



U.S. Department
of Transportation
**Pipeline and Hazardous
Materials Safety
Administration**

1200 New Jersey Ave., S.E.
Washington, DC 20590

DEC 17 2008

Mr. Henry Ames
Director of Strategic Marketing
Sensitech, Inc.
800 Cummings Center, Suite 258x
Beverly, MA 01915

Ref. No.: 08-0290

Dear Mr. Ames:

This is in response to your inquiry, submitted by email, dated December 1, 2008, and subsequent emails and phone conversations, concerning the compliance of certain temperature and humidity monitoring devices marketed by Sensitech with requirements of the Hazardous Material Regulations (HMR; 49 CFR Parts 171-180), particularly with regard to the provisions of Special Provision (SP) 188 of § 172.102(c)(1).

You described these monitoring devices as incorporating small, primary lithium batteries and provided information on each type of battery, with regard to lithium content, and compliance with applicable regulatory standards such as SP 188 and the UN Manual of Tests and Criteria, and on the test regimen (electromagnetic compatibility testing, vibration testing, shock testing, and water resistance and submersion testing) to which each type of device has been subjected. Using your nomenclature, the products are described as VaxAlert, FreezeAlert, TempTale 4 (TT4), TT4 USB, TT4 RF, TagAlert, TTMini, and TT4 Dry Ice. You indicated the devices are used to monitor temperature- and humidity-sensitive products, many of which are pharmaceuticals, and may be attached to pallets or packages, placed inside a package, or built into a packaging containing these products.

You indicated there is some confusion as to whether these cargo monitoring devices are subject to the HMR. The devices are offered for transport and transported in commerce; thus, to the extent they contain hazardous materials, they are subject to applicable provisions of the HMR.

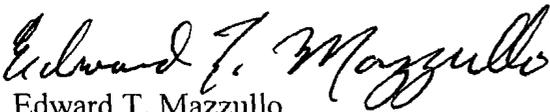
Based on the information you have provided, we agree with your assessment that these devices qualify for the exceptions provided for small lithium batteries under SP 188. Specifically, the batteries conform to the provisions in paragraph a(2) as they are contained in equipment and meet the quantity and net weight limits specified. Therefore, the devices are not prohibited for transport aboard passenger aircraft nor are they subject to the marking requirement of paragraph a(1). Moreover, the batteries conform to the lithium content limitations of paragraphs b and c, and it appears that all battery types meet, or will meet by

October 1, 2009, the test requirements of paragraph d. The batteries are separated so as to prevent short circuits and contained in equipment in conformance with the requirements of paragraph e. Finally, based on the information you provided concerning the test regimen to which the devices are subject, the devices conform to the requirements of § 173.21 of the HMR, in that they do not appear likely to create sparks or generate a dangerous quantity of heat and, thus, meet the requirements of paragraph g. Paragraphs f and h do not apply to your situation.

With regard to your request that certain information contained in your submissions not be made available for public release, please see 49 CFR 105.30 for the procedure for requesting confidential treatment. Also, note that the HMR do not address electromagnetic compatibility requirements, which fall under the Federal Aviation Regulations. If you have questions concerning those requirements, they should be addressed to the Federal Aviation Administration.

I trust this satisfies your inquiry. If we can be of further assistance, please contact us.

Sincerely,



Edward T. Mazzullo
Director, Office of Hazardous Materials Standards
Pipeline and Hazardous Materials Safety Administration

Mazzullo
§172.102 SP.188
Special Provision
08-0290

URGENT – IMMEDIATE RESPONSE REQUESTED

TOPIC: REQUEST FOR INTERPRETATION OF –

“FEDERAL REGISTER PART III, DEPARTMENT OF TRANSPORTATION (DOT)
PIPELINE AND HAZARDOUS MATERIALS SAFETY ADMINISTRATION
(PHMSA)– 49 CFR PARTS 171, 172, 173, and 175 HAZARDOUS MATERIALS;
TRANSPORTATION of LITHIUM BATTERIES; FINAL RULE
Thursday, August 9, 2007”

Date: Monday, December 01, 2008

FROM:

Henry Ames, Director of Strategic Marketing
Sensitech Inc
800 Cummings Center
Suite 258x
Beverly, MA 01982

TO:

ATTN: Kevin Leary
CC: Ed Mazzullo
CC: Shane Kelley
U.S. Department of Transportation
1200 New Jersey Ave, SE
Washington, DC 20590

Dear Department of Transportation (DOT),

Sensitech respectfully requests that the DOT issue an “Official Interpretation” to include devices like temperature monitors to be covered by DOT (PHMSA) 49 CFR Parts 171, 172, 173, and 175 for all modes of transportation – specifically air transport.

Delta Airlines has brought to Sensitech’s attention a grey area of interpretation in the current CFR. Specifically, Delta and potentially other airlines do not interpret the current CFR to include devices powered by lithium batteries that are used to support or monitor cargo. The current CFR as written primarily covers batteries as cargo both bulk and within equipment itself or batteries in carry-on or checked passenger luggage.

Were the CFR interpreted to include these types of devices, all of Sensitech’s temperature monitoring devices would fall under Part 172.102 Special Provisions Section 188 Small Lithium Cells and Batteries. Please see attached supporting documentation.

This “grey area” in the current CFR creates a serious potential threat to our healthcare system and overall patient safety. NOTE: During The International Air Transport Association’s (IATA) Time and Temperature Task Force (TTTF) subgroup bi-weekly call this morning it was noted that British Airways and American Airlines have both expressed concern for this “grey area” and may adopt Delta’s position – adding to the urgency of this matter.

As you will see in the attached documentation, Delta Airlines notified all of their shippers on August 25, that they will no longer accept “shipments containing devices powered by lithium batteries, regardless of the amount of lithium contained”. The position taken by Delta was described by Jim Shimko, Project Manager in the Corporate Dangerous Goods Group in the following manner: “There is nothing in the regulations that says you can ship these types of monitoring devices along with cargo but there is nothing in regulations that says you cannot either”. Hence, Delta has chosen a conservative interpretation of the regulations despite the fact that our devices are compliant with the limits outlined by Part 172.102 Section 188.

172.102 Special Provision

29.

(a.) “For a lithium metal cell or battery, the lithium content is not more than 1.0g per cell and the aggregate lithium content is not more than 2.0g per battery...” Sensitech utilizes several different types of batteries. The most commonly used is the CR 2032 manufactured by Sony and Panasonic which has a lithium mass of 0.062g. **NOTE: All batteries used by Sensitech comply with this specification. Please see the attached supporting documentation.**

(b.) **NOTE: The cells or batteries used by Sensitech are encased in a device. This section is currently written to address bulk shipments of batteries.**

(c.) **NOTE: This section seems to address bulk shipments of batteries not batteries contained in devices. That being said, as is similar in the points above each cell or battery is individually encased in a device.**

188 Small Lithium Cells and Batteries “Lithium cells or batteries, including cells or batteries packed with or contained in equipment, are not subject to any other requirements of this subchapter if they meet all of the following:” **NOTE: Sensitech feels the words “contained in equipment” should apply to devices like temperature monitors, regardless of operation status (powered on or off).**

(2) “The provisions of paragraph (a)(1) do not apply to packages that contain 5 kg. net weight or less of primary lithium batteries or cells that are contained in or packed with equipment and the package contains no more than the number of lithium batteries or cells necessary to power the piece of equipment.” **NOTE: We believe that all of Sensitech’s products comply with this provision because the batteries are “contained in... equipment” and the net weight is less than 5 kg.**

(b.) "For a lithium metal or lithium alloy cell, the lithium content is not more than 1.0 g. **NOTE: All of Sensitech's products comply with this provision. Please see attached supporting documentation.**

(c.) "For a lithium metal or lithium alloy battery, the aggregate lithium content is not more than 2.0 g. For a lithium-ion battery, the aggregate equivalent lithium content is not more than 8 g." **NOTE: All of Sensitech's products comply with this provision. Please see the attached supporting documentation.**

(d.) "Effective, October 1, 2009, the cell or battery must be of a type proven to meet the requirements of each test in the UN Manual of Tests and Criteria (IBR; see 171.7 of this subchapter)." **NOTE: We are working to obtain the relevant supporting documentation from our battery suppliers. We fully expect compliance within the stated deadline.**

(e.) "Cells or batteries are separated so as to prevent short circuits and are packed in a strong outer packaging or contained in equipment;" **NOTE: Batteries used in Sensitech's devices are "contained in equipment". All temperature monitoring devices are tested and receive a certificate of validation linked to the unique serial number of the device. Should you feel it appropriate, validation package is available for your review.**

(f.) "Effective October 1, 2008, except when contained in equipment, each package containing more than 24 lithium cells or 12 lithium batteries must be;" **NOTE: Because all batteries are "contained in equipment" this provision does not apply to temperature monitors.**

(g.) "Electrical devices must conform to 173.21 of this subchapter; and" **NOTE: We have reviewed 173.21 and feel that all of Sensitech's products comply with this provision.**

I greatly appreciate your prompt review and response to this request. As stated above, eliminating the existing ambiguity within the current 49 CFR Parts 171, 172, 173 and 175 to include devices powered by lithium batteries that are used to monitor shipments is critically important to protect protecting product quality and patient safety.

Please contact me at your earliest convenience to let me know how the DOT will respond.

Sincerely,



Henry Ames
Director, Strategic Marketing
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Email: hames@sensitech.com