

CHILD-RESISTANT PACKAGING REVIEW
Technical Review Branch

IN 05/31/02 OUT 7/15/02

Reviewed by Rosalind L. Gross 7/15/02

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Type Product(s) Insecticide

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Product Mgr./Chemical Review Mgr./Contact Person PM 03 (Richard Gebken)
Division RD

Product Name(s) Select TCS

Company Name(s) Aventis Environmental Science USA LP

Submission Purpose Examine Child-Resistant test to ascertain if acceptable

Active Ingredient(s), PC code, & % Fipronil 0.85%

Summary of Findings

A preliminary child-resistant packaging (CRP) study was submitted that involved 20 children 42-51 months of age and did not include a senior adult test. The child study, which reported no failures, was done involving the use of one station per child, no demonstration at the five minute mark, and a station failure was defined as access to the wick/indicator. The amount of Fipronil per station was not given. Without knowing the amount of Fipronil per station, the number of stations needed to equal 28.5mg Fipronil, and no stipulation by the registrant that access to one station is defined as a child failure **no conclusions can be drawn regarding the child-resistance of this package.**

A sample package from the test was identified as child 1532-1 package 17. However the question remains - Is this the same bait station "modified Protecta Junior (Bell Labs Box)" that passed the efficacy test? If not, what is the MRID for the efficacy

data for this bait station? Additionally, the name and identity of the bait station subjected to the Child-Resistant Effectiveness test is required.

This study did not strictly adhere to the protocol test requirements in 16 CFR 1700.20 and may not in any way be used to fulfilled the CRP requirements in 40 CFR Part 157. There were a number of concerns with this preliminary study which are as follows: a **child failure** in terms of the number of stations equivalent to 28.5mg of Fipronil needs to be agreed to by the registrant and the Agency before testing; the definition of a **station failure** needs to be expanded to include access to the wick/indicator, damage to the station such as cracks, wick falling out, child touch wick, etc.; the **lack of demonstration at the five minute mark** during the child test (the demonstration is required in the protocol test requirements in 16 CFR 1700.20) needs to be agreed to by the registrant and the Agency before testing; and the study did not strictly adhere to the protocol test requirements in 16 CFR 1700.20 in that the sex distribution had more than a 10% preponderance of females in the 42-44 month age group, the number of subjects per site exceeded 20%, and the number of subjects per tester exceeded 30%. Additionally, there was no senior adult test. **In conclusion, this study is of no value in terms of fulfilling the CRP requirements for this product.**

Company Data

A preliminary child-resistant packaging (CRP) study was submitted that involved 20 children 42-51 months of age. The study was done involving the use of one station per child, no demonstration at the five minute mark, and a station failure was defined as access to the wick/indicator. The amount of Fipronil per station was not given. The study reported no failures during the ten minute test period. The study, which did not include a senior adult test, indicated it was a preliminary test for design purposes only and a full study would follow.

Discussion and Conclusion

A preliminary child-resistant packaging (CRP) study was submitted that involved 20 children 42-51 months of age and did not include a senior adult test. The child study, which reported no failures, was done involving the use of one station per child, no demonstration at the five minute mark, and a station failure was defined as access to the wick/indicator. The amount of Fipronil per station was not given. Without knowing the amount of Fipronil per station, the number of stations needed to equal 28.5mg Fipronil, and no stipulation by the registrant that access to one station is defined as a child failure **no conclusions can be drawn regarding the child-resistance of this package.**

A sample package from the test was identified as child 1532-1 package 17. However the question remains - Is this the same bait station "modified Protecta Junior

(Bell Labs Box)" that passed the efficacy test? If not, what is the MRID for the efficacy data for this bait station? Additionally, the name and identity of the bait station subjected to the Child-Resistant Effectiveness test is required.

This study did not strictly adhere to the protocol test requirements in 16 CFR 1700.20 and may not in any way be used to fulfilled the CRP requirements in 40 CFR Part 157. There were a number of concerns with this preliminary study which are as follows:

- (1) Based on the amount of Fipronil per station a **child failure** in terms of the number of stations equivalent to 28.5mg of Fipronil needs to be agreed to by the registrant and the Agency before testing. The registrant may have a more stringent definition of a child failure than 28.5mg of Fipronil. However, any change back to 28.5mg of Fipronil for the definition of a child failure may render the study worthless.
- (2) The definition of a **station failure** needs to be expanded to include access to the wick/indicator, damage to the station such as cracks, wick falling out, child touch wick, etc.
- (3) The lack of demonstration at the five minute mark during the child test (the demonstration is required in the protocol test requirements in 16 CFR 1700.20) needs to be agreed to by the registrant and the Agency before testing.
- (4) The study did not strictly adhere to the protocol test requirements in 16 CFR 1700.20 in a number of areas which are: the sex distribution had more than a 10% preponderance of females in the 42-44 month age group, the number of subjects per site exceeded 20%, and the number of subjects per tester exceeded 30%.

Additionally, there was no senior adult test.

In conclusion, this study is of no value in terms of fulfilling the CRP requirements for this product.