

# Peroxygens Sector Group

26 March 2005

## Information on the Outcome of the EU-Risk Assessment of Hydrogen Peroxide

The CEFIC Peroxygens Sector Group would like to provide some information on the completed EU Risk Assessment of Hydrogen Peroxide.

In the context of the EU Council Regulation (EEC) No. 793/93 on the evaluation and control of existing substances a Final Risk Assessment Report (RAR) including a Summary Report on Hydrogen peroxide has been published in 2003. The report can be downloaded from the European commission Joint Research Centre website ( <http://ecb.jrc.it/existing-chemicals/> )

The CEFIC Peroxygens Sector group has worked closely with the EU commission and the Rapporteur Member State Authorities (Finland) and provided data and assessments on effects to human health and the environment as well as information on exposure and safe handling practice for the various production and use scenarios. The risk assessment report, however, cannot reflect the detailed situation for every single use and has to be generic and precautionary in many cases.

One result of the risk assessment is the change in classification and labelling including changes in the concentration limits, which is adopted in the 29<sup>th</sup> ATP (Annex 1 of Dir. 67/548 EEC).

For details see the CEFIC Peroxygens Sector Group document on the classification and labelling.

The outcome of the risk assessment in short was as follows.

### Environmental risk assessment:

No risk for the atmosphere or soil compartments was identified for the current uses. For the aquatic compartment a predicted no effect level (PNEC) of 10 µg/l was derived from the existing data. However, natural background concentrations in water may reach up to 30 µg/l. As hydrogen peroxide is readily biodegraded in sewage treatment plants a connection to a properly operating wastewater treatment plant should prevent the substance from entering into natural waters.

### Human health risk assessment

#### General

The toxicokinetic evaluation of hydrogen peroxide suggests that only under conditions of very high exposure rates the substance might enter the systemic circulation. When accidental swallowing is excluded, it is unlikely that such high exposures could be reached in any realistic scenario of workplace or consumer exposure. Results from animal studies suggest that local toxicity at the point of contact and no systemic effect is the primary mode of action. No concern was identified with regard to risks for workers and consumers from current uses for acute toxicity, sensitisation, repeated oral toxicity, mutagenicity, carcinogenicity and toxicity to reproduction.



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The risk assessment expressed some concerns for local irritation or corrosivity to skin, eyes and the respiratory tract when hydrogen peroxide is handled in concentrations that could cause local irritant or corrosive effects.

### Workers

For workers some scenarios were identified that could cause some concern with regard to acute local irritant/corrosive effects:

- Loading operations
- Textile bleaching in batch processes
- Aseptic packaging (old type of immersion bath machines)
- Hydrogen peroxide and peracetic acid use in breweries, etching of circuit boards (old process), metal plating and degrading of proteins.
- Eye irritation in hairdressers work

Concern for possible adverse effects through repeated inhalation was identified for

- Loading operations
- Aseptic packaging (all types of processes)
- etching of circuit boards (old process)
- wastewater treatment.

The exposures in those scenarios can however be effectively controlled and the producers are offering advice to improve safe handling practices.

Exposures should be kept below the current occupational exposure limit of 1 ppm (1.4 /m<sup>3</sup>) (8 h TWA and STEL).

### Consumers

For consumers a concern was expressed for eye irritation/corrosivity in hair dyeing and bleaching and for usage as a cleaning agent if preparations are used that contain hydrogen peroxide in irritant concentrations as well as for tooth bleaching with concentrated (35%) hydrogen peroxide solutions.

### Physical chemical risk

With regard to physical chemical hazards although no risk was identified for the normal handling and use in the major industrial settings. Some concern was expressed with regard to possible spontaneous decomposition and the risk of fire when concentrated solutions come into contact with combustible materials, e.g. concerns for the risk of fire hazard caused by spills of the more concentrated (>25%) hydrogen peroxide solutions on combustible materials. This can in exceptional cases also happen in the consumer area.

The results of the risk assessment report have to be taken into consideration when handling hydrogen peroxide. The producers of hydrogen peroxide have already taken account of the RAR in their safety data sheets and the further advice on the safe handling of the product.

The manufacturers of hydrogen peroxide give advice on the methods of safe handling and risk reduction and can be consulted for further information.



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## Risk reduction strategy

A risk reduction strategy has been published on April 29 2004 with a corrigendum on June 7 2004 in the Official Journal of the EU (L144/107 and L199/41). It is stated that all sectors importing, producing, transporting, storing, formulating into a preparation or other processing, using, disposing of and recovering hydrogen peroxide should take into account the results of the risk evaluation and the strategy for limiting the risks.

The text of the risk reduction strategy is quoted below.

## STRATEGY FOR LIMITING RISKS FOR WORKERS

The legislation for workers' protection currently in force at Community level is generally considered to give an adequate framework to limit the risks of the substance to the extent needed and shall apply.

Within this framework it is recommended that:

- employers review any risk assessments produced according to Directive 98/24/EC (Chemical Agents Directive) to take into account the information contained in the risk assessment and risk reduction strategy for hydrogen peroxide produced under Regulation (EEC) 739/93, and take any necessary measures that are required.
- employers using hydrogen peroxide for the uses identified as a concern in the risk assessment (part I) should take note of the practical non-binding guidance, to be developed by the Commission as foreseen under Article 12(2) of Directive 98/24/EC, and of any sector specific guidance developed at national level based on this guidance.

## FOR CONSUMERS

It is recommended that:

- in the framework of Commission Directive (EC) 2003/80<sup>1</sup> regarding the maximum acceptable percentage of hydrogen peroxide for tooth bleaching products used under supervision of a dentist, a concentration limit of up to 6% hydrogen peroxide should be considered, provided appropriate conditions of use and warning are printed on the label.
- textile bleaching agents and cleaning agents which contain  $\geq 5\%$  of hydrogen peroxide should be formulated so that the risk of eye irritation/corrosivity is diminished (e.g. viscous suspensions, cream). In the instructions, the risk of eye irritation/corrosivity should be emphasised and the percentage of  $H_2O_2$  in the product should be indicated. For hair dyes/bleaches the above mentioned recommendations, including the percentage limit, should be considered within the framework of Community legislation on cosmetic products.
- the requirement for child-resistant fastenings in the Directive 1999/45/EC (Dangerous Preparations Directive) should be extended to all household chemicals, which may be accessible to children and contain hydrogen peroxide.

<sup>1</sup> OJ L 224, 06.09.2003, p.27



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FOR ENVIRONMENT

It is recommended that:

- to facilitate permitting under Directive 96/61/EC (Integrated Pollution Prevention and Control) this substance should be included in the ongoing work to develop guidance on 'Best Available Techniques' (BAT). It is recommended that Member States should carefully monitor the implementation of BAT by permitting and report any important developments to the Commission in the framework of the exchange of information on BAT.

The member companies of the CEFIC peroxygen sector group are providing and updating information on safe handling of the product and are in contact with the down stream users. The CEFIC Peroxygen Sector Group is currently working on a Draft BREF document.

With regard to the consumer applications mentioned in the risk reduction strategy Colipa and AISE have provided the following information:

Colipa:

For Tooth bleaching products:

A maximum allowed concentration of 6% in tooth bleaching products, as proposed in the strategy for limiting risks to consumers, has been approved by the SCCNFP in its latest opinion on tooth whitening products (SCCP). This recommendation has now to be transposed into legislation within the framework of the Cosmetics Directive. Appropriate warnings to be printed on the product label are currently under discussion with Member States and the EU Commission

For Hair colouring/bleaching products:

A viscosity of the H<sub>2</sub>O<sub>2</sub> suspension higher than that of the products already on the market will not lead to better protection of the consumer, since the mixing of the dye with the developer is done in a closed container, so that the consumer never gets in contact with the undiluted developer solution. The resulting mixture, which is then applied to the hair, is a viscous gel or paste, which adheres to the hair, so that no dripping or splashing can occur. This presentation in closed containers and thickened formulations that do not drip guarantee the safe use of these products for the consumer. This is confirmed by the low number of complaints and the very few cases listed by the Poison Centres. Warning statements regarding contact of these products with the eye are included in the use instructions.

AISE:

AISE companies have taken into account the results of the risk evaluation for hydrogen peroxide (as required in this Commission Recommendation). In the Strategy for Limiting Risks, the recommendations have been noted and implemented where risks are expected. Current risk reduction measures have also been maintained as recommended. If there are future amendments to the Preparations Directive, then the AISE companies would also be informed about those requirements.

The CEFIC Peroxygens Sector group or your supplier company is at your disposal for any further question concerning the EU Risk Assessment and other present or future EU regulations concerning hydrogen peroxide.



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