

DRS/MtH/IEA.31

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#### **DRS Information Exchange Service**

#### ALERT No. 31

## DIETHYLENE GLYCOL IMPLICATED IN POISONING CASES

Within the past three years, the World Health Organization has been notified of three apparently dissociated events, in two of which many children are reported to have died after having taken locally-formulated medicinal syrups. The products implicated were:

#### • paracetamol syrup (Nigeria, September 1990)

The World Health Organization was informed about an incident in which containers were illegally mislabelled as propylene glycol, but which contained diethylene glycol which was used in Nigeria in the preparation of paracetamol syrup intended for the treatment of common cold symptoms in children. As a result, more than 100 young children died. The Minister of Health immediately issued a directive that the public should be alerted to stop administering paracetamol syrup to children until further notice. The source of the mislabelled diethylene glycol was found and arrests were made. The cases of toxicity were restricted to Nigeria at that time.

• a tonic preparation (Propoleo®: Laboratorios Huilén) containing an extract of propolis (Argentina, August 1992)

Thirty-three cases of acute poisoning were attributed to the mistaken use of diethylene glycol instead of propylene glycol in a single batch of a natural medicine, Propoleo® (Laboratorios Huilén), a popular tonic containing an extract of propolis and other fortifying agents, used mainly by elderly people. All the notified cases were from Buenos Aires and the surrounding provinces. Twenty-three patients died and 10 were reported to be seriously ill.

The product was quickly identified and warnings issued to the public against its use. It is recommended that manufacturers and distributors mark containers of diethylene glycol with distinctive labels identifying the contents and indicating that the substance is highly toxic.

# • several local formulations of paracetamol syrup (Bangladesh, November 1992)

Doctors in Bangladesh have recently reported fatalities among children who had taken various locally manufactured preparations of paracetamol syrup.<sup>(3)</sup> Preliminary reports indicate that several of these preparations contain diethylene glycol instead of propylene glycol. The Government of Bangladesh has withdrawn all such preparations from the market pending the results of chemical analysis.

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A common factor in these incidents is evidence that diethyl glycol rather than propylene glycol was used as a solvent during the manufacture of these products. Diethylene glycol, which is used widely in industry as a solvent and an antifreeze, is acutely toxic to the kidneys and liver. It has been responsible for at least two earlier serious tragedies, one in the United States in 1938 and one in India in 1986, both resulting in the deaths of many infants.

In the light of this information, you may wish to consider whether there is a need to take consequential action in your country. Where there is any doubt in the matter, three measures are of basic importance:

- 1. Inspection reports of manufacturers of all products registered within your country that contain propylene glycol as a declared ingredient should be reviewed, focusing on identity and quality control of the ingredients.
- 2. Relevant documentation and/or chemical analyses of products/materials should be checked and, if necessary, further investigations undertaken.
- All possible information should be obtained on suppliers and channels of distribution of propylene glycol - both locally manufactured and imported - in your country.

WHO is exploring the possibility of developing a simple, fast test method to verify the identity and purity of propylene glycol, or which would at least be able to indicate incidental contamination with diethylene glycol.

We appeal to information officers to provide WHO as soon as possible with all information obtained under point 3 above, together with any other relevant data, in order to enable us to transmit this information to Member States which might help them to prevent further incidents.

### References:

- 1) Information Exchange Service Alert No.13, 26 September 1990.
- 2) Facsimile from the WHO Representative, Argentina, 18 August 1992.
- 3) Facsimile from the WHO Representative, Dhaka, Bangladesh, 23 November 1992.

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