed in compliance with the Commission's Order No. 888 in Docket No. RM95-8-000 and RM94-7-001. CHG&E also has requested waiver of the 60-day notice provision pursuant to 18 CFR 35.11.

A copy of this filing has been served on the Public Service Commission of the State of New York.

*Comment date:* August 14, 1997, in accordance with Standard Paragraph E at the end of this notice.

## 24. Bruce Demars

[Docket No. ID-3057-000]

Take notice that on July 15, 1997, Bruce Demars (Applicant) tendered for filing an application under Section 305(b) of the Federal Power Act to hold the following positions:

Director—Commonwealth Edison

Company

Director—McDermott International, Inc.

*Comment date:* August 15, 1997, in accordance with Standard Paragraph E at the end of this notice.

## 25. Deseret Generation & Transmission Cooperative

[Docket No. OA97-675-000]

Take notice that Deseret Generation and Transmission Cooperative (Deseret) on July 14, 1997, tendered for filing a transmission tariff in compliance with the Commission's Order No. 888-A. Deseret asks the Commission to set an effective date for the tariff of October 16, 1996.

Copies of the filing were served upon Deseret's member cooperatives and customers.

*Comment date:* August 15, 1997, in accordance with Standard Paragraph E at the end of this notice.

## 26. Upper Peninsula Power Company

[Docket No. OA97-676-000]

Take notice that on July 14, 1997, Upper Peninsula Power Company (UPPCO) tendered for filing a revised open access transmission tariff in accordance with FERC Order No. 888-A. UPPCO states that the revised tariff supersedes in its entirety an open access transmission tariff in the form prescribed by FERC Order No. 888 that was previously filed in Docket No. OA97-523-000. UPPCO has proposed to make its revised tariff effective as of July 14, 1997 or such later date as may be prescribed by the Commission for the effectiveness of tariffs conforming to FERC Order No. 888-A.

*Comment date:* August 15, 1997, in accordance with Standard Paragraph E at the end of this notice.

## 27. PJM Interconnection, L.L.C.

[Docket No. OA97-678-000]

Take notice that on July 14, 1997, PJM Interconnection, L.L.C. (PJM), on behalf of Atlantic City Electric Company, Baltimore Gas and Electric Company, Delmarva Power & Light Company, Jersey Central Power & Light Company, Metropolitan Edison Company, Pennsylvania Electric Company, PECO Energy Company, Pennsylvania Power & Light Company, Potomac Electric Power Company and Public Service Electric and Gas Company, tendered for filing revisions to the PJM Open Access Tariff to comply with the requirements of Order No. 888-A.

Copies of this filing were served upon the regulatory commissions of Delaware, the District of Columbia, Maryland, New Jersey, Pennsylvania, and Virginia, members of the PJM Interconnection, LLC, and entities with transmission service agreements under the PJM Tariff.

*Comment date:* August 15, 1997, in accordance with Standard Paragraph E at the end of this notice.

## Standard Paragraph

E. Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, D.C. 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 18 CFR 385.214). All such motions or protests should be filed on or before the comment date. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

**Lois D. Cashell,**

Secretary.

[FR Doc. 97-20799 Filed 8-6-97; 8:45 am]

BILLING CODE 6717-01-P

## ENVIRONMENTAL PROTECTION AGENCY

[PF-750; FRL-5727-3]

## Pesticide Tolerance Petition; Notice of Filing

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

**ACTION:** Notice of filing.

**SUMMARY:** This notice announces the filing of a pesticide petition proposing regulations amending the established tolerances for residues of the insecticidal fluorine compounds cryolite and/or synthetic cryolite (sodium aluminum fluoride or sodium aluminofluoride) in or on cabbage, citrus fruits, collards, eggplant, lettuce, peaches, and tomatoes; and establishing tolerances for the processed foods, raisins and tomato paste. This notice includes a summary of the petition that was prepared by the petitioner, The Cryolite Task Force.

**DATES:** Comments, identified by the docket control number [PF-750], must be received on or before September 8, 1997.

**ADDRESSES:** By mail submit written comments to: Public Information and Records Integrity Branch, Information Resources and Services Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person bring comments to: Rm. 1132, CM #2, 1921 Jefferson Davis Highway, Arlington, VA.

Comments and data may also be submitted electronically by following the instructions under "SUPPLEMENTARY INFORMATION." No confidential business information should be submitted through e-mail.

Information submitted as a comment concerning this document may be claimed confidential by marking any part or all of that information as "Confidential Business Information" (CBI). CBI should not be submitted through e-mail. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice. All written comments will be available for public inspection in Rm. 1132 at the address given above, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

**FOR FURTHER INFORMATION CONTACT:** By mail: Jackie Mosby (7505C), Registration Division, Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. 203, CM #2, 1921 Jefferson Davis Highway, Arlington, VA, (703) 305-6792, e-mail: mosby-romney.jackie@epamail.epa.gov.

**SUPPLEMENTARY INFORMATION:** EPA has received a pesticide petition from The Cryolite Task Force c/o Gowan, P.O. Box 5568, Yuma, AZ 85366. The petition proposes, pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, to amend 40 CFR 180.145 by: (1) Increasing the established tolerances for residues of the insecticidal fluorine compounds cryolite and /or synthetic cryolite in or on the agricultural commodities as listed below; (2) establishing separate tolerances for the residues in or on head and leaf lettuce; and (3) establishing tolerances for the residues in the processed foods, raisins at 55 ppm, and tomato paste at 45 ppm.

Commodity	Current	Proposed
cabbage	7 ppm	45 ppm
citrus fruits	7 ppm	95 ppm
collards	7 ppm	35 ppm
eggplant	7 ppm	30 ppm
lettuce	7 ppm	
lettuce, head		180 ppm
lettuce, leaf		40 ppm
peaches	7 ppm	10 ppm
raisins	none	55 ppm
tomatoes	7 ppm	30 ppm
tomato paste	none	45 ppm

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

As required by section 408(d) of the FFDCA, as recently amended by the Food Quality Protection Act, The Cryolite Task Force included in the petition a summary of the petition and authorization for the summary to be published in the **Federal Register** in a notice of receipt of the petition. The summary represents the views of The Cryolite Task Force; EPA is in the process of evaluating the petition. As required by section 408(d)(3) EPA is including the summary as a part of this notice of filing. EPA may have made minor edits to the summary for purposes of clarity.

The official record for this notice of filing, as well as the public version, has been established for this notice of filing under docket control number PF-750 (including comments and data submitted electronically as described below). A public version of this record, including printed, paper versions of electronic comments, which does not

include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The official record is located at the address in "ADDRESSES" at the beginning of this document.

Electronic comments can be sent directly to EPA at:  
opp-docket@epamail.epa.gov

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comment and data will also be accepted on disks in Wordperfect 5.1 file format or ASCII file format. All comments and data in electronic form must be identified by the docket control number PF-745 and appropriate petition number. Electronic comments on this notice may be filed online at many Federal Depository Libraries.

**List of Subjects**

Environmental Protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: July 31, 1997.

**Peter Caulkins,**

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

**Summary of Petition**

This informative summary is submitted by the Cryolite Task Force (Consortium No. 62569), under section 408 of FFDCA, as most recently amended by FQPA. The Cryolite Task Force is comprised of Elf Atochem North America and Gowan Company. The Cryolite Task Force previously has petitioned the Agency to amend tolerances for residues of cryolite and/or synthetic cryolite (sodium aluminofluoride) in or on the raw agricultural commodities: lettuce (head), lettuce (leaf), cabbage, collards, eggplant, tomatoes, citrus (crop group) and peaches and to establish tolerances for residues of cryolite in processed foods: raisins and tomato paste. EPA approved these new and revised tolerances in the Cryolite Reregistration Eligibility Decision (RED) and noted its intent to propose these in the **Federal Register**. However, prior to publication of the new regulations, FQPA specified additional requirements for tolerance petitions. The purpose of this submission is to provide the additional information specified in the FQPA.

**Cryolite Task Force**

PP 5F4599

**A. Residue Data**

1. *Name, identity, and composition of the residue.* Cryolite (sodium aluminofluoride, sodium hexafluoroaluminate, or sodium aluminum fluoride) is a fluorine containing insecticide which is found in naturally occurring mineral deposits and also is produced synthetically.

Empirical Formula: Na<sub>3</sub>AlF<sub>6</sub>

Molecular Weight: 209.97

CAS Registry No.: 15096-52-3

OPP Chemical Code: 075101

A Reregistration Eligibility Decision (RED) was issued for cryolite in August 1996. As documented in the RED, the Agency has determined that plant residues are inorganic surface residues of cryolite, measured as total fluoride; and that the residue of concern in animals also is total fluoride.

Provisions in the FQPA which are relevant to degradates or metabolites of pesticide chemical residues are not applicable to elemental fluorine.

*Magnitude of the residue in plants.*

Residue data covering all of the uses associated with the RAC tolerances requested by this petition have been reviewed and approved by the Agency (see the Cryolite RED, pages 19 - 26). The proposed tolerance amendments are summarized, below:

Lettuce (head) - 180 ppm

Lettuce (leaf) - 40 ppm

Cabbage - 45 ppm

Collards - 35 ppm

Eggplant - 30 ppm

Tomato - 30 ppm

Citrus fruit group - 95 ppm

Peaches - 10 ppm

2. *Magnitude of the residue in processed food/feed.* As documented in the RED, EPA has concluded that acceptable processing studies support the proposed tolerances of 45 ppm for tomato paste and 55 ppm for raisins.

3. *Directions for use.* Use directions consistent with the proposed revised RAC and new processed food tolerances have been approved by the Agency. Labeling was approved by EPA for the Gowan registration (10163-41) on May 10, 1995. Labeling was approved for the Atochem registration (4581-116) on October 26, 1995.

4. *Analytical method.* EPA concluded in the cryolite RED that adequate methodology is available for data collection and tolerance enforcement. Methods for both plant residues and animal tissues have undergone successful Agency validation and will be published in the *Pesticide Analytical Manual, Vol. II*. Using these methods,

total fluoride is determined using a pH/ion meter with a fluoride-specific electrode. The limit of quantitation is 0.05 ppm. The residue analytical method does not distinguish between naturally occurring fluoride and fluoride resulting from agricultural use of cryolite. Current FDA multi-residue screening protocols are not appropriate for inorganic fluoride residues.

5. *Practical methods for removing residues.* Plant residues are inorganic surface residues of cryolite. Data reviewed by EPA for the RED show that washing, peeling, and trimming are effective methods of removing these residues.

6. *Plant metabolism.* EPA concluded in the cryolite RED that the qualitative nature of the residue in plants is understood and that plant residues are inorganic surface residues of cryolite which are measured as fluoride.

7. *Animal metabolism.* EPA concluded in the cryolite RED that cryolite metabolism in animals manifests itself as free fluoride, that the qualitative nature of the residue is understood and that total fluoride is the residue of concern.

8. *Magnitude of the residue in meat, milk, poultry and eggs.* EPA concluded in the cryolite RED that there is no reasonable expectation of finite fluoride residues in ruminant or poultry tissues as a result of livestock ingestion of cryolite.

**B. Toxicological Data**

The cryolite RED concluded that the toxicological data base supports a reregistration eligibility decision for numerous crops, including head lettuce, leaf lettuce, cabbage, collards, eggplant, tomatoes, citrus (crop group), grapes, and peaches. No additional toxicology requirements were specified in the RED. The cryolite residue of toxicological concern is fluoride; and health effects identified for fluoride in humans and animals are skeletal and dental fluorosis. Dental fluorosis (mottling of tooth enamel) is not considered to be an adverse effect. Further, the Agency has determined that although fluoride accumulation is demonstrated in a number of studies, the accumulation itself is not considered an adverse effect.

1. *Acute toxicity.* A rat acute oral toxicity study (MRID 00138096) showed an LD<sub>50</sub> greater than 5,000 milligrams/kilograms (mg/kg). A rabbit acute dermal toxicity study (MRID 00128107) demonstrated an LD<sub>50</sub> of 2,100 mg/kg. An LC<sub>50</sub> > 2.06 mg/L and < 5.03 mg/L was seen in an acute inhalation study with rats (MRID 00128107). Technical cryolite is a moderate eye irritant in rabbits (MRID 00128106). Cryolite is not

a skin irritant to rabbits (MRID 00128106) and is not a dermal sensitizer to guinea pigs (MRID 00138097).

2. *Subchronic toxicity.* Cryolite was tested in a 28-day range-finding feeding study in rats (MRID 00128109) at dose levels of 0, 250, 500, 1,000, 2,000, 4,000, 10,000, 25,000 and 50,000 ppm in the diet (representing approximately 0, 25, 50, 100, 200, 400, 1,000, 2,500 and 5,000 mg/kg/day). The only compound related effect seen in this study was a change in coloration and physical property of the teeth. A no observed effect level (NOEL) was not determined in this study. The lowest observed effect level (LOEL) is 250 ppm (25 mg/kg/day) based on dental fluorosis.

In a 90-day rat feeding study (MRID 00158000), cryolite was tested at dose levels of 0, 50, 5,000 and 50,000 ppm (corresponding to 0, 3.8, 399.2, and 4,172.3 mg/kg/day in males and 0, 4.5, 455.9 and 4,758.1 mg/kg/day in females). The NOEL was 50 ppm (3.8 mg/kg/day) for effects other than fluoride accumulation. The LOEL was 5,000 ppm (399.2 mg/kg/day) based on lesions observed in the stomach. Fluoride accumulated at all dose levels in this study.

Cryolite was tested in a 90-day dog feeding study (MRID 00157999) at dose levels of 0, 500, 10,000, and 50,000 ppm (corresponding to 0, 17, 368, and 1,692 mg/kg/day). The NOEL was 10,000 ppm (368 mg/kg/day). The LOEL was 50,000 ppm (1,692 mg/kg/day) for effects other than fluoride accumulation. Fluoride accumulation occurred at all dose levels.

A 21-day subchronic dermal toxicity study in rabbits (MRID 41224801) is considered invalid because it is likely that cryolite was ingested by the test animals during the study. For this reason, the systemic dermal NOEL and LOEL could not be determined from this study. EPA noted in the RED that an additional subchronic dermal study is not necessary, because based on its chemical/physical properties, cryolite would not be absorbed through the skin to any appreciable extent.

3. *Genotoxicity.* Cryolite was negative in an Ames reverse mutation test (MRID 41838401) using *Salmonella typhimurium* with and without activation at dose levels of 167, 500, 1,670, 5,000, 7,500 and 10,000 µg/plate. Cryolite was tested in an *in vitro* chromosome aberration assay (MRID 41838402) using human lymphocytes at 100, 500, and 1,000 µg/ml, with and without activation. The results were negative. Cryolite also was negative in an unscheduled DNA synthesis study (MRID 41838403) with rat hepatocytes

at dose levels up to and including 50 µg/ml.

4. *Chronic toxicity.* The Agency concluded in the cryolite RED that the available information does not support the regulation of cryolite insecticides as carcinogens. EPA has classified cryolite as a Group "D" chemical (not classifiable as to human carcinogenicity.) Further, EPA has noted that fluoride has been the subject of a comprehensive review by the National Research Council (National Academy of Sciences Subcommittee of Health Effects of Ingested Fluoride) who concluded that "... the available laboratory data are insufficient to demonstrate a carcinogenic effect of fluoride in animals" and that "... the weight of evidence from more than 50 epidemiological studies does not support the hypothesis of an association between fluoride exposure and increased cancer risk in humans." As stated in the **Federal Register** of May 8, 1996, and reiterated in the cryolite RED, the Agency is in agreement with the conclusions reached by the National Academy of Science (NAS).

The following specific chronic/oncogenicity studies are included in the cryolite toxicology data base:

A 2-year bioassay in B6C3F1 mice (HED DOC No. 009682) was conducted by the National Toxicology Program (NTP) using sodium fluoride as the test material at dose levels of 0, 25, 100, and 175 ppm, in water, representing 0, 2.4, 9.6, and 16.7 mg/kg/day in males and 0, 2.8, 11.3, and 18.8 mg/kg/day in females. The NOEL was less than 25 ppm (2.4 mg/kg/day). The LOEL was 25 ppm (2.4 mg/kg/day) based on attrition of the teeth in males, discoloration and mottling of the teeth in males and females and increased bone fluoride in both sexes. NTP considered that there was "no evidence" of carcinogenic activity in male and female mice. A 2-year bioassay in F344/N rats (HED DOC No. 009682) also was conducted by the National Toxicology Program (NTP) using sodium fluoride as the test material at dose levels of 0, 25, 100, and 175 ppm, in water, representing 0, 1.3, 5.2 and 8.6 mg/kg/day in males and 0, 1.3, 5.5 and 9.5 mg/kg/day in females. Osteosarcoma of the bone was observed only in one male of fifty (1/50) in the 100 ppm group and in three of eighty (3/80) males in the 175 ppm group. The NOEL was less than 25 ppm (1.3 mg/kg/day). The LOEL was 25 ppm (1.3 mg/kg/day) based on mottling of teeth, dentine incisor dysplasia, increased serum, urine and bone fluoride levels in males and females and incisor odontoblast and incisor ameloblast degeneration in males. NTP considered that there was

"equivocal evidence" of carcinogenic activity in male rats in this study and "no evidence" of carcinogenic activity in female rats.

EPA concluded in the cryolite RED that the NTP studies utilizing sodium fluoride in lieu of cryolite satisfy the guideline study requirements for both the rodent chronic feeding study and the rat carcinogenicity study. Fluoride has been identified as the residue of toxicological concern in cryolite and synthetic cryolite and these compounds act as free fluoride. It may be noted that the NTP studies, which utilized freely soluble NaF represent a "worst-case" toxicological scenario on a ppm basis compared to what would be expected with cryolite *per se*, from which fluoride ion dissociation is much more limited.

A 1-year chronic dog feeding study (MRID 42575101) was conducted with cryolite at dose levels of 0, 3,000, 10,000, and 30,000 ppm, representing 0, 95, 366, and 1,137 mg/kg/day in males and 0, 105, 387, and 1,139 mg/kg/day in females (in terms of fluoride the doses are 0, 51, 198, and 614 mg F/kg/day for males and 0, 57, 209, and 615 mg F/kg/day for females). The NOEL was less than 3,000 ppm (95 mg/kg/day in males and 105 mg/kg/day in females). The LOEL was 3,000 ppm based on increases in emesis, nucleated cells in males, renal lesions and a decrease in urine specific gravity in females.

5. *Reproductive toxicity.* A two-generation rat reproduction study (MRID 43387501) was conducted with cryolite at dietary dose levels of 0, 200, 600, and 1,800 ppm (representing 0, 14, 42, and 128 mg/kg/day for males and 0, 16, 49, and 149 mg/kg/day for females, respectively, during premating). The systemic toxicity NOEL was not determined. The LOEL for systemic toxicity was 200 ppm (15 mg/kg/day) based on dental fluorosis. The NOEL and LOEL for reproductive toxicity were 600 and 1,800 ppm, respectively (46 and 138 mg/kg/day) based on decreased pup body weights.

The National Research Council (NRC) has reviewed the potential for reproductive effects from fluoride *per se*. In the report Health Effects of Ingested Fluoride, the NRC concluded that:

There have been reports of adverse effects on reproductive outcomes associated with high levels of fluoride in many animal species. In most of the studies, however, the fluoride concentrations associated with adverse effects were far higher than those encountered in drinking water. The apparent threshold concentration for inducing reproductive effects was 100 mg/L in mice, rats, foxes and cattle; 100-200 mg/L in minks,

owls and kestrels; and over 500 mg/L in hens. Based on these findings, the subcommittee concludes that the fluoride concentrations associated with adverse reproductive effects in animals are far higher than those to which human populations are exposed. Consequently, ingestion of fluoride at current concentrations should have no adverse effects on human reproduction.

6. *Developmental toxicity.* A developmental toxicity study was performed with cryolite in rats (MRID 00128112) at dose levels of 0, 750, 1,500 and 3,000 mg/kg/day (gavage). The NOEL for both developmental and maternal toxicity was 3,000 mg/kg/day. At this dose level, the only observation was whitening of the teeth of dams.

A developmental toxicity study was conducted in female mice (MRID 42297902) with cryolite at dose levels of 0, 30, 100, and 300 mg/kg/day (gavage). The NOEL for maternal toxicity was 30 mg/kg/day and the LOEL was 100 mg/kg/day based on a single mortality in this group. Fetuses at 300 mg/kg/day exhibited bent ribs and bent limb bones. The NOEL for developmental toxicity was 100 mg/kg/day. The LOEL was 300 mg/kg/day based on an increase in bent ribs and bent limbs.

A range-finding developmental toxicity study in female rabbits (MRID 42297901) tested cryolite at dose levels of 0, 10, 30, 100, 300, and 1,000 mg/kg/day (gavage). The NOEL for maternal toxicity was determined to be 10 mg/kg/day and the LOEL was 30 mg/kg/day based on an increased incidence of soft stool and dark colored feces and decreased defecation and urination. The NOEL for developmental toxicity was 30 mg/kg/day. The developmental LOEL could not be assessed due to excessive maternal toxicity at dose levels of  $\leq$  30 mg/kg/day.

7. *Metabolism/metabolite toxicity.* As noted in the RED, cryolite behaves toxicologically as free fluoride. That is, dissociation produces free fluoride ions which are assimilated into bone. There are numerous references in the open literature concerning the metabolism of cryolite and other fluoride salts. The National Research Council concluded in their 1993 comprehensive report entitled Health Effects of Ingested Fluoride that fluoride is readily absorbed by the gut and rapidly becomes associated with teeth and bones. The remaining fluoride is eliminated almost exclusively by the kidneys with the rate of renal clearance related directly to urinary pH.

8. *Endocrine effects.* The two-generation rat reproduction study, the developmental toxicity studies in rats, rabbits and mice and the dog chronic study summarized above did not

demonstrate any effects with cryolite that are similar to those produced by naturally occurring estrogens, or other endocrine effects. No endocrine effects were determined in the rat and mouse NTP studies. In addition, it should be noted that National and International regulatory organizations (U.S. EPA Office of Water, U.S. DHHS, the Canadian Government and the World Health Organization) have assessed potential health risks from exposure to fluoride. EPA has concluded that the endpoints and estimated effect levels documented by these organizations are similar and that the health effects of fluoride in animals and humans include dental and skeletal fluorosis. Endocrine effects have not been recognized as toxicological endpoints for fluoride by any worldwide regulatory authority.

#### C. Aggregate Exposure

1. *Dietary exposure-food.* As noted in the RED, the Agency has estimated dietary exposure to cryolite using reassessed tolerances for all crops (including the proposed tolerances discussed in this petition) and percent of crop treated assumptions. In the RED EPA estimated dietary exposure to cryolite from all crops to be approximately 0.020 mg/kg/day for the U.S. population, 0.024 mg/kg/day for children ages 1 to 6, 0.015 mg/kg/day for children ages 7 to 12 and 0.028 mg/kg/day for the highest exposed subgroup (nursing females 13+ years). The Task Force believes that these exposure estimates in fact greatly overstate actual dietary exposure since cryolite tolerance levels, rather than residues actually present at the consumer level were used by EPA in the exposure assessments.

2. *Dietary exposure-drinking water.* In the Environmental Fate Assessment conducted for the RED, the Agency concluded that the use of cryolite should have negligible impacts on fluoride levels in ground and surface water. For this reason, the contribution of cryolite to potential exposure to fluoride from drinking water need not be considered in the aggregate risk assessment.

However, fluoride is intentionally supplemented to drinking water for prevention of dental caries and may also be present at natural background levels. The U.S. Public Health Service recommends an optimal fluoride concentration of 0.7 - 1.2 mg/L to prevent dental caries and minimize dental fluorosis.

Fluoride levels in public drinking water are regulated under the Safe Drinking Water Act. A Maximum Concentration Limit (MCL) of 4.0 mg/L (0.114 mg/kg/day) has been established.

EPA has estimated previously that levels of fluoride in/on food from the agricultural use of cryolite plus fluoride levels in U.S. drinking water supplies results in a daily dietary intake of fluoride of approximately 0.095 mg/kg/day. This is substantially less than the Maximum Concentration Limit (MCL) of 4.0 mg/L (0.144 mg/kg/day), a level which provides no known or anticipated adverse health effect as determined by the Surgeon General. As noted in the RED, the Agency has concurred with the findings of the Surgeon General that adverse health effects have not been found in the U. S. population below 8 mg F/L (0.23 mg/kg/day).

3. *Non-dietary exposure.* Cryolite is used almost exclusively as an agricultural crop protection insecticide. Conceivably, cryolite also could be used in outdoor homeowner/residential sites for insect control in ornamentals and shade trees. Cryolite is not registered for either lawn or crack and crevice treatments. EPA concluded in the RED that a post-application exposure assessment for cryolite (including both occupational and residential exposure) was not appropriate since no toxicological endpoints relevant to non-dietary exposure have been identified for cryolite.

The Task Force concludes that non-dietary exposure represents a negligible component of potential aggregate exposure to cryolite and need not be considered in the aggregate risk assessment.

#### D. Cumulative Effects

The residue of toxicological concern in cryolite is fluoride. Although fluoride supplements in drinking water are not considered to be pesticidal substances, the dietary contribution of drinking water to overall fluoride exposure has been discussed elsewhere in this summary. Current tolerances for insecticidal fluorine-containing compounds are limited to cryolite and synthetic cryolite. For this reason, consideration of potential cumulative effects of residues from pesticidal substances other than sodium aluminofluoride with a common mechanism of toxicity are not applicable.

#### E. Safety Determination

1. *U.S. population.* As discussed above, non-dietary exposure to cryolite is negligible. As stated in the RED, the OPP's Health Effects Division's RfD Peer Review Committee concluded that "For acute dietary exposure, no endpoint of concern could be found from which an acute dietary risk assessment. . .should

be conducted." There was no endpoint for acute dietary exposure since acute toxicity in animal studies is absent until very high doses of cryolite were used. For chronic dietary exposure to cryolite, EPA has concluded that rather than establishing a traditional Reference Dose (RfD), a weight-of-the-evidence risk assessment is a more appropriate approach. The endpoint for chronic dietary exposure is skeletal fluorosis. As part of the RED decision for cryolite, EPA conducted a chronic exposure analysis using the Dietary Risk Evaluation System (DRES). This analysis was performed using the proposed tolerances that are the subject of this petition. The Agency has approximated that total dietary fluoride levels in food plus drinking water is 0.095 mg/kg/day. Of this total exposure, the dietary (food) contribution is about 0.020 mg/kg/day for the U.S. population and 0.028 mg/kg/day for the highest exposed subgroup. These exposure estimates likely overstate actual dietary exposure, since marketbasket residue levels for cryolite have not been considered. As noted above, the Agency has concurred with the findings of the Surgeon General that adverse health effects (skeletal fluorosis) have not been found in the U. S. population below 8 mg F/L (0.23 mg/kg/day).

2. *Infants and children.* EPA has concluded previously that in rats, the developmental NOEL for cryolite is 3,000 mg/kg/day (1,584 mg/kg/day F), that in mice, the developmental NOEL is 100 mg/kg/day (52.8 mg/kg/day F) and that in rabbits, the developmental NOEL is 30 mg/kg/day (15.8 mg/kg/day F). The NOEL for reproductive toxicity of cryolite determined in a 2-generation rat reproduction study was determined by the Agency to be 46 mg/kg/day (24.3 mg/kg/day F). These data show clearly that no additional margin of safety is required for exposure of infants and children to cryolite. The developmental NOEL ranges from more than 166x (rabbit) to more than 16,000x (rat) for the maximum combined exposure of infants and children to residues of fluoride from all agricultural uses of cryolite plus drinking water. The reproductive NOEL is about 256x greater than maximum combined exposure of infants and children to residues of fluoride.

#### F. International Tolerances

No Codex, EC or other international tolerances are in effect for cryolite; thus potential dietary exposure to fluoride from the agricultural use of cryolite on

crops would not include imported foodstuffs.

[FR Doc. 97-20845 Filed 8-6-97; 8:45 am]

BILLING CODE 6560-50-F

## ENVIRONMENTAL PROTECTION AGENCY

[FRL-5872-1]

### Agency Information Collection Activities Under OMB Review

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

**ACTION:** Notice.

**SUMMARY:** This notice announces the Office of Management and Budget's (OMB) responses to Agency clearance requests, in compliance with the Paperwork Reduction Act (44 U.S.C. 3501 et. seq.). An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations are listed in 40 CFR Part 9 and 48 CFR Chapter 15.

**FOR FURTHER INFORMATION CONTACT:** Sandy Farmer (202) 260-2740, please refer to the appropriate EPA Information Collection Request (ICR) Number.

#### SUPPLEMENTARY INFORMATION:

#### OMB Responses to Agency Clearance Requests

##### OMB Approvals

EPA ICR No. 0916.07; Renewal—Annual Updates of Emission Data to the Aerometric Information Retrieval System (AIRS); was approved 06/11/97; OMB No. 2060-0088; expires 10/31/97.

EPA ICR No. 1726.02; Marine Engine Manufacturer In-Use Emission Testing Program; was approved 07/16/97; OMB No. 2060-0322; expires 07/31/2000.

EPA ICR No. 1725.02; Marine Engine Manufacturers Production Line Testing Reporting and Recordkeeping Requirements; was approved 07/16/97; OMB No. 2060-0323; expires 07/31/2000.

EPA ICR No. 1724.02 Marine Selective Enforcement Auditing Reporting and Recordkeeping Requirements; was approved 07/16/97; OMB No. 2060-0319; expires 07/31/2000.

EPA ICR No. 1799.01; NESHP for Recordkeeping and Reporting Requirements for the Mineral Wool Production; was approved 07/16/97; OMB No. 2060-0362; expires 07/31/2000.

EPA ICR No. 0282.09; Motor Vehicle Emission Defect Information; was approved 07/16/97; OMB No. 2060-0048; expires 07/31/2000.

EPA ICR No. 1792.01; Environmental Protection Agency/Chemical Manufacturers Association Root-Cause Analysis Pilot Project; was approved 07/18/97; OMB No. 2020-0008; expires 07/31/2000.

EPA ICR No. 1781.01 NESHP for Pollutants for Pharmaceuticals Production; was approved 07/17/97; OMB No. 2060-0358; expires 07/31/2000.

EPA ICR No. 0095.09; Precertification and Testing Exempting Reporting and Recordkeeping Requirements; was approved 07/17/97; OMB No. 2060-0007; expires 07/31/2000.

EPA ICR No. 1591.07; Standard for Reformulated Gasoline; was approved 07/16/97; OMB No. 2060-0227; expires 07/31/2000.

#### Extensions of Expiration Dates

EPA ICR No. 0234.05; Performance Evaluation Studies on Water and Wastewater Laboratories; OMB No. 2080-0021; expiration date was extended from 07/31/97 to 10/31/97.

EPA ICR No. 1703.01; Radon Measurement Protocol Evaluation Study; OMB No. 2060-0303; expiration date was extended from 11/30/97 to 01/31/98.

Dated: July 31, 1997.

**Joseph Retzer,**

*Division Director, Regulatory Information Division.*

[FR Doc. 97-20826 Filed 8-6-97; 8:45 am]

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## ENVIRONMENTAL PROTECTION AGENCY

[FRL-5871-6]

### Proposed Prospective Purchaser Agreement Under the Comprehensive Environmental Response, Compensation and Liability Act

**AGENCY:** Environmental Protection Agency.

**ACTION:** Notice of a Prospective Purchaser Agreement and Covenant Not to Sue Rosey's Pit Cleaning, Camden, New Jersey for a Property Within the Welsbach/General Gas Mantle Contamination Site.

**SUMMARY:** The United States Environmental Protection Agency (EPA) is proposing to enter into a Prospective Purchaser Agreement to provide Rosey's Pit Cleaning, Camden, New Jersey, a

covenant not to sue under the Comprehensive Environmental Response Compensation and Liability Act of 1980 (CERCLA), as amended, in connection with its proposed purchase and development of a property related to general contamination from the former Gas Mantle facility. This agreement is intended to resolve a potentially responsible party's liability for certain response costs incurred and to be incurred by EPA at the Welsbach/General Gas Mantle Contamination Superfund Site in Camden, New Jersey. Notice is being published to inform the public of the Proposed Prospective Purchaser Agreement and of the opportunity to comment.

**DATE:** Comments must be provided on or before September 8, 1997.

**ADDRESS:** Comments should be addressed to the U.S. Environmental Protection Agency, Office of Regional Counsel, 290 Broadway—17th Floor, New York, NY 10007 and should refer to: In the Matter of the Welsbach/General Gas Mantle Contamination Superfund Site: Rosey's Pit Cleaning, Camden, New Jersey, U.S. EPA Index No. II-CERCLA-97-0113.

**FOR FURTHER INFORMATION CONTACT:** U.S. Environmental Protection Agency, Office of Regional Counsel, 290 Broadway—17th Floor, New York, NY 10007, Attention: Virginia Curry, Esq. (212) 637-3134.

**SUPPLEMENTARY INFORMATION:** Notice is hereby given of a Proposed Prospective Purchaser Agreement with Rosey's Pit Cleaning, Camden, New Jersey, resolving the company's potential liability for a property within the Welsbach/General Gas Mantle Contamination Superfund Site. CERCLA authorizes EPA to enter into this agreement. The Department of Justice approved this agreement pursuant to the inherent settlement authority of the Attorney General to settle claims of the United States.

A copy of the Proposed Prospective Purchaser Agreement may be obtained by mail from EPA's Region II Office of Regional Counsel, 290 Broadway—17th Floor, New York, NY 10007.

Proposed Prospective Purchaser Agreement under CERCLA—Welsbach/General Gas Mantle Contamination Superfund Site.

Dated: June 30, 1997.

**Jeanne M. Fox,**

*Regional Administrator.*

[FR Doc. 97-20823 Filed 8-6-97; 8:45 am]

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