

CHILD-RESISTANT PACKAGING REVIEW

Technical Review Branch

IN 02/01/99 OUT 02/22/99Reviewed by Rosalind L. Gross 02/22/99EPA Reg. No. or File Symbol 65331-2 *R.L. Gross*DP Barcode D253197 D253209

EPA Petition or EUP No. _____

Date Division Received 02/02/99Type Product(s) InsecticideData Accession No(s) 447491-01 (1365-025)Product Mgr./Chemical Review Mgr./Contact Person PM 03 Division RDProduct Name(s) Frontline Top Spot for CatsCompany Name(s) Merial LtdSubmission Purpose Examine to ascertain if packaging is CRPActive Ingredient(s), PC code, & % Fipronil 9.7%**Summary of Findings**

The CRP certification for this product is acceptable. The Senior Adult Use Effectiveness (SAUE) is 98%. 5 children gained access one pipette each. The study is a pass of the child test according to the sequential test chart in 16 CFR 1700.20

Package Description

Package consists of pipette blister shaped like Erlenmeyer flask with elongated neck and a raised Erlenmeyer shaped area containing the product inside a blister. The pipette is opened by snapping its perforated tip. There are 3 blisters connected to each other per card. Pipette is 8.6cm height, 3.3 cm at base, 0.3 cm thick with the raised Erlenmeyer area 2cm at base and 3.9 cm height. Pipette is heated formed shell of

Barex 210 350um, polypropylene 200um incorporating a blue dye sealed to backing of Barex 210 35um, aluminum 12um, and polyethylene terephthalate 12um opacified with titanium. Blister is heat formed shell of polyethylene 75um, polyethylene terephthalate 350um, polypropylene 100um sealed to a backing of polyethylene 50um, aluminum 20um, and polyamide 75um.

Analysis of Data and Conclusion

The pipette contains 0.5 ml of product ($0.5\text{ ml} \times 1.03\text{g/ml} \times 9.7\% \text{ fipronil} = 50\text{mg}$ fipronil). Access to 28.5 mg of fipronil represents a failure consequently access to one pipette represents a failure for a child.

Child Test

A failure is defined as "access to one pipette such that it could be removed from the blister. Breakage of the pipette resulting in leaking external to the blister, irrespective of the extent to which the blister was opened" 50 children 42-51 months of age were tested with a 3 pipette card given to them at the beginning of the test. The results were 5 children gaining access to one pipette each. One child gaining access to one pipette before demonstration and 4 children gaining access to one pipette each after demonstration. One tester exceeded the maximum number of children to be tested and tested 40% of the children tested. The study is a pass of the child test according to the sequential test chart in 16 CFR 1700.20.

Senior Adult Test

A failure is defined as an adult not able to access the pipette contents by the correct method. 100 senior adults 50-70 years of age (70% female) were tested making scissors available in accordance with the package's CRP use directions. There results were a SAUE of 98%. Two senior adults failing to open the second package (one in the 50-54 age group and one in the 55-59 age group). The instructions given to the seniors during testing differs somewhat from the instructions submitted to the Agency on February 1, 1999. There were five errors (18, 40, 45, 83, 100) in reporting the senior age, which were corrected by fax 2/18/99 from Peritt Laboratories. None of these five errors resulted in a change in the age group distributions, which remained with 50-54 years old 25%, 55-59 years old 25% and 60-70 years old 50% as prescribed in 16 CFR 1700.20. The study is a pass of the Senior Adult test in 16 CFR 1700.20.

The CRP certification is acceptable.