

US EPA ARCHIVE DOCUMENT

PRODUCT PERFORMANCE / EFFICACY REVIEW

Mark Suarez, Entomologist - IB



20 Oct 2005

DATE: 20 October 2005

EPA REG. NUMBER: 121-OR
121-OE
121-OG
121-OU
121-OL

PRODUCT NAME: Cutter Insect Repellent 15KP [121-OR]
Cutter Insect Repellent 15KA [121-OE]
Cutter Insect Repellent 12KT [121-OG]
Cutter Insect Repellent 10KP [121-OU]
Cutter Insect Repellent 10KA [121-OL]

REGISTRANT: Spectrum, A Div. of United Industries Corp.

PM: Richard Gebken, PM10

REVIEWER: Joe Tavano

DECISION #.: 353650 [121-OR]
354564 [121-OE]
354566 [121-OG]
354565 [121-OU]
355159 [121-OL]

DP BARCODE: 313953 [121-OR]
315503 [121-OE]
315483 [121-OG]
315494 [121-OU]
315499 [121-OL]

ACTION: R31

ACTIVE INGREDIENT(S): Cutter Insect Repellent 15KP [121-OR]
070705, Picaridin.....15.00
Cutter Insect Repellent 15KA [121-OE]
070705, Picaridin.....15.00
Cutter Insect Repellent 12KT [121-OG]
070705, Picaridin.....12.00%
Cutter Insect Repellent 10KP [121-OU]
070705, Picaridin.....10.00%
Cutter Insect Repellent 10KA [121-OL]
070705, Picaridin.....10.00%

TYPE: Topical (Human Skin) Repellent

OPPTS GUIDELINE(S):	810.1000 810.3000 810.3300
MRID:	46466309 46466310
GLP ?:	No.
SITES:	Human Skin
PESTS:	Mosquitoes
STUDY APPLICATION RATE:	Variable
LABEL APPLICATION RATE:	Typically; understood to be approximately 1.0 g/ 600 cm ² or 0.001667g/cm ² .

STUDY SUMMARIES:

The registrant submitted two studies in support of efficacy claims against mosquitoes and one study supporting claims against ticks on the labels of the 5 registrations desired. Laboratory studies were conducted evaluating two of the subject formulations (10KP and 15KP) against *Culex quinquefasciatus*, *Aedes aegypti*, and *Dermacentor variabilis*. Human volunteers exposed areas of treated skin to caged mosquitoes or ticks. The efficacy of the products was compared to a 10% DEET standard in each study.

MRID 46466309.

This study was a laboratory evaluation of two Cutter picaridin products against a DEET standard. The repellents 10KP and 15 KP were evaluated against *Culex quinquefasciatus*. The 10KP product was efficacious for up to 6 hours (95% C.I.), while the 15KP product demonstrated complete repellency for up to 8 hours (see Table 1 for results). Formulations 10KA, 12KT, and 15KA were not tested. The registrant would like to bridge data from the formulations tested to these similar products.

MRID 46466309.

This study was also a laboratory evaluation of two Cutter picaridin products against a DEET standard. The repellents 10KP and 15 KP were evaluated against *Aedes aegypti*. The 10KP product was efficacious for up to 3.5 hours (95% C.I.), while the 15KP product demonstrated complete repellency for up to 4.5 hours (95% C.I.; see Table 1 for results). In addition to testing the product against mosquitoes, the formulations were tested against the American dog tick, *Dermacentor variabilis*. No formulation specific data were provided for the 10KA, 12KT, or 15KA products. The registrant would like to bridge data from the formulations tested to the untested products.

Formulation	Reg. #	% of Formulation	Species	Reps	Application Rate (g AI/ cm ²)	Mean Time to 1 st Confirmed Bite (Hours-95% CI)	Study
Cutter Insect Repellent 15KP	121-OR	15.00	<i>Cx. quinquefasciatus</i>	4	0.001549	8+	46466309
			<i>Ae. aegypti</i>		0.006667	4.5	46466310
Cutter Insect Repellent 15KA	121-OE	15.00					
Cutter Insect Repellent 12KT	121-OG	12.00					
Cutter Insect Repellent 10KP	121-OU	10.00	<i>Cx. quinquefasciatus</i>	4	0.001549	6	46466309
			<i>Ae. aegypti</i>		0.006667	3.5	46466310
			<i>D. variabilis</i>		0.000796	2	46466310
Cutter Insect Repellent 10KA	121-OL	10.00					
OFF! Skintastic VII Insect Repellent	4822-415	10.00	<i>Cx. quinquefasciatus</i>	4	0.001549	5	46466309
Repel 10% DEET	305-42	10.00	<i>Ae. aegypti</i>		0.006667	3.5	46466310
			<i>D. variabilis</i>		0.000796	2.5	46466310

Table 1. Comparison of the amount of active ingredient and efficaciousness of relevant formulations.

ENTOMOLOGIST'S COMMENTS AND RECOMMENDATIONS:

The data submitted are partially acceptable in support of the inclusion of Mosquitoes, Mosquitoes that may transmit West Nile Virus, and American Dog ticks. Claims related to the duration of efficacy are addressed in sections below. However, due to the nature of repellent insecticides, it is necessary to confirm the results with field data for each formulation.

Recommendations:

1. Label claims for repellency of the American Dog Tick are acceptable. If desired, the length of repellency may be added as in Table 1.
2. Label claims for the following pests are conditionally acceptable:
 - A. Mosquitoes
 - B. Mosquitoes that may transmit West Nile Virus

The inclusion of these claims on the label requires that the registrant submit formulation specific confirmatory data (10KP, 10KA, 12KT, 15KA, and 15KT)

within 12 months of the public release of the final approved 810.3800 repellency guidelines.

3. Label claims for the following pests are not supported. Remove these claims. (Data may submitted or cited to support the inclusion of these claims in a future label amendment.):
 - A. Biting Flies
 - B. Ticks
 - C. Deer Ticks
 - D. Gnats
 - E. No-see-ums
 - F. Chiggers
 - G. Fleas

4. Specific Marketing Claims are addressed below, by label:
 - A. **121-OR** – Optional Marketing Claims listed on page 2 of the 1/18/2005 label.
 - i. #3 – [Long][Longer]-lasting formula; *Remove. Comparative claim/Vague.*
 - ii. #5 – Twice as strong [as Cutter Insect Repellent 7K]; *Remove, this is a comparative claim.*
 - iii. #6 – Twice the protection of Cutter Insect Repellent 7K; *Remove, this is a comparative claim.*
 - iv. #13 – Repels mosquitoes, ticks, [biting flies, deer flies, no-see-ums, chiggers, gnats, and fleas][and other biting insects]; *Remove “ticks, [biting flies, deer flies, no-see-ums, chiggers, gnats, and fleas][and other biting insects]” or submit or cite supporting data.*
 - v. #14—Repels mosquitoes that may [transmit][carry] West Nile Virus; *Acceptable.*
 - vi. #15 – Repels deer ticks that may carry Lyme disease; *Remove, this statement is not supported by data.*
 - vii. #19 -- Next generation...; *This product is no longer the next generation. There are registered, marketed products on store shelves – it is the current generation.*
 - viii. #21 – Repels mosquitoes for up to 8 hours; *Modify to read up to 4.5 hours.*
 - ix. #22 – Up to 8 hour protection from mosquitoes; *Modify to read up to 4.5 hours.*
 - x. #27 – Can be applied to clothing; *Remove, no data to support efficacy on fabric. Submit or cite data for the inclusion of this claim.*
 - xi. #35 – For Extreme Conditions; *Remove, No data to support this claim (e.g., heat, rain, perspiration). Submit or cite data for the inclusion of this claim.*
 - xii. #38 – Dermatologist tested; *Remove, misleading (implies safety).*

- xiii. #39 – Scientifically Tested; *Remove, Implies heightened efficacy.*
- B. **121-OE** – Optional Marketing Claims listed on page 2 of the 1/18/2005 label.
- i. #3 – [Long][Longer]-lasting formula *Remove. Comparative claim/Vague.*
 - ii. #4 – Twice as strong [as Cutter Insect Repellent 7K]; *Remove, this is a comparative claim.*
 - iii. #5 – Twice as strong [as Cutter Insect Repellent 7K]; *Remove, this is a comparative claim.*
 - iv. #6 – Protects twice as long*[*as Cutter Insect Repellent 7K]; *Remove, this is a comparative claim.*
 - v. #12 – Effective, dependable protection; *Remove, implies heightened efficacy.*
 - vi. #13 – Repels mosquitoes, ticks, [biting flies, deer flies, no-see-ums, chiggers, gnats, and fleas][and other biting insects]; *Remove "ticks, [biting flies, deer flies, no-see-ums, chiggers, gnats, and fleas][and other biting insects]" or submit or cite supporting data.*
 - vii. #14 – Repels mosquitoes that may [transmit][carry] West Nile Virus; *Acceptable.*
 - viii. #15 – Repels deer ticks that may carry Lyme disease; *Remove, this statement is not supported by data.*
 - ix. #21 – Next generation...; *This product is no longer the next generation. There are registered, marketed products on store shelves – it is the current generation.*
 - x. #23 – Repels mosquitoes for up to 8 hours; *Modify to read up to 4.5 hours.*
 - xi. #24 – Up to 8 hour protection from mosquitoes; *Modify to read up to 4.5 hours.*
 - xii. #29 – Can be applied to clothing; *Remove, no data to support efficacy on fabric. Submit or cite data for the inclusion of this claim.*
 - xiii. #35 – Long Lasting Protection
 - xiv. #36 – For Extreme Conditions; *Remove, No data to support this claim (e.g., heat, rain, perspiration); Remove, No data to support this claim (e.g., heat, rain, perspiration). Submit or cite data for the inclusion of this claim.*
 - xv. #37 – Tested in Tropical Conditions; *Remove, this claim is not supported by the data submitted.*
 - xvi. #39 – Water resistant [sport][formula]; *Remove, this claim is not supported by the data submitted.*
 - xvii. #40 – Dermatologist tested; *Remove, misleading (implies safety).*
 - xviii. #41 – Scientifically tested; *Remove, Implies heightened efficacy.*

- C. **121-OG** – Optional Marketing Claims listed on page 2 of the 1/18/2005 label.
- i. #3 – [Long][Longer]-lasting formula; ; *Remove. Comparative claim/Vague.*
 - ii. #4 – Twice the level of Picaridin [of Cutter Insect Repellent 5KT]; *Remove, this is a comparative claim.*
 - iii. #5 – Twice as strong [as Cutter Insect Repellent 5KT]; *Remove, this is a comparative claim.*
 - iv. #6 – Protects twice as long* [*as Cutter Insect Repellent 5KT]; *Remove, this is a comparative claim.*
 - v. #12 – Effective, dependable protection; *Remove implies heightened efficacy.*
 - vi. #13 – Repels mosquitoes, ticks, [biting flies, deer flies, no-see-ums, chiggers, gnats, and fleas][and other biting insects]; *Remove "ticks, [biting flies, deer flies, no-see-ums, chiggers, gnats, and fleas][and other biting insects]" or submit or cite supporting data.*
 - vii. #14—Repels mosquitoes that may [transmit][carry] West Nile Virus; *Acceptable.*
 - viii. #15 – Repels deer ticks that may carry Lyme disease; *Remove, this statement is not supported by data.*
 - ix. #19 – Next generation...; *This product is no longer the next generation. There are registered, marketed products on store shelves – it is the current generation.*
 - x. #21 – Repels mosquitoes for up to 8 hours; *Modify to read up to 3.5 hours.*
 - xi. #22 – Up to 8 hour protection from mosquitoes; *Modify to read up to 3.5 hours.*
 - xii. #27 – Can be applied to clothing; *Remove, no data to support efficacy on fabric. Submit or cite data for the inclusion of this claim.*
 - xiii. #33 – Long Lasting Protection; *Remove, vague.*
 - xiv. #34 – For Extreme Conditions; *Remove, No data to support this claim (e.g., heat, rain, perspiration). Submit or cite data for the inclusion of this claim.*
 - xv. #35 – Tested in tropical conditions; *Remove, this claim is not supported by the data submitted.*
 - xvi. #37 – Water resistant [sport][formula]; *Remove, this claim is not supported by the data submitted.*
 - xvii. #38 – Dermatologist Tested; *Remove, misleading (implies safety).*
 - xviii. #39 – Scientifically Tested; *Remove, Implies heightened efficacy.*

- D. **121-OU** – Optional Marketing Claims listed on page 2 of the 1/18/2005 label.

- i. #3 – [Long][Longer]-lasting formula; *Remove. Comparative claim/Vague.*
- ii. #9 – Effective, dependable protection; *Remove, implies heightened efficacy.*
- iii. #10 – Repels mosquitoes, ticks, [biting flies, deer flies, no-see-ums, chiggers, gnats, and fleas][and other biting insects]; *Remove “ticks, [biting flies, deer flies, no-see-ums, chiggers, gnats, and fleas][and other biting insects]” or submit or cite supporting data.*
- iv. #11 – Repels mosquitoes that may [transmit][carry] West Nile Virus; *Acceptable.*
- v. #12 – Repels deer ticks that may carry Lyme disease; *Remove, this statement is not supported by data.*
- vi. #17 – Next generation...; *This product is no longer the next generation. There are registered, marketed products on store shelves – it is the current generation.*
- vii. #19 – Repels mosquitoes for up to 6 hours; *Modify to read up to 3.5 hours.*
- viii. #20 – [Protects] Up to 6 hours [of protection] from mosquitoes; *Modify to read up to 3.5 hours.*
- ix. #25 – Can be applied to clothing [for additional protection]; *Remove, no data to support efficacy on fabric. Submit or cite data for the inclusion of this claim.*
- x. #31 – Long Lasting Protection; *Remove, vague.*
- xi. #32 – For Extreme Conditions; *Remove, No data to support this claim (e.g., heat, rain, perspiration). Submit or cite data for the inclusion of this claim.*
- xii. #33 – Tested in tropical conditions; *Remove, this claim is not supported by the data submitted.*
- xiii. #35 – Water resistant [sport][formula]; *Remove, this claim is not supported by the data submitted.*
- xiv. #36 – Dermatologist Tested; *Remove, misleading (implies safety).*
- xv. #37 – Scientifically Tested; *Remove, Implies heightened efficacy.*

E. **121-OL** – Optional Marketing Claims listed on page 2 of the 1/18/2005 label.

- i. #3 – [Long][Longer]-lasting formula; ; *Remove. Comparative claim/Vague.*
- ii. #9 – Effective, dependable protection; *Remove, Implies heightened efficacy.*
- iii. #10 – Repels mosquitoes, ticks, [biting flies, deer flies, no-see-ums, chiggers, gnats, and fleas][and other biting insects]; *Remove “ticks, [biting flies, deer flies, no-see-ums, chiggers, gnats, and fleas][and other biting insects]” or submit or cite supporting data.*

- iv. #11 – Repels mosquitoes that may [transmit][carry] West Nile Virus; *Acceptable.*
- v. #12 – Repels deer ticks that may carry Lyme disease; *Remove, this statement is not supported by data.*
- vi. #17 – Next generation...; *This product is no longer the next generation. There are registered, marketed products on store shelves – it is the current generation.*
- vii. #19 – Repels mosquitoes for up to 6 hours; *Modify to read up to 3.5 hours.*
- viii. #20 – Up to 6 hours of protection from mosquitoes; *Modify to read up to 3.5 hours.*
- ix. #25 – Can be applied to clothing [for additional protection]; *Remove, no data to support efficacy on fabric. Submit or cite data for the inclusion of this claim.*
- x. #31 – Long Lasting Protection; *Remove, vague.*
- xi. #32 – For Extreme Conditions ; *Remove, No data to support this claim (e.g., heat, rain, perspiration). Submit or cite data for the inclusion of this claim.*
- xii. #33 – Tested in tropical conditions; *Remove, this claim is not supported by the data submitted.*
- xiii. #35 – Water resistant [sport][formula]; *Remove, this claim is not supported by the data submitted.*
- xiv. #36 – Dermatologist Tested; *Remove, misleading (implies safety).*
- xv. #37 – Scientifically Tested; *Remove, Implies heightened efficacy.*

F. **121-OG** – Optional Marketing Claims listed on page 2 of the 1/18/2005 label.

- i. #3 – [Long][Longer]-lasting formula; ; *Remove. Comparative claim/Vague.*
- ii. #4 – Twice as strong [as Cutter Insect Repellent 7K]; *Remove, this is a comparative claim.*
- iii. #5 – Twice as strong [as Cutter Insect Repellent 7K]; *Remove, this is a comparative claim.*
- iv. #6 – Protects twice as long*[*as Cutter Insect Repellent 7K]; *Remove, this is a comparative claim.*
- v. #12 – Effective, dependable protection; *Remove, implies heightened efficacy.*
- vi. #13 – Repels mosquitoes, ticks, [biting flies, deer flies, no-see-ums, chiggers, gnats, and fleas][and other biting insects]; *Remove “ticks, [biting flies, deer flies, no-see-ums, chiggers, gnats, and fleas][and other biting insects]” or submit or cite supporting data.*

- vii. #14 – Repels mosquitoes that may [transmit][carry] West Nile Virus; *Acceptable.*
- viii. #15 – Repels deer ticks that may carry Lyme disease; *Remove, this statement is not supported by data.*
- ix. #21 – Next generation...; *This product is no longer the next generation. There are registered, marketed products on store shelves – it is the current generation.*
- x. #23 – Repels mosquitoes for up to 8 hours; *Modify to read up to 4.5 hours.*
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- xii. #29 – Can be applied to clothing; *Remove, no data to support efficacy on fabric. Submit or cite data for the inclusion of this claim.*
- xiii. #35 – Long Lasting Protection
- xiv. #36 – For Extreme Conditions; *Remove, No data to support this claim (e.g., heat, rain, perspiration). Submit or cite data for the inclusion of this claim.*
- xv. #37 – Tested in Tropical Conditions;
- xvi. #39 – Water resistant [sport][formula]; *Remove, No data to support this claim. Submit or cite data for the inclusion of this claim.*
- xvii. #40 – Dermatologist tested; *Remove, misleading (implies safety).*
- xviii. #41 – Scientifically tested; *Remove, Implies heightened efficacy.*

Enclosure
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