

October 18, 1999

Ms. Sonia Christensen Stewart
Bayer Business Group Diagnostics
4560 Horton Street, Mailstop W-810
Emeryville, CA 94608

Ref. No. 99-0231

Dear Ms. Stewart:

This is in response to your letter dated August 19, 1999, inquiring whether your product, "Saccomanno's Fixative", which is a Class 3, Packing Group II material, qualifies for shipment as a Consumer commodity, ORM-D, under the Hazardous Materials Regulation (49 CFR Parts 171-180).

You stated that the fixative product is composed of alcohols (50%), methyl isobutyl ketone, and a non-hazardous ingredient. This product will be packaged in quantities of 60 ml per inner receptacle in conformance with the limited quantity provision in § 173.150 (b)(2). The product is primarily used by medical professionals and their patients as a preservative for diagnostic specimens and is not directly distributed for retail sale.

The definition of a consumer commodity in § 171.8 includes a material that is packaged and distributed in a form suitable for retail sale for consumption by individuals for purposes of personal care or household use even if not specifically intended. This definition includes drugs and medicines. It is our opinion that your fixative product, in the first transportation scenario from the medical professional to the patient, qualifies for shipment as "Consumer commodity, ORM-D."

In the second scenario, you state that the patient places a sputum sample in the fixative product, packages the sample in a triple package with absorbent material per your instructions, and then offers the sample for transportation by common carrier to a medical center for diagnosis. In this scenario, the material being offered for transportation does not qualify as a consumer commodity. The material may be transported under the limited quantity provisions in § 173.150(b). Also, you may consider reducing the quantity to 30 ml per inner receptacle and offering the material for transportation as a small quantity in accordance with the conditions prescribed in § 173.4 or submitting an application for an exemption under § 107.105 to offer a greater quantity of material.

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

Sincerely,

Hattie L. Mitchell
Chief Regulatory Review and Reinvention
Office of Hazardous Materials Standards

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