

Consistency, Compliance, and Usability



SDSs vs. Labels

SDSs

- Regulated by OSHA
- (Mostly) intended for workplace audiences
- Developed by a single federal bureau in the 1960s, with changes in the 1980s, 1990s, and 2010s

Labels

- Mandated by a variety of agencies (CPSC, EPA, FDA, etc.)
- (Mostly) intended for consumers
- Developed inconsistently over a long period of time, from early the 1900s to the 1970s

Example: Nail Polish Remover (FP -4° F)

SDS Section 2 OSHA Label (hypothetical)

• Pictogram:



- Signal Word: Danger
- Hazard Statement: Highly flammable liquid and vapor

CPSC Label (hypothetical)

- Signal Word: Danger
- Statement of Principal Hazard: Extremely Flammable

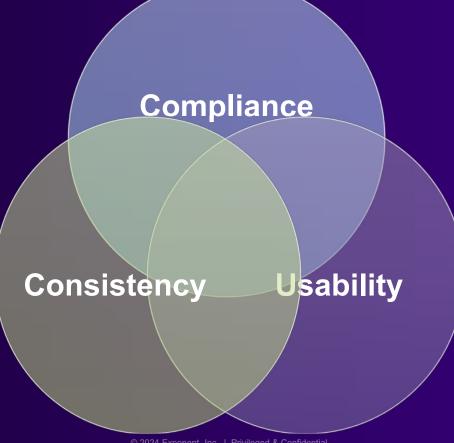
FDA Cosmetic Label

 [warning statement; no language specified by regulation]

Why does this seem like a "new" problem?

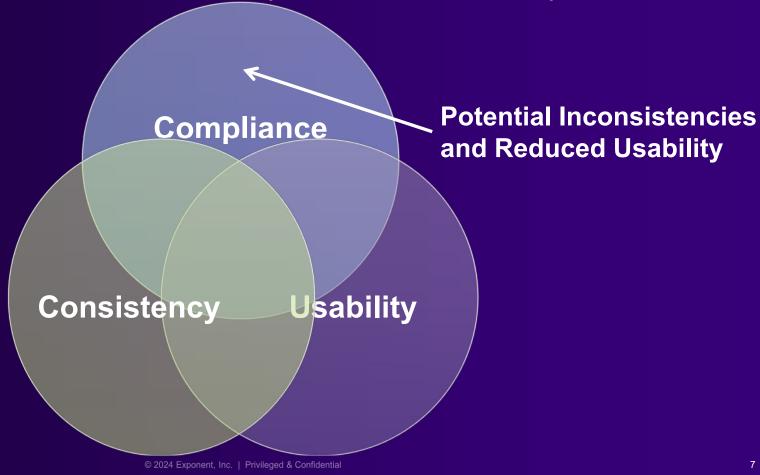
- Before HazCom 2012:
 - FDA: Performance standard
 - EPA: Specification standard
 - CPSC: Specification standard
 - OSHA: Performance standard

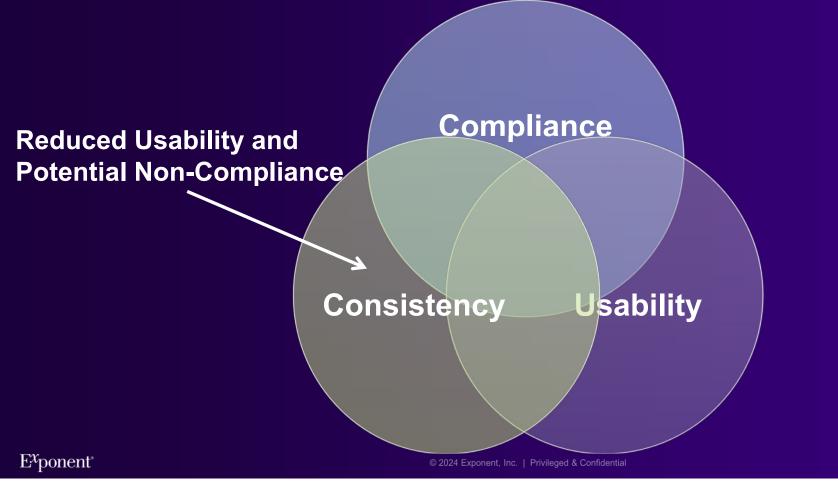
- After HazCom 2012:
 - FDA: Performance standard
 - EPA: Specification standard
 - CPSC: Specification standard
 - OSHA: Specification standard

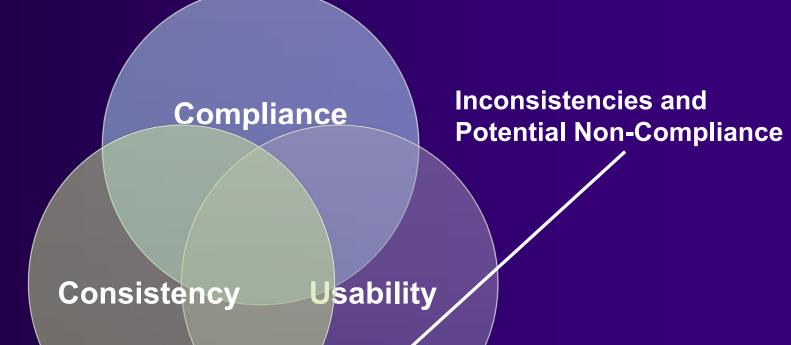


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What guidance have U.S. regulatory agencies provided about this?

OSHA HazCom Exemptions

- 29 CFR 1910.1200(b)(5) exempts from labeling [but still requires SDSs for]:
 - Foods, drugs, and cosmetics labeled under FDCA [FDA]
 - Pesticides labeled under FIFRA [EPA]
 - Substances or mixtures labeled under TSCA [EPA]
 - Consumer products labeled under CPSA or FHSA [CPSC]
 - Alcoholic beverages for non-industrial use labeled under FAAA [ATF]
 - Agricultural or vegetable seed treated with pesticides and labeled under the Federal Seed Act [Dept. of Agriculture]

OSHA HazCom Exemptions (continued)

- 29 CFR 1910.1200(b)(6) fully exempts [and does not require labels or SDSs for]:
 - Food or alcoholic beverages in a retail establishment or for personal consumption by employees
 - Drugs in solid, final form for direct administration, packaged for retail sale, or for personal consumption by employees
 - Cosmetics packaged for retail sale or for personal consumption by employees
 - Hazardous waste regulated under RCRA [EPA]
 - Hazardous substances being remediated under CERCLA [EPA]
 - [list continues]

OSHA HazCom Exemptions (continued)

- 29 CFR 1910.1200(b)(6) fully exempts [and does not require labels or SDSs for]:
 - Consumer products or hazardous substances regulated under CPSA or FHSA "where the employer can show that it is used in the workplace for the purpose intended by the chemical manufacturer or importer of the product, and the use results in a duration and frequency of exposure which is not greater than the range of exposures that could reasonably be experienced by consumers when used for the purpose intended"

OSHA HazCom 2012 Final Rule

• "After noting that CPSC labels often do not contain all hazard information relevant to worker exposures, [...] 'OSHA nevertheless decided to permit the CPSC labels to suffice so as not to disrupt the extensive labeling conducted in accordance with those rules. OSHA believed that this could be justified on the basis that some information is provided on the labels that would be useful to workers, and that the requirement for MSDSs would provide what information is necessary to supplement the labels. [...]' OSHA sees no need to revisit this issue now [...]." (2012 Final Rule, 77 FR 17695-6 [quoting 1988 Final Rule, 53 FR 29834])

CPSC FHSA FAQs



Can I rely on information from a safety data sheet (SDS) to create a cautionary label under the FHSA?

Not always.

Safety data sheets (SDS) rely on the hazards and classifications of the Globally Harmonized System of Classification and Labeling of Chemicals (GHS) managed by the United Nations and adopted by the Occupational Safety and Health Administration (OSHA) under their Hazard Communication Standard. Please also see the OSHA's Occupational Chemical Database for detailed information on regulated substances under OSHA's guidelines.

The GHS standards and classifications can differ from the requirements under the FHSA. An example would be the differences in the flammability hazard between the two. GHS classifies a "flammable liquid" as a liquid with a flashpoint less than or equal to 199.4 °F (93 °C). FHSA, which doesn't differentiate flammability between liquid and solid/gas, has three separate classifications as follows: "extremely flammable" is a substance with a flashpoint less than or equal to 20 °F (-6.7 °C); "flammable" is a substance with a flashpoint between 20 to 100 °F (-6.7 to 37.8 °C), exclusive; and "combustible" is a substance with a flashpoint between 100 to 150 °F (37.8 to 65.6 °C), inclusive. Further, GHS allows for a number of different test methods, whereas FHSA identifies a single test method.

https://www.cpsc.gov/FAQ/FHSA-Cautionary-Labeling

CPSC FHSA FAQs



Can a hazardous substance be labeled to satisfy both FHSA and GHS requirements?

Yes, with some caveats.

The FHSA text must be kept together and separate from the GHS text, and the GHS label must not contradict the FHSA label.

https://www.cpsc.gov/FAQ/FHSA-Cautionary-Labeling

EPA PRN 2012-1: Material Safety Data Sheets as Pesticide Labeling

• "EPA believes that generally explaining why the FIFRA label and the SDS contain different hazard communication will prevent users from being misled by the inconsistencies. To provide an adequate explanation so the labeling is not misleading, EPA recommends registrants include in their SDSs the FIFRA label information and a brief explanation for any differences between that information and the SDS information. Section 15 of the SDS ("Regulatory Information") is an appropriate place to insert this information."

https://www.epa.gov/pesticide-registration/prn-2012-1-material-safety-data-sheets-pesticide-labeling

EPA PRN 2012-1: Material Safety Data Sheets as Pesticide Labeling (continued)

- "The following statement may be used to introduce the FIFRA hazard information and explain the differences between the HCS and FIFRA classification and labeling systems.
 - This chemical is a pesticide product registered by the United States Environmental Protection Agency and is subject to certain labeling requirements under federal pesticide law. These requirements differ from the classification criteria and hazard information required for safety data sheets (SDS), and for workplace labels of non-pesticide chemicals. The hazard information required on the pesticide label is reproduced below. The pesticide label also includes other important information, including directions for use. [Insert FIFRA label hazard information]"

https://www.epa.gov/pesticide-registration/prn-2012-1-material-safety-data-sheets-pesticide-labeling

FDA Cosmetics Labeling Guide

Performance requirement for warning statements:

21 CFR 740 (1) and (2)

Regulations require that "[the label of a cosmetic product shall bear a warning statement whenever necessary or appropriate to prevent a health hazard that may be associated with the product" [21 CFR 740(1)]. A cosmetic not bearing a necessary warning statement may be considered misbranded under sec. 602(a) of the FD&C Act because it fails to reveal a fact "material ... with respect to consequences which may result from the use of the article" [sec 201(n), FD&C Act].

Is further harmonization the solution?



Questions?



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