Evaluation and Testing of Drugs For Mutagenicity - Principles and Problems : Report of A Who Scientific Group.

s.n - Difficulties in conceiving and applying guidelines for the safety evaluation of biotechnologically

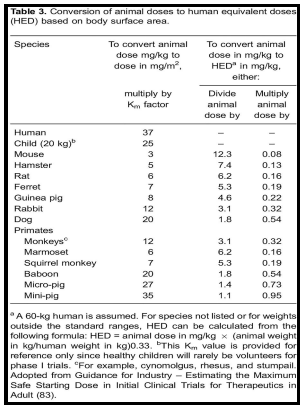

Table 3. Conversion of animal doses to human equivalent doses (HED) based on body surface area.

Species	To convert animal dose mg/kg to dose in mg/m², multiply by K_m factor	To convert animal dose in mg/kg to HED[a] in mg/kg, either: Divide animal dose by	Multiply animal dose by
Human	37	–	–
Child (20 kg)[b]	25	–	–
Mouse	3	12.3	0.08
Hamster	5	7.4	0.13
Rat	6	6.2	0.16
Ferret	7	5.3	0.19
Guinea pig	8	4.6	0.22
Rabbit	12	3.1	0.32
Dog	20	1.8	0.54
Primates			
Monkeys[c]	12	3.1	0.32
Marmoset	6	6.2	0.16
Squirrel monkey	7	5.3	0.19
Baboon	20	1.8	0.54
Micro-pig	27	1.4	0.73
Mini-pig	35	1.1	0.95

[a] A 60-kg human is assumed. For species not listed or for weights outside the standard ranges, HED can be calculated from the following formula: HED = animal dose in mg/kg × (animal weight in kg/human weight in kg)0.33. [b]This K_m value is provided for reference only since healthy children will rarely be volunteers for phase I trials. [c]For example, cynomolgus, rhesus, and stumpail. Adopted from Guidance for Industry – Estimating the Maximum Safe Starting Dose in Initial Clinical Trials for Therapeutics in Adult (83).

Description: -
-Evaluation and Testing of Drugs For Mutagenicity - Principles and Problems : Report of A Who Scientific Group.
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His: Obras completas ; 9
Technical report series (World Health Organization) -- 482Evaluation and Testing of Drugs For Mutagenicity - Principles and Problems : Report of A Who Scientific Group.
Notes: 1
This edition was published in 1971

Tags: #4 #METHODS #FOR #TOXICITY #TESTING

The role of the world health organization in pesticide research

After necropsy, the weights of certain organs are also recorded. Knowledge of reactivity with, or binding to, macromolecules may allow specific design of mechanism experiments, when these macromolecules are essential tissue and cell constituents.

Japanese guidelines for mutagenicity testing, Environmental and Molecular Mutagenesis

Persons with diminished autonomy or capacity are entitled to protection. Johnson 1975 recently reviewed the problems encountered in the pursuit of the mechanism of delayed peripheral neuropathy produced by some organophosphorus esters. EPA has issued 194 registration standards on 350 chemicals used as active and inert ingredients in pesticide products.

Difficulties in conceiving and applying guidelines for the safety evaluation of biotechnologically

Chronic studies, such as reproduction studies and lasting 1 year or longer in the rat or dog are used for this purpose. A postnatal development toxicity study Guideline 83-6; EPA, 1984 is proposed as a conditional requirement. FACTORS INFLUENCING THE DESIGN OF TOXICITY STUDIES 2.

Difficulties in conceiving and applying guidelines for the safety evaluation of biotechnologically

Doses should be administered over the period of major organogenesis major visceral and skeletal formation in the fetus. This is a domain where society at large has a role to play. General Description Developmental toxicity studies are designed to assess the potential of developmental effects in offspring resulting from the mother's exposure to the test substance during pregnancy.

Japanese guidelines for mutagenicity testing, Environmental and Molecular Mutagenesis

Roe 1968 discussed various problems encountered in the design and interpretation of inhalation toxicity studies related to species differences in the anatomy of the respiratory tree.

313. Annexes (WHO Pesticide Residues Series 4)

Since gut microflora are changed in certain gastrointestinal diseases in man, modifications of the quality and distribution of microflora in experimental animals might be a useful model for special tests Williams, 1972.

The role of the world health organization in pesticide research

Finney 1952a has discussed various transformations that can be used to make dose-effect curves linear. WHO 1957 WHO Technical Report Series No. The duration of pregnancy should be determined from the time evidence of mating was first observed.

4 METHODS FOR TOXICITY TESTING

Required unless repeated dermal exposure does not occur under conditions of use.

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