

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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PERFORMANCE OF PACKAGINGS, INCLUDING IBCS

Pharmaceutical Aerosols, Revised Text

Transmitted by the Expert of Sweden and FEA

6.2.4.3 With the approval of the competent authority, aerosols and receptacles small are not subject to 6.2.4.1 and 6.2.4.2, if they are required to be sterile but may be adversely affected by water bath testing, provided

- (a) they contain a non-flammable gas and either
 - (i) contain other substances that are constituent parts of pharmaceutical products for medical, veterinary or similar purposes, or
 - (ii) contain other substances used in the production process for pharmaceutical products, or
 - (iii) are used in medical, veterinary or similar applications;
 - (b) an equivalent level of safety is achieved by the manufacturer's use of alternative methods for leak detection and pressure resistance, such as helium detection and water bathing a statistical sample of at least 1 in 2 000 from each production batch; and
 - (c) for pharmaceutical products according to (a)(i) and (iii) above, they are manufactured under the authority of a national health administration. If required by the competent authority, follow the principles of Good Manufacturing Practice (GMP) established by the World Health Organization (WHO).
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