



COMMITTEE FOR VETERINARY MEDICINAL PRODUCTS

n-BUTANOL

SUMMARY REPORT

1. n-Butanol is used as a preservative or stabilising solvent in veterinary medicinal products.
2. n-Butanol is used as a flavouring agent in butter, cream, food, liquor, rum and whiskey. It is used as an extractant in food producing operations in the manufacture of hormones, antibiotics, vitamins and as a solvent for many industrial and cleansing activities.
3. n-Butanol is readily absorbed through lungs, skin and the intestinal tract. It is oxidised by alcohol and aldehyde dehydrogenases to butyric acid, which in turn is oxidised to carbon dioxide and water.
4. The acute toxicity of n-butanol is low to moderate, irrespective of the route of administration. (LD₅₀ orally is 700 to 2100 mg/kg bw; LD₅₀ in mice following intravenous administration is 377 mg/kg bw).
5. Administration of n-butanol 16,020 mg/kg bw/day to rabbits for 30 days was tolerated without ill effect.
6. In rats dosed by gavage for 13 weeks, a dose of 125 mg/kg bw/day was considered a no-observed-adverse-effect level (NOEL). Ataxia and hyperactivity were observed in animals given 500 mg/kg bw/day.
7. In rats exposed by inhalation to n-butanol, the only teratogenic effect was a slight increase in skeletal malformations (primarily rudimentary cervical ribs) at doses of 18,000 mg/m³ air and above.
8. n-Butanol did not cause point mutations in a range of mutagenicity studies.
9. The most important effects of n-butanol inhalation in man are symptoms intoxication and narcosis. Concentrations of more than 153.9 mg/m³ air are irritant to the conjunctivae of the eye.
10. A number of scientific committees including the EC Scientific Committee on Food and the Joint FAO/WHO Expert Committee on Food Additives have concluded that it is not possible to determine a NOEL on the basis of lack of information on the long-term oral effects of n-butanol.
11. n-Butanol is rapidly excreted from treated rats; in rats dosed by gavage with 450 mg 1-butanol/kg bw, 83.3% of the dose was excreted as carbon dioxide at 24 hours. Less than 1% was eliminated in the faeces, 4.4% in the urine, and 12.3% remained in the carcass.
12. In view of the rapid metabolism excretion in animals it is not necessary to establish maximum residue limits for n-butanol. It is therefore appropriate to include n-butanol into Annex II of Council Regulation (EC) N° 2377/90.