COMMITTEE ON TOXICITY OF CHEMICALS IN FOOD, CONSUMER PRODUCTS AND THE ENVIRONMENT

STATEMENT: USE OF PAVA (NONIVAMIDE) AS AN INCAPACITANT SPRAY: REFORMULATION OF CAPTOR

Background to request for advice

1. The COT provided advice to the Home Office in 2002 and 2004 on the health effects of pelargonyl vanillylamide (PAVA or nonivamide) when used as an incapacitant spray (Captor I), and in 2006, on combined exposure to PAVA and CS gas.[1,2,3] PAVA is the synthetic equivalent of capsaicin (the active ingredient of pepper) and it is a sensory irritant. PAVA is used as a food flavour (up to 10 ppm) in Europe and in the USA where it has been given GRAS (Generally Agreed as Safe) status by the FDA. It is also used in human medicine as a rubefacient for topical application (0.012% a.i. in the UK).

2. The Civil Defence Supply (CDS) has proposed a reformulation of the product. The new formulation would contain the same amount of PAVA (0.3%) as Captor I, but with the ethanol/water (50:50) solvent replaced by a mixture of propylene glycol (72%), water (25%) and ethanol (2.7%). The instructions for application would remain the same. The new product is called Captor II. The new formulation was developed in response to requests for a formulation compatible with the use of TASER (an electroshock stun gun).

Advice requested from COT

3. The COT was asked to provide toxicological advice on the revised formulation and whether there was any increased risk to those directly or indirectly exposed to PAVA from Captor II in comparison with Captor I.

Submission October 2006.

4. CDS provided information on the purity of PAVA in the revised formulation and submitted a manufacturer's safety data sheet.[4] A further data sheet was provided to the COT for information by the secretariat. A representative from CDS attended the COT meeting to answer members' questions.

5. The COT concluded that data were required on droplet size for the reformulated product to help in the evaluation of risk on inhalation. The COT considered that the potential for systemic toxicity following dermal exposure to Captor II was low, but noted that formulation effects could be difficult to predict. CDS were asked to produce a written risk assessment regarding site of contact effects and systemic toxicity from Captor II. The risk assessment for respiratory effects would require information on droplet size to be considered. There would need to be consideration also of the potential for

cross contamination. The COT asked for further information on the statements from one manufacturer's safety data sheet regarding potential skin sensitisation.

Submission May 2007

6. CDS had provided the further data requested by COT on the effect of propylene glycol on percutaneous absorption of PAVA, and on droplet size in the aerosol spray released during use of Captor II.[5,6] Representatives for CDS attended the meeting to answer questions raised by the COT.

7. The company had been able to show that the report of skin sensitisation with propylene glycol in one manufacturers' material safety data sheet was incorrect and that published data did not support a skin sensitisation hazard for propylene glycol. Members were generally reassured that the data provided were of good quality and that the new formulation was an improvement on the previous PAVA spray. The proportion of spray droplets below 10 µm emitted from Captor II and sampled following a rebound test was substantially lower than for Captor I. It was agreed that the current monitoring of PAVA use and reporting of any adverse effects (especially relating to respiratory symptoms, in particular in asthmatics) should continue, but that Captor II should present a lower risk than Captor I with regard to potential for induction of respiratory symptoms.

8. Questions were put to the representatives from CDS who had prepared the submission for the COT. One COT member noted an apparent contradiction in the submitted document between the statement that propylene glycol may increase dermal absorption and the conclusion that the new formulation is easier to wash off. The COT requested that the CDS representatives clarify the situation should the solution remain on the skin for any length of time. The representatives from CDS explained that whilst propylene glycol was more likely to cross into the skin, it was much less likely to carry the PAVA in with it. Most PAVA would remain on the skin and would be more readily removed by wiping or washing. Volatility of the new formulation was much less than Captor I. This contributed to a lower potential for cross contamination than for Captor I.

9. The COT noted that the company would be asked to provide information relevant to the Home Office Scientific Division (e.g. on product usage and standardisation) directly to the Home Office.

COT conclusion

10. The COT concluded the information submitted on the toxicological risk assessment of Captor II in relation to direct and indirect exposure, provided adequate reassurance that the risk was lower than for the previous formulation (Captor I).

11. The COT restated that monitoring of experience-in-use should be continued.

References.

1. COT Statement on the use of PAVA (nonivamide) as an incapacitant spray (COT/02/2- April 2002)

2. COT statement on the use of PAVA (nonivamide) as an incapacitant spray. (COT/04/6- November 2004).

3. COT statement on combined exposure to CS and PAVA. January 2006.

4. CDS (Commercial in confidence) Submission of information 27 September 2006.

5. CDS (Commercial in confidence). Reformulation of PAVA. Submission of risk assessment April 2007.

6. AEA Energy Environment (Commercial in confidence). PAVA spray droplet sizing, EP47355. January 2007.