

CHILD-RESISTANT PACKAGING REVIEW
Technical Review Branch

IN 06/11/02 OUT 7/15/02

Reviewed by Rosalind L. Gross 7/15/02

EPA Reg. No. or File Symbol 432-REUI

DP Barcode D283530

EPA Petition or EUP No. _____

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Type Product(s) Insecticide

Data Accession No(s). _____

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 Develop bracketing child test scheme and senior adult use effectiveness test along with other requirements to fulfill CRP requirements for this product

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

See attached document for Type of Data Necessary for EPA Reg No. 432-REUI Bait Station and questions regarding the child and adult testing and preliminary data. Based on my 7/11/02 conversation with Aventis (Dr. Adrian Krygsman) all answers to these issues **must be submitted in writing including draft testing protocols before testing** commences to preclude rejection due to faulty test methodology.

Note based on my understanding that this is **not same bait station "modified Protecta Junior (Bell Labs Box)" that passed efficacy test**. You may want to have Kevin Sweeney look into the MRID for the efficacy data for this bait station to confirm it is okay. Both the efficacy and CRP data should be acceptable for the same bait station.

Questions on 432-REUI Regarding Child and Adult Testing and Preliminary Data

1. How far back into the station does the wick go? 5 inches?
2. Identify the bait station labeled 1532-1 package 17?
3. It is my understanding that the **bait station labeled 1532-1 package 17 is not** the modified Protecta Junior (Bell Labs Box). Is this correct?
4. What is the MRID for the efficacy data for the **bait station labeled 1532-1 package 17**? It is my understanding that this is **not same bait station "modified Protecta Junior (Bell Labs Box)" that passed efficacy test.**
5. How much Fipronil is on each wick? Is it 25.5 mg Fipronil?
6. How many wicks are in each station? Is there only 1 wick per station?
7. What is the minimum number of bait stations per residence? Is this number going to be 10?
8. What is the maximum number of bait stations per residence? Is this number going to be 50?
9. Regarding the Senior Adult Test -

Senior actions should mimic PCO action to the extent test environment permits and is reasonable

- A. It is my understanding that the station is manufactured and delivered to the PCO ready to use with no appreciable gap in the 3 month product life. When the product is registered and mass production occurs what is the shelf life of the product?
- B. Will there be any appreciable gap from time of manufacture until the stations are put into use for their 3 month product life?
- C. Will any type of packaging be used to wrap the bait station to preserve the wick's 3 month product life? If so, this outer wrapping could necessitate retesting for either or both the senior adults and the children dependent on whether or not it is considered strictly an "outer package". Any changes to the current style of delivering the bait stations to the PCO should receive Agency approval before use.

- D. How does PCO put station into use?
- E. What is gutter spike?
- F. Is this what PCO uses?
- G. Are the gutter spike and the ground spike the same?
- H. A package failure for Senior Adult Test is defined as - putting the bait station into use upside down, on its side, etc, not attaching it with the gutter spikes provided, or somehow cracking or damaging the bait station. If the registrant disagrees with this definition, another definition must be provided and approved prior to the Senior Adult Test .
- I. Senior Adult Test is 70% female
- J. Senior Adult Test pass is 90% or more SAUE per 16 CFR 1700.15

Notes for Type of Data Necessary for EPA Reg No. 432-REUI Bait Station

For the child-resistant packaging (CRP) requirements for this product to be met the following items must be submitted:

- (1) Both Child-Resistant and Senior Adult Use Effectiveness studies per 40 CFR Part 157 must be conducted on bait stations weathered for the life of the product. When these studies are submitted both an electronic (per PR Notice 97-9) and hard copies must be submitted. The details of the weathering (e.g. time, conditions) must be provided. **Note** any change in the color, composition, size, life of the product, etc. for the bait station or any of its components from what was originally tested may necessitate retesting.
- (2) A simulated saliva solubility test must be conducted to determine if child can obtain toxic or harmful amount of product by biting, chewing, sucking, or oral manipulation. Testing should be done at 100°F (3 samples at each time) 10, 20, 30 minutes per our previous discussions. This data must be submitted.
- (3) A water soaking evaluation (solubility) of the bait station/wick must be conducted to determine some of the effects of the climate and use conditions over the product life on the level of child-resistant effectiveness (weathering and solubility of the product e.g. will the child be able to pick up a bait station outside and as a result of rain/snow have a liquid with high concentration of product (toxic or harmful amount) immediately available).
- (4) A CRP certification in accordance with 40 CFR Part 157 must be submitted. The CRP certification should also specify the wick size, the amount of active ingredient (Fipronil) on the wick, the number of wicks per bait station, the bait station size, composition (e.g. plastic thickness, etc.), life of the product, and the bait station design. **Note** if any changes occur in the color, composition, size, life of the product, etc. for the bait station or any of its components from what was originally tested a new CRP certification is required and retesting may be required.

Child Test

For the **Child Test** a number of issues should be agreed upon before testing, which are as follows:

Define a **child failure** in terms of the number of bait stations equivalent to 28.5mg of Fipronil based on the amount of Fipronil per bait station. You 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.

The definition of a **child test bait station failure** needs to include access to the wick/indicator, damage to the bait station such as cracks, wick falling out, child touch wick, etc.

The **demonstration at the five minute mark** during the child test, which is specified in the protocol test requirements in 16 CFR 1700.20, needs to be **discussed**. It may be eliminated/replaced (stop test for time comparable to demonstration period) by mutual consent based on what is ultimately determined to be the Senior Adult Use Effectiveness test protocol. Before testing the registrant needs to advise the Agency of whether the demonstration at the five minute mark during the child test will be eliminated/replaced.

The study needs to adhere to the protocol test requirements in 16 CFR 1700.20.

Child Tests Bracketing

The **bracketing of child tests** needs to be discussed in terms of the number of tests and what constitutes each test using the weathered bait stations. If **reuse** of weathered bait stations may be needed, it should be discussed before testing. How many times would a bait station need to be used? Under what conditions would a bait station be disqualified from reuse (e.g. child previously accessed bait station, cracked, etc.)? The need for different color dyes develops with the need to detect access to more than one bait station.

The **bracketing tests using weathered bait stations** are:

1. Give each child one bait station at the beginning of the test. If the child gains entry to one bait station then the child gets another bait station and so on up to a maximum number of 50 bait stations for the ten minute test period. (based on 50 being the maximum number of bait stations per residence).
2. Give each child 50/10¹ bait stations at the start of the ten minute test period (based on 50 being the maximum and 10 being the minimum number of bait stations per residence). In the past we would have used 50 bait stations, but due to the size of the bait stations a smaller number may be considered the worst case scenario. We need to discuss the number of bait stations for this test and agree before testing is started. (Note 10 stations in 2 stacks is 7.6 x 11 x

¹10 bait stations at the start of the ten minute test period is preferable over the 50 bait stations.

12.5 inches.)

3. One test panel might give each child the number of bait stations necessary for a child failure or two bait stations² at the start of the ten minute test period.

Normally, tests 1 and 2 (using 50 bait stations) as discussed herein would be sufficient. The combination of the two tests would permit use of anywhere from 1 to 50 bait stations per residence. Since we have no experience with this type of bait station and its size, test 3 is being added here. Despite the bracketed approach **the Agency reserves the right to question the child resistance of the package involved should any human experience/ epidemiological evidence indicate a problem once the product is in the marketplace.**

Final Report and Addendum

The **hard copy Final Report** or an **Addendum** to it should:

State that weathered bait stations were used

Indicate how many bait stations the child got at the start of the test and if they were given any more during the test (e.g. test 1 of bracketing)

Report the **number of bait stations each child accessed** not just whether or not it was a child failure

Define a **child failure** in terms of the number of bait stations equivalent to 28.5mg of Fipronil based on the amount of Fipronil per bait station.

Define a **child test bait station failure** as including access to the wick/indicator, damage to the bait station such as cracks, wick falling out, child touch wick, etc.

Define what constitutes a **demonstration at the five minute mark** for the child test.

Describe the **Senior Adult Protocol** used

Define a **Senior Adult test failure**

²Giving each child two bait stations at the start of the ten minute test period is preferable even if a child failure is defined as one bait station because the one bait station concept is covered by bracketing test 1 as discussed herein.

List the details of the weathering (e.g. time, conditions)

Specify the wick size

Specify the amount of active ingredient (Fipronil) on the wick

Indicate the number of wicks per bait station

Give the name of the bait station subjected to the Child-Resistant Effectiveness and Senior Adult Use Effectiveness tests and identify the bait station - e.g. the modified Protecta Junior (Bell Labs Box) for the bait station

Was the same bait station used for the Child-Resistant Effectiveness and Senior Adult Use Effectiveness test? If not, why?

State whether or not the same bait station was used for efficacy testing and if not, why

Specify the MRID for the efficacy data for the bait station subjected to the Child-Resistant Effectiveness and Senior Adult Use Effectiveness tests

Indicate the bait station size, composition (e.g. plastic thickness, etc.), life of the product, and the bait station design.

Senior Adult Use Effectiveness Test

We need to discuss the Senior Adult Use Effectiveness (SAUE) Test for the bait station in terms of:

Is it a prefilled, nonrefillable bait station not designed or intended to be opened or activated in a manner that exposes the contents to human contact? This question should be answered in the final report or its addendum.

What constitutes putting it into use?

How does PCO put bait station into use?

What would the use directions be?

Define a SAUE test protocol - Senior actions should mimic PCO action to the extent test environment permits and is reasonable.