Download Principles For The Selection Of Doses In Chronic Rodent Bioassays

INTERNATIONAL PROGRAMME ON CHEMICAL SAFETY ENVIRONMENTAL HEALTH CRITERIA 6 PRINCIPLES AND METHODS FOR EVALUATING THE TOXICITY OF CHEMICALS PART I This report contains the collective views of an international group of experts and does not necessarily represent the decisions or the stated policy of the United Nations Environment Programme, the International Labour Organisation, or the World ...1.. IntroductionResidual impurities resulting from manufacturing and formulation, or from degradation of the active pharmaceutical ingredient (API) 1 and excipients, may be present in pharmaceutical products. A subset of these impurities may present a potential for genotoxicity and therefore pose an additional safety concern to clinical subjects and patients.Monoclonal antibodies (mAbs) are a well established class of therapeutics as evidenced by a large number of FDA approved mAbs for the treatment of cancers and autoimmune diseases. Monoclonal antibodies that are molecularly engineered for enhancedCompound-specific toxicology limits were developed for common potential impurities in drug substances. • A class-specific limit of 15 ?g/day was developed for monofunctional alkyl bromides.