Value Guidelines for New Personal Insect Repellent Products and Label Amendments

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Table of Contents

1.0 Introduction

The value of a pest control product, as defined by the *Pest Control Products Act* (PCPA), is the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration. This includes the product's efficacy, health, safety and environmental benefits, and social and economic impact. In determining acceptable value, a weight of evidence approach is taken that considers all the factors that may contribute to a product's value. The value assessment determines the acceptable use pattern, (in other words, use directions), which informs the risk assessment. Personal insect repellents are intended to protect users from pests of public health concern, including disease vectors (for example, mosquitoes, ticks). Given the potential human health implications, efficacy data are required to support these types of uses. Benefit analysis and use history can be used as supplemental supporting information, but cannot substitute for trial data. Because the pests controlled by these products may pose a concern to public health, personal insect repellents may not be eligible for reduced value/efficacy data requirements or reduced use claims even if they contain non-conventional active ingredients (Regulatory Directive *DIR2012-01 Guidelines for the Registration of Non-Conventional Pest Control Products*).

The purpose of this document is to provide guidance and clarification on the data requirements and design of studies to evaluate the efficacy of personal insect repellents for humans as part of the Pest Management Regulatory Agency's (PMRA) requirements for the Part 10 Value data package. As the specific details regarding the use of a personal insect repellent can vary significantly from one situation to the next, there is flexibility with regards to the manner in which efficacy data requirements can be addressed. The type of information that can be provided to address these requirements can vary from experimental data generated from dedicated research trials to rationales based on accepted scientific principles and existing scientific literature. These guidelines are intended primarily for applications to register personal insect repellents based on new or registered active ingredients, and to amend the labels of currently registered personal insect repellent products.

These guidelines deal solely with products that are applied directly to human skin, or devices or items which are clipped to or worn on a person's clothing or body. They do not apply to companion animal products (for example, products to repel fleas and ticks from pets), treated clothing, or products for use against bed bugs.

These guidelines are intended to be general, and product-specific requirements may be different from the general requirements. For guidance on generating efficacy data to support a specific product, and/or for advice on research authorisations or pre-submission consultations, please contact the PMRA Information Service at pmra.infoserv@hc-sc.gc.ca or 1-800-267-6315 (toll free) or 613-736-3799 by telephone.

The guidance presented here is consistent with other international efficacy guidelines (for example, United States Environmental Protection Agency 2010, World Health Organisation 2009) or standard protocols (for example, ASTM E939-94 2006, ASTM E951- 94 2006). These or other guidelines or protocols may also be consulted; however, in cases where guidance differs from this document, study design should default to PMRA guidelines. If PMRA recommendations are not followed, the choice of experimental protocol must be explained and justified.

2.0 Definitions

Bite: The act of penetrating human skin by the mouthparts of an insect or other arthropod.

Bridging information: Trials, rationales or data to justify the provision of efficacy data produced using one product to support efficacy claims for another product. The two products contain the same active ingredient, likely in a different formulation.

Complete Protection Time (CPT): The time from application of a repellent until the second event showing efficacy failure.

Crossing: The act of passage by a tick or chigger from an area of untreated skin to an area of treated skin. A crossing may be quantified by the distance the tick moves onto treated skin, or by the length of time the tick remains on treated skin.

Event: A landing, bite, or crossing, depending on the study endpoint.

Extrapolation: Use of efficacy data on one pest genus to support a claim on another pest genus. This may be possible based on sound, scientific rationales. Rationales should be based on factors such as pest biology, behaviour and feeding habits.

Landing: The act of a flying or jumping insect or other arthropod alighting on human skin without probing or biting.

Personal Insect Repellents: Products which are intended to repel arthropod pests from humans (for example, mosquitoes, ticks, fleas, biting flies, chiggers). Personal insect repellents are applied directly to the human skin or clothing, or are devices or repellent items which are clipped or worn on a person's clothing or body.

Rationale: A sound, scientific explanation provided in lieu of or in support of scientific data.

Representative species: Species that are representative of the Canadian pest situation. These are species for which repellents are likely to be used in Canada, (for example, *Aedes vexans*, *Culex tarsalis* for mosquitoes, or *Dermacentor variabilis* for ticks).

3.0 General Principles and Considerations of Value Assessments

Value assessments consider the benefits of the proposed use, determine whether the product is likely to provide acceptable efficacy when used according to label directions, and establish the use pattern that serves as the basis for the risk assessment. Value assessments are based on sound science, and a weight of evidence approach is used in formulating conclusions.

Personal insect repellents are intended to protect users from pests of public health concern, including disease vectors (for example, mosquitoes, ticks). Given the potential human health implications, strict efficacy data requirements and a high level of product performance (in other words, ≥95% repellency) are required in support of registration by regulatory agencies worldwide, including the United States Environmental Protection Agency (USEPA). Benefit analysis and use history can be used as supplemental supporting information, but cannot

substitute for trial data. Because the pests controlled by these products may pose a concern to public health, personal insect repellents may not be eligible for reduced value/efficacy data requirements or reduced use claims even if they contain non-conventional active ingredients (*DIR2012-01 Guidelines for the Registration of Non-Conventional Pest Control Products*).

The requirements outlined in this document are standard for a new, unregistered use for an end-use product. Actual efficacy data requirements (for example, number of studies required, target pests) may vary depending on the product for which registration is sought. For example, a new end-use product formulated with a registered active ingredient may only require a sub-set of the data outlined below to meet the minimum PMRA efficacy data requirements. To determine data requirements for a specific end-use product, the PMRA should be contacted to request a pre-submission consultation.

3.1 General Principles for Conducting Efficacy Trials and Satisfying Efficacy Data Requirements

Refer to Section 5 for specific guidance regarding the design and number of studies required to demonstrate efficacy for specific pests.

Note that the section on dose-determination studies and the application methods discussed below are targeted at skin-applied products, and should be modified as necessary for other types of products (for example, clip-on products, wrist bands).

Any differences from the general principles described below (for example, testing a product formulation which varies from the proposed formulation, testing pest species not found in Canada) must be justified with a scientific rationale.

(i) Protection standards. The applicant may choose either complete protection time (CPT) or duration of 95% repellency as the end-point for a trial and subsequent label claim. Either claim must be supported by trials which demonstrate a minimum duration of complete protection or repellency of 30 minutes. If a label claim of CPT is desired, the submitted trials must test CPT. If a label claim of repels is desired, the submitted trials must test the duration of 95% repellency.

(ii) Test materials. Repellent efficacy must be tested using the end-use formulation as registered or as proposed for registration. The storage and handling procedures for the test materials (for example, temperature, humidity etc.) should be described.

(iii) Use of Human Subjects. Personal insect repellent trials must be conducted on human test subjects. All studies submitted to the PMRA involving human test subjects, whether conducted in Canada or elsewhere, must be in accordance with the PMRA's Science Policy Note SPN2016-01 *Restricted Use of Human Studies with Pesticides for Regulatory Purposes*. Every effort must be made in the design of these studies to minimise risk to human subjects. Studies will be assessed for ethical conduct in addition to scientific acceptability.

(iv) Sample size. The sample size (in other words, number of human subjects used in a study) must be large enough to allow for sound statistical analysis.

(v) Representative sampling. Test subjects must include adults of various ages and both sexes. Prior to participation in repellent testing, recruited candidates should be tested for attractiveness to the target pest species. Testing must be conducted with a sample of subjects representative of the target population. If testing with a sample of subjects known to be unrepresentative of the target population is proposed, it must be justified.

(vi) Duration of study. Repellency testing must continue for a time period that is sufficient to assess the duration of protection provided by the repellent (in other words, at least as long as the proposed duration of protection), and until such time that failure of efficacy occurs for all or most test subjects. If subjects must be withdrawn before failure of efficacy occurs the validity of the results may be compromised. In this case, the study protocol must describe how premature withdrawal of subjects will be treated statistically. For products with an extended duration of repellency (for example, six hours), reliable results may be obtained by treating subjects up to several hours before test exposure, with exposures timed to coincide with periods of pest activity. This approach minimizes prolonged exposure of subjects to pests in the field, helps to reduce early withdrawal of subjects due to excessively long trials, and minimizes variability from non-target species landing on subjects.

(vii) Allocation of subjects to treatments. Test subjects should be randomly allocated to treatments. To minimise bias, subjects and investigators should be blinded to treatment allocation when possible so that they are not aware of the nature of the treatment. Multiple insect repellents may not be applied simultaneously to the same test subject, unless the intention is to study the effects of different insect repellent treatments in combination.

(viii) Pest species. Studies should be conducted on pest species that are established in Canada. Data on species that are not found in Canada may be considered supplemental. If studies conducted outside of Canada or the northern USA, are submitted in support of an application for registration, a rationale must be provided to justify how data generated on species that are not major pests in Canada can be extrapolated to Canadian pest species, (for example, how the pests evaluated show similar responses to pests in Canada).

(ix) Dose-Determination Studies. All test subjects participating in repellency testing must be treated with the test material at a standard dose rate in other words, “typical consumer dose”. The standard dose rate is typically expressed either by weight as mg/cm^2 of treated skin surface, or volumetrically as ml/cm^2 of treated skin surface. For example, in testing lotion formulations containing DEET (N,N-diethyl-meta-toluamide), a standard dose rate of 1 g per 600 cm^2 (equivalent to 1.67 mg per cm^2) has typically been used in repellency tests. For many repellents, this standard dose may be appropriate. Otherwise, a dose-determination study should be conducted. Recommended methods for selecting the standard dose rate depend in part on the active ingredient(s) and formulation(s) of the test material. A standard dose rate should be established as described below.

(a) Test Material. The end-use formulation should be used according to the proposed or registered label directions.

(b) Sample Size. The sample size (in other words, number of human subjects used in a study) must be large enough to allow for sound statistical analysis. Inclusion of equal numbers of male and female subjects is recommended.

(c) Treated Area Size and Preparation. The surface area of the test subject's forearm, from wrist to elbow, and/or leg, from ankle to knee, must be measured. The test surface must be washed with soap and water and dried before the test, and cleaned with soap and water and then a solution of ethanol or isopropyl alcohol between and after applications to remove any repellent. Subjects should self-treat with the repellent, which should be provided in the type of container and delivery system (for example, pump spray, aerosol spray, towelette, or lotion) and with the directions for use intended for commercial distribution. Each subject should apply enough repellent on the test surface to achieve thorough coverage, with the amount of repellent applied measured and recorded for each limb. The mean dose applied by each subject to each limb and the grand mean dose across all subjects should be calculated. This grand mean dose should be used as the standard dose for repellency testing, scaling it to the treated surface area of each subject's limb or limbs.

3.2 Other Components of the Value Package

Insight into the actual or potential benefits associated with the availability of a new use or new product can be used as a component of the value assessment. Information may be provided to show how and to what extent its registration would benefit Canadian users. The components of benefit information include elements such as a survey of alternatives, or social, health and safety benefits. The projected benefits of the proposed use should be described in relation to the pest problem. Quantitative estimates are preferable, although qualitative information is also useful.

4.0 Laboratory and Field Efficacy Studies

A combination of field and laboratory data may be submitted for most pests, however field data are required for certain pests (for example, mosquitoes and black flies), as they provide a better indication of product performance in a real world situation. Laboratory data are acceptable to determine dose-response information for a product, and to establish subject attractiveness to pests, while field data are best for establishing efficacy claims. Laboratory data are acceptable to demonstrate efficacy against pests which would be difficult or onerous to test in a field study (for example, ticks, fleas). Laboratory data should not form the bulk of the efficacy data package for claims against mosquitoes and black flies. Please see the specific data requirements for each pest to determine whether field, laboratory or a combination of both are appropriate for each pest claim (Section 5).

4.1 Laboratory Studies

(i) Insect Rearing. Insects should be reared according to a standard rearing technique, which must be described. The stage, age and sex of test insects used must be reported.

(ii) Test Cages and Insect Density. Tests must be conducted in cages that permit a clear view of the test surface from all angles. A standard test protocol for the insect species being tested must be consulted to determine appropriate density of test insects in cages. Insect density must be reported.

(iii) Treated Area Size and Preparation. The proposed product must be applied according to proposed label directions. The amount of product applied and location of application on the body must be reported. All subjects participating in repellency testing must be treated with the test material at a standard dose rate.

The human forearm is usually used as the test surface in laboratory studies on skin-applied products. Dosages are adjusted for larger or smaller than average arms, with the appropriate dose established by a dose-determination study. A glove and sleeve must be worn to protect the untreated hand and upper arm from attack. The test surface must be washed with soap and water and dried before the test, and cleaned with soap, water and alcohol afterwards.

(iv) Exposure period. Treated forearms are exposed to the test insects in the cages for a period of at least three minutes. These exposures are continued every 30 minutes until failure of efficacy is demonstrated (in other words, either the second event of efficacy failure occurs, or repellency falls below 95%).

(v) Untreated controls. An untreated control is required to be included in every study. There are two options for untreated controls: one is to have at least one completely untreated subject, the second is to treat one arm/leg of a subject and leave the other arm/leg untreated. Variation in subject attractiveness to target pests should be taken into account when completely untreated subjects serve as untreated controls (for example, by determining relative attractiveness). Ideally, each subject will act as an untreated control at least once during testing. When subjects serve as their own untreated controls, there must be sufficient pest pressure on control limbs. It must be noted that application of a volatile product on treated limbs may affect pest pressure on untreated limbs, resulting in underestimation of pest pressure. Having subjects serve as their own untreated control is not preferred, however, it may be necessary for reasons of practicality.

(vi) Positive control. It is recommended to include a standard repellent treatment of known effectiveness in each series of tests. Although 20% w/v solution of DEET in isopropyl alcohol has been used as the standard in Canada, the ASTM standard (ASTM E939 – 94, 2006) of 25% w/v DEET in ethanol is also acceptable. If the standard treatment does not perform as expected, the trial should be repeated.

(vii) Pest pressure. The readiness of the test insects to bite must be determined before each test by placing an untreated forearm in the test cage. Continued pest pressure must be confirmed at regular intervals throughout the testing period. Refer to Section 5 for required pest pressure for specific pests.

4.2 Field Studies

(i) Treated Area Size and Preparation. The proposed product must be applied according to proposed label directions. Registered products used as positive control treatments must be applied according to registered label directions. For both proposed and registered products, detailed information must be provided describing the application procedure (for example, quantity of product applied in ml/cm^2 or mg/cm^2 of treated skin surface, area of the body treated, description of dose-determination studies, etc.).

The surface tested is usually the bared forearms of each subject, from wrist to elbow, or the legs from ankle to knee, depending on the attack behaviour of the arthropods concerned. Non-test parts of the body should be protected by untreated bite-proof (for example, tight-weave) clothing, gloves and headnets, if necessary, to concentrate the attacks on the exposed areas. The appropriate dose should be established by dose-determination studies. Dosages are to be adjusted for unusually large or small subjects.

(ii) Exposure period. Continuous exposure of treated subjects throughout the exposure period is required. Reliable results may be obtained for extended periods of exposure by treating subjects up to several hours before exposure, with exposures timed to coincide with periods of pest activity. This approach minimizes prolonged exposure of subjects to pests in the field, helps to reduce early withdrawal of subjects due to excessively long trials, and minimizes variability from non-target species landing on subjects. For example, long-term repellency can be assessed by treating different subjects at different times (for example, zero, two, four, six, eight, or 10 hours before exposure), and then exposing all subjects at the same time when target pests are active. When this approach is used, care must be taken to prevent abrasion, wetting or any other circumstance which may remove the treatment from a subject's skin.

(iii) Untreated controls. An untreated control is required to be included in every study. There are two options for untreated controls: one is to have at least one completely untreated subject, the second is to treat one arm/leg of a subject and leave the other arm/leg untreated. Variation in subject attractiveness to target pests should be taken into account when completely untreated subjects serve as untreated controls (for example, by determining relative attractiveness). Ideally, each subject will act as an untreated control at least once during testing. When subjects serve as their own untreated controls, there must be sufficient pest pressure on control limbs. It must be noted that application of a volatile product on treated limbs may affect pest pressure on untreated limbs, resulting in underestimation of pest pressure. Having subjects serve as their own untreated control is not preferred, however, it may be necessary for reasons of practicality.

(iv) Positive control. It is recommended to include a standard repellent treatment of known effectiveness in each series of tests. Although DEET in isopropyl alcohol has been used as the standard in Canada, the ASTM standard (ASTM E939 – 94, 2006) of 25% w/v DEET in ethanol is also acceptable. If the standard treatment does not perform as expected, the trial should be repeated.

(v) Pest pressure. Pest pressure must be measured before treatment and intermittently throughout the course of the test by untreated control subjects. The test must only be conducted if the pest pressure on an untreated subject is above a certain minimum. Refer to Section 5 for required minimum pest pressure for specific pests.

(vi) Environmental conditions. The tests should preferably take place at those times of day or evening when biting activity is normally highest; however, tests may take place at any time when pest pressure is above the minimum requirements. It is recommended that temperature, humidity, wind speed, light intensity and general weather conditions at the time of the test be recorded for each test location for each day of testing, as this information may be useful to explain any unexpected results (for example, trial failure or departures from planned experimental procedure).

5.0 Requirements by Pest

Please see subsections 4.1 and 4.2 for general guidance in conducting laboratory and field studies respectively.

5.1 Mosquitoes

Minimum number and type of studies
A minimum of three well designed and well replicated (in other words, sufficiently replicated to provide meaningful statistical analysis) scientific studies is required. At least two of these must be field studies, but the third may be a laboratory study. Field studies should preferably be conducted either in Canada or the northern US. It is preferable that these studies are conducted in environmentally distinct locations, as this will maximise the variety of conditions and pest species present during the studies. Additional laboratory studies may be submitted as supplemental data, but cannot be used in lieu of field studies. Additional studies may be required if the minimum number of studies does not produce sufficient acceptable data to support the proposed use.

Minimum pest pressure
Field studies: Testing must not be conducted or continued unless at least five mosquitoes land on an untreated limb within five minutes of the start of exposure. Exposure of the untreated limb may be discontinued as soon as five mosquitoes land on it, even if this occurs before five minutes have passed.

Laboratory studies: If at any time fewer than ten mosquitoes land on the untreated control forearm within 60 seconds of the start of exposure, fresh mosquitoes should be added to all cages in the study, and their readiness to bite should be confirmed as stated above before repellency testing continues.

Minimum number of genera to be tested in field studies
At least three representative mosquito genera (for example, *Aedes*, *Culex* and *Anopheles*) must be tested over the course of the field studies. The target species should be considered major pests in Canada (for example, *Aedes vexans*, *Culex tarsalis*). A representative sample of pests must be collected during each field study and identified to species.

5.2 Ticks

Minimum number and type of studies
A minimum of three well designed and well replicated (in other words, sufficiently replicated to provide meaningful statistical analysis) scientific studies is required. These may be field or laboratory studies or a combination of both. Additional studies may be required if the minimum number of studies does not produce sufficient acceptable data to support the proposed use.

Recommended methodology
Laboratory studies: Each subject should place the fingers of one hand on a flat surface, with the elbow above the wrist and the forearm held at an angle of 30° or more to the surface. The subject's forearm should be treated with repellent from the elbow to a boundary line drawn an appropriate distance from the wrist. With a suitable instrument (such as an artist's paintbrush, forceps, or a cotton swab), ticks should be placed, one at a time, on the subject's wrist, at a release point marked three centimetres below the boundary of the treated area of the forearm. The tick should be oriented gently toward the treated area. After its first movement up the arm toward the margin of the treated area, each tick should be allowed three minutes to move across the boundary onto the treated area. A tick that crosses at least three centimetres into the treated area (toward the elbow) is reported as "not repelled". One that does not cross into the treated area, or that crawls into the treated area but immediately turns back or falls off, is reported as "repelled". Fresh ticks are exposed to the treated area one at a time, at regular intervals for the duration of the test.

While the general definition of a "crossing" is constant, the details must be optimised for each species and life stage of ticks to be tested. For example, a release point three centimetres distant from the treated area and scoring of a crossing when a tick moves at least three centimetres into the treated area have worked effectively in tests with nymphal *Ixodes scapularis*.

Required tick species
At least one representative Canadian tick species must be tested. Testing of deer or blacklegged tick *(Ixodes scapularis)* and/or American dog tick (*Dermacentor variabilis)* is recommended. Other acceptable Canadian tick species include Rocky Mountain wood tick (*D. andersoni*), groundhog tick (*I. cookei)* or western blacklegged tick (*I. pacificus*). Test arthropods should be identified by genus and species. The life stage tested must be one that is considered a human pest or nuisance. For example, for American dog ticks, adults should be used as nymphs do not feed upon humans, while for blacklegged ticks, both adults and nymphs readily bite humans therefore either stage is acceptable for testing.

5.3 Black flies

Minimum number and type of studies
A minimum of three well designed and well replicated (in other words, sufficiently replicated to provide meaningful statistical analysis) scientific studies is required. At least two of these must be field studies, conducted either in Canada or the northern USA. Additional studies may be required if the minimum number of studies does not produce sufficient acceptable data to support the proposed use. Biting studies are required for black flies.

Minimum pest pressure
Field studies: Testing must not be conducted or continued unless at least five black flies land and bite on an untreated limb within five minutes of the start of exposure.

Required black fly species
At least one species from a representative Canadian black fly genus (*Simulium* or *Prosimulium*) must be tested.

5.4 Other blood-feeding fly species: ceratopogonids (no-see-ums, punkies, biting midges), tabanids (for example, deer fly, horse fly), or stable flies

Minimum number and type of studies
A minimum of one well designed and well replicated (in other words, sufficiently replicated to provide meaningful statistical analysis) scientific study is required for each proposed group of blood-feeding flies. This may be either a laboratory or a field study. It may be possible to extrapolate from data generated on one or more groups to one or more other groups using sound, scientific rationales. Additional studies may be required if this study does not produce acceptable data to support the proposed use(s).

Minimum pest pressure
Field studies: Testing should not be conducted or continued unless at least one fly lands on and bites the untreated limb within five minutes of the start of exposure. Exposure of the untreated limb may be discontinued as soon as a fly lands on it and bites, even if this occurs before five minutes have passed. Biting is the preferred indication of pest pressure. However, if landing rather than biting is used as an indication of pest pressure, a rationale justifying this approach must be provided.

Laboratory studies: If at any time fewer than five flies land on the untreated control forearm within 60 seconds of the start of exposure, fresh flies should be added to all cages in the study, and their readiness to bite should be confirmed before repellency testing continues.

5.5 Fleas

Minimum number and type of studies
A minimum of one well designed and well replicated (in other words, sufficiently replicated to provide meaningful statistical analysis) scientific laboratory study is required. Additional studies may be required if this study does not produce acceptable data to support the proposed use.

Minimum pest pressure
Laboratory studies: Before exposing a treated forearm, an untreated forearm should be inserted into the container and exposed to fleas for up to 60 seconds to verify landing pressure. If no landings occur within 60 seconds of the start of exposure, additional fleas should be added to the cage until one landing occurs within 60 seconds. The forearm should be removed from the test container as soon as one landing has occurred.

5.6 Chiggers

Minimum number and type of studies
A minimum of one well designed and well replicated (in other words, sufficiently replicated to provide meaningful statistical analysis) scientific study is required. Additional studies will be required if this study does not produce acceptable data to support the proposed use.

Recommended methodology
Please see the recommended methodology for ticks. The same methodology is recommended for chiggers.

6.0 Preparation of the Value Package

(i) Research authorisations. A research authorisation must be obtained from the PMRA prior to conducting any studies in Canada involving human subjects. An institutional review board (IRB) report is required. It is the researcher's responsibility to obtain an IRB report for the purpose of ensuring ethical conduct of the research. The IRB report and the experimental protocol must be submitted to the PMRA when applying for a research authorisation. For further information on use of human test subjects see PMRA publication SPN2016-01 (*Restricted Use of Human Studies with Pesticides for Regulatory Purposes).*

(ii) Pre-submission Consultation. Applicants are encouraged to discuss with the PMRA the proposed uses of their product and the potential data requirements and the manner by which they can be addressed prior to submitting an application for registration. The pre-submission consultation process enables applicants to obtain guidance for preparing a complete and concise submission package that addresses all of the proposed label claims, and contributes to an efficient review process.

(iii) Bridging information (trials, rationales and data). Bridging information from one product to another may be acceptable if the products have the same active ingredient and are similar in formulation. In order to enable bridging from one product to another, efficacy of the products is tested in a side-by-side comparison to demonstrate that the proposed product provides a level of efficacy equivalent to the comparison product. Once comparable efficacy is established, bridging information may serve to reduce the amount of new data to be generated. All regulations applicable to data protection must be followed.

(iv) Acceptable pest names. Pest names must be specific and representative of the pest claim. Vague, ambiguous or incorrect pest names are not permitted on personal insect repellent labels. Pest names which are not permitted include, but are not limited to: "biting flies", "biting insects", "bugs", "flies", "gnats", "midges" and "sand flies" from the English labels; "chiques", "cousins", "frelons", "insects piquants", "mites", "moucherons", "mooches", "mouches piquants", "mouches des sables", "phlebotomes", "thrips" and "tique brune du chien" from the French labels.

7.0 References

ASTM E939 - 94(2006) Standard Test Method of Field Testing Topical Applications of Compounds as Repellents for Medically Important and Pest Arthropods (Including Insects, Ticks, and Mites): I Mosquitoes

ASTM E951 - 94(2006) Standard Test Methods for Laboratory Testing of Non-Commercial Mosquito Repellent Formulations On the Skin

United States Environmental Protection Agency (2010) OPPTS 810.3700 Product Performance Test Guidelines: Insect Repellents to be Applied to Human Skin

World Health Organisation 2009. Guidelines for Efficacy Testing of Mosquito Repellents for Human Skin