Position Paper for the CMR-Classification of Ethanol according to CLP Regulation 1272/2008 – May 2014

To whom it may concern

The CLP regulation aims at protecting workers, consumers and the environment by means of labelling which reflects the potential hazardous effects of a particular chemical substance or mixture. The application of the CLP regulation rules should result in an appropriate hazard communication leading to a high level of protection.

However, in exceptional cases the application of the CLP regulation may result in an inappropriate hazard communication which will not protect workers, consumers or the environment from the hazard identified and/or will generate a significant hazard itself. Such cases do not meet the objectives of the CLP regulation and require individual case by case discussions.

CLP-Requirements for Ethanol (CAS 64-17-5, EINECS 200-578-6)

The CLP-requirements for ethanol are of a special concern in the evaluation for the inclusion of the substance in Annex I under the Biocidal Products Directive 98/8/EC. Taking into account the scientific information on the hazardous properties of ethanol, the following hazard communication according to Regulation 1272/2008/EC was proposed by a Competent Authority within the evaluation process:

- Irritancy to the eye and to the respiratory tract
  - Eye Irrit. 2 H319 Causes serious eye irritation
  - STOT SE 3 H335 May cause respiratory irritation
- Carcinogenicity, Mutagenicity, Reprotoxicity (CMR)
  - Carc. 1A or 1B H350 May cause cancer
  - Muta. 1B H340 May cause genetic defects
  - Repr. 1A H360FD May damage fertility or the unborn child
  - Lact. H362 May cause harm to breast-fed children

It is the CMR classification which we believe to be a dangerous addition to the substance classification.

CMR Classification of Ethanol

The CMR classification proposed is derived from clinical and non-clinical data. However, the CMR effects were observed only after chronic oral consumption in amounts beyond levels normally tested. It is an accepted fact that only after oral intake serum levels of ethanol are reached which may cause the effects reported.

The proposed CMR classification informs the user about hazards that are exclusively evident if ethanol is regularly consumed orally, e.g. as an alcoholic beverage.

Thus taking into account that:

- alcoholic beverages are regarded as foodstuff for which the CLP regulation does not apply
- alcoholic beverages are therefore not labelled with this information
- all known applications of ethanol which fall under the scope of the CLP regulation explicitly exclude oral use
- sources of Ethanol for a biocidal use are denatured to limit the risk of oral consumption

It becomes clear that the proposed CMR labelling is not appropriate to protect workers or consumers from the hazards identified. The only application for which the hazard is evident (oral use) is explicitly excluded from the labelling of the product.

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The toxicological profile of ethanol and its effects on human health have already been discussed in the EU Classification & Labelling Group and this has not resulted in a CMR classification. In addition the OECD came to the following conclusion in their Screening Information Data Set from October 2004:

"Evidence of the carcinogenicity of ethanol is confined to epidemiological studies assessing the impact of alcoholic beverage consumption. These do not indicate any such hazard exists from potential exposure to ethanol in the work place or from the use of ethanol in consumer products"

Further Consequences

One can easily foresee that a CMR labelling of ethanol containing biocidal products may have an impact on the acceptance of the product by end users, even if they are excluded from oral use by authorities.

The lack of acceptance induced by a CMR classification will be of high relevance in the case of products that have to be applied routinely to the user's skin. In this regard, non-acceptance of Ethanol based hand disinfectants will likely cause a dramatic increase in the risk of infections for patients and medical staff:

- Hand disinfection ("hygienic handrub") is regarded by the worldwide medical community, e.g. WHO, as the single most efficient procedure to achieve proper medical hygiene, i.e. to prevent nosocomial infections and the spread of pathogens including "multiresistant" microorganisms.
- The frequent use of hand disinfectants by medical staff before and after each patient contact and even when leaving the patient's surroundings is required for that reason.
- Ethanol based products are superior to other alcohol containing products in preventing the transmission of viruses, especially non-enveloped viruses.
- A formulation containing 80% (v/v) ethanol is explicitly recommended by WHO for frequent use as a hygienic hand disinfectant.
- With respect to skin corrosiveness, only hand disinfectants based on alcohols are regarded suitable for frequent use in a medical routine. It has been demonstrated that they are even better tolerated by the user's skin than (good) soap and water.

In addition the proposed CMR classification for Ethanol based biocidal wipes and disinfection solutions for surfaces would also prove dangerous. This is because ethanol is highly effective against bacteria and viruses with limited alternatives so any reduction in acceptance, use or compliance would increase the risk of infections.

Conclusion

Any negative impact on the user's acceptance and compliance of alcohol products will be associated with a reduced number of applications. The acceptance will decrease considerably even for products used only temporarily or without direct contact to the skin, e.g. for surface disinfection. Thus, the level of hygiene will inevitably decrease, associated by a significant increase of nosocomial infections.

Taking into account these scenarios, it becomes obvious that the proposed CMR labelling of ethanol containing products itself will generate a relevant hazard to public health. We propose that no CMR classification or labelling should be applied to ethanol or ethanol containing products.

Yours Faithfully,

Alcohol Task Force Members

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