Recommended standardized operating procedures for acute inhalation toxicity criteria

1. In the assessment and evaluation of the toxic characteristics of chemicals in a vapour or aerosol state determination of acute inhalation toxicity is necessary. In every case, when it is possible, this test should be preceded by subcutaneous toxicity determination. Data from these studies constitute the initial steps in the establishing of a dosage regimen in subchronic and other studies and may provide additional information on the mode of toxic action of a substance.

Three categories of agents were defined on the basis of their toxicity:

- (i) super-toxic lethal chemicals;
- (ii) other lethal chemicals;
- (iii) other harmful chemicals.

Lethality limits in terms of LCt₅₀ for inhalatory application were established to separate three toxic categories at 2,000 mg min/m³ and 20,000 mg min/m³.

2. Principles of the test method

A group of animals is exposed for a defined period to the test substance in concentration corresponding exactly to the category limits (2,000 mg min/m 3 or 20,000 mg min/m 3) respectively. If in an actual test the death rate was greater than 50 per cent, then the material would fall into the higher toxicity category; if it was lower than 50 per cent, the material would fall into the lower toxicity category.

3. Description of the test procedure

- 3.1 Experimental animal Healthy young adult male albino rats of Wistar strain weighing 200 ± 20 g should be used. The animals should be acclimatized to the laboratory conditions for at least five days prior to the test. The temperature of the animal room before and during the test should be 22 ± 3°C and the relative humidity should be 50-70 per cent. With artificial lighting, the sequence should be 12 hours light, 12 hours dark. Conventional laboratory diets may be used for feeding with an unlimited supply of drinking water. The animals should be group-caged but the number of animals per cage should not interfere with proper observation of each animal. Prior to the test the animals are randomized and divided into two groups; 20 animals in each group.
- 3.2 Test substance Each test substance should be appropriately identified (chemical composition, origin, batch number, purity, solubility, stability, boiling point, flash point, vapour pressure etc.) and stored under conditions ensuring its stability. The stability of the substance under the test conditions should also be known.