



U.S. Department  
of Transportation

Pipeline and Hazardous Materials  
Safety Administration

1200 New Jersey Avenue SE  
Washington DC 20590

NOV 28 2014

Mr. David Dietrich  
Dietrich Engineering  
P.O. Box 7  
Cool, CA 95614

Ref. No.: 14-0153

Dear Mr. Dietrich:

This responds to your July 28, 2014 letter requesting clarification of the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180) applicable to a self-heating material classified as a Division 4.2 spontaneously combustible material. In your letter, you state that you have a client, Gesellschaft fuer Gefahrgut m.b.H., in Romanshorn, Switzerland, that is arranging import of a pharmaceutical comprised of an iron-based phosphate binder for kidney disease patients. You further state that this material has been classified as "UN3088, Self-heating solid, organic, n.o.s, 4.2, PG II." Finally, you reference 5.2.2 of Appendix 6 (Screening Procedures) of the United Nations (UN) Manual of Tests and Criteria which specifies that for *Substances which may be liable to spontaneous combustion (Division 4.2)*:

The classification procedure for *self-heating substances* need not be applied if the results of a screening test can be adequately correlated with the classification test and an appropriate safety margin is applied. Examples of screening tests are:

- a) The Grewer Oven test (VDI guideline 2263, part 1, 1990, *Test methods for the Determination of the Safety Characteristics of Dusts*) with an onset temperature 80 K above the reference temperature for a volume of 1 l (33.3.1.6);
- b) The Bulk Powder Screening Test (Gibson, N. Harper, D.J. Rogers, R. *Evaluation of the fire and explosion risk in drying powders*, Plant Operations Progress, 4 (3), 181-189, 1985) with an onset temperature 60 K above the reference temperature for a volume of 1 l (33.3.1.6).

Your questions are paraphrased and answered below.

Q1: You ask whether Appendix 6 is permitted to be used under the HMR?

A1: The answer is yes. As provided in § 171.7(dd) of the HMR, the "UN Recommendations on the Transport of Dangerous Goods, Model Regulations (UN Recommendations), 17th revised edition, Volumes I and II (2011)," and the "UN Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria (UN Manual of Tests and Criteria), Fifth revised edition, amendment 1 (2011)" are matters incorporated by reference in the HMR. Therefore, Appendix 6 to the UN Manual of Tests and Criteria is appropriate for use under the HMR.

Q2: You ask whether Screening Procedure 5.2.2 of Appendix 6 can be considered an alternative "classification method"?

A2: The answer is yes, but with the following caveats. As required by § 173.22 of the HMR, it is the shipper's responsibility to properly class a hazardous material. This Office generally does not perform this function. Appendix 6 to the UN Manual of Tests and Criteria provides the screening procedures industry uses to identify the hazard potential of raw materials, reactive mixtures and intermediates, products, and by-products. The use of such procedures is essential to ensure safety during research and development and to ensure that new products and processes are as safe as possible. These procedures usually consist of a combination of a theoretical appraisal and small-scale tests, and in many cases, enable an adequate hazard evaluation to be carried out without the need for larger scale classification tests. This reduces the quantity of material required, lessens any detrimental effect on the environment, and minimizes the amount of unnecessary testing.

The purpose of Appendix 6 to the UN Manual of Tests and Criteria is to present examples of screening procedures. It should be used in conjunction with any screening procedures given in the introductions to the relevant test series. With the specified safety margin, the results from the screening procedures adequately predict when it is not necessary to perform the classification test as a negative result would be obtained. They are presented for guidance and their use is not compulsory. Other screening procedures may be used provided that adequate correlation has been obtained with the classification tests on a representative range of substances and there is a suitable safety margin.

If you perform the Grever Oven test or the Bulk Powder Screening test as provided in 5.2.2 of Appendix 6 of the UN Manual of Tests and Criteria and the results of those screening tests can be adequately correlated with the classification test and an appropriate safety margin, then the classification procedure for self-heating substances need not be applied. However, depending on the results of those tests, a packing group could still need to be determined or the material you are classifying may meet the definition of another hazard class altogether.

Q3: You ask whether a Special Permit is required?

A3: The answer is no.

I trust this satisfies your inquiry. Please contact us if we can be of further assistance.

Sincerely,



T. Glenn Foster  
Chief, Regulatory Review and Reinvention Branch  
Standards and Rulemaking Division

Nickels  
173.125  
Packaging  
14-0153

Dietrich Engineering  
P.O.Box 7  
Cool, CA 95614  
28 July 2013

U.S. Dept. of Transportation  
PHMSA East Bldg, 2nd Floor  
1200 New Jersey Ave. SE  
Washington, DC 20590

Attn: Office of Standards  
Re: Inquiry Letter

To whom it may concern:

On 23 July 2014, I spoke to Mr. Matt Nichols about this matter. On 25 July I spoke to Ms. Diane Lavallo about special permits. Both staff of PHMSA were knowledgeable and helpful. Because the technical questions are so complicated, I am requesting a written clarification.

This inquiry involves a conflict between 49CFR and the UN classification of dangerous goods. My client, Gesellschaft fuer Gefahrgut m.b.H., in Romanshorn, Switzerland, seeks to arrange import of a pharmaceutical based on UN3088, a solid, iron-based phosphate binder for kidney disease patients. My client's UN3088 is Division 4.2, PG-II, according to the UN Manual of Tests as required in 49CFR173.125. That's the key, both 49CFR and UN regulations specify the same lab test manual.

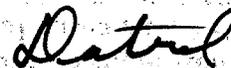
Appendix 6 of that same UN Manual allows an alternative method of classification for Division 4.2 in that:

"5.2.2. The classification procedure for self-heating substances need not be applied if the results of a screening test can be adequately correlated with the classification test and an appropriate safety margin is applied. Examples of screening tests are (...Grewer Oven Test and Bulk Powder Screening Test)."

That gets to my question. I do not find Appendix 6 mentioned in 49CFR. Is that alternative classification method available in the PHMSA view? Is a special permit required or is there a simpler way?

Thank you for your attention to this urgent matter.

Sincerely,



David Dietrich, PE

email  
modesto3@gmail.com