

US EPA ARCHIVE DOCUMENT

EFFICACY REVIEW

PRODUCT: ProMeris for Dogs

DATE: December 17, 2008

REG NUMBER: 80490-2

DB BARCODE: D 359470

DECISION: 400894

GLP: N/A

CHEMICAL: Metaflumazone (14.34%)
Amitraz (14.34%)

CHEMICAL NUMBER: Metaflumazone - 281250
Amitraz - 106201

PURPOSE: To respond to rebuttal of Agency review dated December 2, 2008 (D357599).

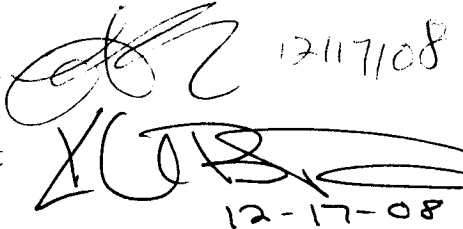
MRIDS: N/A

TEAM REVIEWER: Julie Chao

EFFICACY REVIEWER: Autumn Metzger, Biologist

SECONDARY EFFICACY REVIEWER: Kable Bo Davis, Entomologist

BACKGROUND:



The handwritten notes include a signature of Autumn Metzger with the date 12/17/08, and a signature of Kable Bo Davis with the date 12-17-08.

Promeris for dogs (EPA Reg. No. 80490-2) is intended for the control of fleas and ticks infesting dogs and puppies eight weeks of age and older. Agency review dated December 2, 2008 (D357599) contained the following recommendations:

- Remove claims, “Rapidly kills ticks” and “kills and controls most tick species within 24 hours”
- The claim “Starts killing most tick species within 24 hours” was proposed alternatively.

The above referenced rebuttal was submitted in an attempt to address these comments. For specifics on previously submitted data, please see Agency reviews dated April 19, 2008 (D311483), July 1, 2008 (D354170), September 3, 2008 (D355723) and December 2, 2008 (D357599).

RECOMMENDATIONS:

Although none of the submitted studies proved that Promeris caused “death” of tick species, a significant ($P < .05$) decline of attached ticks was noted in the studies supporting the claim, therefore the word kill can be used in these marketing claims denoting “rapid” results. The alternative wording, “control” refers to residual claims. Therefore, for the newly proposed claims the following recommendations apply:

Claim 1: “Starts killing ticks within 4 hours” is acceptable.

Claim 2: “Rapidly controls most tick species within 24 hours” is acceptable if the claim is revised to read: “Rapidly kills most tick species within 24 hours.”