

CHILD-RESISTANT PACKAGING REVIEW

Technical Review Branch

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Product Mgr./Chemical Review Mgr./Contact Person PM 03 Division RD
Product Name(s) Frontline Spray Treatment
Company Name(s) Merial Ltd
Submission Purpose Examine to ascertain if packaging is CRP
Active Ingredient(s), PC code, & % Fipronil (PC Code 129121) .30%

Summary of Findings

The CRP certification for this product is acceptable though there is a discrepancy in definition of failure. The leakage test showed no leakage. The Senior Adult Use Effectiveness (SAUE) is 95%. Two children gained access to packages during the test. 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 an Owens-Brockway non-removable, child resistant, trigger spray pump on a 500 ml PETE Bottle; ASTM Type IX (B) (1).

Analysis of Data and Conclusion

In the child study report the registrant defines failure for the child resistance test as " i) successfully spraying the pump greater than 7 times, ii) causing leaks that resulted in greater than 11 ml of product coming out of the bottle, iia) reproducible leakage, iii) obtaining access to the total contents of the bottle or any volume greater than 11 ml by any mechanism." In the CRP Certification, the registrant defines failure as "the ability to activate the pre-assembled unit and to dispense a volume contained in eight pumps during the testing period."

For this submission the concentration of fipronil is 2.9 mg/l. Access to 28.5 mg of fipronil represents a failure. The Agency's definition of failure, then, is spraying the pump 7 times ($28.5 \text{ mg} \div 2.9 \text{ mg/l} = 10 \text{ ml}$ or 7 sprays @ 1.5 ml/spray). Also, access to 10 ml through leakage or access to any amount of contents by any other mechanism, e.g., loosening the cap from the bottle, represents a failure.

Child Test

50 children 42-51 months of age were tested with a trigger spray bottle given to them at the beginning of the test. The results were that one child 42-44 months opened the package before demonstration and one child 49-51 months opened the package after demonstration for a total of two failures as defined above. 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 the inability to activate the pump mechanism and relock the unit during the test period. 100 senior adults 50-70 years of age (70% female) were tested in accordance with the package's CRP use directions. The results were a SAUE of 95%. Three of the 5 senior adults failed to open the first package (1 senior 55-59 years old, 2 seniors 60-70 years old), one senior adult (60-70 years old) failed to open the second package, and one senior adult (55-59 years old) failed to close the second package. The directions given to the seniors during testing were the same as the directions given on the label submitted. The registrant miscalculated six ages. Four stayed within the same age grouping. However, in two instances (samples # 60 and # 82), the age groupings changed. The result is that the age distribution is now 27 50-54 years old, 24 55-59 years old, 49 60-70 years old which disagrees with the age distributions specified in 16 CFR 1700.20. The study is a pass of the Senior Adult test in 16 CFR 1700.20.

Leakage Test

The leakage test is designed to determine whether any product leaks out of the package since once leakage occurs, it will occur during all subsequent sprays. A leaking package is no longer functioning properly and will not meet compatibility and durability requirements of 40 CFR Part 157. Leakage can also result in child failure since access to 10 ml of leaked product = access to a toxic or harmful amount. The procedure for the leakage test involved a total of ten bottles filled with iso-propanol. The contents of each bottle were pumped through the spray until empty which at a spray volume of 1.5 ml/spray amounted to approximately 330 pumps. No leaking was observed with any bottle or spray mechanism at any stage during the test. Therefore, leakage is not an issue.

The CRP certification is acceptable. However, it should be noted that the Agency's definition of failure, i.e., spraying the pump 7 times and/or accessing 10 ml through leakage and/or accessing any amount of contents by any other mechanism, is different from that of the registrant's.