



U.S. Department
of Transportation

**Pipeline and Hazardous
Materials Safety
Administration**

1200 New Jersey Avenue, SE
Washington, DC 20590

APR 22 2019

Chaz Barit, Pharm.D.
VA Pacific Islands Health Care System (119)
459 Patterson Road
Honolulu, HI 96819

Reference No. 18-0131

Dear Dr. Barit:

This letter is in response to your October 11, 2018, letter requesting clarification of the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180) applicable to ground and/or air shipments of pharmaceuticals throughout the Hawaiian Islands. Specifically, you provided safety data sheets that describe two products and ask how they should be transported. You note in your letter that the products described meet no other hazardous material classification (*e.g.*, marine pollutant). We have paraphrased and answered your questions below.

You describe Product 1 as a gel that contains 20% isopropanol, has a flashpoint of 18.5 °C (65.3 °F), and is classed as “UN1987, Alcohols, n.o.s., Class 3 (flammable liquid), Packing Group (PG) III.” You asked the following five questions about this material.

- Q1. You ask if Product 1 can be reclassified as a combustible liquid (alcohol < 24%) in conformance with § 173.150(e)(1) for transportation by aircraft.
- A1. Yes. An aqueous solution containing 24% or less alcohol by volume and no other hazardous materials may be reclassified as a combustible liquid regardless of the mode of transport provided it complies with § 173.150(e)(1). Additionally, combustible liquids transported in “non-bulk” packagings—as defined in § 171.8—are only subject to the HMR if they meet the definition of a hazardous substance, hazardous waste, or marine pollutant (*see* § 173.150(f)(2)).
- Q2. You ask if it is necessary to consider the flashpoint (referenced in § 173.150(f)) of Product 1 if it is reclassified in conformance with the exception in § 173.150(e)(1).
- A2. No. The subparagraphs in § 173.150(e) stand alone. Therefore, for the reasons discussed in Answer A1, an aqueous solution containing 24% or less alcohol by volume and no other hazardous material may be reclassified as a combustible liquid. If the solution contains 50% or more water, it is excepted from the HMR (*see* § 173.150(e)(2)).

Q3. You seek confirmation of your understanding that Product 1 is excepted from the HMR when reclassified as a combustible liquid and placed in a non-bulk packaging provided the product is not a hazardous substance, hazardous waste, or marine pollutant.

A3. Your understanding is correct. See Answer A1.

Q4. You ask if Product 1 must qualify for the exception in § 173.150(f)(1) before it can be considered for the exception prescribed in paragraph (f)(2) of this section.

A4. No. See Answer A2.

Q5. You seek confirmation of your understanding that Product 1 is not subject to the HMR and may be transported in commerce to patients in the State of Hawaii by railcar, motor vehicle, or aircraft.

A5. Your understanding is correct. See Answer A1.

You describe Product 2 as a gel that contains 55–70% ethanol, has a flashpoint of 21.7 °C (71.06 °F), and is classed as “UN1170, Ethanol solution, Class 3, PG II.” You asked the following two questions about this material.

Q6. You ask if Product 2 is excepted from the HMR under § 173.150(g)(1).

A6. Provided all the applicable requirements in § 173.150(g)(1) are met, the answer is yes.

Q7. You seek confirmation of your understanding that Product 2 is not subject to the HMR and may be transported in commerce to patients in the State of Hawaii by railcar, motor vehicle, or aircraft provided the shipment complies with §§ 173.150(g)(1)(i)–(iii) and 173.150(g)(3)(i).

A7. Your understanding is correct. See Answer A6.

I hope this information is helpful. Please contact us if we can be of further assistance.

Sincerely,



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

Edmonson

18-0131

Dr. Chaz Barit, Pharm.D.
VA Pacific Islands Health Care System (119)
459 Patterson Rd
Honolulu, HI 96819
October 11, 2018

U.S. DOT
PHMSA Office of Hazardous Materials Standards
Attn: PHH-10
East Building
1200 New Jersey Avenue, SE.
Washington, DC 20590-0001

Dear U.S. DOT:

VA Pacific Island's Health Care System Pharmacy provides medications through shipping in commerce (non-bulk packaging), that may be considered hazardous in ground or air transport, throughout the islands in the state of Hawaii. Therefore, we are requesting a clarification of the applicable regulations with several scenarios below, with a response in a formal letter of interpretation.

It is understood that it is the shipper's responsibility to properly classify a hazardous material, and that the PHMSA Office does not perform that function. However, we appreciate your guidance with the following questions.

Product #1 in question: Diclofenac 1% gel

Diclofenac 1% gel is a product that contains 20% Isopropanol (CAS# 67-63-0). The MSDS for this product states its classification as Class 3, UN 1987, Alcohols n.o.s, flash point 18.5°C, PG-III. There are no other classifications associated with this product (ie, marine pollutant, etc). In looking to ship this product via air, we determined the applicability of 173.150(e)(1) to reclassify this product as a combustible liquid (alcohol <24%). Is this a correct interpretation of the CFR based on the product information provided? Do we need to consider the flash point if we have already reclassified the product per 173.150(e)(1)?

Continuing the latter, after reclassifying the Diclofenac 1% gel product as a combustible liquid we have determined that 173.150(f)(2) applies in that the requirements in this subchapter do not apply to a material classed as a combustible liquid in a non-bulk packaging unless the combustible liquid is a hazardous substance, a hazardous waste, or a marine pollutant. It is our understanding that the product is not applicable via 173.150(f)(1) due to its flashpoint, but we have already determined to

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reclassify it as previous mentioned. Is this a correct interpretation and use of the CFR? Does the product need to follow 173.150(f)(1) first to be considered for 173.150(f)(2)?

Continuing the latter, it is our interpretation that shipping this product is not subject to the regulations of this subchapter, therefore we are able to ship this product in commerce to patients in the state of Hawaii via ground or air without full regulation set forth by the CFR. Is that an accurate interpretation?

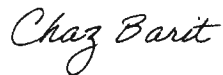
Product #2 in question: Testosterone 1.62% gel

Testosterone 1.62% gel is a product that contains 55-70% Ethanol (CAS# 64-17-5). The MSDS for this product states its classification as Class 3, UN1170, Ethanol Solution, PG-III. There are no other classifications associated with this product (ie, marine pollutant, etc). In looking into the CFR, we have determined that this product is excepted from the HMR per 173.150(g)(1) as it contains no more than 70% ethanol (ethyl alcohol). Is this a correct interpretation of the CFR?

Continuing the latter, it is our interpretation that since this product is excepted from the HMR, we are able to ship this product in commerce to patients in the state of Hawaii via ground or air without full regulation set forth by the CFR, provided we follow the requirements of 173.150(g)(1)(i-iii) and 173.150(g)(3)(i). Is that an accurate interpretation?

We appreciate the time and attention towards our request and look forward to your response. If you have questions please feel free to contact me at 808-433-4979.

Sincerely,



Dr. Chaz Barit, Pharm.D.
VA Pacific Islands Health Care System (119)