



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

OFFICE OF
PREVENTION, PESTICIDES
AND
TOXIC SUBSTANCES

November 14, 2008

NOTE TO RM 10 Ann Sibold

SUBJECT: Protocol Review for Compliance with Child-Resistant Packaging Regulations
EPA FILE NO: 65331-2, 65331-3, 65331-4, and 65331-5 DP357383, 357384,
357420, and 357421, Decision # 401081, 401084, 401083, and 401082

Company Submission

The package consists of one pipette containing product inside a hanging card. There is one hanging card per package. The hanging card is supposed to be CRP. The hanging card requires scissors in order to open it. The actual directions for opening the hanging card were not in the submission. The hanging card in the submission is clear with a whitish backing that has a picture of a pair of scissors and where to cut the card on it.

The registrant submitted a protocol to cover testing 4 different products. The CRP testing would involve two hanging card sizes (small and medium based on cavity size), two different colors pipettes (green or blue), and 5 different volumes of product in the pipette [(0.5, 0.68, and 1.34 in small hanging card) and (2.68, and 4.02 ml in medium hanging card)]. The registrant would test the packages by filling the pipettes with water and placing them in a hanging card. Testing would be conducted per 16 CFR 1700.20 for both child-resistant effectiveness (CRE) and senior adult use effectiveness (SAUE). The registrant proposes testing one small hanging card with 1.34 ml of product in both blue and green color and using the data for the 0.5 and 0.68 ml package as well. Additionally, one medium hanging card with 4.02 ml would be tested in both blue and green color and using the data for the 2.68 ml package as well.

Conclusion

Testing should involve more than one size pipette for bracketing purposes. The testing scheme for the pipettes filled with water in the hanging card should involve:

- Testing a small hanging card with a 0.5 ml blue pipette
- Testing a small hanging card with a 1.34 ml green pipette
- Testing a medium hanging card with a 2.68 ml green pipette
- Testing a medium hanging card with a 4.02 ml blue pipette

Testing of the 0.5 ml and 1.34 ml would cover the 0.68 ml size pipette assuming both the tests were high passes and not marginal. Data on the 2.68 ml and 4.02 ml size pipette would be better than data on just one size.

A child test failure for all pipette sizes would be considered access to one pipette, which is more than 28.5mg of fipronil (a toxic or harmful amount) for all 4 products in pipettes sizes from 0.5 ml to 4.02 ml. **A child test failure is defined** as access to one pipette such that it could be removed from the hanging card, breakage of the pipette resulting in leaking external to the hanging card, irrespective of the extent to which the hanging card was opened, or access to the contents of the pipette in any fashion.

A senior adult use effectiveness failure is defined as an adult not able to access the pipette contents by the correct method within the 5 minute test or the one minute test.

The CRP data should be submitted both as hard copy and electronically for review along with a CRP certification for each product. The directions for opening the hanging card and the picture on the back of the card used in testing should be included in the final report submitted with the CRP data. **Note:**

- The use directions and picture on the back of the card used in testing must be the identical to those provided with the actual retail package.
- If the hanging card or pipette size, materials, color, thickness, etc. change testing may be required.
- The final report should specify the amount of water and color of the pipettes used for testing.
- If scissors should accompany the retail package then the children would be given them for testing.
- An amended label may be required if the use directions for opening the hanging card are on the label.
- If more than one hanging card is marketed in a retail package testing is required.

Please place a copy of this note in the registration jackets for the above named products. If you have any questions please contact me at (703)-308-7368.



Rosalind L. Gross