4 July 2014

Memo

New classification for White Spirits

Background

In the 1970s and 1980s, several occupational studies carried out in the Nordics claimed that regular and long-term use of three hydrocarbon solvents, known as white spirits namely Stoddard solvent Solvent naphtha and Naptha, may constitute a health risk to workers. In particular, long term exposure to these solvents were found to be associated to reducing mental functioning and health problems related to the central nervous system. From 2009, the Danish Environmental Protection Agency (EPA) included these substances on their List of Undesirable Substances (LOUS) and two of the three substances have been classified at national level since 1988. In the 1990s, the Danish EPA proposed to review the classification of a group of white spirits at European level. However, this proposal was rejected due to a lack of scientific evidence.

In the meantime, the EU chemicals policy was developed and strengthened, notably with REACH and the EU Regulation on the classification, labelling and packaging of substances and mixtures (CLP). Within this framework, the Danish EPA submitted in January 2010 a new proposal to the European Chemicals Agency (ECHA) proposing that these three substances are classified as STOT RE 1, H372 (equivalent to Xn, R48/20).

Review of the classification for three white spirits

On 10 June 2011, the Risk Assessment Committee (RAC) of the ECHA delivered an opinion on the Danish proposal[1]. The RAC concluded that the three hydrocarbon solvents may have negative effects on the central nervous system and therefore should be classified as STOT RE 1, H372.
The three substances referred to are:

Name	EC Number	CAS Number	Solvent identified by HSPA naming
Stoddard solvent	919-164-8 919-446-0	8052-41-3	Hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics, aromatics (2-25%) Hydrocarbons, C9-C12, n-alkanes, isoalkanes, cyclics, aromatics (2-25%)
solvent naphtha (petroleum), medium aliphatic [Type 0]	919-446-0	64742-88-7	Hydrocarbons, C9-C12, n-alkanes, isoalkanes, cyclics, aromatics (2-25%)
Naptha (petroleum), hydrodesulphurized heavy [Type 1]	919-164-8 919-446-0 927-344-2 928-136-4	 64742-82-1	Hydrocarbons, C10-C13, n-alkanes, isoalkanes, cyclics, aromatics (2-25%) Hydrocarbons, C9-C12, n-alkanes, isoalkanes, cyclics, aromatics (2-25%) Hydrocarbons, C9-C10, n-alkanes, isoalkanes, cyclics, aromatics (2-25%) Hydrocarbons, C8-C12, n-alkanes, isoalkanes, cyclics, aromatics (2-25%)

[1] RAC opinion proposing harmonised classification and labelling at Community level of white spirit
http://echa.europa.eu/documents/10162/8af9e92e-2259-422f-aa52-aae5e5d7ed75

The newly agreed classifications are:

- STOT RE 1: specifically targets organ toxicity due to repeated exposure;
- H372: causes damage to organs through prolonged or repeated exposure.

These substances have then been added to the list of harmonised classifications, which has recently been implemented in the 5th Adaptation to Technical Progress (ATP) to the CLP Regulation, adopted on 2 October 2013[2]. This regulation shall apply from 1 January 2015 to all operators in the EU.

The Hydrocarbon Solvents Producers Association (HSPA) position

HSPA does not agree with this classification and submitted a number of comments to the ECHA[3]:

- There is no direct correlation of the illness of workers related to solvents. Illness caused may also be associated to other types of substances used.
- There is inconsistent evidence to support the claim that high dose exposure to white spirits can provoke severe neurological effects in humans or animals. This is based on the toxicology studies which revealed negative results for neurological damage exposed in rats.
- Furthermore, no neurotoxic or behavioral effects used in the Danish experimental studies were observed. The basis for classification relies on human case studies or epidemiological data, which when reviewed found shortcomings and uncertainties of the epidemiological data available.
- Other studies have also found that the "weight of evidence suggests that there are no consistent associations between reduced neurobehavioral test performance and low-level hydrocarbon solvent exposures occurring at current exposure levels"[4].

In conclusion, HSPA believes that the evidence is inconclusive and does not support the classification for STOT RE 1, H372 for the three substances known as white spirits.

Nonetheless, HSPA takes note of the RAC opinion and is committed to implement and communicate these changes in the classification to downstream users.

In order to differentiate hydrocarbon solvents from the different petroleum products when identifying and registering these substances under REACH, HSPA developed a new naming convention which was approved by ECHA. By developing a hydrocarbon naming convention HSPA have ensured the classification and labelling requirements of each substance are fully aligned with the toxicology of each material. This approach is entirely in line with REACH and all the hydrocarbon categories have been appropriately registered.

---

[2] COMMISSION REGULATION (EU) No 944/2013 of 2 October 2013 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixture
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:261:0005:0022:EN:PDF
Committee for Risk Assessment RAC Annex 2: Response to comments document (RCOM) to the Opinion proposing harmonised classification and labelling at Community level of white spirit

[3] http://echa.europa.eu/documents/10162/4a7614a7-bb44-42d8-b163-269079686036

[4] Gamble, J. (2000). Low-level hydrocarbon solvent exposure and neurobehavioural effects. Occupational Medicine 50:81-102.

While the new classification requirements following the RAC opinion on white spirits only apply to substances broadly identified by their CAS number, HSPA decided to correlate the CAS numbers with the identifiers for hydrocarbon solvents and to proactively apply the new classification and labeling to this category of substances. This reflects HSPA strong commitment to the responsible management and the safe handling of solvents.

Implications for the supply chain

As stipulated by the CLP regulation, manufacturing companies need to communicate the change in the classification of these three substances to all actors in the supply chain. **All operators placing these substances on the European market need to adapt the labeling and packaging of substances and mixtures to the new classification as from 1 January 2015.**

For more information, please contact Antoine Brossier, Director General of the European Solvents Industry Group at abr@cefic.be or Veronique Schoune at vsc@cefic.be