US EPA ARCHIVE DOCUMENT

CHILD-RESISTANT PACKAGING REVIEW
Technical Review Branch

IN 9/19/2006 OUT 11/13/2006

Reviewed by Rosalind L. Gross 11/13/2006

EPA Reg. No. or File Symbol 80490-G

DP Barcode 332604

Decision No. 354816

EPA Petition or EUP No. _____

Date Division Received 08/29/2006

Type Product(s) Insecticide

Data Accession No(s). _____

Product Mgr./Chemical Review Mgr/Contact Person RM 07(Hebert)
Division RD

Product Name(s) Promeris Spot On For Cats

Company Name(s) Fort Dodge Animal Health

Submission Purpose Examine data for 2 CRP tests to ascertain if CRP is acceptable for 0.8ml Cat Product and use bracket data from EPA Reg. No. 80490-E Dog Product for 1.6ml Cat Product

Active Ingredient(s), PC code, & % Metaflumizone 18.53%

Summary of Findings

Note based on product toxicity CRP is voluntary for both the 0.8ml and 1.6ml size. The CRP certification was acceptable. A Senior Adult Use Effectiveness Test (SAUE) (MRID 469217-02) was done using the 0.8ml pipette in the blister. **The results were 100% SAUE. The study is a pass of the Senior Adult test** in **16 CFR 1700.20.**

The Child-Resistant Effectiveness Test (CRE) (MRID 469217-01) was done using the 0.8ml pipette filled with water inside the blister. Each child was given 9 blisters at the beginning of the test. **The results were no child failures. This study is a pass of the child test according to the sequential test chart in 16 CFR**

1700.20. The 0.8ml size of EPA Reg. No. 80490-G has met all the criteria for CRP. The 1.6 ml size of EPA Reg. No. 80490-G does not have any data. However, the 1.6ml size of the product was to be covered under a bracketing scheme that involved testing the 1.33ml and 3.33ml sizes of EPA Reg. No. 80490-E in a similar package. Therefore, the **1.6ml size of EPA Reg. No. 80490-G may conditionally** be considered to have met the criteria for CRP **pending the evaluation and acceptance of CRP test data for the 1.33ml and 3.33ml sizes of EPA Reg. No. 80490-E.**

Note since the desiccant strip was not used in the test package if any human experience/epidemiological evidence indicates a problem once the product is in the marketplace, the Agency reserves the right to question the child resistance of the package involved.

Company Data

A CRP certification, a SAUE Study MRID 469217-02, and a CRE Study MRID 469217-01 were submitted. Both of the studies were submitted as hard copy and electronically. The two studies were done on the 0.8ml size of the product. The 1.6ml size of the product was to be covered under a bracketing scheme that involved testing 4 sizes of EPA Reg. No. 80490-E in a similar package (the 1.33ml and 3.33ml size for the 1.6ml size). The registrant notes that **based on product toxicity CRP is voluntary for both the 0.8ml and 1.6ml size.**

A SAUE was done using the 0.8ml pipette in the blister. **The results were 100% SAUE.** The CRE was done using the 0.8ml pipette filled with water inside the blister. Each child was given 3 cards with 3 blisters each (9 blisters total) at the beginning of the test. A **blister failure** was defined as any breach into the unsealed/formed area of the package. A **child failure** was considered access to 9 blisters based on the product toxicity. **The results were no child failures.** 11 children accessed one unit each.

Packaging

The package tested was a plastic pipette inside a blue plastic-aluminum blister, ASTM D3475-06 type VIIID(2). The pipettes were filled with water. The blister is the intended child-resistant package. Each card contains 3 blisters each with a pipette. The instructions on the blister read "CUT AT DOTTED LINE" AND "FOLD AT LINE TEAR AT SLIT". These instructions allow a test subject to either use a tool or not. **In the marketplace each blister will contain a 10 x50 mm desiccant strip, but this was not included in the test packages.**

Toxicity

This product is not subject to CRP based on acute toxicity criteria in 40 CFR 157.22. This product is in voluntary CRP. The toxicity data for this product indicate a worst case acute oral LD_{50} of 5g/kg, which for an 11.4kg child represents a

toxic or harmful amount of 57g. With a product density of 1.11g/ml each 0.8ml pipette represents 0.888g and it would require 65 pipettes to represent a toxic or harmful amount of product. For the 1.6ml pipette it would require 33 pipettes to represent a toxic or harmful amount of product. Therefore for the purposes of **CRP testing a child failure will represent access to 9 units/blisters.**

Discussion and Conclusion

Note based on product toxicity CRP is voluntary for both the 0.8ml and 1.6ml size. A CRP certification, a SAUE Study MRID 469217-02, and a CRE Study MRID 469217-01 were submitted. The two studies were done on the 0.8ml size of the product. The 1.6ml size of the product was to be covered under a bracketing scheme that involved testing the 1.33ml and 3.33ml sizes of EPA Reg. No. 80490-E in a similar package. **The CRP certification was acceptable.**

A SAUE (MRID 469217-02) was done using the 0.8ml pipette in the blister. A senior adult failure was defined as any senior unable to open the package in the first five minute test period that passed the screening test or unable to open the package in the one minute test period. The package could be opened with or without a tool. A number of the Senior Adults used a tool to open the blister. **The results were 100% SAUE. The study is a pass of the Senior Adult test in 16 CFR 1700.20.**

The CRE (MRID 469217-01) was done using the 0.8ml pipette filled with water inside the blister. Each child was given 3 cards with 3 blisters each (9 blisters total) at the beginning of the test. A **blister failure** was defined as any breach into the unsealed/formed area of the package. A **child failure** was considered access to 9 blisters based on the product toxicity. **The results were no child failures.** 11 children accessed one unit each. Specifically, a 43 month old female and 50 month old male accessed one unit in the first 5 minute test period, a 43 month old female, 43 month old male, a 45 month old male, two 46 month old females, a 47 month old female, 47 month old male, a 49 month old male, and a 51 month old female each accessed one unit in the second 5 minute test period. **This study is a pass of the child test according to the sequential test chart in 16 CFR 1700.20.**

The 0.8ml size of EPA Reg. No. 80490-G has met all the criteria for CRP. The 1.6 ml size of EPA Reg. No. 80490-G does not have any data. However, the 1.6ml size of the product was to be covered under a bracketing scheme that involved testing the 1.33ml and 3.33ml sizes of EPA Reg. No. 80490-E in a similar package. Therefore, the **1.6ml size of EPA Reg. No. 80490-G may conditionally** be considered to have met the criteria for CRP **pending the evaluation and acceptance of CRP test data for the 1.33ml and 3.33ml sizes of EPA Reg. No. 80490-E.**

Note since the desiccant strip was not used in the test package if any human experience/epidemiological evidence indicates a problem once the product is in the marketplace, the Agency reserves the right to question the child resistance of the package involved.

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