

CHILD-RESISTANT PACKAGING REVIEW
Technical Review Branch

IN 04/08/2010 OUT 05/26/2010

RD, TRB, Reviewed by Rosalind L. Gross 05/26/2010

EPA Reg. No. or File Symbol 65331-5

DP Barcode 376180

Decision # 430153

EPA Petition or EUP No. _____

Date Division Received 03/22/2010

Type Product(s) Insecticide (flea product)

Data Accession No(s). 480388-01, 480388-02, 480388-03, 480388-04

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

Product Name(s) Frontline Plus for Dogs

Company Name(s) Merial Ltd.

Submission Purpose Review of CRP studies to determine if they are adequate to support CRP certification for 5 different pipette sizes in green and blue for 4 different dog and cat products

Active Ingredient(s), PC code, & % Fipronil 9.8%
S-Methoprene 8.8%

Summary of Findings

The CRP certifications dated March 2, 2010 for EPA Registration No. 65331-2, 65331-3, 65331-4, and 65331-5 are acceptable. Eight CRP studies were reviewed: 0.5ml size blue pipette EPA Reg. No. 65331-2 (MRID 480388-01); 4.02ml size blue pipette EPA Reg. No. 65331-3 (MRID 480388-04); 1.34ml size green pipette EPA Reg. No. 65331-5 (MRID 480388-02); and the 2.68ml size green pipette EPA Reg. No. 65331-5 (MRID 480388-03). These eight studies were used to extrapolate to the other sizes and colors for EPA Reg. No. 65331-2, 65331-3, 65331-4, and 65331-5 where CRP studies were not done (CRP for both the blue and green pipettes in 5 different sizes (0.017, 0.023, 0.045, 0.91, and 0.136 fl. oz.)). This approach was based on an Agency approved protocol Nov. 14, 2008 DP 357383, 357384, 357420, 357421.

The results of the comprehensive review for MRID numbers 480388-01, 480388-02, 480388-03, and 480388-04 indicate these studies pass the CRE (Child-Resistant Effectiveness) sequential test chart in 16 CFR 1700.20 and SAUE (Senior Adult Use Effectiveness) requirements per 16 CFR 1700.20 test protocol and 16 CFR 1700.15(b) effectiveness specifications. **For the details of each study refer to the attached summary chart (summarycht65331-2,3,4,5.doc).**

The following sizes and colors are accepted on the basis of extrapolation [For the details of each study refer to the attached summary chart (summarycht65331-2,3,4,5.doc).]:

EPA Reg. No. 65331-3 1 blue pipette 0.67ml (0.023 fl. oz.) size in small hanging card;
 EPA Reg. No. 65331-3 1 blue pipette 1.34ml (0.045 fl. oz.) size in small hanging card;
 EPA Reg. No. 65331-3 1 blue pipette 2.68ml (0.091 fl. oz.) size in medium hanging card;
 EPA Reg. No. 65331-4 1 green pipette 0.5ml (0.017 fl. oz.) size in small hanging card;
 EPA Reg. No. 65331-5 1 green pipette 0.67ml (0.023 fl. oz.) size in small hanging card;
 and EPA Reg. No. 65331-5 1 green pipette 4.02ml (0.136 fl. oz.) size in medium hanging card.

In conclusion all the requirements for CRP have been met for EPA Reg. No. 65331-2 (blue pipette), 65331-3 (blue pipette), 65331-4 (green pipette), and 65331-5 (green pipette) in 5 different sizes (0.017, 0.023, 0.045, 0.91, and 0.136 fl. oz.). The directions on opening the package given to consumers must be identical to those given to the seniors during testing for the hanging card. The senior testing directions are on the labels submitted March 3, 2010 for EPA Reg. No. 65331-2, 65331-3, 65331-4, and 65331-5. Should any human experience/epidemiological evidence indicate a problem once the product is in the marketplace, the Agency reserves the right to reexamine this data comprehensively and to question the child resistance of the package involved.

Package

The package is a plastic hanging card containing a blue pipette (EPA Reg. No. 65331-2 or 65331-3) or a green pipette (EPA Reg. No. 65331-4 or 65331-5). The hanging card and not the pipette is the child-resistant package. The directions to open the package are a dashed line with a scissors icon (there are no written instructions). The pipette comes in 5 different sizes (0.017, 0.023, 0.045, 0.91, and 0.136 fl. oz.).

Toxicity

The toxicity of the product is based on the toxicity of Fipronil. The toxic or harmful amount of Fipronil for an 11.4 kg child is 2.5mg/kg times 11.4kg, which equals 28.5mg. A toxic or harmful amt of Fipronil = **28.5mg** = 28.5mg divided by [1030mg/ml x .097 fipronil] = 0.285ml = **0.29ml for Frontline (EPA Reg. No. 65331-2 or 65331-3).** A

toxic or harmful amt of Fipronil = **28.5mg** = 28.5mg divided by [1020mg/ml x .098 fipronil] = 0.285ml = **0.29ml for Frontline Plus (EPA Reg. No. 65331-4 or 65331-5).**
 Access to one pipette represents a failure for a child for all sizes greater than 0.29ml for EPA Reg. No. 65331-2, 3, 4, and 5.

Toxicity, Child Failure, and Package

EPA Reg #	ml (1ml = 0.0338 fl. oz.)	Fl. Oz. (29.6ml = 1 fl. oz.)	Product Density g/ml	% Fipronil	mg Fipronil	# unit = tox /harmful amt
65331-2 cat frontline	0.5	0.017	1.03	9.7	49.96	1
65331-3 dog frontline	0.67	0.023	1.03	9.7	66.94	1
65331-3 dog frontline	1.34	0.045	1.03	9.7	133.88	1
65331-3 dog frontline	2.68	0.091	1.03	9.7	267.76	1
65331-3 dog frontline	4.02	0.136	1.03	9.7	401.64	1
65331-4 cat frontline plus	0.5	0.017	1.02	9.8	49.98	1
65331-5 dog frontline plus	0.67	0.023	1.02	9.8	66.97	1
65331-5 dog frontline plus	1.34	0.045	1.02	9.8	133.95	1

EPA Reg #	ml (1ml = 0.0338 fl. oz.)	Fl. Oz. (29.6ml =1 fl. oz.)	Product Density g/ml	% Fipronil	mg Fipronil	# unit = tox /harmful amt
65331-5 dog frontline plus	2.68	0.091	1.02	9.8	267.89	1
65331-5 dog frontline plus	4.02	0.136	1.02	9.8	401.84	1

Failure

For the purposes of CRP testing a **child failure** is access to one hanging card for all pipette sizes greater than 0.29ml for EPA Reg. No. 65331-2, 65331-3, 65331-4, and 65331-5.

A **unit (hanging card) failure for the child test** was defined as access to the pipette or any partial or complete access to the placebo (water) for EPA Reg. No. 65331-2, 65331-3, 65331-4, and 65331-5.

A **Senior Adult Use Effectiveness failure** is the inability to access the pipette by the correct mechanism in the prescribed test time of 5 minutes for the first package or 1 minute for the second package.

Analysis of Data and Conclusion

The CRP certifications dated March 2, 2010 for EPA Registration No. 65331-2, 65331-3, 65331-4, and 65331-5 are acceptable. Eight CRP studies were reviewed: 0.5ml size blue pipette EPA Reg. No. 65331-2 (MRID 480388-01); 4.02ml size blue pipette EPA Reg. No. 65331-3 (MRID 480388-04); 1.34ml size green pipette EPA Reg. No. 65331-5 (MRID 480388-02); and the 2.68ml size green pipette EPA Reg. No. 65331-5 (MRID 480388-03). These eight studies were used to extrapolate to the other sizes and colors for EPA Reg. No. 65331-2, 65331-3, 65331-4, and 65331-5 where CRP studies were not done (CRP for both the blue and green pipettes in 5 different sizes (0.017, 0.023, 0.045, 0.91, and .136 fl. oz.)). This approach was based on an Agency approved protocol Nov. 14, 2008 DP 357383, 357384, 357420, 357421.

Child Study 1 blue pipette 0.5ml (0.017 fl. oz.) size in small hanging card (MRID 480388-01) involved giving each child 1 hanging card with 1 pipette each containing 0.5ml (0.017 fl. oz) of water at the start of the test. A child failure was

defined as access to one hanging card (containing 1 pipette) as the hanging card was the child-resistant feature. The results were 2 child failures, a 49 month old male and a 47 month old female each accessed 1 pipette. **This study was a pass according to the child sequential test in 16 CFR 1700.20.**

Senior Adult Use Effectiveness Study 1 blue pipette 0.5ml (0.017 fl. oz.) size in small hanging card (MRID 480388-01) involved having the test subjects open one hanging card during a 5 minute test period and a one minute test period. Scissors were made available during testing because the test directions given to the seniors called for their use. **The SAUE is 100%, the study is a pass.**

Child Study 1 green pipette 1.34ml (0.045 fl. oz.) size in small hanging card (MRID 480388-02) involved giving each child 1 hanging card with 1 pipette each containing 1.34ml (0.045 fl. oz) of water at the start of the test. A child failure was defined as access to one hanging card (containing 1 pipette) as the hanging card was the child-resistant feature. The results were no child failures. **This study was a pass according to the child sequential test in 16 CFR 1700.20.**

Senior Adult Use Effectiveness Study 1 green pipette 1.34ml (0.045 fl. oz.) size in small hanging card (MRID 480388-02) involved having the test subjects open one hanging card during a 5 minute test period and a one minute test period. Scissors were made available during testing because the test directions given to the seniors called for their use. Data analysis showed an age calculation error, a 50 year old female was reported as 53 years old. However, the subject remained in the same age group. The age and sex distribution remains okay. The results are not affected. **The SAUE is 100%, study is a pass.**

Child Study 1 green pipette 2.68ml (0.091 fl. oz.) size in medium hanging card (MRID 480388-03) involved giving each child 1 hanging card with 1 pipette each containing 2.68ml (0.091 fl. oz) of water at the start of the test. A child failure was defined as access to one hanging card (containing 1 pipette) as the hanging card was the child-resistant feature. The results were one child failure, a 47 month old female accessed 1 pipette. **This study was a pass according to the child sequential test in 16 CFR 1700.20.**

Senior Adult Use Effectiveness Study 1 green pipette 2.68ml (0.091 fl. oz.) size in medium hanging card (MRID 480388-03) involved having the test subjects open one hanging card during a 5 minute test period and a one minute test period. Scissors were made available during testing because the test directions given to the seniors called for their use. Data analysis showed an age calculation error, a 64 year old male was reported as 53 years old. The age group and sex distribution are off, which means there are more test subjects and males in the 60-70 year old group. The SAUE is 100%. The results are still a pass of the SAUE per 16 CFR 1700.20 test protocol and 16 CFR 1700.15(b) effectiveness specifications.

Child Study 1 blue pipette 4.02ml (0.136 fl. oz.) size in medium hanging card (MRID 480388-04) involved giving each child 1 hanging card with 1 pipette each containing 4.02ml (0.136 fl. oz) of water at the start of the test. A child failure was defined as access to one hanging card (containing 1 pipette) as the hanging card was the child-resistant feature. The results were 2 child failures, a 49 month old female and a 43 month old male each accessed 1 pipette. **This study was a pass according to the child sequential test in 16 CFR 1700.20.**

Senior Adult Use Effectiveness Study 1 blue pipette 4.02ml (0.136 fl. oz.) size in medium hanging card (MRID 480388-04) involved having the test subjects open one hanging card during a 5 minute test period and a one minute test period. Scissors were made available during testing because the test directions given to the seniors called for their use. Data analysis showed an age calculation error, a 56 year old female was reported as 66 years old. The age group and sex distribution are off, which means there are less test subjects and females in the 60-70 year old group. One 51 year old male failed the first 5 minute test period. The SAUE is 99%. The results are still a pass of the SAUE per 16 CFR 1700.20 test protocol and 16 CFR 1700.15(b) effectiveness specifications.

The following sizes and colors are accepted on the basis of extrapolation [For the details of each study refer to the attached summary chart (summarycht65331-2,3,4,5.doc).]:

EPA Reg. No. 65331-3 1 blue pipette 0.67ml (0.023 fl. oz.) size in small hanging card is accepted as CRP based on passing CRE and SAUE values per 16 CFR 1700 for MRID 480388-01 (Frontline product 65331-2, 0.5ml) and MRID 480388-02 (Frontline Plus product 65331-5, 1.34ml).

EPA Reg. No. 65331-3 1 blue pipette 1.34ml (0.045 fl. oz.) size in small hanging card is accepted as CRP based on passing CRE and SAUE values per 16 CFR 1700 for MRID 480388-02 (Frontline Plus product 65331-5, 1.34ml).

EPA Reg. No. 65331-3 1 blue pipette 2.68ml (0.091 fl. oz.) size in medium hanging card is accepted as CRP based on passing CRE and SAUE values per 16 CFR 1700 for MRID 480388-03 (Frontline Plus product 65331-5, 2.68ml).

EPA Reg. No. 65331-4 1 green pipette 0.5ml (0.017 fl. oz.) size in small hanging card is accepted as CRP based on passing CRE and SAUE values per 16 CFR 1700 for MRID 480388-01 (Frontline product 65331-2, 0.5ml).

EPA Reg. No. 65331-5 1 green pipette 0.67ml (0.023 fl. oz.) size in small hanging card is accepted as CRP based on passing CRE and SAUE values per 16 CFR 1700 for MRID 480388-01 (Frontline product 65331-2, 0.5ml) and MRID 480388-02 (Frontline Plus product 65331-5, 1.34ml).

EPA Reg. No. 65331-5 1 green pipette 4.02ml (0.136 fl. oz.) size in medium hanging card is accepted as CRP based on passing CRE and SAUE values per 16 CFR 1700 for MRID 480388-04 (Frontline product 65331-3, 4.02ml).

In conclusion all the requirements for CRP have been met for EPA Reg. No. 65331-2 (blue pipette), 65331-3 (blue pipette), 65331-4 (green pipette), and 65331-5 (green pipette) in 5 different sizes (0.017, 0.023, 0.045, 0.91, and 0.136 fl. oz.). The directions on opening the package given to consumers must be identical to those given to the seniors during testing for the hanging card. The senior testing directions are on the labels submitted March 3, 2010 for EPA Reg. No. 65331-2, 65331-3, 65331-4, and 65331-5. Should any human experience/epidemiological evidence indicate a problem once the product is in the marketplace, the Agency reserves the right to reexamine this data comprehensively and to question the child resistance of the package involved.

May 24, 2010

CRPdatasummarycht

EPA REG # 65331-2 Frontline Top Spot for Cats and 65331-3 Frontline Top Spot for Dogs

Chemical - Fipronil 9.7%

Company Name Merial Ltd

A **child failure** is access to 1 unit (the hanging card, which is the CRP). Access to 1 unit is more than 28.5mg of Fipronil for all sizes.

A **unit failure** is access to the pipette or any partial or complete access to the placebo (water).

A **senior failure** is the inability to access the pipette by the correct mechanism in the allotted time of 5 min. for the 1st pkg or 1 min for the 2nd pkg

Access to a toxic or harmful amt = **28.5mg** = 28.5mg divided by [1030mg/ml x .097 fipronil] = 0.285ml = **0.29ml for frontline**

Access to a toxic or harmful amt = **28.5mg** = 28.5mg divided by [1020mg/ml x .098 fipronil] = 0.285ml = **0.29ml for frontline plus**

% AI - Fipronil 9.7%

Note:

1. The pipette sizes are filled in ml. Therefore, the number of ml x 0.0338 fl.oz./per ml is the number of fluid oz.
2. There were only 8 CRP studies done and they were used to extrapolate to the other sizes and colors where CRP studies were not done. This approach was based on an Agency approved protocol Nov. 14, 2008, DP 357383, 357384, 357420, 357421.

EPA REG #	MRID	PKG Description Include ml per Pkg # unit/pkg, child fail = # units, color, tox/harm = # units	# Pkges Child Get at Begin Test	Company Data		Data		Conclusion include CRE & SAUE via computer analysis
				CRE	SAUE	Comprehensive Review & why	Only Computer Analysis	
65331-2	480388-01 cat product 1365-080	1blue pipette in small hanging card 0.5ml water placebo in pipette Tox/harm = 1 unit, child fail = 1 unit	1	2 child failures = Pass 50 child test. 1 child access 1 pipette before demo, 1 child access 1 pipette after demo		X see note 2 at start of table		CRP Certification is ok. Label submitted 3/3/2010 same CRP directions as in study. There were 2 child failures, a 49 month old male and a 47 month old female each accessed 1 pipette. Study is a pass of the child test according to the sequential test chart in 16 CFR 1700.20.

EPA REG #	MRID	PKG Description Include ml per Pkg # unit/pkg, child fail = # units, color, tox/harm = # units	# Pkges Child Get at Begin Test	Company Data		Data		Conclusion include CRE & SAUE via computer analysis
				CRE	SAUE	Comprehensive Review & why	Only Computer Analysis	
65331-2	480388-01 cat product 1365-080	1blue pipette in small hanging card 0.5ml water placebo in pipette Tox/harm = 1 unit, child fail = 1 unit			100% SAUE	X see note 2 at start of table		CRP Certification is ok. Label submitted 3/3/2010 same CRP directions as in study. SAUE is 100%, study is a pass.
65331-3	dog product	1blue pipette in small hanging card 0.67ml Tox/harm = 1 unit, child fail = 1 unit						CRP Certification is ok. Label submitted 3/3/2010 same CRP directions as in both studies mentioned below. Size accepted based on passing CRE & SAUE values per 16 CFR 1700 for 480388-01 (Frontline product 65331-2, 0.5ml) and 480388-02 (Frontline Plus product 65331-5, 1.34ml)
65331-3	dog product	1blue pipette in small hanging card 1.34ml Tox/harm = 1 unit, child fail = 1 unit						CRP Certification is ok. Label submitted 3/3/2010 same CRP directions as in study mentioned below. Size accepted based on passing CRE & SAUE values per 16 CFR 1700 for 480388-02 (Frontline Plus product 65331-5, 1.34ml)
65331-3	dog product	1blue pipette in medium hanging card 2.68ml Tox/harm = 1 unit, child fail = 1 unit						CRP Certification is ok. Label submitted 3/3/2010 same CRP directions as in study mentioned below. Size accepted based on passing CRE & SAUE values per 16 CFR 1700 for 480388-03 (Frontline Plus product 65331-5, 2.68ml)

EPA REG #	MRID	PKG Description Include ml per Pkg # unit/pkg, child fail = # units, color, tox/harm = # units	# Pkges Child Get at Begin Test	Company Data		Data		Conclusion include CRE & SAUE via computer analysis
				CRE	SAUE	Comprehensive Review & why	Only Computer Analysis	
65331-3	480388-04 dog product 1365-081	1blue pipette in medium hanging card 4.02ml water placebo Tox/harm = 1 unit, child fail = 1 unit	1	2 child failures = Pass 50 child test. 1 child access 1 pipette before demo, 1 child access 1 pipette after demo		X see note 2 at start of table		CRP Certification is ok. Label submitted 3/3/2010 same CRP directions as in study. There were 2 child failures, a 49 month old female and a 43 month old male each accessed 1 pipette. Study is a pass of the child test according to the sequential test chart in 16 CFR 1700.20.
65331-3	480388-04 dog product 1365-081	1blue pipette in medium hanging card 4.02ml water placebo Tox/harm = 1 unit, child fail = 1 unit			99% SAUE 1 senior (age 51 yr male) fail in 5 min for 1 st pkg	X see note 2 at start of table		CRP Certification is ok. Label submitted 3/3/2010 same CRP directions as in study. Data analysis showed an age calculation error, a 56 year old female was reported as 66 years old. The age group and sex distribution are off, which means there are less test subjects and females in the 60-70 year old group. One 51 year old male failed the 1 st 5 minute test period. The SAUE is 99%. The results are still a pass of the SAUE per 16 CFR 1700.20 test protocol and 16 CFR 1700.15(b) effectiveness specifications.

May 24, 2010

CRPdatasummarycht

EPA REG # 65331-4 Frontline Plus for Cats

Chemical - Fipronil 9.8%
S-Methoprene 11.8%

Company Name Merial Ltd

A **child failure** is access to 1 unit (the hanging card, which is the CRP). Access to 1 unit is more than 28.5mg of Fipronil for all sizes.

A **unit failure** is access to the pipette or any partial or complete access to the placebo (water).

A **senior failure** is the inability to access the pipette by the correct mechanism in the allotted time of 5 min. for the 1st pkg or 1 min for the 2nd pkg

Access to a toxic or harmful amt = **28.5mg** = 28.5mg divided by [1030mg/ml x .097 fipronil] = 0.285ml = **0.29ml for frontline**

Access to a toxic or harmful amt = **28.5mg** = 28.5mg divided by [1020mg/ml x .098 fipronil] = 0.285ml = **0.29ml for frontline plus**

% AI - Fipronil 9.8%

S-Methoprene 11.8%

Note:

1. The pipette sizes are filled in ml. Therefore, the number of ml x 0.0338 fl.oz./per ml is the number of fluid oz.
2. There were only 8 CRP studies done and they were used to extrapolate to the other sizes and colors where CRP studies were not done. This approach was based on an Agency approved protocol Nov. 14, 2008, DP 357383, 357384, 357420, 357421.

EPA REG #	MRID	PKG Description Include ml per Pkg # unit/pkg, child fail = # units, color, tox/harm = # units	# Pkges Child Get at Begin Test	Company Data		Data		Conclusion
				CRE	SAUE	Comprehensive Review & why	Only Computer Analysis	
65331-4	cat product	1green pipette in small hanging card 0.5ml Tox/harm = 1 unit, child fail = 1 unit						CRP Certification is ok. Label submitted 3/3/2010 same CRP directions as in study mentioned below. Size accepted based on passing CRE & SAUE values per 16 CFR 1700 for 480388-01 (Frontline product 65331-2, 0.5ml)

May 24, 2010

CRPdatasummarycht

EPA REG # 65331-5 Frontline Plus for Dogs

Chemical - Fipronil 9.8%
S-Methoprene 8.8%

Company Name Merial Ltd

A **child failure** is access to 1 unit (the hanging card, which is the CRP). Access to 1 unit is more than 28.5mg of Fipronil for all sizes.

A **unit failure** is access to the pipette or any partial or complete access to the placebo (water).

A **senior failure** is the inability to access the pipette by the correct mechanism in the allotted time of 5 min. for the 1st pkg or 1 min for 2nd pkg

Access to a toxic or harmful amt = **28.5mg** = 28.5mg divided by [1030mg/ml x .097 fipronil] = 0.285ml = **0.29ml for frontline**

Access to a toxic or harmful amt = **28.5mg** = 28.5mg divided by [1020mg/ml x .098 fipronil] = 0.285ml = **0.29ml for frontline plus**

% AI - Fipronil 9.8%

S-Methoprene 8.8%

Note:

1. The pipette sizes are filled in ml. Therefore, the number of ml x 0.0338 fl.oz./per ml is the number of fluid oz.
2. There were only 8 CRP studies done and they were used to extrapolate to the other sizes and colors where CRP studies were not done. This approach was based on an Agency approved protocol Nov. 14, 2008, DP 357383, 357384, 357420, 357421.

EPA REG #	MRID	PKG Description Include ml per Pkg # unit/pkg, child fail = # units, color, tox/harm = # units	# Pkges Child Get at Begin Test	Company Data		Data		Conclusion
				CRE	SAUE	Comprehensive Review & why	Only Computer Analysis	
65331-5	dog product	1green pipette in small hanging card 0.67ml Tox/harm = 1 unit, child fail = 1 unit						CRP Certification is ok. Label submitted 3/3/2010 same CRP directions as in both studies mentioned below. Size accepted based on passing CRE & SAUE values per 16 CFR 1700 for 480388-01 (Frontline product 65331-2, 0.5ml) and 480388-02 (Frontline Plus product 65331-5, 1.34ml)

EPA REG #	MRID	PKG Description Include ml per Pkg # unit/pkg, child fail = # units, color, tox/harm = # units	# Pkges Child Get at Begin Test	Company Data		Data		Conclusion include CRE & SAUE via computer analysis
				CRE	SAUE	Comprehensive Review & why	Only Computer Analysis	
65331-5	480388-02 dog product 1365-078	1green pipette in small hanging card 1.34ml water placebo Tox/harm = 1 unit, child fail = 1 unit	1	0 child failures = Pass 50 child test.		X see note 2 at start of table		CRP Certification is ok. Label submitted 3/3/2010 same CRP directions as in study. There were no child failures. Study is a pass of the child test according to the sequential test chart in 16 CFR 1700.20.
65331-5	480388-02 dog product 1365-078	1green pipette in small hanging card 1.34ml water placebo Tox/harm = 1 unit, child fail = 1 unit			100% SAUE	X see note 2 at start of table		CRP Certification is ok. Label submitted 3/3/2010 same CRP directions as in study. Data analysis showed an age calculation error, a 50 year old female was reported as 53 years old. However, the subject remained in the same age group. The age and sex distribution remains okay. The results are not affected. The SAUE is 100%, study is a pass.
65331-5	480388-03 dog product 1365-079	1green pipette in medium hanging card 2.68ml water placebo Tox/harm = 1 unit, child fail = 1 unit	1	1 child failure = Pass 50 child test. 1 child access 1 pipette after demo		X see note 2 at start of table		CRP Certification is ok. Label submitted 3/3/2010 same CRP directions as in study. There was one child failure, a 47 month old female accessed 1 pipette. Study is a pass of the child test according to the sequential test chart in 16 CFR 1700.20.
65331-5	480388-03 dog product 1365-079	1green pipette in medium hanging card 2.68ml water placebo Tox/harm = 1 unit, child fail = 1 unit			100% SAUE	X see note 2 at start of table		CRP Certification is ok. Label submitted 3/3/2010 same CRP directions as in study. Data analysis showed an age calculation error, a 64 year old male was reported as 53 years old. The age group and sex distribution are off, which means there are more test subjects and males in the 60-70 year old group. The SAUE is 100%. The results are still a pass of the SAUE per 16 CFR 1700.20 test protocol and 16 CFR 1700.15(b) effectiveness specifications.

EPA REG #	MRID	PKG Description Include ml per Pkg # unit/pkg, child fail = # units, color, tox/harm = # units	# Pkges Child Get at Begin Test	Company Data		Data		Conclusion include CRE & SAUE via computer analysis
				CRE	SAUE	Comprehensive Review & why	Only Computer Analysis	
65331-5	dog product	1green pipette in medium hanging card 4.02ml Tox/harm = 1 unit, child fail = 1 unit						CRP Certification is ok. Label submitted 3/3/2010 same CRP directions as in study mentioned below. Size accepted based on passing CRE & SAUE values per 16 CFR 1700 for 480388-04 (Frontline product 65331-3, 4.02ml)

Product Toxicity based on Fipronil Toxicity

Access to a toxic or harmful amt = **28.5mg** = 28.5mg divided by [1030mg/ml x .097 fipronil] = 0.285ml = **0.29ml for frontline**

Access to a toxic or harmful amt = **28.5mg** = 28.5mg divided by [1020mg/ml x .098 fipronil] = 0.285ml = **0.29ml for frontline plus**

EPA Reg #	ml (1ml = 0.0338 fl. oz.)	Fl. Oz. (29.6ml = 1 fl. oz.)	Product Density g/ml	% Fipronil	mg Fipronil	# unit = tox /harmful amt
65331-2 cat frontline	0.5	0.017	1.03	9.7	49.96	1
65331-3 dog frontline	0.67	0.023	1.03	9.7	66.94	1
65331-3 dog frontline	1.34	0.045	1.03	9.7	133.88	1
65331-3 dog frontline	2.68	0.091	1.03	9.7	267.76	1
65331-3 dog frontline	4.02	0.136	1.03	9.7	401.64	1
65331-4 cat frontline plus	0.5	0.017	1.02	9.8	49.98	1
65331-5 dog frontline plus	0.67	0.023	1.02	9.8	66.97	1
65331-5 dog frontline plus	1.34	0.045	1.02	9.8	133.95	1
65331-5 dog frontline plus	2.68	0.091	1.02	9.8	267.89	1
65331-5 dog frontline plus	4.02	0.136	1.02	9.8	401.84	1