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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).

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[†]Now known as Huntingdon Life Sciences.

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 ¹⁴C- 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[®](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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