



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C., 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

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MEMORANDUM

Subject: ADDENDUM: Registration Review – Preliminary Problem Formulation for the Ecological Risk and Drinking Water Exposure Assessments for Cryolite (PC Code 075101; DP Barcode 383606)

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[Signature] 10/5/11
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This memo serves as an addendum to the Registration Review – Preliminary Problem Formulation (PF) for the Ecological Risk and Drinking Water Exposure Assessments for Cryolite (PC Code 075101; DP Barcode 383606). In response to comments on the PF from the Fluoride Action Network (FAN) (D383606), the Environmental Fate and Effects Division (EFED) has revised its recommendations for data to be requested to support the environmental risk assessment for cryolite. In the original PF (docket EPA-HQ-OPP-2011-0173), EFED recommended requesting the following studies:

- 850.4100 Terrestrial plant toxicity (seedling emergence)
- 850.4150 Terrestrial plant toxicity, Tier I (vegetative vigor)
- 850.4400 Aquatic plant toxicity test using *Lemna* spp. Tier I
- 850.5400 Algal toxicity, Tier I
- 850.1025 Oyster acute toxicity test (shell deposition)
- 850.1075 Fish acute toxicity test, freshwater and marine

In EFED's response to the comments from FAN (D383606), EFED concluded:

"... (T)he incremental addition of cryolite is not expected to cause elemental exceedance of natural background concentrations, especially for aluminum and sodium, in soil or water. More importantly, chemical equilibrium in soil and aquatic environments is expected to buffer concentrations of Al^{3+} and F^- . Therefore, additional toxicity data using aquatic animals would not likely alter cryolite risk conclusions. Therefore, EFED does not recommend requesting additional toxicity data on aquatic animals for the Registration Review ecological risk assessment for cryolite."

Therefore, to clarify, the assumption in the cryolite ecological risk assessment will be that the use of cryolite is not expected to cause higher levels of aluminum, sodium, or fluoride in water or soil beyond what is normally found as background levels in water and soil (see D383606 for details). Therefore, toxicity data from aquatic organisms or terrestrial plants (exposed via water and/or soil; *i.e.*, seedling emergence) are not expected to impact risk conclusions [because exposure levels of aluminum, sodium, or fluoride are not expected to increase beyond background levels from the registered use(s) of cryolite].

Additionally, as stated in EFED's responses to the comments from FAN (D383606):

"EFED... does agree that there is a potential for terrestrial animals to be exposed to cryolite via ingestion of vegetative dietary items that have been treated with cryolite (either directly or via spray drift). Additionally, due to cryolite's use pattern, there is a potential for repeated exposure to cryolite (cryolite can be applied to crops several times per season). Therefore, EFED agrees that risk to birds and mammals from chronic exposure via the ingestion of contaminated vegetative dietary items should be assessed in the risk assessment conducted for cryolite for Registration Review.

... No chronic toxicity data for cryolite are currently available for birds. Therefore, to adequately assess risks to birds from potential repeated exposure to cryolite, EFED recommends that an avian reproduction study (850.2300) be conducted for cryolite."

Therefore, EFED recommends requesting an avian reproduction study for the cryolite ecological risk assessment.

In conclusion, and based on the response to comments from FAN, the only outstanding studies that EFED recommends requesting for the ecological risk assessment conducted for cryolite during Registration Review are:

- 850.4150 Terrestrial plant toxicity, Tier I (vegetative vigor)
- 850.2300 Avian reproduction