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Cryolite Summary Document
Registration Review: Initial Docket
March 2011

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Case No. 0087

Approved By:

Richard P Keigwin, Jr

Richard P. Keigwin, Jr.
Director, Pesticide Re-evaluation Division

3-25-2011

Date

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Please Note

This Preliminary Work Plan and Fact Sheet summarize the Environmental Protection Agency's current position based on the following documents:

1. Registration Review – Preliminary Problem Formulation for the Ecological Risk and Drinking Water Exposure Assessments for Cryolite. March 8, 2011.

2. Cryolite. Human Health Scoping Document in Support of Registration Review. March 16, 2011.

3. Sulfuryl Fluoride – Revised Human Health Risk Assessment for Fluoride to Incorporate New Hazard and Exposure Information. January 7, 2011. Available in the sulfuryl fluoride docket EPA-HQ-OPP-2005-0174.

4. Updated Review of Cryolite Incident Reports. November 30, 2010.

5. Chemical Profile for Registration Review: Cryolite. November 10, 2010.

6. Screening Level Use Analysis (SLUA) for Cryolite. June 21, 2010.

7. Appendix A for Cryolite. September 2, 2010.

Additional supporting documents for cryolite may be found in the cryolite registration review docket located on the internet at: www.regulations.gov

I. Preliminary Work Plan – Cryolite

Introduction:

The Food Quality Protection Act (FQPA) of 1996 mandated a registration review program. All pesticides sold or distributed in the United States generally must be registered by the Environmental Protection Agency (EPA), based on scientific data showing that they will not cause unreasonable risks to human health or the environment when used as directed on product labeling. The registration review program is intended to make sure that, as the ability to assess risk evolves and as policies and practices change, all registered pesticides continue to meet the statutory standard of no unreasonable adverse effects to human health or the environment. Changes in science, public policy, and pesticide use practices will occur over time. Through the registration review program, the Agency periodically reevaluates pesticides to make sure that as change occurs, products in the marketplace can be used safely. Information on this program is provided at: http://www.epa.gov/oppsrrd1/registration_review/.

The Agency is implementing the registration review program pursuant to Section 3(g) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), and will review each registered pesticide every 15 years to determine whether it continues to meet the FIFRA standard for registration. The Agency will consider benefits information and data as required by FIFRA. The public phase of registration review begins when the initial docket is opened for each case. The docket is the Agency's opportunity to state what it knows about the pesticide and what additional risk analyses and data or information it believes are needed to make a registration review decision. After reviewing and responding to comments and data received in the docket during this initial comment period, the Agency will develop and commit to a final work plan and schedule for the registration review of cryolite.

Cryolite is a naturally-occurring mineral of sodium aluminum fluoride, and is part of the inorganic fluorine chemical family. Products included in this registration review case include both natural and synthetic sources. Cryolite is registered for use in agricultural settings on various fruits and vegetables, as well as for some uses on ornamental plants. There are no residential or public recreational uses of cryolite.

Furthermore, cryolite's toxicity is attributed to its dissociation into fluoride ions in the environment. The only residue of concern for the tolerance expression for cryolite is fluoride. Therefore, all cryolite food tolerances are expressed in terms of fluoride. Cryolite was subject to a Reregistration Eligibility Decision (RED), which was completed in June 1996. The 1996 RED evaluated data on both cryolite and fluoride. Cryolite tolerances were reassessed in 1997 in conjunction with a registration action.

On January 19, 2011, EPA published a proposed order granting objections to tolerances and a stay request with regard to sulfuryl fluoride and fluoride tolerances promulgated in 2004 and 2005 under section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA) (FRL–8857–9). The objections and stay request were filed by the Fluoride Action Network (FAN), the

Environmental Working Group (EWG), and Beyond Pesticides. The Objectors argue that the fluoride tolerances should not have been established by EPA because aggregate exposure to fluoride is unsafe under FFDCA section 408. EPA is currently seeking public comment on all aspects of the proposed resolution of objections, including the scientific evaluations and the flouride aggregate risk assessment (EPA Docket No. EPA–HQ–OPP–2005–0174). This action is relevant to cryolite because, like sulfuryl fluoride, cryolite breaks down into fluoride. The aggregate fluoride risk assessment, which served as the basis for EPA's proposed order to withdraw the sulfuryl fluoride tolerances, considered all sources of fluoride exposure including fluoride exposure as a result of the use of cryolite. Therefore, this action may affect cryolite's registration review timeline and decision.

Anticipated Risk Assessment and Data Needs:

The Agency anticipates updating and revising the ecological risk assessment (including an endangered species risk assessment) and the human health risk assessment for all uses of cryolite. Below is a summary of the issues relevant to the registration review of cryolite and the data the Agency anticipates requiring:

Ecological Risk:

- The most recent ecological risk assessment for cryolite was completed in 1996 in support of the RED.

- The Agency has not conducted an ecological risk assessment that supports a complete endangered species determination for cryolite. The ecological risk assessment planned during registration review will allow the Agency to determine whether cryolite's use has "no effect" or "may affect" federally listed threatened or endangered species (listed species) or their designated critical habitats. When an assessment concludes that a pesticide's use "may affect" a listed species or its designated critical habitat, the Agency will consult with the U.S. Fish and Wildlife Service (FWS) and/or National Marine Fisheries Service (NMFS) (the Services), as appropriate.

- The Agency does not anticipate requiring environmental fate data during registration review. However, the Agency anticipates requiring the following environmental effects data for use in conducting a complete ecological risk assessment, including an endangered species assessment, for all uses:

    - Guideline (GLN) No. 850.2100 – Avian Oral Toxicity (Passerine)
    - GLN No. 850.1025 – Acute Toxicity Estuarine/Marine Organisms (Oyster)
    - GLN No. 850.1075 – Freshwater Fish Toxicity (Estuarine/Marine)

- GLN No. 850.4100 – Nontarget Area Phytotoxicity Tier II, Seedling Emergence[1]
- GLN No. 850.4150 – Nontarget Area Phytotoxicity Tier II, Vegetative Vigor[1]
  GLN No. 850.4400 – Nontarget Area Phytotoxicity Tier II, Aquatic Plant Growth (Vascular Plants) [1]
- GLN No. 850.5400 – Nontarget Area Phytotoxicity Tier II, Aquatic Plant Growth (Algal Plants) [1]

- Please refer to *Registration Review – Preliminary Problem Formulation for the Ecological Risk and Drinking Water Exposure Assessments for Cryolite*, March 8, 2011, located in the docket, for a detailed discussion of these anticipated risk assessment and data needs.

Human Health Risk:

- A comprehensive human health risk assessment was completed in 1996 in support of reregistration, which assessed dietary (food and water) and occupational exposures. The 1996 RED evaluated data on both cryolite and fluoride because cryolite's toxicity is attributed to its dissociation into fluoride ions.

- On January 7, 2011, the Office of Pesticide Programs and the Office of Water completed an aggregate risk assessment for all dietary exposure sources of fluoride in food and drinking water, including the pesticide cryolite and sulfuryl fluoride.

- Based on an endpoint of severe dental fluorosis, exposures for some sub-populations exceeded the Agency's level of concern particularly for children living in areas with high levels of naturally-occurring fluoride in their drinking water. The Agency is currently seeking comment on this risk assessment (EPA Docket No. EPA-HQ-OPP-2005-0174).

- Since fluoride is the only residue of concern from cryolite applications, the Agency will: 1) review all the comments received on the January 2011 fluoride aggregate risk assessment; 2) determine if a new aggregate risk assessment for cryolite is needed; and 3) determine whether cryolite meets the FFDCA safety standard. The registration review timeline for cryolite, described on page 8 of this document, is contingent upon the Agency's safety standard determination for cryolite following the review of comments received on the January 2011 fluoride aggregate risk assessment.

- Currently, there are no registered uses for cryolite that would result in residential exposure. However, residential bystander inhalation exposures resulting from off-site transport (e.g., spray drift) may occur as a result of applications of cryolite. The Agency

[1]A Tier II study is expected to be required. The DCI expected to be issued will provide that a Tier I plant study may be conducted in lieu of a Tier II study with the understanding that any adverse effects observed by the Tier I study would necessitate conduct and submission of a Tier II study as well.

is in the process of examining its policies and refining the methods used to complete residential exposure assessments. Therefore, the potential need for a bystander inhalation risk assessment for cryolite will be examined during registration review.

- If an applicable endpoint is identified in the anticipated 90-Day Inhalation Toxicity study, the Agency intends to conduct a quantitative risk assessment for occupational exposure. The Agency is currently evaluating the March 2, 2010 Scientific Advisory Panel (SAP) final report on issues related to volatilization of pesticides and may, as appropriate, develop policies and procedures to identify whether to incorporate post-application inhalation exposure into the Agency's risk assessments, and methods to assess post-application inhalation exposure. If new policies or procedures are implemented, the Agency would anticipate revisiting the need for a quantitative occupational post-application inhalation exposure assessment for cryolite.

- Since the residue of concern for cryolite applications is fluoride, tolerance levels and residue definition may need to be modified or revoked in the future based on a determination of fluoride aggregate risks and whether cryolite meets the FFDCA safety standard.

- For a discussion of tolerances, see *Cryolite: Registration Review Scoping Document for Human Health Assessments,* dated March 16, 2011.

- The toxicity database is complete except for the following studies, which the Agency anticipates requiring in order to conduct a complete human health assessment:

    - GLN No. 870.3465 - 90-Day Inhalation Toxicity
    - GLN No. 870.7800 - Immunotoxicity

- Please refer to the *Cryolite. Human Health Scoping Document in Support of Registration Review,* March 16, 2011, located in the docket, for a detailed discussion of the anticipated risk assessment and data needs for human health.

Endocrine Disruptor Screening Program:

As required by FIFRA and FFDCA, EPA reviews numerous studies to assess potential adverse outcomes from exposure to chemicals. Collectively, these studies include acute, subchronic and chronic toxicity, including assessments of carcinogenicity, neurotoxicity, developmental, reproductive, and general or systemic toxicity. These studies include endpoints which may be susceptible to endocrine influence, including effects on endocrine target organ histopathology, organ weights, estrus cyclicity, sexual maturation, fertility, pregnancy rates, reproductive loss, and sex ratios in offspring. For ecological hazard assessments, EPA evaluates acute tests and chronic studies that assess growth, developmental and reproductive effects in different taxonomic groups. As part of its most recent registration decision, EPA reviewed these data and selected the most sensitive endpoints for relevant risk assessment scenarios from the existing

hazard database. However, as required by FFDCA section 408(p), cryolite is subject to the endocrine screening part of the Endocrine Disruptor Screening Program (EDSP).

EPA has developed the EDSP to determine whether certain substances (including pesticide active and other ingredients) may have an effect in humans or wildlife similar to an effect produced by a "naturally occurring estrogen, or other such endocrine effects as the Administrator may designate." The EDSP employs a two-tiered approach to making the statutorily required determinations. Tier 1 consists of a battery of 11 screening assays to identify the potential of a chemical substance to interact with the estrogen, androgen, or thyroid (E, A, or T) hormonal systems. Chemicals that go through Tier 1 screening and are found to have the potential to interact with E, A, or T hormonal systems will proceed to the next stage of the EDSP where EPA will determine which, if any, of the Tier 2 tests are necessary based on the available data. Tier 2 testing is designed to identify any adverse endocrine-related effects caused by the substance, and establish a dose-response relationship between the dose and the E, A, or T effect.

Under FFDCA section 408(p), the Agency must screen all pesticide chemicals. Between October 2009 and February 2010, EPA issued test orders/data call-ins for the first group of 67 chemicals, which contains 58 pesticide active ingredients and 9 inert ingredients. Cryolite is not among the group of 58 pesticide active ingredients on the initial list to be screened under the EDSP. EPA may issue future EDSP orders/data call-ins as part of registration review requiring the submission of EDSP screening assays for cryolite. This action will be contingent on the regulatory safety determination of cryolite following the review of comments on the January 2011 fluoride aggregate risk assessment. For further information on the status of the EDSP, the policies and procedures, the list of 67 chemicals, future lists, the test guidelines and the Tier 1 screening battery, please visit our website: http://www.epa.gov/endo/.

Timeline:

EPA has created the following estimated timeline for the completion of the cryolite registration review. It should be noted that this timeline will be contingent on the regulatory safety determination of cryolite following the review of comments on the January 2011 fluoride aggregate risk assessment.

Registration Review for Cryolite– Projected Registration Review Timeline	
Activities	**Estimated Date**
Opening the Docket	
Open Docket and Public Comment Period	2011 – March
Close Public Comment	2011 – May
Case Development	
Final Work Plan	2011 – August
Issue DCI	2012 – April – June
Data Submission	2014 – April – June
Open Public Comment Period for Draft Risk Assessments	2015 – Oct. – Dec.

Registration Review for Cryolite– Projected Registration Review Timeline	
Close Public Comment Period	2016 – Jan. – March
Registration Review Decision	
Open Public Comment Period for Proposed Registration Review Decision	2016 – April – June
Close Public Comment Period	2016 – July – Sept.
Registration Review Decision and Begin Post-Decision Follow-up	2017
Total (years)	6

Guidance for Commenters:

The public is invited to comment on EPA's preliminary work plan and rationale. The Agency will carefully consider all comments as well as any additional information or data provided in a timely manner prior to issuing a final work plan (FWP) for cryolite.

Trade Irritants:

Through the registration review process, the Agency intends to solicit information on trade irritants and, to the extent feasible, take steps toward facilitating irritant resolution. Growers and other stakeholders are asked to comment on any trade irritant issues resulting from lack of Maximum Residue Limits (MRLs) or disparities between U.S. tolerances and MRLs in key export markets, providing as much specificity as possible regarding the nature of the concern.

Water Quality:

Neither cryolite nor fluoride are identified as a cause of impairment for any water bodies listed as impaired under section 303(d) of the Clean Water Act[2]. In addition, no Total Maximum Daily Loads (TMDL) have been developed for cryolite[3]. More information on impaired water bodies and TMDLs can be found on the Agency's website[4]. The Agency invites submission of water quality data for this pesticide. To the extent possible, data should conform to the quality standards in Appendix A of the *OPP Standard Operating Procedure: Inclusion of Impaired Water Body and Other Water Quality Data in OPP's Registration Review Risk Assessment and Management Process*[5] in order to ensure they can be used quantitatively or qualitatively in pesticide risk assessments.

Environmental Justice:

EPA seeks to achieve environmental justice, the fair treatment and meaningful involvement of all people, regardless of race, color, national origin, or income, in the development, implementation,

[2] http://iaspub.epa.gov/tmdl_waters10/attains_nation_cy.cause_detail_303d?p_cause_group_id=885
[3] http://iaspub.epa.gov/tmdl_waters10/attains_nation.tmdl_pollutant_detail?p_pollutant_group_id=885&p_pollutant_group_name=PESTICIDES
[4] http://www.epa.gov/owow/tmdl/
[5] http://www.epa.gov/oppsrrd1/registration_review/water_quality_sop.htm

and enforcement of environmental laws, regulations, and policies. To help address potential environmental justice issues, the Agency seeks information on any groups or segments of the population who, as a result of their location, cultural practices, or other factors, may have atypical, unusually high exposure to cryolite, compared to the general population. Please comment if you are aware of any sub-populations that may have atypical, unusually high exposure compared to the general population.

Other Information:

Stakeholders are also specifically asked to provide information and data that will assist the Agency in refining the risk assessments, including any species-specific ecological effects determinations. The Agency is interested in receiving the following information:

1. confirmation on the following label information;
    a. sites of application
    b. formulations
    c. application methods and equipment
    d. maximum application rates in units related to mass per unit area of treatment zone
    e. frequency of application, application intervals and maximum number of applications per season
    f. geographic limitations on use
2. use or potential use distribution (e.g., acreage and geographical distribution of relevant crops);
3. use history;
4. median and 90th percentile reported use rates (lbs. a.i./acre) from usage data – national, state, and county;
5. application timing (date of first application and application intervals) by crop – national, state and county;
6. sub-county crop location data;
7. directly acquired county-level usage data (not derived from state level data);
    a. maximum reported use rate (lbs. a.i./acre) from usage data – county
    b. percent crop treated – county
    c. median and 90th percentile number of applications – county
    d. total pounds per year – county
    e. the year the pesticide was last used in the county/sub-county area
    f. the years in which the pesticide was applied in the county/sub-county area
8. typical interval (days);
9. state or local use restrictions;
10. ecological incidents (non-target plant damage and avian, fish, reptilian, amphibian and mammalian mortalities) not already reported to the Agency;
11. pests controlled by cryolite and what are the chemical and non-chemical alternatives to cryolite for these pest(s);

12. barriers for adopting chemical and non-chemical alternatives for pest(s) controlled by cryolite (e.g., price, relative efficacy, use restrictions, application methods, etc.);

Next Steps:

After the 60-day comment period closes, the Agency will review and respond to any comments received in a timely manner, and then issue its Final Work Plan (FWP) for cryolite.

II. FACT SHEET

Background Information:

- Cryolite PC code: 075101, CAS No.: 15096-52-3.
- Registration review case number: 0087.
- Technical registrants: AMVAC Chemical Company; United Phosphorous, Incorporated; and Gowan Company.
- First registered for use in the U.S. in 1957.
- The RED for cryolite was completed in June, 1996.
- Cryolite product reregistration is complete, and the mitigation specified in the 1996 RED is on current labels.
- Cryolite tolerances were reassessed in December 5, 1997 in conjunction with a registration action (62 FR 64294-64301).
- There are currently four end-use products and two technical products registered.
- There are multiple tolerances for use of cryolite in or on food crops under 40 CFR § 180.1045.
- Pesticide Re-evaluation Division Chemical Review Manager: Molly Clayton, *clayton.molly@epa.gov.*
- Registration Division Contact: Venus Eagle, *eagle.venus@epa.gov*.

Use & Usage Information: (For additional details, please refer to the Appendix A, SLUA, and Chemical Profile documents in the cryolite docket.)

- Cryolite is an inorganic fluorine compound registered for use as an insecticide and used primarily on raisins and table grapes to control leafrollers, leaffolders, worms, and mites.
- Cryolite is formulated as bait/solid, wettable powder/dust, and dust and dry flowable. It may be applied as a broadcast foliar spray in early summer and late spring, as chemigation with sprinkler irrigation, and as a dust or spray with aircraft.
- The agricultural usage for cryolite from 1998-2008 averaged almost 2 million pounds active ingredient for use in about 300,000 acres per year.
- From 1998-2008, the largest markets in terms of total pounds of active ingredient applied were: raisin grapes (71%), table grapes (12%), and wine grapes (9%).

Recent and Pending Actions:

- On January 19, 2011, EPA published a proposed order granting objections to tolerances and a stay request with regard to sulfuryl fluoride and fluoride tolerances promulgated in 2004 and 2005 under section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA) (FRL–8857–9). The objections and stay request were filed by the Fluoride Action Network, the Environmental Working Group, and Beyond Pesticides. The Objectors argue that the fluoride tolerances should not have been established by EPA because aggregate exposure to fluoride is unsafe under FFDCA section 408. EPA is

currently seeking public comment on all aspects of the proposed resolution of objections, including the scientific evaluations and the aggregate risk assessment (EPA Docket No. EPA–HQ–OPP–2005–0174).

Ecological Risk Assessment Status:

The following are key findings of the most recent ecological risk assessment for cryolite. Please refer to the *Registration Review – Preliminary Problem Formulation for the Ecological Risk and Drinking Water Exposure Assessments for Cryolite,* March 8, 2011, located in the docket, for a detailed discussion of the ecological risk assessment.

Environmental Fate:

- Cryolite is a naturally-occurring mineral; however, most present day supplies of cryolite pesticide products are synthetically produced. Open-literature data were used in conjunction with registrant submitted data in the 1996 ecological assessment to address the environmental chemistry of cryolite. The fate of the elemental components in cryolite (Na, Al, and F) is dependent on the natural biogeochemical cycles influenced by the soil chemical and mineralogical properties.

Risk Estimates:

- While some acute avian and mammalian risk quotients (RQs) exceeded the Agency's level of concern (LOC) in the 1996 assessment, risk to birds and mammals was not expected from any registered use of cryolite based on the likelihood of the species to receive significant dietary exposure at the anticipated low exposure levels. Similarly, risks to terrestrial invertebrates and plants (i.e., foliage) were not expected.

- In the 1996 assessment, risk to aquatic organisms was not quantitatively assessed. Ground or surface water effects were expected to be negligible. No significant difference in the accumulation of aluminum or fluoride moieties in plants or animals was expected to occur.

- There is sufficient information to characterize cryolite as practically nontoxic to honey bees based on data evaluated from an acute bee contact study. Cryolite's insecticidal mode of action requires ingestion and non-target terrestrial invertebrates are not expected to be sensitive to this pesticide via a contact route of exposure. Additionally, insects with piercing/sucking mouthparts (including bees) are not expected to be affected by cryolite via an oral route because they cannot ingest crystals.

Human Health Risk Assessment Status:

The following are key findings of the most recent human health risk assessments for cryolite. Please refer to the *Cryolite. Human Health Assessment Scoping Document in Support of*

Registration Review, March 16, 2011, located in the docket, for a detailed discussion of the human health risk assessment.

- The most recent human health risk assessment for cryolite was completed in 1996 in support of reregistration. An aggregate risk assessment that included contributions from all sources of fluoride, including exposures from cryolite, was completed in January 2011.

Hazard Characterization:

- The 1996 RED evaluated data on both cryolite and fluoride because cryolite's toxicity is attributed to its dissociation into fluoride ions. Data evaluated included guideline toxicity studies with cryolite, carcinogenicity studies with fluoride, and assessments by several government agencies on fluoride in drinking water.

- Currently, severe dental fluorosis, including enamel pitting and other effects, is the effect of concern from dietary exposure. The Office of Water has recently completed a benchmark dose analysis in order to select a point of departure based on severe dental fluorosis from exposure to fluoride.

- Dental lesions in rats and mice cryolite toxicity studies were due to enamel fluorosis and included effects such as attrition, deformity, mottling, and degeneration. Fluoride can also accumulate in bone, and increased bone density in rats after treatment with cryolite has been noted in toxicity studies.

- The recent aggregate risk assessment for fluoride included an analysis for potential sensitivity of children to fluoride. Given the relative completeness of the fluoride toxicology database; the use of a child-specific endpoint (i.e., the most sensitive effect and well-documented outcome in the literature); the data indicating a U-shaped dose-response curve for oral health; and the understanding of the potential exposures to fluoride, the Agency reduced the FQPA Safety Factor for fluoride to 1X.

- The Agency did not require a dermal toxicity study for its 1996 reregistration decision. Given the chemical properties of parent cryolite and degradate (fluoride ions), the Agency considered dermal absorption unlikely.

- As it is well-known that cryolite dissociates into fluoride, the Agency did not require a metabolism study.

- Cryolite was classified as “not classifiable as to human carcinogenicity.”

Dietary (Food and Water):

- The Agency has recently completed a dietary exposure assessment for all sources of

fluoride in food and drinking water, including the pesticides cryolite and sulfuryl fluoride.

- Monitoring data were used to account for residues of fluoride as a result of cryolite application; residues in grapes and raisins were higher than other crops (consistent with the usage assessment).

Residential:

- Cryolite is not registered for use in residential or public recreational settings. Therefore, a standard residential exposure risk assessment was not conducted for the 1996 RED.

Aggregate:

- In January 2011, the Agency completed an aggregate risk assessment for exposure to fluoride, including the following sources of fluoride: dietary exposure from the pesticides cryolite and sulfuryl fluoride; water exposure from naturally occurring sources of fluoride in the environment as well as the intentional addition of fluoride to drinking water sources to prevent dental caries; incidental ingestion of fluoride while brushing teeth; and soil ingestion by children.

- This aggregate assessment identified some sub-populations whose exposure exceeded the Agency's level of concern for fluoride, particularly children living in areas with high levels of naturally-occurring sources of fluoride in their drinking water.

Occupational:

- In the most recent occupational risk assessment (1996), no dermal or inhalation toxicological endpoints were identified; therefore, a quantitative occupational risk assessment for occupational exposures was not conducted.

- Toxicity via the dermal route was not expected due to the ionic nature of cryolite.

Cumulative:

- Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to cryolite and any other substances. As described in the aggregate section above, fluoride is a degradate of cryolite, and has been previously assessed. For the purposes of this registration review assessment of data needs, EPA has not assumed nor determined that cryolite has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common

mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at: http://www.epa.gov/pesticides/cumulative/. If, in the future, the Agency determines that new information on cryolite is available that could potentially impact a cumulative risk assessment and result in a risk of concern, the Agency will revisit the need for a cumulative risk assessment.

Incidents:

Ecological:

- The Ecological Incident Information System (EIIS) was consulted for reports of ecological incidents associated with cryolite. There is one 1992 reported incident in Delaware in which a wettable powder containing cryolite was sprayed on potatoes. One thousand fish were killed from the runoff. The certainty code is unlikely and the legal status of the particular use in relation to the product label is unknown.

Human Health:

- No cryolite poisoning incidents were reported in the Office of Pesticide Programs Incident Data System (IDS) since 2002.

Tolerances and International Harmonization:

- The residue of concern for the tolerance expression for cryolite is fluoride. All food tolerances are expressed in terms of fluoride. Although uses of cryolite are registered for animal feed commodities, the Agency had previously determined that there is no reasonable expectation of finite residues in livestock; therefore, livestock commodity tolerances are not needed.

- No maximum residue limits (MRLs) have been established by Codex or Canada for residues of cryolite or fluoride. Mexico adopts US tolerances and/or Codex MRLs for its export purposes.

Data Call-In Status:

- Generic data call-ins (GDCI-075101-16283, GDCI-075101-15979, and GDCI-075101-16944) were issued in January 1980, January 1991, and November 1996, respectively. All of these data requirements have been fulfilled.

Labels:

- The labels for cryolite can be obtained from the Pesticide Product Label System (PPLS) website at: http://oaspub.epa.gov/pestlabl/ppls.home.

Cryolite Registrations as of March 4, 2011		
Registration No.	**Product Name**	**Company Name**
5481-132	Cryolite 93	AMVAC Chemical Corporation
10163-41	PROKIL Cryolite 96	Gowan Company
10163-185	PROKIL Cryolite Water Dispersable Granular	Gowan Company
10163-225	Gowan Cryolite Bait	Gowan Company
10163-242	PROKIL Cryolite 75 Dust	Gowan Company
10163-243	PROKIL Cryolite 50 Dust	Gowan Company
70506-172	Kryocide Insecticide	United Phosphorus, Inc.

III. Summary of Data Gaps

The table below summarizes the anticipated data requirements for cryolite.

Guideline Number	Study Title	Test Material	Estimated Timeframe (Measured in Months)
850.2100	Avian Oral Toxicity (Passerine)	TGAI[6]	12
850.1075	Freshwater Fish Toxicity (Estuarine/Marine)	TGAI	12
850.1025	Acute Toxicity Estuarine/Marine Organisms (Oyster)	TGAI	12
850.4100	Nontarget Area Phytotoxicity Tier II, Seedling Emergence[7]	TGAI	12
850.4150	Nontarget Area Phytotoxicity Tier II, Vegetative Vigor[7]	TGAI	12
850.4400	Nontarget Area Phytotoxicity Tier II, Aquatic Plant Growth (Aquatic Vascular Plants) [7]	TGAI	12
850.5400	Nontarget Area Phytotoxicity Tier II, Aquatic Plant Growth (Algal Plants) [7]	TGAI	12
870.3465	90-Day Inhalation Toxicity	TGAI	24
870.7800	Immunotoxicity	TGAI	12

[6] Technical Grade Active Ingredient (TGAI).

[7] A Tier II study is expected to be required. The DCI expected to be issued will provide that a Tier I plant study may be conducted in lieu of a Tier II study with the understanding that any adverse effects observed by the Tier I study would necessitate conduct and submission of a Tier II study as well. The purpose of a Tier II study is to establish both a definitive No Observed Adverse Effect Concentration (NOAEC), or alternatively, a concentration at which there is a 5% observed inhibition effect (IC_{05}) to be used in a risk assessment and effects determination for endangered or threatened species (listed species), and a definitive IC_{25} (concentration at which there is a 25% observed inhibition effect) for assessing risk to non-listed nontarget plants. If any adverse effects are observed in a Tier I study and neither a definitive NOAEC nor a definitive IC_{05} value is available, then the Agency may have to presume in its effects determination, that cryolite "may affect" and is “likely to adversely affect” listed plant species.