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## Sucralose: Assessment of Teratogenic Potential in the Rat and the Rabbit

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**Abstract**—The teratogenic potential of sucralose was examined following gavage administration to pregnant rats and rabbits during organogenesis. Groups of 20 mated rats were dosed on days 6–15 of gestation inclusive at 500, 1000 or 2000 mg/kg/day; groups of 16 to 18 inseminated rabbits were dosed on days 6 to 19 of gestation inclusive at 175, 350 or 700 mg/kg/day following preliminary studies at higher doses. Concurrent control groups received vehicle alone. Rats were killed on day 21 and rabbits on day 29 of gestation. Foetuses were evaluated at necropsy and after processing for possible soft tissue and skeletal alterations. There was no evidence of teratogenicity for either species. The only observed response to treatment in rats was a slight increase in water intake. Some adult rabbits receiving 700 mg/kg/day exhibited marked gastrointestinal disturbance, also seen at higher doses in preliminary studies. Gastrointestinal effects such as these occur non-specifically in response to high doses of poorly absorbed compounds, and in the present study were considered to be responsible for two maternal deaths and four abortions. Full evaluation of rabbit foetuses in the main study (up to 700 mg/kg/day) and necropsy of foetuses in a preliminary study with pregnant animals (up to 1000 mg/kg/day) showed no evidence of adverse foetal response to sucralose. These teratology studies in both pregnant rodent and non-rodent animal models demonstrate that maternal consumption of high levels of sucralose during the period of organogenesis has no effect on normal foetal development in the rat or rabbit. © 2000 Elsevier Science Ltd. All rights reserved

**Keywords:** sucralose; teratology; rats; rabbits; artificial sweeteners.

### INTRODUCTION

Previous evidence suggested that small amounts of sucralose may cross the placenta (McNeil, 1987). Because sucralose will be consumed by women of child-bearing potential, studies were conducted to evaluate the potential for this water-soluble molecule to adversely affect normal embryonic and foetal development.

The work reported here is an evaluation of the teratogenic potential of sucralose in pregnant CD rats and New Zealand White rabbits.

### MATERIALS AND METHODS

These studies were conducted in accordance with Good Laboratory Practice Regulations for non-clinical safety assessment studies (FDA, 1978).

### Test material

Sucralose was supplied as a white powder (by Linson Ltd, Swords, Co. Dublin, Eire). Batch number 153002 MT 205 (purity >97.4%) was used for the rat teratology study; batch number 953011 (purity 99.3%) was used for the rabbit preliminary and main teratology studies. Uniformly radio-labelled <sup>14</sup>C- sucralose (batch number CFQ.3102) was supplied by Amersham International plc at a specific activity of 1.2835 µCi/mg.

### Animals and husbandry

**Rats.** Virgin female CD rats [CrI:CD<sup>®</sup>(SD) BR strain from Charles River (UK) Ltd, Margate, Kent, UK] at 8–9 wk of age were allowed 6 days' acclimatization and were then mated with proven stock males from the same strain and source.

Cages consisted of high-density polypropylene bodies with lids of stainless-steel grid. During acclimatization and pairing, the animals were in cages with stainless-steel grid floors but during gestation the females were housed individually in cages with solid polypropylene floors provided with autoclaved wood shavings as bedding. Cages were distributed

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# Evaluation Of The Teratogenic Potential Of Chemicals In The Rat

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**Evaluation of the Teratogenic Potential of Chemicals in the Rat** H. Fritz, K. Giese, 1990-01-01      **Toxicological Testing Handbook** David Jacobson-Kram, Kit A. Keller, 2016-04-19 Furnishing essential data on all areas of toxicity testing this Second Edition provides guidance on the design and evaluation of product safety studies to help ensure regulatory acceptance Every chapter highlights regulatory requirements specific to the United States Europe and Japan and in addition to expanded information on data      **Drugs in Pregnancy and Lactation** Gerald G. Briggs, Roger K. Freeman, Sumner J. Yaffe, 2008 Featuring 127 new drug entries the eighth edition of this popular reference provides practical reliable information on more than 1 175 drugs that may be used by pregnant and lactating women      Chemically Induced Birth Defects James Schardein, 2000-04-11 This thoroughly revised and updated reference addresses the drugs and chemicals causing malformations and congenital anomalies in the human fetus comprehensively reviewing experimental studies in animals and clinical data on human development primarily in the organogenesis period Addressing current public health concerns over teratogens Chemical      **Clinical and Experimental Toxicology of Organophosphates and Carbamates** Bryan Ballantyne, Timothy C. Marrs, 2017-01-31 Clinical biochemical determination of cholinesterase activity in fluids and tissues intermediate syndrome in anticholinesterase neurotoxicity structure activity relationships and anticholinesterase activity and the molecular events in delayed neuropathy Other parts deal with the cardiac effects of anticholinesterase agents and the ecotoxicological consequences of interactions between avian esterases and organophosphorus compounds These topics are followed by discussions on the analysis of the cutaneous and respiratory tract absorption of anticholinesterases and the use of organophosphorus compounds as chemical warfare agents The final parts are devoted to the toxicity of anticholinesterases to aquatic organisms The book can provide useful information to toxicologists doctors students and researchers

**Cumulated Index Medicus**, 1996      **Safety Evaluation of Certain Food Additives and Contaminants** Joint FAO/WHO Expert Committee on Food Additives. Meeting, World Health Organization, 2013 This volume contains monographs prepared at the seventy seventh meeting of the Joint FAO WHO Expert Committee on Food Additives JECFA which met in Rome Italy from 4 to 13 June 2013 The toxicological monographs in this volume summarize the safety data on three food additives advantame glucoamylase from *Trichoderma reesei* expressed in *Trichoderma reesei* and nisin Toxicological and dietary exposure information and information on specifications for all of the food additives and contaminants considered by the Committee are annexed to the volume This volume and others in the WHO Food Additives series contain information that is useful to those who produce and use food additives and veterinary drugs and those involved with controlling contaminants in food government and food regulatory officers industrial testing laboratories toxicological laboratories and universities

*Teratology and Congenital Malformations: KWIC index, Mephenesin-Zymogram. Author index* Lois Weinstein, 1976 Over 14 000 entries to international literature on congenital malformations caused by a variety of agents Includes journal articles

books book reviews symposia proceedings and abstracts from meetings Consists of retrospective searches undertaken in 1962 by Lederle Laboratories plus all references in Lederle s journal titled Teratogenicity mutagenicity and carcinogenicity 1963 1973 Emphasizes experimental work but also includes clinical Accession number arrangement Entries include bibliographical information abbreviation of foreign language and secondary source KWIC author indexes

**Drug Safety Evaluation** Shayne Cox Gad,2016-11-07 This practical guide presents a road map for safety assessment as an integral part of the development of new drugs and therapeutics Helps readers solve scientific technical and regulatory issues in preclinical safety assessment and early clinical drug development Explains scientific and philosophical bases for evaluation of specific concerns including local tissue tolerance target organ toxicity and carcinogenicity developmental toxicity immunogenicity and immunotoxicity Covers the development of new small and large molecules generics 505 b 2 route NDAs and biosimilars Revises material to reflect new drug products small synthetic large proteins and cells and tissues harmonized global and national regulations and new technologies for safety evaluation Adds almost 20% new and thoroughly updates existing content from the last edition

**Health Risk Assessment Dermal and Inhalation Exposure and Absorption of Toxicants** Rhoda G.M. Wang,James B. Knaak,Howard I. Maibach,2017-11-22 Health Risk Assessment is a comprehensive reference focusing on dermal absorption cholinesterase inhibition adverse reproductive effects and carcinogenicity The book features contributions from over 40 top scientists and covers topics such as PBPK modeling cytochrome P 450 metabolism in skin percutaneous absorption adverse effects new skin models and the role of epidemiology in assessing the hazards of toxicants Health Risk Assessment is essential for toxicologists environmental chemists pharmacologists risk assessors and managers working in industrial pesticide and pharmaceutical development The book will also benefit individuals in environmental regulatory and registration affairs as well as academicians and students

**Toxicological Assessment of Combined Chemicals in the Environment** De-Sheng Pei,Yiyun Liu,2025-02-05 Comprehensive resource covering toxicology fundamentals distribution of pollutants in the environment and research methodologies for toxicological assessment of chemical mixtures Toxicological Assessment of Combined Chemicals in the Environment offers an in depth exploration of various approaches and molecular mechanisms regarding how minor alterations in chemical mixtures can influence an organism s toxicity along with discussion of the challenges associated with assessing mixtures The first section of the book provides a concise introduction to the background and significance of combined toxicity Section two delves into the primary sources and enrichment mechanisms of different chemical mixtures elucidating the biological exposure pathways of these compounds Section three introduces both classical and emerging toxicological research models in detail Building on the descriptions of compound emission migration accumulation and transformation processes and the analysis of combined molecular toxicity in the preceding sections section four introduces computer mathematical modeling methods for hazard assessment of compound mixtures The final section details the challenges and future trends in this field Written by a highly

qualified author and seasoned research contributor in the field Toxicological Assessment of Combined Chemicals in the Environment covers sample topics including The degradation oxidation absorption distribution biotransformation and excretion of various compounds in both the environment and in organisms A variety of cell models and in vivo research models of model organisms supplemented with case studies Combined molecular toxicity mechanisms of heavy metals pesticides persistent organic pollutants POPs and pharmaceutical and personal care products PPCPs Principal sources fate and mechanism of chemical mixtures in the environment as well as experimental designs and sampling strategies for combined toxicity studies based on concentrations Toxicological Assessment of Combined Chemicals in the Environment serves as a valuable reference for researchers students and policymakers involved in environmental management and protection It is particularly relevant for toxicologists risk assessors and those engaged in the molecular modeling of toxic mixtures

**Organophosphates Chemistry, Fate, and Effects** Janice E. Chambers, Patricia E. Levi, 2013-10-22 This volume pulls together a wealth of up to date information on the toxicology of this diverse and ubiquitous class of insecticides Leading experts review the reactivity of organophosphorus compounds with cholinesterase as well as their metabolism and biological effects on humans and other nontarget organisms The book not only covers the anticholinesterase actions of organophosphates but also other presumably independent effects such as teratogenicity delayed neuropathy immunotoxicity and behavioral toxicity Offers crucial overviews of chemical and biochemical reactivity and biological responsiveness of mainly nontarget organisms Reviews new developments in assessment of metabolism and disposition of organophosphorus compounds Examines organophosphorus compound induced toxicity mediated by mechanisms other than inhibition of acetylcholinesterase Covers new research on differences in toxicity induced by the variety of organophosphorus Analyzes current controversies on the relevance of certain biochemical parameters in actual organophosphate toxicity in vivo

**Toxicology Research Projects Directory**, 1978 Alternative Methodologies for the Safety Evaluation of Chemicals in the Cosmetic Industry Nicola Loprieno, 2019-08-15 First published in 1995 Alternative Methodologies for the Safety Evaluation of Chemicals in the Cosmetic Industry presents a categorization and collection of information available for the evaluation of safety using in vitro techniques It offers a comprehensive and complete look at the entire field In doing so the author provides the foundation for the next phase of significant growth for this discipline

**Patty's Toxicology, 6 Volume Set** Eula Bingham, Barbara Cohrssen, 2012-07-31 Featuring the improved format used in the 5th edition this updated set presents in logical groupings comprehensive toxicological data for industrial compounds including CAS numbers physical and chemical properties exposure limits and biological tolerance values for occupational exposures making it essential for toxicologists and industrial hygienists This edition has about 40% new authors who have brought a new and international perspective to interpreting industrial toxicology and discusses new subjects such as nanotechnology flavorings and the food industry reactive chemical control to comprehensive chemical policy metalworking fluids and pharmaceuticals

**Environmental Health Perspectives** ,1993      *Hayes' Handbook of Pesticide Toxicology* ,2010-02-15 The Handbook of Pesticide Toxicology is a comprehensive two volume reference guide to the properties effects and regulation of pesticides that provides the latest and most complete information to researchers investigating the environmental agricultural veterinary and human health impacts of pesticide use Written by international experts from academia government and the private sector the Handbook of Pesticide Toxicology is an in depth examination of critical issues related to the need for use of and nature of chemicals used in modern pest management This updated 3e carries on the book s tradition of serving as the definitive reference on pesticide toxicology and recognizes the seminal contribution of Wayland J Hayes Jr co Editor of the first edition Presents a comprehensive look at all aspects of pesticide toxicology in one reference work Clear exposition of hazard identification and dose response relationships in each chapter featuring pesticide agents and actions All major classes of pesticide considered Different routes of exposure critically evaluated      *Air Toxics and Risk Assessment* Edward J. Calabrese,Elaina Kenyon,1991-03-25 Unlike most books this one actually does risk assessments for you for over 110 chemicals that are confirmed or probable air toxics All chemicals are analyzed with a scientifically sound methodology outlined in the book to assess public health risk associated with exposure to air toxics Methodology will allow you to properly handle all air toxic health concerns within a practical decision free framework This permits the application of methodology to any new chemical Each chemical or compound is organized by synonym molecular weight molecular formula AALG occupational limits drinking water limits toxicity profile and indexed by CAS number and synonyms      *Environmental Biology & Toxicology* Sharma P D,      **Pesticide residues in food 2022 - Evaluations - Part II - Toxicological** Food and Agriculture Organization of the United Nations,World Health Organization,2024-05-23 A Joint Meeting of the Food and Agriculture Organization of the United Nations FAO Panel of experts on Pesticide Residues in Food and the Environment and the World Health Organization WHO Core assessment Group on Pesticide Residues JMPR was held in Rome Switzerland from 12 to 22 September 2019 Author The FAO Panel Members met in preparatory sessions from 8 to 12 September Author

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