

CHILD-RESISTANT PACKAGING REVIEW
Technical Review Branch

IN 05/20/03 & 6/17/03 OUT 06/23/03

Reviewed by Rosalind L. Gross

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06/23/03

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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) Bayer Environmental Science

Submission Purpose Review Protocol Testing Data from 3 Child-Resistant Effectiveness Tests (Including Bracketing Scheme) and Senior Adult Use Effectiveness Test along with other requirements to fulfill CRP requirements for this product (Saliva Solubility Test, and Soaking Test)

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

Summary

For the child-resistant packaging (CRP) requirements for this product to be met in addition to the Child-Resistant Effectiveness, Senior Adult Use Effectiveness tests, a CRP certification, a water solubility evaluation (soaking) and the simulated saliva solubility test were required.

In conclusion, all 3 Child-Resistant Effectiveness tests were a pass of the sequential test in 16 CFR 1700.20. The Senior Adult Use Effectiveness was 100%,

which is a pass of the senior adult test in 16 CFR 1700.20. The water solubility and saliva solubility tests are acceptable. The CRP certification dated 4/28/03 is acceptable. All the requirements for CRP have been met.

Efficacy of Bait Station

The bait station subjected to the Child-Resistant Effectiveness and Senior Adult Use Effectiveness tests was designed by B & G and was used in the EUP and Section 18 program in 2002 in CT, NJ, and NY. It is not the original Bell Lab bait station. **The Product Manager will need to determine if this bait station has efficacy data associated with it.**

Company Data

Package Description

The bait station is black box measuring 7.5 " long X 5.5" wide X 2.625" deep with a 1.75" X 1.75" rodent opening according to the registrant. Each box will have 4 tabs with a hole that are 0.75" in length from the opposite side of the rodent opening, 2 per side. Each box contains one wick that will contain 25.5 mg of Fipronil. The box is nonrefillable and will be used for three months. A large home will use 20 bait stations and some homes on a few acres may use 30 bait stations.

Child Test

Three Child-Resistant Effectiveness (CRE) tests were conducted and the data submitted. All three tests involve bait stations weathered for 3 months that would contain 25 mg of Fipronil in actual use. A **child failure** is defined as access to two bait stations.¹ A **bait station failure** is defined as either partial or complete access to bait from a bait station, which includes any cracks or other damage to the bait station that allow a child potential access to the bait, or touching the indicator. Evidence of failure will involve checking the hands or other areas for placebo indicator, etc. The demonstration will consist of a 5 second break because the unit is not intended to be opened.

One CRE test (1557-001 MRID 459259-01) involves a child receiving one bait station at the beginning of the test. If the child gains access to the bait station then the child gets a second bait station and so on up to a maximum of five bait stations. It should be noted that the child never has access to more than one bait station at a time, each time the child gets another bait station the station accessed is removed from testing. The results are one child failure.

¹A toxic or harmful amount of Fipronil is 28.5mg.

The second CRE test (1557-002 MRID 459259-02) involves a child receiving two bait stations at the beginning of the test and has access to both bait stations throughout the test. There were no child failures.

The third CRE test (1557-003 MRID 459259-03) involves a child receiving five bait stations at the beginning of the test and has access to all five bait stations throughout the test. There were no child failures.

Senior Adult Use Effectiveness Test

The **Senior Adult Use Effectiveness (SAUE) test definition of a failure** is any form of final deployment for either of the bait stations resulting in cracking, damage, or the increased potential of access to the bait by a child. An **inability to deploy** the bait station according to directions without increased potential for child access is **not a failure**.

The bait station is not intended to be opened. Therefore the **SAUE test (1557-004 MRID 459259-04)**, which has a 70% female panel, consists of having seniors use deployment instructions to attach the bait station to a Styrofoam block using 2 spikes and a hammer. The seniors will do the procedure with **two 5 minute test periods** rather than the 5 minute and 1 minute test periods per 16 CFR 1700.20.

According to the testing laboratory (email 5/29/03) the second 5 minute test period was used rather than the 1 minute test period per 16 CFR 1700.20 to allow enough time to complete the deployment and maximize the chance of damage to the bait station due to deployment.

The results of the test were no failures as defined above. However there were 8 panelists that either did not deploy one or both bait stations, but passed the screening test. Since these undeployed bait stations did not result in increased potential for child access they were not failures. Additionally there were 20 damaged bait stations.

Based on the uniqueness of this bait station and our lack of experience all station failures, damage, cracks etc. are accompanied by digital photographs as jpg files.

Two jpg files (23 and 34) and the bait stations associated with them were questioned. Number 23 jpg (package 35 b- second package) according to the testing laboratory (email 5/29/03) had the grommet broken off and a hole to the inside of the station measuring 2cm x 1.5cm x 1cm, which is divided in half by a post. The hole was 8cm away from the wick. The testing laboratory thought a child could not access the wick and it was not considered to be a failure. Number 34 jpg according to the testing laboratory (email 6/5/03) had the grommet broken off, but it was external station damage only with no hole to the inside of the station, it was not a failure.

Water Solubility (Soaking) Test

The **water solubility test (CRP-ES-WS-060903)** consisted of five bait stations with a 25mg of active ingredient each (0.7% Fipronil per station) being placed in 2800ml water at 16-20°C for 48 hours. At the end of the 48 hours after stirring the solution a single 100ml aliquot was taken for each station. The average residue for the five stations was 33.72ppb Fipronil, the worst case was 44.7ppb Fipronil ($44.7 (10^{-3})\text{mg/L}$).

Saliva Solubility Test

The **saliva solubility test (1557-005 MRID 459259-05)** consisted of three bait stations with a 25mg of active ingredient each being placed in 5000ml solution at pH 6.9 to 100°F for 30 minutes. 50 ml aliquots of each solution will be taken at the 10, 20, and 30 minutes time period. These aliquots were evaluated for the amount of active ingredient and its metabolites. The worst case was 13.99 ppb of Fipronil = $13.99 (10^{-3})\text{mg/L}$.

Analysis of Data and Discussion

Child Test

Three Child-Resistant Effectiveness (CRE) tests were conducted and the data submitted. All three tests involve bait stations weathered for 3 months that would contain 25 mg of Fipronil in actual use. A **child failure** is defined as access to two bait stations.² A **bait station failure** is defined as either partial or complete access to bait from a bait station, which includes any cracks or other damage to the bait station that allow a child potential access to the bait, or touching the indicator. Evidence of failure will involve checking the hands or other areas for placebo indicator, etc. The demonstration will consist of a 5 second break because the unit is not intended to be opened.

One CRE test (1557-001 MRID 459259-01) involves a child receiving one bait station at the beginning of the test. If the child gains access to the bait station then the child gets a second bait station and so on up to a maximum of five bait stations. It should be noted that the child never has access to more than one bait station at a time, each time the child gets another bait station the station accessed is removed from testing. The results are one 46 month female child accessed 2 bait stations in the first 5 minutes before the demonstration and one 42 month male accessed one bait station. There is one child failure. The 50 child study is a pass of the sequential test in 16 CFR 1700.20. This first test where the child gets one bait station at a time is not a stand alone test, because the child is not guaranteed access to the number of bait stations that constitute a failure. The first test only has meaning as part of a bracketing scheme.

The second CRE test (1557-002 MRID 459259-02) involves a child receiving

²A toxic or harmful amount of Fipronil is 28.5mg.

two bait stations at the beginning of the test and has access to both bait stations throughout the test. The results are one 45 month female child accessed 1 bait station. There were no child failures. There was one age calculation error where a 48 month female was counted as being 47 months but this does not affect the results as both ages are in the same age group. The 50 child study is a pass of the sequential test in 16 CFR 1700.20.

The third CRE test (1557-003 MRID 459259-03) involves a child receiving five bait stations at the beginning of the test and has access to all five bait stations throughout the test. No children accessed even one bait station. There were no child failures. The 50 child study is a pass of the sequential test in 16 CFR 1700.20.

Based on the size of the bait stations it was agreed at a 11/5/02 meeting with the registrant that the most bait stations a child needed to receive either at the beginning of test or one at a time as a station was accessed (e.g. (1557-001)) would be 5 bait stations. By passing all three 50 child sequential tests the registrant may use not only 1-5 bait stations per residence, but also more than 5 bait stations up to e.g. 20 stations can be used. Giving a child more than 5 bait stations such as 20 bait stations (7.5 " long X 5.5" wide X 2.625" deep with a 1.75" X 1.75" rodent opening) would serve to potentially overwhelm the child.

Senior Adult Use Effectiveness Test

The **Senior Adult Use Effectiveness (SAUE) test definition of a failure** is any form of final deployment for either of the bait stations resulting in cracking, damage, or the increased potential of access to the bait by a child. An **inability to deploy** the bait station according to directions without increased potential for child access is **not a failure**.

The bait station is not intended to be opened. Therefore the **SAUE test (1557-004 MRID 459259-04)**, which has a 70% female panel, consists of having seniors use deployment instructions to attach the bait station to a Styrofoam block using 2 spikes and a hammer. The seniors will do the procedure with **two 5 minute test periods** rather than the 5 minute and 1 minute test periods per 16 CFR 1700.20.

According to the testing laboratory (email 5/29/03) the second 5 minute test period was used rather than the 1 minute test period per 16 CFR 1700.20 to allow enough time to complete the deployment and maximize the chance of damage to the bait station due to deployment. The standard 5 minute and 1 minute test periods per 16 CFR 1700.20 is normally more stringent than two 5 minute test periods. In this situation that is not the case. Since the two 5 minute test periods are more stringent in this situation than testing per 16 CFR 1700.20, this deviation from the test protocol will be allowed.

The results of the test were no failures as defined above. However there were 8 panelists that either did not deploy one or both bait stations, but passed the screening test. Since these undeployed bait stations did not result in increased potential for child access they were not failures. Additionally there were 20 damaged bait stations.

Based on the uniqueness of this bait station and our lack of experience all station failures, damage, cracks etc. are accompanied by digital photographs as jpg files.

Two jpg files (23 and 34) and the bait stations associated with them were questioned. Number 23 jpg (package 35 b- second package) according to the testing laboratory (email 5/29/03) had the grommet broken off and a hole to the inside of the station measuring 2cm x 1.5cm x 1cm, which is divided in half by a post. The hole was 8cm away from the wick. Based on the anthropometric measurements for a 3.5-4.5 year old³ a child could potentially fit a finger into the hole in the station but the finger would not be long enough to reach the wick. Therefore, while the station was damaged it would not be a failure. Number 34 jpg according to the testing laboratory (email 6/5/03) had the grommet broken off, but it was external station damage only with no hole to the inside of the station, it was not a failure. In conclusion, none of the 20 damaged bait stations resulted in increased potential for child access and they were not failures. The results were a 100% SAUE, which is a pass of the senior adult test in 16 CFR 1700.20.

Water Solubility (Soaking) Test

The **water solubility test (CRP-ES-WS-060903)** consisted of five bait stations with a 25mg of active ingredient each (0.7% Fipronil per station) being placed in 2800ml water at 16-20°C for 48 hours. At the end of the 48 hours after stirring the solution a single 100ml aliquot was taken for each station. The average residue for the five stations was 33.72ppb Fipronil, the worst case was 44.7ppb Fipronil (44.7 (10⁻³)mg/L). The maximum amount a child would ingest is 1 Liter, which is the equivalent of 0.045mg Fipronil and a toxic or harmful amount of Fipronil is 28.5mg. Therefore an adequate margin of safety exists in terms of water solubility. **The water solubility test is acceptable.**

Saliva Solubility Test

The **saliva solubility test (1557-005 MRID 459259-05)** consisted of three bait stations with a 25mg of active ingredient each being placed in 5000ml solution at pH 6.9 to 100°F for 30 minutes. 50 ml aliquots of each solution will be taken at the 10, 20, and 30 minutes time period. These aliquots were evaluated for the amount of active ingredient and its metabolites. The worst case was 13.99 ppb of Fipronil = 13.99 (10⁻³)mg/L. The amount of saliva generated would be considerably less than 1L (0.014mg Fipronil) and a toxic or harmful amount of Fipronil is 28.5mg. Therefore an

³2nd finger at the 2nd knuckle - 1.2cm width x 1.1cm thick x 4.7cm long from September 1977 CPSC study by Owings, C.L. et. al. CPSC-C-76-0119 at University of Michigan Ann Arbor, MI

adequate margin of safety exists in terms of an saliva solubility. **The saliva solubility test is acceptable.**

Conclusion

In conclusion, all 3 Child-Resistant Effectiveness tests were a pass of the sequential test in 16 CFR 1700.20. The Senior Adult Use Effectiveness was 100%, which is a pass of the senior adult test in 16 CFR 1700.20. The water solubility and saliva solubility tests are acceptable. The CRP certification dated 4/28/03 is acceptable. All the requirements for CRP have been met.