

Guidance Relative to the Classification of Corrosive Materials

Based on recent revisions to the U.S. Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180) of *in vitro* skin corrosion testing protocols, the Pipeline and Hazardous Materials Safety Administration's (PHMSA) Office of Hazardous Materials Safety is working to ensure that all information relevant to the use of such test methods is available immediately to stakeholders via its website.

The attached guidance issued in conjunction with a Final Rule published in the Federal Register on January 19, 2011 [76 FR 3308] under Docket No. PHMSA-2009-0126 (HM-215K) is the most currently available and is provided for the benefit of all concerned parties.

Section 173.137

Section 173.137 establishes test criteria and packing group assignments for Class 8 (corrosive) material. Since 1993, PHMSA has authorized under the terms of a special permit (*i.e.*, DOT-SP 10904) an *in vitro* test method (available commercially as Corrositex®) as an alternative form of testing to that specified in the HMR, which is based on live animal test results, to determine the corrosivity of certain materials. Materials authorized for analysis using the alternative test method include acids (and their derivatives), acyl halides, alkylamines and polyalkylamines, bases, chlorosilanes, metal halides, and oxyhalides.

The UN COE recently recognized and adopted *in vitro* test methods in the UN Model Regulations as an alternative form of testing to that specified in OECD Guideline for Testing of Chemicals, Number 404, "Acute Dermal Irritation/

Corrosion.” The following alternative *in vitro* test methods include OECD Guidelines for the Testing of Chemicals:

- No. 430, “*In Vitro* Skin Corrosion: Transcutaneous Electrical Resistance Test (TER)” (2004);
- No. 431, “*In Vitro* Skin Corrosion: Human Skin Model Test” (2004); and
- No. 435, “*In Vitro* Membrane Barrier Test Method for Skin Corrosion” (2006).

A positive test result under *in vitro* methods 430 and 431 may be used to determine corrosivity for transportation purposes but cannot be used to determine the PG assignment. A negative result for corrosivity under *in vitro* methods 430 and 431 can preclude further testing to determine PG assignment using method 404, the current OECD Guideline involving *in vivo* testing, or method 435, the newly adopted OECD Guideline involving *in vitro* testing.

Based on the adoption of three new OECD guidelines for the *in vitro* testing of materials for corrosivity in the UN Model Regulations and through encouragement from PETA to adopt these new test methods in a petition for rulemaking (P-1550), we proposed to adopt such guidelines as matter incorporated by reference (IBR) in §§ 171.7 and 173.137 of the HMR.

In response to our proposal to incorporate several *in vitro* test methods for determination of corrosivity, PHMSA has received over 900 comments supporting the proposal, including a comment from PETA. We received no opposition. Therefore, we are adopting the OECD Guideline Test Nos. 430, 431, and 435, and revising Test No. 404 as proposed. Further, PETA urged PHMSA to facilitate access to DOT-SP 10904 through our Web site until such a time that this final rule becomes effective, and requested that PHMSA remove letters of interpretation that they believe recommend the use of *in vivo* testing even though alternative *in vitro* testing is available.

With regard to PETA’s additional requests, they are beyond the scope of this rulemaking. However, we note that in prior correspondence with PETA, PHMSA has indicated that information about DOT-SP 10904 can be obtained by entering “Corrositex” in the search feature of the PHMSA Office of Hazmat Safety Web site. Also, the special permit may be accessed by entering “10904” in the search feature on our special permits Web site or by conducting a group number search.

We agree with PETA that non-live animal testing should be used where available and encourage shippers to use the *in vitro* test methods to determine the classification of a material as

corrosive and assignment of a packing group. We also remind shippers that historical data may also be used to classify a material in accordance with § 173.136(c). Thus, in this final rule we are revising § 173.136(a) to codify the authorization to use *in vitro* test methods and to highlight the availability of classifying a material based on historical data.