

APPENDIX A: Verification Memorandum for Bromethalin



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

OFFICE OF
CHEMICAL SAFETY &
POLLUTION PREVENTION

MEMORANDUM

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SUBJECT: Verification Memorandum for Bromethalin for SF Bay Species

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This memorandum serves to provide additional information on the use pattern of bromethalin not captured in the LUIS process. RD and PRD's role in the verification process are to fill information gaps and provide division appropriate expertise as outlined in the LUIS Verification SOP for RD and PRD.

PRD provides information and status regarding changes to the chemical use (such as application parameters, cancellations, or label language) that occurred as a result of the reregistration process. RD provides information regarding changes to the chemical use that may have occurred after the date of the LUIS label extraction. In the case a "Data Doer Only"¹ report was conducted, the CRM and PM will ensure that all highest application rates are reflected on the EFED Spreadsheet. The CRM and PM have drafted the "Registration and Reregistration Verification" section of this memo to clarify knowledge gaps a risk assessor may encounter while using the data contained in the LUIS report.

Finally, if further clarification is needed please contact Rusty Wasem (305-6979 or wasem.russell@epa.gov) or Dan Peacock (305-5407 or peacock.dan@epa.gov).

¹ This type of LUIS report is conducted when the AI of interest has more than 50 products. This report will contain: 1. Products actively registered to the data doer; 2. All technical registrations regardless of registrant; 3. All active California special local needs (SLN) registrations.

Registration and Reregistration Verification

Date and Scope of the RED and RMD

- The RED for bromethalin was issued in July 1998. The Risk Mitigation Decision for Ten Rodenticides (RMD) that included bromethalin was issued in May 2008 and revised in June 2008. The 2008 RMD only considered, “non-restricted” commensal uses, in and around (50 feet) buildings. The 2008 RED excluded pocket gopher and mole uses in closed burrow systems around (50 feet) buildings if the companies added specific exclusionary text on their labels. All uses registered at the time (including field and orchard uses) were covered under the 1998 RED.

Required Through the RED Process

- List any cancelled uses as part of the reregistration process.
 - 1998 RED – No uses cancelled
 - 2008 RMD – No uses cancelled
- List any rate changes that occurred as part of the reregistration process.
 - 1998 RED – No rate changes required
 - 2008 RMD – No rate changes required
- Indicate whether mitigation has been required through the reregistration process and whether any or all of the mitigation has been implemented on the product labels.
 - 1998 RED – No ecologically relevant mitigation measures
 - 2008 RMD:

Consumer Product Mitigation

- **Bait Form:** Block or other solid form only. Meal, treated whole-grain, or pelleted forms of bait are prohibited. The Agency will consider another bait form, like a paste, if the registrant shows that it has the same protective features as the block form.

- **Products:** Must contain 1 pound of bait or less.

- **Bait Stations:** Bait must be sold packaged in a bait station meeting the requirements of Tiers 1, 2, 3, or 4. Bait stations for mouse control must accommodate bait placements of between 0.25 and 1 ounce of bait. Bait stations for rat control must accommodate bait placements between 1 and 6 ounces of bait for bromethalin baits.

- **Refills:** Products for either mouse or rat control may not contain more than 1 pound of bait. The one pound limit includes the initial bait placement in the bait station, plus any refills. Tier 4 bait stations are not refillable.

- **Labeling:** Mandatory Labeling Requirements to Distinguish Residential, Preloaded, Refillable Bait Stations, Tier 1, Tier 2, Tier 3, and Tier 4. (See *Table 1* for description of bait stations)

- **Sites:** Residential use sites.

- Applications made outdoors must be in a Tier I bait station (tamper, weather, and dog resistant) and must be applied within 50 feet of a building.²
- This product may only be used to control moles and/or pocket gophers in manual, below-ground applications.³ Bait must be applied directly into moles' and/or pocket gophers' burrow systems.⁴

Professional Applicator Products (Agricultural & PCO)

- **Applicator:** Professional (Agricultural and PCO) applicators
- **Bait Form:** Meal, pellet, block, paste.
- **Packaging:** Must contain four pounds of bait or greater.
- **Sites:** In and around buildings and inside of transport vehicles.
- This product may only be used to control moles and/or pocket gophers in manual, below-ground applications. Bait must be applied directly into moles' and/or pocket gophers' burrow systems.
- **Bait Stations:** Mandatory for outdoor, above-ground use.
- **Labeling:**
 1. Add "This product may only be used inside and within 50 feet of buildings or inside of transport vehicles (ships, trains, or aircraft)."⁵
 2. Add "Do not sell this product in individual containers holding less than 4 pounds of bait."

Terms/Conditions of Sale/Distribution:

1. Product may not be sold in packaging that holds less than 4 pounds of bait.
- All of the mitigation measures from the 2008 RMD have been incorporated for 31 of the 46 bromethalin products. The last day for rodenticide manufacturers to sell or distribute bromethalin products that do not include the mitigation listed above is June 4, 2011. Products sold by rodenticide manufacturers on or before June 4, 2011, may be sold until stocks are exhausted.
 - All of the active bromethalin registrations were included in the LUIS data.

Product Reregistration

- The Agency is scheduled to complete the re-registration process for the remaining bromethalin products in May 2011. Ecologically relevant mitigation was not required by the bromethalin RED.

² Building, for purposes of commensal use rodenticide application, has been defined as a structure that has walls and a roof.

³ The only bromethalin products labeled for moles and voles are Professional Use Products.

⁴ Bait stations not required for below ground applications of bromethalin.

⁵ Building, for purposes of commensal use rodenticide application, has been defined as a structure that has walls and a roof.

Registration Division Review

- No actions involving bromethalin have occurred since December 3, 2010, the *Current As of Date* listed on BEAD's *Bromethalin EFED Label Data Report*, that impact the use or application of the active ingredient (including new uses, deletion of uses, changes to application parameters, etc.). There are currently no pending actions (ie. new uses, increased app rates, new formulations) involving bromethalin.
- Application rate changes have not occurred since the RED.

Bait Station Tiers

Table I: Mandatory Labeling Requirements to Distinguish Residential, Preloaded, Refillable Bait Stations (Tier 1, Tier 2, Tier 3, and Tier 4)				
Tier	This Unit is:	May Use:	Front Panel Text:⁶	Use Restriction Text:
1	Tamper-resistant and Weather-resistant	Indoors Outdoors (near buildings)	This Bait Station is Resistant to Weather and to Tampering by Children and Dogs. Use Indoors and Outdoors (near Buildings) Only.	This bait station may be used in indoor and outdoor areas accessible to children and pets, consistent with all use restrictions and other requirements indicated on this label.
2	Tamper-resistant (but not weather-resistant)	Indoors	This Bait Station is Resistant to Tampering by Children and Dogs. Use Indoors Only.	This bait station may be used in indoor areas accessible to children and pets, consistent with all use restrictions and other requirements indicated in this label. DO NOT USE THIS PRODUCT OUTDOORS.
3	Tamper-resistant for young children (only)	Indoors	This Bait Station is Resistant to Tampering by Children. Use Indoors Only in Areas Inaccessible to Pets.	This bait station may be used in indoor areas accessible to children, consistent with all use restrictions and other requirements indicated in this label. DO NOT USE THIS PRODUCT OUTDOORS OR IN AREAS ACCESSIBLE TO PETS.
4	Untested or tested without meeting any criteria for tamper-resistance	Indoors	THIS BAIT STATION IS NOT TAMPER-RESISTANT. It is not Resistant to Tampering by Children and Dogs. Use Indoors Only in Areas Inaccessible to Children and Pets.	DO NOT USE THIS PRODUCT OUTDOORS OR IN AREAS ACCESSIBLE TO CHILDREN, PETS, DOMESTIC ANIMALS, OR NONTARGET WILDLIFE.

⁶ Place required text, 1) **bolded**, 2) on Front Panel, 3) immediately under product name, 4) in a box, 5) in type size equal to "Keep Out of Reach of Children" or 8 Point Type (which ever is larger), 6) on contrasting background, and 7) clearly readable by average person at the point of sale.