**Dunkelberg H. Assessment of compatibility of microbial barrier properties of packaging material of terminally sterilized products with the airborne microbial challenge during the storage period**

# Abstract text (incl. references and figure legends):


**Question**

The question of this presentation was to demonstrate the compatibility of barrier performance (i.e. filtration efficiency) of medical packaging material with the exposure to airborne microorganisms during the storage period.

**Methods**

The compatibility of the microbial filtration efficiency of the packaging material with the airborne microbial challenge ($N_0$) was calculated according to this equation:

$N_0$ x [100-filtration efficiency (%)]/100 x n =< $10^{-6}$

where

$N_0$ = airborne microbial challenge; it is depends of the airborne microbial concentration and the volume of air that enters the packaging during storage (caused by air pressure and temperature variations, see the Boyle-Mariotte and Gay-Lussac laws),

n = number of events causing a microbial challenge according to $N_0$,

$10^{-6}$ = sterility assurance level (SAL).

The exposure chamber method was used to detect the filtration efficiency of paper/film pouches (16x18 cm) denoted by A and B and of non-woven/film pouches denoted by C. 30 pouches per group were charged with uncovered thermo-resistant and CASO-agar filled petri dishes, sealed and sterilized, and then exposed. The exposure chamber with a capacity of 1 m³ was equipped with a vacuum pump in order to reduce the atmospheric pressure periodically by 70 hPa which leads to an air flow through the permeable component of the packaging. A microbial aerosol of Micrococcus luteus with a mean particle size of about 3 µm was generated by a nebulizer. The pressure in the chamber was measured digitally with a pressure sensor and a data logger. A glass impinger air sampler was used to determine the airborne microbial concentration. After exposure, the pouches were incubated at 36 °C for 72 hours. The number of colony forming units (CFU) was registered after removing the packaging material. The filtration efficiency was calculated by means of the ratio of the microbial challenge and the CFUs observed on the dishes.

The following example was used to calculate the maintenance of sterility. Volume of the pouch: 150 cm³, one event reflects a daily temperature variation of 2 °C at room temperature of 20 °C, and an airborne microbial concentration of 10 CFU (particle size: < 3 µm).

**Results**

The filtration efficiencies of the pouches type A were 98.4, of type B 98.8 and of type C 85.6 % respectively. The air volume that enters the packaging per one event according to the given example was about 1 cm³, a microbial challenge of 0.00001 microbes could be calculated for one event. We obtained the following results for n (= number of events or days) which demonstrate that the used packaging material maintains sterility at the SAL: n= 6.25 (type A), 8.3 (type B) and 0.7 (type C).

**Conclusion**

The filtration efficiency and the estimated airborne microbial challenge were used to assess the compatibility of the medical packaging material with specified exposure conditions at the SAL. The tested pouches guaranteed sterility at the SAL for only a few days.