HazCom2012 labels for small reference standard packages

Darcy Ramisch SDSRP

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Introduction

USP is a scientific nonprofit organization that sets standards for medicines, food ingredients, and dietary supplements manufactured, distributed, and consumed worldwide. USP Reference Standards are highly-characterized physical specimens used in testing by pharmaceutical and related industries to help ensure the identity, strength, quality, and purity of medicines (drugs, biologics, and excipients), dietary supplements, and food ingredients. These reference standards are generally packaged in 5 milliliter vials or 2 to 5 millliliter ampules, with labels as small as 1 x 1.5 inches.

In 2013, USP requested that OSHA allow us to omit the precautionary statements from the reference standards labels, similar to the exemption for small packages in the European Union. OSHA rejected this request, referencing their practical accommodation.

OSHA: practical accommodation

"OSHA has developed a practical accommodation to address situations where the manufacturer can show that it is not feasible to use pull-out labels, fold-back labels, or tags containing the full HCS 2012 required information for shipped small containers (i.e., the actual container holding the hazardous chemical). **This practical accommodation requires the manufacturer to include, at a minimum, the following information on the label of the immediate container:**

- Product identifier
- Appropriate pictograms
- Manufacturer's name and phone number
- Signal word
- A statement indicating the full label information for the chemical is provided on the outside package.

Additionally, the outside packaging, at a minimum, must comply with the following:
All the applicable label elements, as defined in 29 CFR 1910.1200(f)(1). The outside package must be clearly marked to ensure the complete label elements are visible and it must clearly inform users that the small container must be stored in the outer container bearing the complete label. The complete label must be maintained on the outer package (e.g., not torn, defaced, destroyed).

The manufacturer must ensure that any alternative labeling used does not conflict with any other standards. As such, the outside packaging must not present a hazard while the material is being stored.

The outside packaging is the container (e.g., bag, box) that the immediate product container is placed into, which may or may not be the exterior shipping container."

Galassi, Thomas (Directorate of Enforcement Programs, Occupational Safety & Health Administration). Letter of interpretation. 20 September 2013

Secondary containers

Cardboard containers for individual vials were considered, but the cost of the additional equipment as well as space for the equipment, stock, and additional storage space needed for finished products made this prohibitively expensive.

Reference standards are shipped in cardboard boxes with padded inserts; and the feasibility of affixing hazard labels to the exterior of the packing containers was evaluated. This method presented additional challenges, such as an additional quality assurance function in distribution to make sure that the labels and vials were correctly matched. It was also expected that customers would not retain the outer container after receipt.

Secondary containers were a solution for ampules, which are sold individually and in multipacks. For individual ampules, the label contains the pictogram, signal word, and hazard statement(s) along with "See outer package for full hazard information." The outer package (a plastic tube for individual vials or a plastic clamshell for multipacks) includes all label elements and the instruction "Keep ampule in secondary container."

Expanded content labels

Use of expanded content labels similar to those used on pharmaceutical containers was explored, but accordion-fold or booklet type labels require use of professional printing services. In reference standard production, label text unrelated to the hazard classification is not finalized until testing is complete, then there is a short amount of time (four weeks or less) for packaging, labeling, and release. Lot sizes are also relatively small compared to most industries (average 1800 units). These factors made outsourced label printing infeasible.

Adhesive wrap labels provided sufficient space to print all of the required label elements and allowed the printing function to remain in house. With this solution, the precautionary statements are printed on an inner panel of the label affixed to the vial, and the other elements are printed on the front portion of the label that wraps over the inner panel. The customer can peel back the label to read the precautionary statements, with pressure-sensitive adhesive allowing the label to be unrolled and rolled multiple times.

Expanded content labels

Improvements

In 2013 the only commercially available color printers for the wrap labels were thermal printers with separate red and black ribbons. As the labels printed, the printheads would occasionally shift, resulting in the pictogram images not being centered in the red borders. Staff had to monitor the printer throughout the entire printing process.

Thermal printers have been replaced with digital inkjet printers with improved resolution and graphics. These printers are also faster, quieter, and run without monitoring.

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Andrea Iwanik, Sarah Koegel, Kent Mullen

Contact

Darcy Ramisch
Senior Manager, HCP & Safety
Reference Standards Production

12601 Twinbrook Parkway
Rockville, MD 20852
301-816-8378
drs@usp.org