

US EPA ARCHIVE DOCUMENT

CHILD-RESISTANT PACKAGING REVIEW
Technical Review Branch

IN 12/07/99 OUT 12/20/99

Reviewed by Rosalind L. Gross *R.L. Gross*
12/20/99

EPA Reg. No. or File Symbol 64240 - 33 & 64248-5-64240

DP Barcode D261574 ID# 292438

EPA Petition or EUP No. _____

Date Division Received 11/18/98

Type Product(s) Insecticide

Data Accession No(s). 446942-01 (98-069) GLM 16386A

Product Mgr./Chemical Review Mgr./Contact Person PM 03 Division RD

Product Name(s) Combat Small Roach Bait F .03

Company Name(s) Combat Insect Control Systems

Submission Purpose Examine to ascertain if packaging is CRP

Active Ingredient(s), PC code, & % Fipronil 0.03% and Hydramethylnon 2.15%

Summary of Findings

A total of 16 children (32%) accessed one or more bait stations with 8 children accessing 1 bait station, 3 children accessing 2 bait stations, 1 child accessing 3 bait stations, 1 child accessing 4 bait stations, 1 child accessing 6 bait stations, and 2 children accessing 9 bait stations. There were two child failures. The study is a pass of the child-resistant packaging (CRP) child test according to the sequential test chart in 16 CFR 1700.20. The CRP is only for the bait stations and not the syringe. The CRP certification is acceptable. **However, the plunger should have remained with the syringe and been given to the children for testing. In the future this may be cause for rejection of the study.** There were several cases of stations tearing during separation, which suggest the package could have better quality control. Finally, the registrant is reminded the review of this study and the definition of failure in terms of CRP as access to more than 8 bait stations is based on the active ingredients and the amount present in each of the two products, EPA REG # 64240 - 33 & 64248-5-64240.

If anything changes the study would have to be reexamined to ascertain the definition of failure.

Package Description

Package consists of 12 debossed index welded bait stations (2 6-ups) containing 1.4g bait at 0.03% Fipronil and one 12g capped syringe at 2.15% Hydramethylnon. The bait stations are 2.25" x 2.25" x 3/8" with black 25ml HIPS base and lid and 4 holes 0.25". The black plastic syringe consists of a cap, tube, and plunger. The syringe from cap to exposed end of plunger is 6 5/8" long, the plunger is 2 5/16", the tube is 4 5/16", the plunger diameter is 7/8", the tube is 1" diameter where the plunger inserts and 6/8" for the main body.

Child-resistant packaging (CRP) is only being claimed for the bait stations and not the syringe. The testing involves the syringe because it is in the same package as the bait stations.

Definition of Failure

Each bait station contains 0.42mg Fipronil (1.4 g bait at 0.03% Fipronil) and 12 stations contain 5.04mg Fipronil. Access to 28.5mg Fipronil is a failure based on acute neurotoxicity NOEL, which would represent 68 bait stations. Consequently, access to more than 8 bait stations is a failure.

The syringe contains 258mg Hydramethylnon(12g capped syringe at 2.15% Hydramethylnon). Access to 9120mg Hydramethylnon is a failure based on acute reproductive NOEL, which would represent considerably more than the 258mg in one 12g syringe.

Note the review of this study and the definition of failure in terms of CRP as access to more than 8 bait stations is based on the active ingredients and the amount present in each of the two products, EPA REG # 64240 - 33 & 64248-5-64240. If anything changes the study would have to be reexamined to ascertain the definition of failure.

Company Data

Station tested is 2.25" x 2.25" x 0.3/8" with 4 holes 0.25". The station is 25ml black HIPS base and 25ml black HIPS debossed combat logo lid index weld. The station sold is the same as the station tested. Included in the same package is

one 12g capped black plastic syringe consisting of a cap, tube, and plunger.

Station containing lipstick placebo mixture were tested with children getting 12 stations (as 2 6-ups) at the beginning of the test. Children were also given an empty recapped syringe without the plunger. Failure was defined as evidence of lipstick indicator on the child or meeting a set of criteria agreed to by EPA and the registrant. A child failure was defined as access to more than eight individual bait stations.

The tabular data indicates 15 children accessed one or more bait stations, with 7 children accessing 1 bait station, 3 children accessed 2 bait stations, 1 child accessed 3 bait stations, 1 child accessed 4 bait stations, 1 child accessed 6 bait stations, and 2 children accessed 9 bait stations. However, the tester comments on page 42 for package 42 indicate the child tore pieces off the top into the fins of one unit. There were two child failures.

Discussion and Conclusions

Station tested is 2.25" x 2.25" x 0.3/8" with 4 holes 0.25". The station is 25ml black HIPS base and 25ml black HIPS debossed combat logo lid index weld. The station sold is the same as the station tested. Included in the same package is one 12g capped black plastic syringe consisting of a cap, tube, and plunger. The syringe from cap to exposed end of plunger is 6 5/8" long, the plunger is 2 5/16", the tube is 4 5/16", the plunger diameter is 7/8", the tube is 1" diameter where the plunger inserts and 6/8" for the main body.

Station containing lipstick placebo mixture were tested with children getting 12 stations (as 2 6-ups) at the beginning of the test. Children were also given an empty recapped syringe without the plunger. However, the plunger should have remained with the syringe and been given to the children for testing. Failure was defined as evidence of lipstick indicator on the child or meeting a set of criteria agreed to by EPA and the registrant. A child failure was defined as access to more than eight individual bait stations.

The tabular data indicates 15 children accessed one or more bait stations, with 7 children accessing 1 bait station. However, the tester comments on page 42 for package 42 indicate the child tore pieces off the top into the fins of one unit. This package should be a failure based on the definition of failure that includes "any cracks, holes or other breaks that affect rectangular bait well zone.....". Therefore a total of 16 children accessed one or more bait stations with 8 children accessing 1 bait station, 3 children accessing 2 bait stations, 1 child accessing 3 bait stations, 1 child accessing 4 bait stations, 1 child accessing 6 bait stations, and 2 children accessing 9 bait stations. There were two child failures. The study is a pass of the CRP child test according to the sequential test chart in 16 CFR 1700.20. The CRP is only for the bait stations and

not the syringe. The CRP certification is acceptable. **However, the plunger should have remained with the syringe and been given to the children for testing. In the future this may be cause for rejection of the study.** There were several cases of stations tearing during separation, which suggest the package could have better quality control. Finally, the registrant is reminded the review of this study and the definition of failure in terms of CRP as access to more than 8 bait stations is based on the active ingredients and the amount present in each of the two products, EPA REG # 64240 - 33 & 64248-5-64240. If anything changes the study would have to be reexamined to ascertain the definition of failure.