

Appendix A

Verification Memo for Warfarin



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

OFFICE OF CHEMICAL SAFETY &
POLLUTION PREVENTION

MEMORANDUM

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SUBJECT: Verification Memorandum for Warfarin for SF Bay Species

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This memorandum serves to provide additional information on the use pattern of warfarin 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.

If further clarification is needed please contact Rusty Wasem (305-6979 or wasem.russell@epa.gov) and John Hebert (308-6249 or hebert.john@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

- In June 1991, EPA completed a RED for warfarin and its sodium salt which assessed all uses and called in additional data and required ecologically relevant mitigation measures (discussed below).
 - Continued Restricted Use Pesticide (RUP) classification to warfarin tracking powder products.
 - To protect children and non-target animals, bait products labels were to require the use of tamper-resistant bait stations wherever bait placements otherwise would be within the reach of children, pets, domestic animals, or nontarget wildlife.
- While warfarin was not included in the Rodenticides Cluster RED, which was issued in 1998, warfarin products were required to adopt the mitigation measures in the Rodenticide Cluster RED.
- The Risk Mitigation Decision for Ten Rodenticides (RMD) that included warfarin was issued in May 2008 and revised in June 2008. The 2008 RMD only considered commensal uses.

Required Through the RED Process

- List any cancelled uses as part of the reregistration process.
 - 1991 RED – No uses cancelled
 - 1998 Cluster RED – No uses cancelled
 - 2008 RMD – No uses cancelled
- List any rate changes that occurred as part of the reregistration process.
 - 1991 RED – No rate changes required
 - 1998 Cluster 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.
 - 1991 RED – Ecologically relevant mitigation measures superseded by RMD
 - 1998 RED – No ecological relevant mitigation measures
 - 2008 RMD - Most products are now compliant with RMD. EPA has formally proposed to cancel non-conforming product. See additional details below.

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 of between 4 and 16 ounces of bait for warfarin 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:** Include additional mandatory text found in next table, "Mandatory Labeling Requirements to Distinguish Residential, Preloaded, Refillable Bait Stations, Tier 1, Tier 2, Tier 3, and Tier 4." (See *Table I* below for description of bait stations)
- **Sites:** Residential use sites (e.g., inside homes).
- For products with outdoor use sites (Tier 1 bait stations only), add: "Do not apply further than 50 feet from home or building."

Professional Applicator Products (Agricultural & PCO)

- **Applicator:** Professional applicators
- **Bait Form:** Meal, pellet, block, paste
- **Packaging:** Contains greater than four pounds of bait.
- **Sites:** In and Around Buildings and Inside of Transport Vehicles
- **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)."
 2. Add "Do not sell this product in individual containers holding less than 4 pounds of bait."

Terms/Conditions of Sale/Distribution:

3. 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 adopted for 15 of the 20 warfarin products. The last day for rodenticide manufacturers to sell or distribute warfarin products that do not include the mitigation listed above was June 4, 2011. Products sold by rodenticide manufacturers on or before June 4, 2011, may be sold until stocks are exhausted.
- The five warfarin products that did not adopt the mitigation measures of the 2008 RMD will be cancelled and are subject to the pending Notice of Intent to Cancel. These five products, along with their reasons for non-conformance with the 2008 RMD. (See *Table II* for a list of non-conforming warfarin products subject to cancellation).
- All of the active warfarin registrations were included in the LUIS data.

Product Reregistration

- All warfarin products completed product reregistration in 1995.

Registration Division Review

- List the action(s) that have occurred since the August 19, 2011, that could impact the use or application of the active ingredient (including new uses, deletion of uses, changes to application parameters, etc.). If actions are pending (ie. new uses, increased app rates, new formulations) please provide PRIA date(s) and RD contact handling action.

New Use: Kaput Field Rodent Bait B (EPA Registration No. 72500-11) Warfarin + Imidacloprid, Prairie Dogs, PRIA Date: Dec 10, 2011, RD Contact: Dan Peacock.

- Note any application rates that have changed since the RED. Are these rates accurately reflected in the BEAD data?

None

Table I. Bait Station Tiers: 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: ²	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.

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² 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 (whichever is larger), 6) on contrasting background, and 7) clearly readable by average person at the point of sale.

Table II. Warfarin Products Subject to Cancellation for Failure to Conform to the RMD

Registration Number	Product Name	Reasons for Non-Conformance with 2008 RMD
3282-3	D-CON CONCENTRATE KILLS RATS & MICE	unapproved formulation for homeowner needs bait station missing 50 ft restriction
3282-4	D- READY MIXED KILLS RATS & MICE	unapproved formulation for homeowner needs bait station missing 50 ft restriction
3282-9	D- MOUSE PRUFE KILLS MICE	unapproved formulation for homeowner needs bait station missing 50 ft restriction
3282-15	D- PELLETS KILLS RATS & MICE	unapproved formulation for homeowner needs bait station missing 50 ft restriction
8845-39	RID-A-RAT RAT & MOUSE KILLER	unapproved formulation for homeowner needs bait station missing 50 ft restriction