

TABLE 1
Summary of Definitive Preclinical Toxicology Studies with Aspartame^a

Study type	Specific studies	Species	Outcome	Maximum dose (mg/kg body wt)
Genetic toxicology	Dominant lethal mutation assay	Rats	Negative	
	Host-mediated assay	Rats and mice	Negative	
	<i>In vivo</i> cytogenetics assay	Rats	Negative	
	Ames test	Standard strains	Negative	
Acute toxicology		Rats	No deaths	5000
		Mice	No deaths	5000
		Rabbits	No deaths	5000
Subchronic studies	Various lengths	Rats	Dose setting	
	Various lengths	Mice	Dose setting	
	Various lengths	Dogs	Dose setting	
Chronic toxicology and carcinogenicity	2 years	Rats	Negative	6000–8000
	2 years, <i>in utero</i> exposure	Rats	Negative	4000
	2 years	Rats	Negative	3000 : 1000
	(aspartame : DKP 3 : 1 Ratio)			aspartame : DKP ratio
	2 years	Mice	Negative	4000
	2 years	Dogs	Negative	4000
Reproduction	Two-generation	Rats	Negative	3500–7000
	Reproduction/fertility (segment I)	Rats	Negative	4100–4900
	Perinatal/postnatal (segment III)	Rats	Negative	4000–7000
	Postnatal (39 weeks)	Monkeys	Negative	3000
Teratology	<i>In utero</i> (segment II)	Rats	Negative	4100
	<i>In utero</i> (segment II)	Mice	Negative	5700
	<i>In utero</i> (segment II)	Rabbits	Negative	2400
	<i>In utero</i> (segment II)	Rabbits	Negative	2000
	(aspartame : DKP 3 : 1 Ratio)			