

CHILD-RESISTANT PACKAGING REVIEW

IN 12/06/96 & 01/06/97 & 02/19/97 OUT February 27, 1997

RD, RSB, PCS Reviewed by Rosalind L. Gross *R. L. Gross* February 27, 1997

EPA Reg. No. or File Symbol 64240-GN

DP Barcode D231917 & D232415

Date Division Received 10/16/96 & 12/23/96 & 02/19/97

Type Product(s) Insecticide (ant product)

Data Accession No(s). 441337-01 & 441841-01

Product Mgr./Chemical Review Mgr/Contact Person PM 10 Division RD

Product Name(s) Combat Ant Bait F1

Company Name(s) Combat Insect Control Systems

Submission Purpose Examine registration application to ascertain if packaging is
CRP GLM studies 14273A, 14598A, 15040A

Active Ingredient(s), PC code, & % Fipronil (129121) - 0.01%

Summary of Findings

In conclusion GLM 15040A indicated 4 children accessed \geq one bait station (2 before & 2 after demonstration). 2 children opened one bait station & 2 children opened two bait stations. This is a pass of the child test according to the sequential test chart in 16 CFR 1700.20. **This study may be used to demonstrate the CRE for EPA REG #64240-GN (both outdoor & indoor use).** GLM studies 14273A, 14598A, MRID 441337-01 & 441841-01 are not applicable to this product. GLM study 14273A had a number of errors in test methodology, which do not allow any conclusions to be drawn from it. GLM study 14598A was an acceptable study, but it did not involve giving the children the stakes with the bait stations. Since the stakes accompany the bait station in the retail package, it is not applicable to this product. See chart for details.

None of these studies involved a senior adult or younger adult test. Only child test data was submitted.

Under 40 CFR 157.32(a) child-resistant packaging for pesticides must meet the effectiveness specifications described in 16 CFR 1700.15(b) when tested by the protocol specified in 16 CFR 1700.20. The Agency has recently granted an exemption from the adult effectiveness specifications as described in 16 CFR 1700.15(b)(2) ease of adult opening. The Agency will publish a Notice in the Federal Register of the granting of the exemption. This exemption applies only to prefilled, nonrefillable insecticide bait stations that are not designed or intended to be opened or activated in a manner that exposes the contents to human contact. This exemption is only from the adult effectiveness specifications as described in 16 CFR 1700.15(b)(2) ease of adult opening. The exemption will be for a five year time period and will apply to other products of substantially similar composition and intended uses.

Therefore the child test data submitted is sufficient to fulfill the CRP requirements of registration provided that:

1. The CRP certification, which must comply with PR96-2, specifies that this package does not comply with the senior and younger adult effectiveness specifications per the aforementioned exemption.
2. The product as packaged still fully complies with all other child-resistant packaging effectiveness, compatibility, and durability standards as well as all other requirements of 40 CFR Part 157.

FIPRONIL

Fipronil has an acute dietary NOEL of 0.5mg/kg for neurotoxicity (memorandum S.Diwan,R.Keigwin 6/25/96)

A failure for fipronil is access to 5.7mg of fipronil.¹

EPA REG #	MRID	GLM#	CLOROX #	# STATION/ PKG	# G BAIT/ STATION	% AI	AMT AI/ STATION MG	AMT AI/ PKG MG	FAIL = 5.7MG AI = # STATION ²
64240-GN (outdoor)	441337-01	14273A	96-067A	3, 6	1.5g	0.01	0.15mg	0.45 - 0.90mg	38
64240-GN (indoor ³)	441841-01	14598A	96-119A	3,6	1.5g	0.01	0.15mg	0.45 - 0.90mg	38
64240-GN		15040A	97-007A	3,6	1.5g	0.01	0.15mg	0.45- 0.90mg	38
64240-GE	441841-01	14598A	96-119A	12	1g	0.05	0.5mg	6mg	11 (11.4)
64240-GG	441841-01	14598A	96-119A	12	1.4g	0.03	0.42mg	5.04mg	>13 (13.6)
64248-RR	441357-01	14358A	96-075A	8	1.5g	0.05	0.75mg	6mg	>7 (7.6)
64248-RN	441357-01	14358A	96-075A	24	1.5g	0.01	0.15mg	3.6mg	38
64240-GU	441336-02	14507A	96-095A	8	1.75g	0.03	0.525mg	4.2mg	>10 (10.9)
64240-GU	441336-02	14507A	96-095A	8	2.75g	0.03	0.825mg	6.6mg	>6 (6.9)
64248-RE	441336-02	14507A	96-095A	8	1.75g	0.03	0.525mg	4.2mg	>10 (10.9)
64248-RE	441336-02	14507A	96-095A	8	2.75g	0.03	0.825mg	6.6mg	>6 (6.9)

¹5.7mg = 0.5mg/kg times 11.4kg, which is the NOEL for acute neurotoxicity times the weight of a 25 lb child.

²If the # Station is more than 9, then according to 16 CFR 1700.20 access to 9 stations (more than 8) is a failure.

³For indoor use stake is not used with bait station, but stake is sold with bait station in retail boxes. Therefore bait station must be tested with stakes given to children.

FIPRONIL

A failure for fipronil is access to 5.7mg fipronil. A worst case scenario is assumed when the number of stations per retail package or the amount of bait per station varies for the same EPA REG #.

EPA REG #	MRID	GLM#	CLOROX #	PKG THICK	PKG DESCRIPTION	COMPANY DATA
64240-GN (outdoor use)	441337-01	14273A (6/96)	96-067A	30ml HIPS green lid & black base	Retail package contains green lid & black base with green "L" shape stake (7.5 cm long 4.5 cm on top & 0.5cm diameter). Station 5.2cm x 5.2 cm x 1.1 cm high. Station has 0.7cm diameter hole for stake. Station has 4 holes 0.5cm wide for insect to access bait.	Weathered station tested by give child stake & 1 station at a time up to 12 if continue to open stations. Failure = access to 9 bait stations. 14 children access 1 or more stations (2 child 2 stations, 1 child 3 stations) Report 100% CRE. Note: Registrant stated that 1 station is how child would encounter it in the home scenario. Furthermore they feel GLM14598A where the child has multiple units would corroborate the CRE of this station. Additionally, their test experience led to an observation that children try to get into the station more when given them 1 x 1 rather than multiple stations at one time.

EPA REG #	MRID	GLM#	CLOROX #	PKG THICK	PKG DESCRIPTION	COMPANY DATA
64240-GN (indoor use)	441841-01	14598A	96-119A	30 ml black lid & base	Retail package contains black lid and black base station. Station is 5.3cm x 5.3 cm x 1.1cm high. Station has 4 holes 0.7cm wide for insect to access bait.	According to registrant a failure is access to one bait station, and the children were given 2 six-ups (12 stations) at the beginning of the test. The GLM report confirms the children were given 2 bait cards at the beginning of the test. 5 children accessed one bait station(1 before demonstration & 4 after demonstration)
64240-GN		15040A	97-007A	30ml HIPS green lid, 25ml HIPS black base	Retail package contains green lid & black base with green "L" shape stake (7.5 cm long 4.5 cm on top & 0.5cm diameter). Station 5.2cm x 5.2 cm x 1.0 cm high. Station has 0.7cm diameter hole for stake. Station has 4 holes 0.7cm wide for insect to access bait.	Weathered station tested by give child <u>(12)</u> stations (2 6-ups) at beginning of test. No written report was submitted for this study.
64240-GE	441841-01	14598A	96-119A	30 ml black lid & base	Retail package contains black lid and black base station. Station is 5.3cm x 5.3 cm x 1.1cm high. Station has 4 holes 0.7cm wide for insect to access bait.	According to registrant a failure is access to one bait station, and the children were given 2 six-ups (12 stations) at the beginning of the test. The GLM report confirms the children were given 2 bait cards at the beginning of the test. 5 children accessed one bait station(1 before demonstration & 4 after demonstration)

EPA REG #	MRID	GLM#	CLOROX #	PKG THICK	PKG DESCRIPTION	COMPANY DATA
64240-GG	441841-01	14598A	96-119A	30 ml black lid & base	Retail package contains black lid and black base station. Station is 5.3cm x 5.3 cm x 1.1cm high. Station has 4 holes 0.7cm wide for insect to access bait.	According to registrant a failure is access to one bait station, and the children were given 2 six-ups (12 stations) at the beginning of the test. The GLM report confirms the children were given 2 bait cards at the beginning of the test. 5 children accessed one bait station(1 before demonstration & 4 after demonstration)
64248-RR	441357-01	14358A	96-075A	25ml HIPS black base & 30ml red see thru K-resin lid	Retail package contains red see thru lid & black base. Station 5.3cm x 5.3 cm x 1.1 cm high. Station has 4 holes 0.5cm wide for insect to access bait.	Children were given 2 six-ups (12 stations) at the beginning of the test. Failure = access to 9 bait stations. One child opened 4 stations (1 before demonstration) and one child opened one station after demonstration.
64248-RN	441357-01	14358A	96-075A	25ml HIPS black base & 30ml red see thru K-resin lid	Retail package contains red see thru lid & black base. Station 5.3cm x 5.3 cm x 1.1 cm high. Station has 4 holes 0.5cm wide for insect to access bait	Children were given 2 six-ups (12 stations) at the beginning of the test. Failure = access to 9 bait stations. One child opened 4 stations (1 before demonstration) and one child opened one station after demonstration.

EPA REG #	MRID	GLM#	COLOROX #	PKG THICK	PKG DESCRIPTION	COMPANY DATA
64240-GU	441336-02	14507A	96-095A	Black HIPS 0.04"	Retail package contains black lid & black base. Station 8.2cm x 8.2 cm x 1.7 cm high. Station has 4 holes 1.2cm wide for insect to access bait	According to registrant a failure is access to one bait station. Children were given 2 four-ups (8 stations) at the beginning of the test. One child opened 2 stations before demonstration.
64240-GU	441336-02	14507A	96-095A	Black HIPS 0.04"	Retail package contains black lid & black base. Station 8.2cm x 8.2 cm x 1.7 cm high. Station has 4 holes 1.2cm wide for insect to access bait	According to registrant a failure is access to one bait station. Children were given 2 four-ups (8 stations) at the beginning of the test. One child opened 2 stations before demonstration.
64248-RE	441336-02	14507A	96-095A	Black HIPS 0.04"	Retail package contains black lid & black base. Station 8.2cm x 8.2 cm x 1.7 cm high. Station has 4 holes 1.2cm wide for insect to access bait	According to registrant a failure is access to one bait station. Children were given 2 four-ups (8 stations) at the beginning of the test. One child opened 2 stations before demonstration.
64248-RE	441336-02	14507A	96-095A	Black HIPS 0.04"	Retail package contains black lid & black base. Station 8.2cm x 8.2 cm x 1.7 cm high. Station has 4 holes 1.2cm wide for insect to access bait	According to registrant a failure is access to one bait station. Children were given 2 four-ups (8 stations) at the beginning of the test. One child opened 2 stations before demonstration.

FIPRONIL

EPA REG #	MRID	GLM#	COLOROX #	CRP CERT ¹	CONCLUSIONS
64240-GN (outdoor use)	441337-01	14273A (6/96)	96-067A	Yes 11/27/95	The child test was not conducted according to the protocol of giving all stations to the child at the beginning of the test. Therefore, no conclusions could be drawn from the data. Other discrepancies with the protocol were: the age of four test subjects (pkges 13, 7, 21, & 34) were miscalculated resulting in 1 subject being age 33 months; leaving only 49 valid test subjects. One tester (61) tested more than 30% of the children, and one site (75) was used for more than 20% of the children. 14 children access 1 or more stations (2 child 2 stations, 1 child 3 stations). In response to the registrant's request to use this study to support CRE for the station - The other studies do test children with multiple units, but without the advantage of the stake for use in opening the packaging. No data has been seen testing the exact station with children getting the package 1 x 1 versus multiple units at once to ascertain if the registrant's observations are accurate. However GLM 15040A is an acceptable substitute for study GLM 14273A and may be used to support the CRE for this station.
64240-GN (indoor use)	441841-01	14598A	96-119A	Yes 11/27/95	5 children accessed one bait station(1 before demonstration & 4 after demonstration). This is a pass of the child test according to the sequential test chart in 16 CFR 1700.20. Although acceptable, this study cannot be used for EPA REG #64240-GN (indoor use) because there was no stake involved in this test. EPA REG #64240-GN (indoor use) involves the use of a stake in the retail package and the child test must involve giving the children the stakes with the bait stations.

EPA REG #	MRID	GLM#	COLOROX #	CRP CERT ¹	CONCLUSIONS
64240-GN		15040A	97-007A	No	4 children accessed <u>zone</u> bait station (2 before & 2 after demonstration). 2 children opened one bait station & 2 children opened two bait stations. This is a pass of the child test according to the sequential test chart in 16 CFR 1700.20. This study may be used to demonstrate the CRE for EPA REG #64240-GN (both outdoor & indoor use).
64240-GE	441841-01	14598A	96-119A	Yes 8/15/96	5 children accessed one bait station(1 before demonstration & 4 after demonstration). This is a pass of the child test according to the sequential test chart in 16 CFR 1700.20.
64240-GG	441841-01	14598A	96-119A	Yes 12/20/96	5 children accessed one bait station(1 before demonstration & 4 after demonstration). This is a pass of the child test according to the sequential test chart in 16 CFR 1700.20.
64248-RR	441357-01	14358A	96-075A	Yes 10/10/96	EPA REG # 64248-RR a failure is 8 stations not 9 based on toxicity of the fipronil. One child opened 4 stations (1 before demonstration) and one child opened one station after demonstration. This is a pass of the child test according to the sequential test chart in 16 CFR 1700.20.
64248-RN	441357-01	14358A	96-075A	Yes 11/27/95	Note EPA REG # 64248-RN contains 24 stations and as such children should have been given 24 stations at the beginning of the test. It would be preferred for the registrant to limit the number of stations per retail package to 12 to be consistent with the number of stations tested with the children. However, the amount of fipronil in all 24 stations is less than 5.7mg, the children did get 12 stations at the beginning of the test, and only one child opened multiple stations (4 stations - 1 before demonstration) and one child opened one station after demonstration. it is doubtful, that giving the children an additional 12 stations would change the results of the test from a CRE to a non CRE package. This test will be adequate to show the CRE of the station.

EPA REG #	MRID	GLM#	COLORX #	CRP CERT ¹	CONCLUSIONS
64240-GU	441336-02	14507A	96-095A	Yes 10/21/96	There is no photograph of the package tested nor is the thickness of plastic used clear. A failure based on the worst case scenario (2.75 g bait/station) and filproniil toxicity is 7 stations . One child opened two stations before demonstration. This is a pass of the child test according to the sequential test chart in 16 CFR 1700.20.
64240-GU	441336-02	14507A	96-095A	Yes 10/21/96	There is no photograph of the package tested nor is the thickness of plastic used clear. A failure based on the worst case scenario (2.75 g bait/station) and filproniil toxicity is 7 stations . One child opened two stations before demonstration. This is a pass of the child test according to the sequential test chart in 16 CFR 1700.20.
64248-RE	441336-02	14507A	96-095A	Yes 10/21/96	There is no photograph of the package tested nor is the thickness of plastic used clear. A failure based on the worst case scenario (2.75 g bait/station) and filproniil toxicity is 7 stations . One child opened two stations before demonstration. This is a pass of the child test according to the sequential test chart in 16 CFR 1700.20.
64248-RE	441336-02	14507A	96-095A	Yes 10/21/96	There is no photograph of the package tested nor is the thickness of plastic used clear. A failure based on the worst case scenario (2.75 g bait/station) and filproniil toxicity is 7 stations . One child opened two stations before demonstration. This is a pass of the child test according to the sequential test chart in 16 CFR 1700.20.

1. Child test only, new certifications required per PR 96-2 by 1/21/98.