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B. Electronic Access

You may access this **Federal Register** document electronically through the EPA Internet under the "**Federal Register**" listings at <http://www.epa.gov/fedrgstr/>. You may also obtain copies of test guidelines from the EPA Internet Home Page at <http://www.epa.gov/opptsfrs/home/guidelin.htm>.

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III. What Action is EPA Taking?

EPA is announcing the availability of the revised final test guideline for Series 870-Health Effects Test Guideline, OPPTS 870.2600 Skin Sensitization. In 1996, the SAP reviewed the use of the Local Lymph Node Assay (LLNA) as a screening method in the Agency's harmonized test guideline OPPTS 870.2600 Skin sensitization. The LLNA is a test method for assessing the potential allergic contact dermatitis (skin sensitization) of chemicals and compounds. In January 2001, the assay was found to be scientifically valid by ICCVAM peer review (Ref. 1) as an alternative method, where applicable, to the traditional guinea pig tests (Guinea Pig Maximization Test (GPMT) (Ref. 2) and Buehler tests (Ref. 3)) which are currently accepted by regulatory authorities. This alternative test also provides animal welfare advantages. The Agency has now revised its harmonized test guideline OPPTS 870.2600 Skin Sensitization to incorporate the LLNA for use as an alternative method for assessing skin sensitization under the appropriate circumstances. The availability of the draft revised final test guideline OPPTS 870.2600 was announced in the **Federal Register** on September 12, 2001 (66 FR 47478) (FRL-6801-6). The draft revised guideline was reviewed by EPA's SAP in a public meeting on December 11,

2001, and recommendations of the SAP were incorporated into the revised test protocol. The guideline has been harmonized with OECD test guideline 429 Skin Sensitization: Local Lymph Node Assay which was adopted by OECD on April 24, 2002. It should be recognized that there are certain testing situations that may necessitate the use of traditional guinea pig tests. The LLNA may not be appropriate for all types of test materials, such as certain metallic compounds, high molecular weight proteins, strong dermal irritants and materials that do not sufficiently adhere to the ear for an acceptable period of time during treatment. When using the LLNA, particular care should be taken to ensure that hydrophilic materials are incorporated into a vehicle system that wets the skin and does not immediately run off. Thus, wholly aqueous vehicles or test materials and runny liquids are to be avoided. In all instances, the tester must document that appropriate techniques were used to facilitate adherence to the mouse ear for an adequate exposure duration. It may be possible to use the LLNA to test some of these materials if appropriate techniques are used to facilitate adherence. In situations for test materials where the LLNA is not applicable or may provide unreliable or problematic results, the GPMT tests are recommended. Although the LLNA, GPMT, or Buehler tests are considered to be acceptable tests, it is recognized that other tests may give useful results. If other tests are used, the investigator must provide justification/reasoning for use of other procedures and methods and protocols must be provided. A positive and negative control group must be included in each test.

IV. Are There Any Applicable Voluntary Consensus Standards That EPA Should Consider?

This notice of availability does not involve a proposed regulatory action that would require the Agency to consider voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note). Section 12(d) of NTTAA directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. The NTTAA requires EPA to provide an explanation to

Congress, through Office of Management and Budget (OMB), when the Agency decides not to use available and applicable voluntary consensus standards when the NTTAA directs the Agency to do so.

V. References

The following references are cited in this document.

(1) *The Murine Local Lymph Node Assay: A Test Method for Assessing the Allergic Contact Dermatitis Potential of Chemicals/Compounds*. Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM), National Institutes of Environmental Health Sciences, NIH Publication No. 99-4494 (1999). (Document available at <http://iccvam.niehs.nih.gov/methods/lnadocs/lnarep.pdf>.)

(2) Magnusson, B. Identification of contact sensitizers by animal assay. *Contact Dermatology* 6:46 (1980).

(3) Buehler, L.V. Occ1usive patch method for skin sensitization in guinea pigs: the Buehler method. *Food and Chemical Toxicology* 32:97101 (1994).

List of Subjects

Environmental protection, Chemical testing, Test guideline.

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ENVIRONMENTAL PROTECTION AGENCY

[FRL-7473-5]

National Electric Coil Superfund Site; Notice of Proposed Settlement

AGENCY: Environmental Protection Agency.

ACTION: Notice of proposed settlement.

SUMMARY: The United States Environmental Protection Agency is proposing to enter into an administrative settlement with responsible parties for response costs pursuant to section 122 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), 42 U.S.C. 9622(h)(1) concerning the National Electric Coil Superfund Site located in Dayhoit, Harlan County, Kentucky. EPA will consider public comments on the proposed settlement for thirty (30) days. EPA may withdraw from or modify the