

Regulatory Compliance Services

Classification, Labeling and Packaging (“CLP”) and Safety Data Sheet (“SDS”) Support for Pharmaceutical and Other Chemicals

Regulatory Deadline Approaching for CLP Compliance

The EU classification, labeling and packaging of substances and mixtures regulation (“EU CLP”) requires that:

- Substances must be classified and labeled in accordance with CLP by **December 3, 2010**.
- Manufacturers and importers who place a hazardous substance on the market will have to notify to the C&L inventory by **January 3, 2011**.
- Mixtures must be classified and labeled in accordance with CLP by **June 1, 2015**.

Although the European Registration, Evaluation, Authorization of Chemicals (“REACH”) regulation exempts pharmaceutical substances from registration, evaluation and authorization, CLP **will** require a regulatory submission (notification) of all pharmaceutical substances being “placed on the market”.

Important Questions about the Applicability and Requirements of CLP and Pharmaceuticals

What does “placing on the market” really mean?

- “Supplying or making available, whether in return for payment or free of charge, to a third party. Import shall be deemed to be placing on the market.”

Which substances have to be notified to the Classification and Labeling (C&L) Inventory?

- Those subject to registration under REACH (≥ 1 tonne/year) and placed on the market.
- Those classified as hazardous under CLP and placed on the market irrespective of the tonnage (including those exempted from registration).
- Those classified as hazardous under CLP and present in a mixture above the concentration limits specified in Annex I of CLP or as specified in Directive 1999/45/EC.

Will medicinal products need to be classified and notified to the C&L Inventory?

- Active pharmaceutical ingredients (“APIs”) or excipients, not yet in the finished state, are subject to the CLP and will have to be notified to the C&L Inventory if placed on the market.
- Substances and mixtures in the finished state and intended for the final user are exempt.

Note: There are currently NO exemptions from notification to the C&L inventory for quantity, research compounds, or active pharmaceutical ingredients. Although non-EU manufacturers are not subject to the requirement, it is reasonably certain that your European customers will be looking to you to help them with the notification, if not perform the notifications for them.

SafeBridge Can Provide:

- An SDS which is European and US-compliant
- Compliant language for labeling
- Notification services under CLP

The “SafeBridge Advantage” is that we understand the regulations as they apply to pharmaceuticals and related compounds, we have a staff of trained toxicologists and industrial hygienists and we have offices in both the US and Europe. For more information on these services, contact:

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