CHILD-RESISTANT PACKAGING REVIEW
Technical Review Branch

IN 10/31/02 OUT 11/04/02

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Reviewed by Rosalind L. Gross 11/04/02

EPA Reg. No. or File Symbol 432-REUI

DP Barcode D286498

EPA Petition or EUP No. _____

Date Division Received 10/22/02

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) Bayer Cropscience LP

Submission Purpose Review protocol testing scheme for child-resistant effectiveness test (including bracketing 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%

Summary

Child Test

The first child resistant effectiveness test should be modified so that the child gets 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 the maximum number of bait stations per residence. **Then a third child resistant effectiveness test needs to be added.** The third child resistant effectiveness test would involve giving each child the maximum number bait stations at the start of the ten minute test period. Due to the size of the bait stations a maximum number of 10 bait stations may be considered the worst case scenario. **What is the maximum number of bait stations**

per residence? The only way the maximum of bait stations the child receives should remain at 2 bait stations for the first test and a third test is unnecessary is if the maximum number of bait stations per residence is two. **Note the second child-resistant effectiveness test should still be done** to see what happens if a child is given access to the number of bait stations that constitute a failure (2 bait stations) at the beginning of the test.

The **bait station failure** is defined as either partial or complete access to bait from a bait station. This definition should be **expanded** to include any cracks or other damage to the bait station that allow a child potential access to the bait, e.g. to the wick/indicator, wick falling out, child touch wick, etc. Evidence of failure, which will involve checking the hands or other areas for placebo indicator should also mention checking the mouth and clothes specifically for evidence of the placebo indicator. The demonstration will consist of a 5 second break, which is acceptable. **Based on the uniqueness of this bait station and our lack of experience all station damage, cracks etc. should be described in detail and accompanied by detailed digital photographs as jpg files on a disc.**

Senior Adult Use Effectiveness Test

The senior adult use effectiveness test **definition of a failure should be any form of deployment resulting in the increased probability of access to the bait by a child (e.g. cracked or damaged). Certain assumptions should be clarified** in this protocol such as the fact that the hammer and spikes will not be provided to the PCO with the bait station in actual use, the senior adult test panel will be 70% female, and that the two times the seniors do the procedure will be the 5 minute and 1 minute test per 16 CFR 1700.20. Will the senior test bait stations have placebo-indicator? Will the spikes be examined for indicator as part of the definition of failure? **Based on the uniqueness of this bait station and our lack of experience all station failures, damage, cracks etc. should be described in detail and accompanied by detailed digital photographs as jpg files on a disc.**

Efficacy of 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) 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.

For the child-resistant packaging (CRP) requirements for this product to be met the

following items must be submitted in addition to the Child-Resistant Effectiveness and Senior Adult Use Effectiveness tests:

1. A simulated saliva solubility test.

2. A water soaking evaluation (solubility) of the bait station/wick.

3. A CRP certification in accordance with 40 CFR Part 157 must be submitted.

Company Data

Child Test

Two child-resistant effectiveness and one senior adult use effectiveness testing protocols were submitted. One child resistant effectiveness test 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 up to a maximum of two bait stations. The second child resistant effectiveness test involves a child receiving two bait stations at the beginning of the test. Both 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. A bait station failure is defined as either partial or complete access to bait from a bait station. Evidence of failure will involve checking the hands or other areas for placebo indicator. The demonstration will consist of a 5 second break.

Senior Adult Use Effectiveness Test

The senior adult use effectiveness test 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 be asked to do this procedure twice and a failure will be any form of deployment resulting in the increased probability of access to the bait by a child.

Analysis of Data and Discussion

Child Test

Two child-resistant effectiveness and one senior adult use effectiveness testing protocols were submitted. One child resistant effectiveness test 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 up to a maximum of two bait stations. The second child resistant effectiveness test involves a child receiving two bait stations at the beginning of the test. Both 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. A bait station failure is defined as either partial or complete access to bait from a bait station. Evidence of failure will involve checking the hands or other areas for placebo indicator. The demonstration will consist of a 5 second break.

The two child resistant effectiveness tests are part of a bracketing scheme. Since access to a toxic or harmful amount of Fipronil is equal to 28.5 mg, a child failure is access to two bait stations. This means the 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. However, the bracketing scheme should take into account the maximum number of bait stations per residence. Therefore, the first test should be modified so that the child gets 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 the maximum number of bait stations per residence. Then a third child resistant effectiveness test needs to be added. The third child resistant effectiveness test would involve giving each child the maximum number bait stations at the start of the ten minute test period. Due to the size of the bait stations a maximum number of 10 bait stations may be considered the worst case scenario. What is the maximum number of bait stations per residence? The only way the maximum of bait stations the child receives should remain at 2 bait stations for the first test and a third test is unnecessary is if the maximum number of bait stations per residence is two. Note the second child-resistant effectiveness test should still be done to see what happens if a child is given access to the number of bait stations that constitute a failure (2 bait stations) at the beginning of the test.

The bait station failure is defined as either partial or complete access to bait from a bait station. This definition should be expanded to include any cracks or other damage to the bait station that allow a child potential access to the bait, e.g. to the wick/indicator, wick falling out, child touch wick, etc. Evidence of failure, which will involve checking the hands or other areas for placebo indicator should also mention checking the mouth and clothes specifically for evidence of the placebo indicator. The demonstration will consist of a 5 second break, which is acceptable. Based on the uniqueness of this bait station and our lack of experience all station damage, cracks etc. should be described in detail and accompanied by detailed digital photographs as jpg files on a disc.

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The senior adult use effectiveness test 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 be asked to do this procedure twice and a failure will

be any form of deployment resulting in the increased probability of access to the bait by a child (e.g. cracked or damaged). Certain assumptions should be clarified in this protocol such as the fact that the hammer and spikes will not be provided to the PCO with the bait station in actual use, the senior adult test panel will be 70% female, and that the two times the seniors do the procedure will be the 5 minute and 1 minute test per 16 CFR 1700.20. Will the senior test bait stations have placebo-indicator? Will the spikes be examined for indicator as part of the definition of failure? Based on the uniqueness of this bait station and our lack of experience all station failures, damage, cracks etc. should be described in detail and accompanied by detailed digital photographs as jpg files on a disc.

Efficacy of 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) 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.

Final Report and Addendum

The hard copy Final Report or an Addendum to it in addition to the requirements in 16 CFR 1700.20 should include:

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.

Define a bait station failure.

Describe the Senior Adult Protocol used.

Define a Senior Adult test failure.

Indicate the amount of product per bait station, bait station size, composition

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

State that the bait station is a prefilled, nonrefillable bait station not designed or intended to be opened or activated in a manner that exposes the contents to human contact.

Include a copy of the deployment instructions used in Senior Adult Use Effectiveness test.

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.