U.S. Department of Transportation

Pipeline and Hazardous Materials Safety Administration

1200 New Jersey Ave, SE
Washington, D.C. 20590

JAN 12 2011

Mr. David Schaper
Senior Manager Environmental Health and Safety
Solstice Neurosciences
701 Gateway Boulevard, Suite 250
South San Francisco, CA 94080

Reference No. 09-0151

Dear Mr. Schaper:

This is in response to your e-mail to this Office, and telephone conversation with a member of my staff, requesting clarification of the requirements for determining if your company's licensed drug product, "Myobloc," a dilute Type B botulism toxin, meets the definition of a Division 6.1 (poisonous) hazardous material under the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180). We apologize for the delay in responding and any inconvenience this may have caused.

According to your e-mail, you state the drug product may be best described as "UN 3172, Toxins extracted from living sources, liquid, n.o.s.," but your company's toxicity test results for this material are outside the parameters prescribed in § 173.133 of the HMR for a Division 6.1 material. You also e-mailed a copy of the product's test report (Report No. 09D0529G-X01G, dated June 4, 2009) that states the product "produced no mortality or toxic signs."

As specified in § 173.22, it is the shipper's responsibility to properly class and describe a hazardous material. Such determinations are not required to be verified by this office. However, based on the information you provided, it is our opinion that the product does not meet the definition of a Division 6.1 material under the HMR. If the material does not meet any other hazard class definition, the tested material is not subject to the HMR and not regulated for purposes of the transportation of hazardous materials in commerce. Please note, a shipping name from the Hazardous Materials Table (§ 172.101), such as "Toxins extracted from living sources, liquid, n.o.s.," may be used to describe a non-hazardous material provided neither the hazard class or identification number (UN or NA) are used in the description. See §§ 172.202(e) and 172.303(b)(3).

I hope this satisfies your request.

Sincerely,

T. Glenn Foster

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

Drakeford, Carolyn (PHMSA)

From: INFOCNTR (PHMSA)
Sent: Wednesday, July 01, 2009 9:39 AM
To: Drakeford, Carolyn (PHMSA)
Subject: FW: Hazmat Information Center Feedback: Hazardous Materials Table, Special Provisions, Hazardous Materials Communications

McIntyre
§172.101
§173.133
Applicability
09-0157

-----Original Message-----
From: PHMSA-Feedback [mailto:PHMSA-Feedback]
Sent: Tuesday, June 30, 2009 4:15 PM
To: PHMSA HM InfoCenter; PHMSA Webmaster
Subject: Hazmat Information Center Feedback: Hazardous Materials Table, Special Provisions, Hazardous Materials Communications

Mr. Edward T. Mazzullo,

I am requesting clarification of the designation we have assigned to our licensed drug product under the Hazardous Materials Regulations (HMR; 49 CFR 171-180).

According to 49 CFR 172.101 our product meets the definition of a hazardous material as it is listed on the table as: Toxins, extracted from living sources, liquid,n.o.s. with a hazard class of 6.1.

However, our toxicity results are outside the parameters of the tables in 49 CFR 173.133 and therefore we believe it does not meet the criteria to be classified as a hazardous material.

Do you agree with our conclusion that this material is not classified as a hazardous material under 49CFR 171-180?

Thank you,

David Schaper
Sr. Manager EHS
Solstice Neurosciences
701 Gateway Blvd., Suite 250
S. San Francisco, CA 94080
650-291-8206
david.schaper@solsticeneuro.com

Name: David Schaper
Organization: Solstice Neurosciences
Email: david.schaper@solsticeneuro.com
Address: 701 Gateway Blvd. Suite 250
City: South San Francisco
Zip Code: 94080
Phone: 650-291-8206
FAX: 650-243-4478