CHILD-RESISTANT PACKAGING REVIEW
Technical Review Branch

IN 03/25/09 OUT 04/01/09

Reviewed by Rosalind L. Gross 04/01/09

EPA Reg. No. or File Symbol 65331-1

DP Barcode D363432

Decision No. 405092

EPA Petition or EUP No. _____

Date Division Received_____

Submission Dated 01/23/2009

Type Product(s) Insecticide

Data Accession No(s). 476541-00, 476541-01

Product Mgr./Chemical Review Mgr/Contact Person RM 10 (Bonaventure Akinlosotu)
Division RD

Product Name(s) Frontline Spray Treatment

Company Name(s) Merial Limited

Submission Purpose Review CR Protocol Trigger Sprayer Information

Active Ingredient(s), PC code, & % Fipronil 0.29%

Summary of Findings

The proposed approach is unacceptable. However, the Agency does accept CRP test data done by a CRP manufacturer based on a combination of factors such as its market history and a review of the actual CRP test data. It is proposed that the registrant submit he CRP manufacturer test data for the purposes of CRP certification. The Agency would have to **review the actual CRP test data** from Spray Plast S. p. A. for the Vela CR trigger sprayer (ASTM Type IXB (1)). **Additional information would have to be provided along with the test data (which is described in the Analysis**

of Information and Conclusion section). If this additional information is unavailable or should more information be necessary, the registrant should discuss how to proceed with the Agency. Any additional senior adult use effectiveness testing (SAUE) or child-resistance effectiveness testing (CRE) should be not be considered until review of the CRP manufacturer's test data is completed.

Additionally, the registrant would have to indicate the container neck closure sizes for the 250 and 500ml packages. The container neck closure size tested should be approximately the same as the sizes used. Note if both the **250 and 500ml** packages have the **same container neck closure size then only one** of the two sizes would have to be **tested per 16 CFR 1700.20**. The registrant would have to confirm the Vela CR trigger sprayer is **"permanently" attached to the container neck finish by continuous threading and engagement of matching ratchets in the closure and on the container neck finish.** The registrant should submit samples of the Vela CR trigger sprayer and the bottle they want to use both assembled and unassembled. The leakage test described by the registrant as being similar to that done for MRID 448277-01 would be acceptable, to demonstrate no leakage for the life of the product. However to cover both the 250 and 500ml sizes, the 500ml would have to be the size tested as it is the larger of the two sizes. Note the registrant will need to submit a CRP certification for their product with the test data per 40 CFR Part 157. This CRP certification must be signed by the registrant not the CRP manufacturer, because we regulate the registrant and not the CRP manufacturer.

Company Submission

The registrant submitted a request to use a Spray Plast S. p. A. Vela CR trigger sprayer for a 250 and 500 ml spray bottle based on CRP test data done by the CRP manufacturer, Spray Plast S. p. A. The registrant referenced a January 22, 2004 EPA letter for using CRP test data done by the CRP manufacturer, which was specific for a MeadWestvaco Calmar Inc. Mixor HP trigger sprayer.

The registrant would provide samples of the Spray Plast S. p. A. Vela CR trigger sprayer, perform a leakage test similar to MRID 448277-01, and a child-resistant effectiveness test, which defined failure as access to 28.5ml of fipronil.

Package

The Agency previously listed the Spray Plast S. p. A. Vela CR trigger sprayer, which was an ASTM type IXB (3). This package was removed based on information from the CRP manufacturer that it was not CRP. Rather, the Spray Plast S. p. A. Vela CR trigger sprayer, which is currently available as having passed CRP test criteria (per the CRP manufacturer) is an ASTM type IXB (1) package. The Agency is planning on adding this package to the CRP Website. The Vela CR (ASTM type IXB (1)) is a

trigger sprayer designed to deliver **1.3 ml per trigger activation** according to the manufacturer's internet listing (http://www.sprayplast.it/Mainpage.asp?pag=prodo_professional.asp) and not 1.48 ml, as indicated by the registrant. The trigger sprayer closure is a **28mm/400** (per the manufacturer's internet listing) and it is **"permanently" attached by continuous threading and engagement of matching ratchets in the closure and on the container neck finish.**

Analysis of Information and Conclusion

The Agency does accept CRP test data done by a CRP manufacturer based on a combination of factors such as its market history and a review of the actual CRP test data. The referenced January 22, 2004 EPA letter discussing use of CRP test data done by the CRP manufacturer was **specific for a MeadWestvaco Calmar Inc. Mixor HP trigger sprayer**. In that situation the Agency **had reviewed the CRP test data**, which was submitted by the CRP manufacturer. The conditions described in that letter **do not apply to Spray Plast S. p. A. Vela CR trigger sprayer.**

The Agency has seen a **summary** of the test data for the Spray Plast S. p. A. Vela CR trigger sprayer, which is a new package. We **have not reviewed the test data, nor did we require it for listing on the CRP Website, per our disclaimers.**[1]

For the purposes of CRP certification, the Agency would have to **review the actual CRP test data** from Spray Plast S. p. A. for the Vela CR trigger sprayer (ASTM Type IXB (1)). **Information regarding the following questions would have to be provided along with the test data:**
Are pictures of the package tested included in the senior and child testing reports (they should be)?
Will the senior and child testing reports include raw data indicating the test site, tester, test subject, the subject's birth date and test date?
What was the Torque Inch Pounds (TIP) used to assemble the trigger sprayer for the senior and child test? If TIP was not recorded how were the trigger sprayers assembled for the senior and child test?

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1 These disclaimers state: "Packages are designated as child-resistant solely on the basis of the manufacturers' claims. EPA has not reviewed the manufacturers' test data on CRP as a prerequisite for inclusion in the guide. The appearance of a package in this publication is not intended in any manner to denote approval, certification, or endorsement of the package by the EPA." in the package ASTM listing, and "**Note:** It is the responsibility of a pesticide registrant to determine whether a particular package meets the EPA's CRP regulations (40 CFR 157.32) based on the pesticide product with which it would be used. It is the responsibility of a pesticide registrant to determine the suitability of a package for use in a given situation." in the CRP Manufacturer list.

What size bottle was tested in the senior and child test?
What was the neck finish size for the bottle and trigger sprayer closure tested in the senior and child test? What would be neck finish size for the bottle and trigger sprayer closure to be used by the registrant?
Were the test packages for seniors filled with placebo?
Were the 1 minute senior test packages examined after testing to visually determine resecuring? If not, why?
Was an adult resecuring test per 16CFR1700.20(d)(2) necessary to determine resecuring? If so, was it done?
What were the directions given to the seniors for testing the trigger sprayer?
Were the directions used for senior testing given to the subjects in **English**[2]? If not, what language were the directions?
Would these directions be used on the registrant's label (an amended label would be required)?
Was the definition of a **senior failure** - no access to the package contents through the correct mechanism, a failure to properly resecure the package in the 1 minute test, access to the contents through an incorrect mechanism such as sprayer removal from the bottle? **If not, what was it?**
Was any **leakage** of the trigger sprayer noted during the senior test? If so, what was its frequency and the amount noted? Was leakage considered a failure?
Were the **test packages for children filled with placebo**?
Did the **child test packages have dip tubes**?
Were the **child test packages primed** before testing?
Was the definition of a **child failure** – access to any amount of product, activation of the trigger (full or partial), opening the trigger sprayer, removal of the sprayer from the bottle, any amount of leakage? **Note since the CRP manufacturer does not necessarily know the toxicity of the product in the package, it should pass as a worst case scenario, which is any access or opening of the package is a failure regardless of the amount involved. If not, what was the definition of a child failure?**
Was any **leakage** of the trigger sprayer noted during the child test? If so, what was its frequency and the amount noted? Was leakage considered a failure?

Additionally, the registrant would have to indicate the container neck closure sizes for the 250 and 500ml packages. The container neck closure size tested should be approximately the same as the sizes used. Note if both the **250 and 500ml** packages have the **same container neck closure size then only one** of the two sizes would have to be **tested per 16 CFR 1700.20**. The registrant would have to confirm the Vela CR trigger sprayer is **"permanently" attached to the container neck finish by continuous threading and engagement of matching ratchets in the closure and**

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2 If the directions used during testing were not in English, retesting may be necessary with the directions in English.

on the container neck finish. The registrant should submit samples of the Vela CR trigger sprayer (ASTM Type IXB (1)) and the bottle they want to use both assembled and unassembled. For any **testing** such as the CRP testing per 16 CFR 1700.20 and the leakage test the **trigger sprayer should be applied with the same TIP as will be used to apply the trigger sprayer in production**. The leakage test described by the registrant as being similar to that done for MRID 448277-01 would be acceptable, to demonstrate no leakage for the life of the product. However to cover both the 250 and 500ml sizes, the 500ml would have to be the size tested as it is the larger of the two sizes. The leakage test should involve the use of 10 samples, 500ml each filled with placebo of the same density as the actual product. Each sample should be sprayed until empty. The amount of leakage of each sample should be reported. Note the registrant will need to submit a CRP certification for their product with the test data per 40 CFR Part 157. **This CRP certification must be signed by the registrant not the CRP manufacturer, because we regulate the registrant and not the CRP manufacturer.**

Any additional SAUE or CRE should be not be considered until review of the CRP manufacturer's test data is completed. **Note:** the actual test packages should be saved at least until the Agency has reviewed and accepted the test data. The rationale behind this request is that the Agency may have questions regarding certain test packages prior to accepting the test data. However, this may not be possible.

There is some question regarding the product concentration of Fipronil in this product based on the 6/4/96 CSF, which further suggests it is better to do a worst case scenario evaluation to see if the package can pass with a child failure being access to any amount of product, activation of the trigger (full or partial), opening the trigger sprayer, removal of the sprayer from the bottle, any amount of leakage?