The European Agency for the Evaluation of Medicinal Products
*Veterinary Medicines Evaluation Unit*

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# COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

## HYDROGEN PEROXIDE (2)

## SUMMARY REPORT

1. Hydrogen Peroxide has many industrial uses as a bleaching and oxidising agent. It is used to treat sewage and industrial effluent. It is used in cosmetics, especially hair preparations, and in the processing of some foods. The USA FDA has affirmed that hydrogen peroxide is generally recognised as safe (GRAS) with specific limitations, as a direct human food ingredient. It may be used as an alternative to chlorine for the treatment of water intended for human consumption. Dilute solutions are used in human medicines as mouthwashes, eardrops and wound irrigation solutions. Solutions are also used in veterinary medicine as a disinfectant and in fish as a "bath" treatment for the control of ectoparasites.

2. In the absence of a stabilising agent hydrogen peroxide rapidly decomposes to oxygen and water. It decomposes in contact with oxidasable organic matter, and in contact with certain metals, and if allowed to become alkaline.

3. Strong solutions of hydrogen peroxide are toxic to humans if ingested and are corrosive to the skin, eyes and mucous membranes. Repeat-doses studies have been carried out in laboratory animals using various routes of administration. The findings included mortality and reduced body weight gain at high dose levels and effects which were associated with the corrosive nature of the substance. Although reported to be toxic to spermatozoa *in vitro*, hydrogen peroxide did not affect fertility and was not teratogenic. There has been an interest in its possible mutagenecity and carcinogenecity due to its potential for forming epoxides. However, there is no evidence that it is carcinogenetic at the concentrations to which humans would be exposed.

4. Hydrogen peroxide is a normal product of aerobic metabolism and may result from a number of oxidase- catalysed reactions. It has been calculated that the human liver produces 150-270 mg hydrogen peroxide per hour under normal conditions. However, it is rapidly metabolised by catalase so that the steady state concentration in human liver is approximately 30 ng/kg.

5. Following treatment with hydrogen peroxide, residues in fish and other products of animal origin cannot be distinguished from the endogenous levels. Spectrophotometric methods are available for the determination of residues of hydrogen peroxide down to 0.01 mg/l (0.01 mg/kg).

6. Hydrogen peroxide has already been included in Annex II of Council Regulation (EEC) Nº 2377/90 for use in fish.

7 Westferry Circus, Canary Wharf, London E14 4HB, UK
Switchboard: (+44-171) 418 84 00 Fax: (+44-171) 418 84 47

**Conclusions and recommendation**

Therefore, the Committe for Veterinary Medicinal Products considers that there is no need to establish an MRL for hydrogen peroxide for animal species other than fish and recommends its inclusion into Annex II of Council Regulation (EEC) No 2377/90 in accordance with the following table:

| Pharmacologically active substance(s) | Animal species | Other provisions |
|---|---|---|
| Hydrogen peroxide | All food producing species | |