CEFIC/EUROMETAUX/FECC/DUCC Workshop

How to classify Mixtures under CLP HEALTH HAZARDS ASPIRATION

Helmut Fleig Brussels; 19 May 2014

Definitions and specific Considerations (§ 3.10.1)

- "Aspiration" means the entry of a liquid or solid substance or mixture directly through the oral or nasal cavity, or indirectly from vomiting, into the trachea and lower respiratory system.
- Aspiration toxicity includes severe acute effects such as chemical pneumonia, varying degrees of pulmonary injury or death following aspiration.
- **Remark**: the classification criteria refer to liquids only

Criteria (1) (§3.10.3)

• Classification when data are available for the complete mixture:

A mixture is classified in Category 1 based on reliable and good quality **human evidence**.

- A mixture which contains a total of 10 % or more of a substance or substances classified in Category 1, and has a kinematic viscosity of 20,5 m² /s or less, measured at 40° C, shall be classified in Category 1.
- Test methods:
 - ISO 2431 (Paints and varnishes)
 - ISO 3104 (Petroleum products)
 - ISO 3219 (Plasics-Polymers/Resins, liquid..)

Criteria (2) (§3.10.3)

Classification when data are not available for the complete mixture bridging principles:

Where the mixture itself has not been tested to determine its aspiration toxicity, but there are sufficient data on the individual ingredients and similar tested mixtures to adequately characterise the hazard of the mixture, these data shall be used in accordance with the bridging principles set out in section 1.1.3. However, in the case of application of the **dilution bridging principle**, the **concentration of aspiration toxicant(s) shall be 10 % or more**.

Criteria (3)

In the case of a mixture which separates into two or more distinct layers, **one of which contains 10 % or more of a substance or substances classified in Category 1 and has a kinematic viscosity of 20,5 mm o /s or less**, measured at 40 o C, then the entire mixture is classified in Category 1.

Special Issues (1)

- Screening: only some hydrocarbons (petroleum distillates and certain chlorinated hydrocarbons) are covered
- No classification for some substances having this property in Annex VI, e.g:
 - Ethylbenzene: 139/3400 notifications with Asp.1; H 304
 - Xylene

Background: classification under DSD before Aspiration criteria were established

Special rule in Germany (2005): classification with Xn; R65 for mixtures containing xylene > 10% and "...having a low viscosity..."

Special Issues (2)

- Often no appropriate data in § 9 of the SDS
- Extrapolation of data established at 20/25°C to data at 40°C as required in the criteria: Initiative of IPPIC/CEPE an UNSCEGHS for developing criteria for extrapolation, since many data for paints and printing inks only from measurements at 20 or 23°C and there is no simple relationship Kinematik viscosity values of ethylbenzene at different temperatures: 20°C: 0.773 mm²/sec
- **§** 40°C: 0.641 mm²/sec

Thank you!