



U.S. Department
of Transportation

**Pipeline and Hazardous
Materials Safety
Administration**

1200 New Jersey Avenue, SE
Washington, DC 20590

MAY 02 2019

Mark R. Kaster
Partner
Dorsey and Whitney LLP
50 South Sixth Street
Suite 1500
Minneapolis, MN 55402-1498

Reference No. 18-0159

Dear Mr. Kaster:

This letter is in response to your December 13, 2018, email requesting clarification of the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180) applicable to hazard communication requirements for packages containing lithium button cell batteries installed in equipment. You describe a blood glucose monitoring device that contains lithium metal button cell batteries of a type that meets the criteria in the United Nations (UN) Manual of Tests and Criteria Part III, Sub Section 38.3. You state that each device is placed in its own boxed packaging for retail distribution and sale, which is then placed in an overpack. Each overpack contains 12–24 retail units. Specifically, you ask whether packages containing lithium button cell batteries installed in equipment must display the lithium battery mark in accordance with § 173.185(c)(3).

The answer is no. Packages containing only lithium button cell batteries installed in equipment, including the button cells in your blood glucose monitoring devices, that comply with the requirements of § 173.185(c) are not required to display the lithium battery mark. This applies regardless of the number of packages per consignment, the number of pieces of equipment per package, or the number of lithium button cell batteries installed in each piece of equipment.

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
Standards and Rulemaking Division

Andrews

18-0159

January, Ikeya CTR (PHMSA)

From: INFOCNTR (PHMSA)
Sent: Friday, December 14, 2018 2:14 PM
To: Hazmat Interps
Subject: FW: Request for Interpretation

Hello Alice and Ikeya,

I talked with Mark about his interpretation request and mentioned that a couple of other letters on the same situation are in the works. He would still like to submit his request for a formal letter of interpretation. Thanks!

Sincerely,

Lynsie Patschke
Transportation Regulatory Specialist
Hazardous Materials Information Center (HMIC)

From: Kaster.Mark@dorsey.com [mailto:Kaster.Mark@dorsey.com]
Sent: Thursday, December 13, 2018 3:32 PM
To: INFOCNTR (PHMSA) <INFOCNTR.INFOCNTR@dot.gov>
Subject: RE: Request for Interpretation

Via E-mail - infocntr@dot.gov

Shane Kelley, Director
Standards and Rulemaking Division
U.S. DOT/PHMSA (PHH-10)
1200 New Jersey Avenue, SE East Building, 2nd Floor
Washington, DC 20590

Re: Request for Letter Interpretation of Hazardous Materials Regulations (HMR) for Lithium Cells and Batteries, 49 C.F.R. § 173.185(c)(3)

Dear Mr. Kelley:

I am counsel for ARKRAY USA, Inc. I am submitting this to request a formal interpretation of the lithium battery regulations ("HMR Regulations") found in 49 C.F.R. § 173.185(c)(3).

My client manufacturers Blood Glucose Monitoring Meters** (herein "Meter(s)") that include a small lithium metal button battery with a lithium content of .07 grams installed in the device. The lithium metal button batteries are manufactured according to the requirements of UN Manual of Tests and Criteria. Each Meter is placed in its own boxed packaging for retail distribution and sale. There is no spare battery provided within the packaging. The Meters are transported to retailers, mostly through ground, but occasionally through air modes of transportation. The shipments may include overpacks containing multiple units (usually in counts of 12-24 retail units in an overpack) of individual packaged products.

**The specific products involved are noted below and can be viewed at:

https://www.walmart.com/search/?cat_id=976760_2289975_9391152_6927535&grid=true&query=relion+prime&typeahead=relion#searchProductResult

- Arkray Item# 701103 ReliOn Prime Meter Kit Red
WMIT# 556621084
- Arkray Item# 782001 ReliOn Premier BLU Basic Meter
WMIT# 565694297
- Arkray Item# 783110 ReliOn Premier Compact Meter Kit
WMIT# 570597542

Questions for which Clarification is Requested

Does transport of a product containing a small lithium metal button battery installed in a medical device fall under the marking exception in 49 C.F.R. Part 173.185(c)(3)? In other words, does the provision in 173.185(c)(3) which states that “a package display the lithium battery mark except when a package contains button cell batteries installed in equipment (including circuit boards), or no more than four lithium cells or two lithium batteries contained in equipment, where there are not more than two packages in the consignment” mean that that button battery installed in equipment are exempt and not qualified by the last phrase referencing two or more packages in a consignment.

Discussion

I previously contacted the agency in 2015 and requested an interpretation regarding marking requirements for lithium button batteries installed in a product under 173.185(c). The agency’s response (Reference No. 15-0114) confirmed that button batteries as described were exempt from the marking requirements, including when individual packages were aggregated and shipped in an overpack or on a pallet. Since the language of 173.185(c) has slightly changed from the prior 2015 version of the regulation, I contacted the PHMSA hotline and also spoke with Kevin Leary of your staff to confirm that the marking exemption for button batteries was still applicable to the ARKRAY products. I was informed that the marking exemption was still in place, and that the products as described were still exempt from any marking requirements. My client has a retail customer (Walmart) who has asked that we obtain a formal letter to confirm the information provided orally by PHMSA staff.

Conclusion

My client wants to confirm that no marking is required for the transport of packages, overpacks and/or pallets by surface or air transportation where the packaging contains products with small lithium metal button batteries installed in the products.

Please contact me should you have any questions.

Thank you for your assistance.

Mark

Mark R. Kaster
Partner



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