Read This First

Completed Skin Irritation and Sensitization Patch Tests

a. Read this first: annotated bibliography

b. Redacted supplement responding to EPA Questions. This document, submitted March 2, 2007, addresses EPA questions raised in emails of November 16, 2006 and January 30, 2007. The questions and the responses concern both the 48-h Irritation Study and the Repeated Insult Patch Test (RIPT) for sensitization. Although multiple copies were submitted directed to different EPA case files, their content is identical, and only one copy is provided here.

WHO Evaluations of Repellent Active Ingredients. These three documents, from the series "WHO Specifications and Evaluations for Public Health Pesticides", address the three principal active ingredients used in repellents. They may assist the members of the HSRB to understand the properties and effects of these materials. Because the composition of the products tested in these patch studies is subject to a claim of confidentiality EPA cannot identify the active ingredient in the products, but it does appear in currently registered repellent products.

c. WHO Picaridin Evaluation October 2004

d. WHO IR3535 Evaluation April 2006

e. WHO DEET Specification December 1999. WHO has issued full evaluations in the format used for IR3535 and Picaridin only since 2002. This is the only specification found on their website for DEET.

f. EPA DEET RED Fact Sheet April 1998. This document, issued by EPA concurrently with the DEET Reregistration Eligibility Document (RED), contains more information about the properties of DEET than is included in the WHO specification.

48-hour Irritation Study

An animal test of acute dermal irritation is a standard EPA requirement for registration of end-use pesticide products. This human study was submitted as an alternative to the required animal test. It was conducted with five test materials; separate reports were submitted for two of the five, identified here as Product A and Product B. No information is available to EPA concerning the remaining three test materials.

a. **Redacted 48-h Irritation Product A.** This is the revised redaction reflecting the narrowing of the scope of CBI claims to cover only the sponsor, the product name, and the product composition. This document reports results only for Product A; it is otherwise identical to the report below.

b. **Redacted 48-h Irritation Product B.** This is the revised redaction reflecting the narrowing of the scope of CBI claims to cover only the sponsor, the product name, and the product composition. This document reports results only for Product B; it is otherwise identical to the report above.

c. **Science Review: 48-h Irritation.** This review addresses the common elements in the two reports, and the results for both products A and B.

d. **Ethics Review: 48-h Irritation 3/15/07.** This review addresses the ethical conduct of the study, without regard to the specific products tested. Page references are to the redacted report for Product A.

Repeated Insult Patch Test (RIPT) Study

An animal test of skin sensitization is a standard requirement for registration of end-use pesticide products. This human study was submitted as an alternative to the required animal test. It was conducted as two sub-studies, one involving a total of 14 test materials and the other involving 15 test materials. At least Products A and B were tested in both sub-studies; no information is available to EPA concerning the remaining test materials. Each of the submitted reports covers one test material, including the results of both sub-studies.

a. Redacted RIPT Product A. This is the revised redaction reflecting the narrowing of the scope of CBI claims to cover only the sponsor, the product name, and the product composition. This document reports results only for Product A; it is otherwise identical to the report below.

b. Redacted RIPT Product B. This is the revised redaction reflecting the narrowing of the scope of CBI claims to cover only the sponsor, the product name, and the product composition. This document reports results only for Product B; it is otherwise identical to the report above.

c. Science Review: RIPT Study. This review addresses the common elements in the two reports, and the results for both products A and B.

d. Ethics Review: RIPT Study 3/15/07. This review addresses the ethical conduct of the study, without regard to the specific products tested. Page references are to the redacted report for Product A.

Supplemental Resources. The EC memorandum explains how the EC assesses consumer products for skin sensitization potential, using both human and animal studies. The OECD issue paper summarizes current concerns among regulatory agencies about methods for assessing sensitizers.

e. European Commission Scientific Committee on Consumer Products (2005) Memorandum: Classification and categorization of skin sensitizers and grading of test reactions.

f. OECD Scientific Issue Paper on Strong vs. Weak Sensitizers.