COMMITTEE OF EXPERTS ON THE TRANSPORT OF DANGEROUS GOODS AND ON THE GLOBALLY HARMONIZED SYSTEM OF CLASSIFICATION AND LABELLING OF CHEMICALS

Sub-Committee of Experts on the
Transport of Dangerous Goods

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LISTING, CLASSIFICATION AND PACKING

Ethylene Oxide (UN1040) Sterilization Units –
To add a new Special Provision

Transmitted by the expert from the United Kingdom

Introduction

1. Small quantities of ethylene oxide (less than 30 ml) in glass ampoules are used in special machines for the sterilization of medical instruments in clinics and surgeries. These small glass ampoules are placed in the machines with the items to be sterilized. On activation, the ampoules are broken, releasing the gas to carry out the sterilisation process.

2. Ethylene oxide is a toxic and flammable gas and there are no limited or excepted quantity provisions for the transport of this substance. Packing Instruction P 200 does recognise that this gas can be carried in glass ampoules (special packing provision "l") but this provision requires a UN tested package marked, labelled and documented in accordance with Part 5 of the Model Regulations. These small packages are usually sent to small, local clinics and surgeries and need to be easily transported through the small parcel distribution systems which rely on distributors being able to utilise limited and excepted quantity provisions. Such distribution appears to be carried out worldwide in thousands of separate consignments.

Background

3. Around ten years ago the ICAO Dangerous Goods panel adopted the following special provision:

> "A131 Sterilization devices, when containing less than 30 ml per inner packaging with not more than 300 ml per outer packaging, may be transported on passenger and cargo aircraft in accordance with the provisions in 1;2.4, irrespective of 1;2.4.2.2 and the indication of "Forbidden" in columns 9 to 12 of the Dangerous Goods

List (Table 3-1). In addition, after filling, each inner packaging must be determined to be leak-tight by placing the inner packaging in a hot water bath at a temperature, and for a period of time, sufficient to ensure that an internal pressure equal to the vapour pressure of ethylene oxide at 55 °C is achieved. Any inner packaging showing evidence of leakage, distortion or other defect under this test may not be transported under the terms of this special provision. In addition to the packaging required by 1;2.4, inner packagings must be placed in a sealed plastics bag compatible with ethylene oxide and capable of containing the contents in the event of breakage or leakage of the inner packaging. Glass inner packagings must be placed within a protective shield capable of preventing the glass from puncturing the plastics bag in the event of damage to the packaging (e.g. crushing)."

4. The leak-tightness determination is the same as that found in gas specific provision "l" in Packing Instruction P200. The protective shield referred to is usually provided by a fibreboard tube. Obviously A131 applies only to air transport. At the moment it is impossible for this substance to move by land or sea in the same manner unless the competent authority is willing or able to issue an approval.

Proposal

5. Clearly these substances <u>are</u> now already moving around the world by land and sea. The expert from the United Kingdom believes there is no reason why a provision similar to A131 should not be adopted into the Model Regulations for UN 1040 allowing this substance to be moved multi-modally in the same way. Amendments would be necessary to address multi-modal provisions as follows:

SPXXX Sterilization devices, when containing less than 30 ml per inner packaging with not more than 300 ml per outer packaging, may be transported in accordance with the provisions in Chapter 3.5, irrespective of the indication of E0 in column 7a of the Dangerous Goods List. In addition, after filling, each inner packaging must be determined to be leak-tight by placing the inner packaging in a hot water bath at a temperature, and for a period of time, sufficient to ensure that an internal pressure equal to the vapour pressure of ethylene oxide at 55 °C is achieved. Any inner packaging showing evidence of leakage, distortion or other defect under this test may not be transported under the terms of this special provision. In addition to the packaging required by 3.5.2, inner packagings must be placed in a sealed plastics bag compatible with ethylene oxide and capable of containing the contents in the event of breakage or leakage of the inner packaging. Glass inner packagings must be placed within a protective shield capable of preventing the glass from puncturing the plastics bag in the event of damage to the packaging (e.g. crushing).

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