

CHILD-RESISTANT PACKAGING REVIEW
Technical Review Branch

IN 08/08/2000 & 08/15/2000 OUT 08/17/2000

Reviewed by Rosalind L. Gross 08/17/2000

EPA Reg. No. or File Symbol 64240 - 32

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Date Division Received 08/02/2000 & 08/14/2000

Type Product(s) Insecticide

Data Accession No(s). _____

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

Product Name(s) Combat Gold

Company Name(s) Combat Insect Control Systems

Submission Purpose Examine 6 crp studies, 2 of which involve weathered stations to see if the crp certification is acceptable for this 18 station retail package with a 12 month in use claim

Active Ingredient(s), PC code, & % Fipronil 0.05%

Summary of Findings

On both 8/2/2000 and 8/14/2000 the same three studies were submitted in support of the CRP certification for EPA Reg. No. 64240-32 containing Fipronil 0.05%, 1 g bait station 18 count retail package with 12 month indoor use claim. The station being sold is a 5.7cm x 5.7cm x 1.07cm 25ml black HIPS base and lid that is index welded with the combat logo. The conclusion is the study (Clorox # 98-071) supporting the 18 station retail package is a marginal pass which would lead one to question the continued CRP for the life of the product. **There is no study to support CRP for the life of the product. This CRP certification is not valid for a product life of more than 3 months, which was the product life on the original studies.**

A summary of the three studies indicates the following :

The first Clorox study 97-091A (EPA Reg. No. 64240-30 MRID 446477-01 originally 443875-01 PKG ID 15463A) was a 6 week weathering study in Arizona . Based on the definition of failure as access to more than 8 stations the study was a pass of the child test according to the sequential test chart in 16 CFR 1700.20 despite 41 out of 50 children accessing 1 bait station each. The CRP study was only valid for that package where 18 gray base stations were tested and 12 stations are sold. This study cannot be used for bridging purposes.

The second Clorox study 98-071 (EPA Reg. No. 64240-33 MRID 447332-01 amended, originally 446590-01 PKG ID 16368A) is a pass of the child test according to the sequential test chart in 16 CFR 1700.20, because no child accessed more than eight individual bait stations needed for a child failure. The study was marginal because three children each accessed one bait station and 28 children tore one or more stations either during separation from each other or during testing. There were numerous instances of 3-5 stations being cracked/torn per child. Since the package being used is the same as the package tested in could be used for a CRP certification. If new the package had this many potential child failures, what would happen with a 12 month old package. This study cannot be used for bridging purposes.

The third Clorox study 98-079 (EPA Reg. No. 64240-33 MRID 446680-01) is a pass of the child test according to the sequential test chart in 16 CFR 1700.20 with no child failures. A child failure was defined as access to more than eight individual bait stations and only one child gained access to one bait station. However, this study was only a 12 station study and by itself would only serve for the 12 station size of EPA Reg. No. 64240-32. Additionally, the issue of a 12 month product life is not addressed here.

FIPRONIL

Fipronil has an acute dietary NOEL of 2.5mg/kg

A failure for fipronil is access to 28.5mg of fipronil (2.5mg/kg x 11.4kg)(per 5/21/98 update of Toxicology Hazard Assessment by HED)

EPA REG #	MRID	PKG ID	CLOROX #	# STAT /PKG	#STAT TEST WITH CHILD	# G BAIT/ STAT	% AI	AMT AI/ STAT MG	AMT AI/ PKG MG	FAIL = 28.5MG AI = # STATION
64240-30	446477-01	15463 A	97-091A [F1995.02 44 WEATHE RED ANT STAKE 18 COUNT]	12 (sold)	18	1.5 (per label with MRID 44387 5-01)	.01	0.15	1.8	190
64240-33	447332-01 amended study	16368 A	98-071	18	18	1.0	0.03	.3	5.4	95
64240-33	446680-01		98-079	12	12	1.4*	0.03*	0.42	5.04	68

EPA REG #	MRID	PKG ID	CLOROX #	CRP CERT	CONCLUSIONS
64240-30	446477-01	15463 A	97-091A [F1995.02 44 WEATHE RED ANT STAKE 18 COUNT]	9/04/98(12 station, cert includes 98-078 & 98-077, which have not yet been reviewed & accepted)	The station is weathered 6 weeks in AZ, grey 25ml HIPS base and black 25ml HIPS lid, index welded. Ant stake is involved. Each child was given 3 6-ups and 18 stakes at the beginning of the test. Three children accessed one bait station by breaking pieces of the top off during the second 5 minutes test period. The report states "The tester made the determination that the child could possibly have accessed the material..." There were an additional 37 instances where the child was reported to have broken off some of the plastic or a corner of the bait station, but these cases were not initially considered accessing the station. Registrant amended report to redefine a failure as access to more than 8 bait stations. Additionally, based on a worst case scenario the aforementioned 37 instances where the child was reported to have broken off some of the plastic or a corner of the bait station as well as one case (26) where the child tried to pry off bait station lid were counted as bait station failures. 41 out of 50 children accessed 1 bait station each. Based on the definition of failure as access to more than 8 stations the study is a pass of the child test according to the sequential test chart in 16 CFR 1700.20 despite 41 out of 50 children accessing 1 bait station each. The CRP certification is acceptable only for 97-091A where 18 stations were tested and 12 stations are sold.

EPA REG #	MRID	PKG ID	CLOROX #	CRP CERT	CONCLUSIONS
64240-33	447332-01 amended study	16368 A	98-071	1/14/99 cert only reviewed for 98-071.	The station is 25ml black HIPS base, 25ml black HIPS lid, index weld. Ramp height is ≤ 1cm. Station containing lipstick placebo mixture tested with children getting 18 stations attached to one another at the beginning of the test. Failure was defined as evidence of the lipstick indicator on the child or meeting a set of criteria agreed to by EPA and the registrant. The results indicate two children (12 and 34) each accessed one bait station. The raw data on page 25 as amended on pages 46 and 48 indicate child 21 tore up the base of the station and 0.75 cm up the ramp. Based on the dimensions of the station, child 21 should also be counted as accessing one bait station. Therefore, three children (12, 34, 21) each accessed one bait station. It should be noted that while no access was achieved there were several instances(28) where the child tore one or more stations either during separation from each other or during testing. Additionally, 98-071 reports several instances of tears in the base of the station including the fin. There is some concern that some of these tears could widen the bait station openings such that a child could potentially touch the bait. In Conclusion, three children (12, 34, 21) each accessed one bait station and 28 children tore one or more stations either during separation from each other or during testing, which were not considered access. Since no child accessed 9 stations which is the amount needed for a child failure, the study is a pass of the child test according to the sequential test chart in 16 CFR 1700.20. The certification for 1/14/99 18 pack is acceptable for 98-071. However, it should be noted there is a significant increase in the number of children and number of instances of some station crack tears per child, from studies 97-46 (9 children), 97-091A (41 children), 98-068 (24 children), 98-070 (19 children), 98-071 (31 children with numerous instances of 3-5 stations/child). There is a concern that while technically these studies pass the child test according to the sequential test chart in 16 CFR 1700.20 they are becoming more of a marginal pass and that the public has a false sense of security regarding access to these bait

EPA REG #	MRID	PKG ID	CLOROX #	CRP CERT	CONCLUSIONS
64240-33	446680-01		98-079	10/5/98 acceptable	Station tested is 2.25" x 2.25" x 0.375" with holes 0.25". The station is 25ml black HIPS base and 25ml black HIPS debossed lid index weld. The station sold is the same as the station tested. Station containing lipstick placebo mixture tested with children getting 12 stations (2 6-ups with stations attached to one another) at the beginning of the test. 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 results indicate one child (42), a 51 month old female, gained access to one bait station. There were no child failures. The study is a pass of the child test according to the sequential test chart in 16 CFR 1700.20. The CRP certification is acceptable.