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U.S. Department of Transportation
Research and Special Programs Administration

400 Seventh Street, S.W.
Washington, D.C. 20590

JUN 4 1996

DOT-E 11082
(FIRST REVISION)

EXPIRATION DATE: May 31, 1998

1. GRANTEE: Advanced Tissue Sciences, Inc., La Jolla, California

2. PURPOSE AND LIMITATION: For the offering of hazardous materials for transportation in commerce, this exemption authorizes the use of an in vitro classification test method for the determination of skin corrosivity as an alternative to the in vivo procedure specified in the Hazardous Materials Regulations. This exemption provides no relief from any regulations other than as specifically stated herein.

3. REGULATORY SYSTEM AFFECTED: 49 CFR Parts 106, 107 and 171-180.

4. REGULATIONS FROM WHICH EXEMPTED: 49 CFR Part 107, Appendix B to Subpart B; 173.136(a)(1) and 173.137.

5. BASIS. This exemption is based on Advanced Tissue Sciences' application of April 3, 1996 submitted in accordance with 49 CFR 107.105.

6. HAZARDOUS MATERIALS:

   a. The following types of materials and products (except those described in paragraph 6.b.) containing these materials may be tested and classified as specified by this exemption:

      i. Acids, inorganic and organic.
      ii. Bases, inorganic and organic.
      iii. Quaternary ammoniums
      iv. Surfactants
      v. Silicates
      vi. Hypochlorites

   b. The following types of materials and products containing these materials may not be tested and classified by use of this exemption:

      i. Amines
      ii. Halogen/halogen derivatives
      iii. Other materials potentially corrosive to skin not specifically identified in paragraph 6.a.

No Renewal
Not Active

7. SAFETY CONTROL MEASURES:

a. As an alternative to the procedure specified in §173.136(a)(1), the corrosivity and packing group of a material described in Paragraph 6.a. above may be determined in accordance with the Direction for Use: Skin^{2TM} ZK1350 for Skin Corrosion Testing submitted with your letter dated March 30, 1994, and the Application of the test method specified in Section 4.4A of Advanced Tissue Sciences' application dated July 29, 1993.

b. If the results of the tests of a material indicate a material is non-corrosive, standard hematoxylin and eosin (H&E) histopathology must be used to confirm the material is non-corrosive. A material may only be classified non-corrosive if no identifiable alterations in the H&E anatomy of the tissue specimens are apparent. If H&E histopathology is not used, or indicates a material is corrosive, the material must be further evaluated in accordance with §173.136.

c. If the results of tests of a material are inconclusive according to the criteria specified in the application, the material must be further evaluated in accordance with §173.136.

d. No person may apply the test method authorized by this exemption unless that person understands and can apply the Directions for Use of Skin^{2TM} ZK1350 For Skin Corrosion Testing and is qualified in H&E histopathology if used.

8. SPECIAL PROVISIONS.

a. In addition to the holder of this exemption, this exemption authorizes the use of the Skin^{2TM} ZK1350 test method for the determination of skin corrosivity by any person or class of persons, subject to the terms specified herein. Each person who performs testing with Skin^{2TM} ZK1350 must maintain a current copy of this exemption and the Direction for Use of Skin^{2TM} ZK1350 For Skin Corrosion Testing at each facility where the tests are performed for the purpose of determining the hazard-class and packing group of a material transported in commerce. Test results used to classify a material under the terms of this exemption must be retained by the person making the classification and made available to a representative of Department of Transportation upon request.

b. A current copy of this exemption must be retained by each person initially offering a hazardous material for transportation under this exemption.

c. Packages containing corrosive materials, classed and assigned packing groups as authorized by this exemption, may be offered and reoffered for transportation and transported in the same manner as required for corrosive materials classed according to §173.136(a)(1). Appendix B to Subpart B of Part 107 and §172.203(a) do not apply unless another exemption is involved requiring the display of an exemption number.

9. MODES OF TRANSPORTATION AUTHORIZED. Motor vehicle, rail freight, cargo vessel, passenger carrying aircraft, cargo only aircraft.

10. MODAL REQUIREMENTS: None as a condition of this exemption.

11. COMPLIANCE. Failure by a person, operating under the authority of this exemption, to comply with a term or condition prescribed herein or any applicable regulation of 49 CFR Parts 106, 107, and 171-180 may result in suspension of this exemption, loss of a person's authority to use this exemption and may subject the person to enforcement action under the Hazardous Materials Transportation Act and the Hazardous Materials Regulations. (See 49 CFR 171.2)

12. REPORTING REQUIREMENTS. Only as required under 49 CFR Part 107 to renew or revise this exemption.

Issued at Washington, D.C.:

JUN 4 1996

Alan I. Roberts
Associate Administrator
for Hazardous Materials Safety

(DATE)

Address all inquiries to: Associate Administrator for Hazardous Materials Safety, Research and Special Programs Administration, Department of Transportation, Washington, D.C. 20590-0001, Attention: DHM-31.

The original of this exemption is on file at the above office. Photo reproductions and legible reductions of this exemption are permitted. Any alteration of this exemption is prohibited.

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