

Table 14

Absolute and relative organ weights of male rats treated orally with isocyanuric acid in the combined repeat dose and reproductive/developmental toxicity screening test

	Dose (mg/kg)	No. of animals	B.W. (g)	Brain (g)	Liver (g)	Kidney (g)	Spleen (g)	Heart (g)	Thymus (g)	Thyr. (mg)	Pitui. (mg)	Adrenal (mg)	Testis (g)	Epidid. (g)
Absolute	0	10	483 ± 41	2.14 ± 0.08	13.68 ± 2.09	3.01 ± 0.34	0.74 ± 0.09	1.49 ± 0.08	0.35 ± 0.06	30.3 ± 7.9	15.6 ± 2.2	63.8 ± 8.9	3.60 ± 0.26	1.45 ± 0.17
	10	10	508 ± 19	2.10 ± 0.07	15.71* ± 1.33	3.36 ± 0.37	0.79 ± 0.08	1.48 ± 0.06	0.33 ± 0.07	34.2 ± 5.0	16.6 ± 2.0	63.2 ± 6.2	3.47 ± 0.24	1.37 ± 0.11
	40	10	492 ± 32	2.07 ± 0.06	14.35 ± 1.47	3.06 ± 0.29	0.81 ± 0.11	1.58 ± 0.15	0.34 ± 0.08	36.3 ± 4.9	16.3 ± 0.8	63.2 ± 7.5	3.40 ± 0.14	1.36 ± 0.09
	150	10	495 ± 38	2.06 ± 0.07	14.76 ± 1.48	3.12 ± 0.15	0.78 ± 0.06	1.48 ± 0.12	0.31 ± 0.08	38.2 ± 6.3	19.8*** ± 2.8	66.4 ± 14.5	3.41 ± 0.27	1.41 ± 0.13
	600	10	444* ± 31	2.08 ± 0.08	12.08 ± 1.62	4.62** ± 0.96	0.83 ± 0.10	1.38 ± 0.11	0.28 ± 0.07	33.6 ± 6.4	17.4 ± 2.7	72.1 ± 10.8	3.32 ± 0.24	1.32 ± 0.10
Relative@	0	10	483 ± 41	0.45 ± 0.03	2.82 ± 0.26	0.62 ± 0.03	0.16 ± 0.01	0.31 ± 0.02	0.07 ± 0.02	6.32 ± 1.71	3.23 ± 0.42	13.18 ± 1.19	0.75 ± 0.06	0.30 ± 0.04
	10	10	508 ± 19	0.41 ± 0.02	3.09* ± 0.22	0.66 ± 0.08	0.16 ± 0.02	0.29 ± 0.02	0.07 ± 0.01	6.75 ± 1.01	3.29 ± 0.49	12.46 ± 1.27	0.68 ± 0.04	0.27 ± 0.02
	40	10	492 ± 32	0.42 ± 0.03	2.92 ± 0.19	0.62 ± 0.05	0.16 ± 0.01	0.32 ± 0.02	0.07 ± 0.02	7.38 ± 0.98	3.33 ± 0.22	12.88 ± 1.55	0.69 ± 0.03	0.28 ± 0.02
	150	10	495 ± 38	0.42 ± 0.04	2.98 ± 0.17	0.63 ± 0.05	0.16 ± 0.02	0.30 ± 0.02	0.06 ± 0.01	7.80 ± 1.71	4.02* ± 0.61	13.39 ± 2.64	0.69 ± 0.07	0.28 ± 0.03
	600	10	444* ± 31	0.47 ± 0.03	2.71 ± 0.21	1.04** ± 0.21	0.19** ± 0.02	0.31 ± 0.02	0.07 ± 0.02	7.61 ± 1.62	3.95* ± 0.68	16.23** ± 2.14	0.75 ± 0.07	0.30 ± 0.03

Each value is expressed as mean ± S.D.

@ : Relative organ weight per 100g body weight

* : Significantly different from control at 5% level of probability

** : Significantly different from control at 1% level of probability

Table 15

Absolute and relative organ weights of female rats treated orally with isocyanuric acid in the combined repeat dose and reproductive/developmental toxicity screening test

	Dose (mg/kg)	No. of animals	B.W. (g)	Brain (g)	Liver (g)	Kidney (g)	Spleen (g)	Heart (g)	Thymus (g)	Thyr. (mg)	Pitui. (mg)	Adrenal (mg)
Absolute	0	10	345 ± 16	1.88 ± 0.06	13.93 ± 1.19	1.89 ± 0.13	0.64 ± 0.06	1.04 ± 0.06	0.20 ± 0.06	25.4 ± 3.5	18.6 ± 2.0	73.8 ± 10.1
	10	8	336 ± 17	1.90 ± 0.06	14.20 ± 1.22	1.89 ± 0.13	0.64 ± 0.09	1.01 ± 0.06	0.22 ± 0.09	28.1 ± 3.8	21.6 ± 3.5	77.2 ± 13.3
	40	8	359 ± 14	1.94 ± 0.05	14.55 ± 1.10	1.83 ± 0.11	0.71 ± 0.10	1.07 ± 0.09	0.26 ± 0.06	30.7* ± 3.2	19.5 ± 1.7	76.5 ± 6.6
	150	9	350 ± 16	1.91 ± 0.08	13.87 ± 1.46	1.93 ± 0.10	0.66 ± 0.07	1.07 ± 0.10	0.25 ± 0.09	26.2 ± 3.7	22.0* ± 2.0	74.0 ± 10.0
	600	10	307 ± 38	1.88 ± 0.09	12.33 ± 2.00	2.97* ± 0.41	0.63 ± 0.13	0.98 ± 0.17	0.15 ± 0.08	24.4 ± 3.9	17.7 ± 3.0	80.9 ± 10.3
Relative@	0	10	345 ± 16	0.55 ± 0.02	4.04 ± 0.32	0.55 ± 0.04	0.19 ± 0.02	0.30 ± 0.02	0.06 ± 0.02	7.36 ± 0.90	5.42 ± 0.64	21.47 ± 3.29
	10	8	336 ± 17	0.57 ± 0.03	4.22 ± 0.28	0.56 ± 0.04	0.19 ± 0.02	0.30 ± 0.01	0.06 ± 0.02	8.37 ± 1.09	6.39* ± 0.78	23.02 ± 4.17
	40	8	359 ± 14	0.54 ± 0.03	4.06 ± 0.35	0.51 ± 0.03	0.20 ± 0.03	0.30 ± 0.03	0.07 ± 0.02	8.58 ± 0.96	5.46 ± 0.61	21.36 ± 2.17
	150	9	350 ± 16	0.55 ± 0.03	3.96 ± 0.44	0.55 ± 0.03	0.19 ± 0.03	0.31 ± 0.03	0.07 ± 0.02	7.50 ± 1.28	6.31* ± 0.69	21.23 ± 3.45
	600	10	307 ± 38	0.62* ± 0.06	4.02 ± 0.44	0.99** ± 0.22	0.20 ± 0.03	0.32 ± 0.02	0.05 ± 0.02	7.94 ± 0.81	5.76 ± 0.53	26.69* ± 4.65

Each value is expressed as mean ± S. D.

@ : Relative organ weight per 100g body weight

* : Significantly different from control at 5% level of probability

** : Significantly different from control at 1% level of probability

Table 16 - 1 Incidence of histopathological findings of male rats treated orally with isocyanuric acid in the combined repeat dose and reproductive/developmental toxicity screening test

Organ	Findings	Degree	Dose (mg/kg)			
			0	10	40	
Fate of animals	TK (T)	TK (T)	TK (T)	UC (T)	TK (T)	
						TK (T)
Kidney	Necrosis, tubular epithelium	-	10 (10)	8 (2 (10))	9 (1 (10))	10 (10)
		+	0 (0)	0 (0)	0 (0)	0 (0)
Mineralization, cortex/cortico-medullary junction		-	10 (10)	8 (2 (10))	9 (1 (10))	6 (6)
		+	0 (0)	0 (0)	0 (0)	4 (4)
Cellular infiltration, lymphocyte, cortex		-	9 (9)	8 (2 (10))	9 (1 (10))	10 (10)
		++	1 (1)	0 (0)	0 (0)	0 (0)
Cellular infiltration, neutrophilic, medulla		-	10 (10)	8 (2 (10))	9 (1 (10))	10 (10)
		++	0 (0)	0 (0)	0 (0)	3 (10) **
Eosinophilic body, proximal tubular epithelium		-	8 (8)	4 (1 (5))	7 (1 (8))	10 (10)
		++	1 (1)	2 (2)	1 (1)	0 (0)
Dilatation, distal/collecting tubules, focal		-	10 (10)	6 (2 (8))	9 (1 (10))	10 (10)
		+	0 (0)	2 (2)	0 (0)	0 (0)
Dilatation, renal tubule, diffuse		-	10 (10)	8 (2 (10))	9 (1 (10))	0 (0)
		+++	0 (0)	0 (0)	0 (0)	3 (10) **
Basophilic tubules		-	5 (5)	2 (1 (3))	6 (1 (10))	0 (0)
		+++	0 (0)	0 (0)	0 (0)	0 (0)
Hyperplasia, tubular epithelium		-	10 (10)	8 (2 (10))	9 (1 (10))	2 (2)
		+++	0 (0)	0 (0)	0 (0)	2 (9) **
Fibrosis		-	9 (9)	7 (2 (9))	9 (1 (10))	3 (3)
		++	1 (1)	0 (0)	0 (0)	0 (7) **
Gyst		-	8 (8)	2 (2 (10))	9 (1 (10))	10 (10)
		++	1 (2)	0 (0)	0 (0)	0 (0)
Heart	Myocardial degeneration/fibrosis, focal	-	9 (9)	2 (2)	1 (1)	10 (10)
		+	1 (1)	0 (0)	0 (0)	0 (0)

— : Not examined; - : Negative; + : Slight; ++ : Moderate; +++ : Marked; TK : Terminal Kill; FP : Failed to cause pregnancy; Killed at the termination; UC : Animal with unsuccessful copulation; ++ : Significantly different from control at 5% level of probability; * : Significantly different from control at 1% level of probability

Table 15 - 2 Incidence of histopathological findings of male rats treated orally with isocyanuric acid in the combined repeat dose and reproductive/developmental toxicity screening test

Organ	Findings	Degree	Dose(mg/kg)											
			0		10		40		150		600			
			Fate No. of animals	TK (T)	TK FP (T)	TK UC (T)	TK (T)	TK (T)	TK (T)	TK (T)				
Lung	Mineralization, artery	-	8 (8)	-	1 (1)	-	1 (1)	-	-	-	-	10 (10)		
		+	2 (2)	-	1 (1)	-	0 (0)	-	-	-	-	0 (0)		
			8 (8)	-	2 (2)	-	1 (1)	-	-	-	-	7 (7)		
	Metaplasia, osseous	-	2 (2)	-	0 (0)	-	0 (0)	-	-	-	-	3 (3)		
		+	9 (9)	-	2 (2)	-	1 (1)	-	-	-	8 (8)			
			1 (1)	-	0 (0)	-	0 (0)	-	-	-	0 (0)			
Liver	Microgranuloma	-	6 (6)	1*	2 (3)	-	1 (1)	-	-	-	-	6 (6)		
		+	4 (4)	0	0 (0)	-	0 (0)	-	-	-	4 (4)			
			10 (10)	0	2 (2)	-	1 (1)	-	-	-	10 (10)			
	Fibrosis, capsule	-	0 (0)	1*	0 (1)	-	0 (0)	-	-	-	-	0 (0)		
		+	10 (10)	0	2 (2)	-	1 (1)	-	-	-	10 (10)			
			0 (0)	1*	0 (1)	-	0 (0)	-	-	-	0 (0)			
	Hyperplasia, bile duct	-	10 (10)	0	2 (2)	-	1 (1)	-	-	-	-	10 (10)		
		+	0 (0)	1*	0 (1)	-	0 (0)	-	-	-	0 (0)			
			10 (10)	0	2 (2)	-	1 (1)	-	-	-	10 (10)			
	Hemorrhage	-	0 (0)	1*	0 (1)	-	0 (0)	-	-	-	-	0 (0)		
		+	10 (10)	0	2 (2)	-	1 (1)	-	-	-	10 (10)			
			0 (0)	1*	0 (1)	-	0 (0)	-	-	-	0 (0)			
Pancreas:	Proliferation, ductule	-	8 (8)	-	1 (1)	-	1 (1)	-	-	-	-	9 (9)		
		+	2 (2)	-	1 (1)	-	0 (0)	-	-	-	1 (1)			
			9 (9)	-	2 (2)	-	1 (1)	-	-	-	10 (10)			
Stomach	Hyperplasia, squamous, limiting ridge	-	1 (1)	-	0 (0)	-	0 (0)	-	-	-	-	0 (0)		
		+	9 (9)	-	2 (2)	-	1 (1)	-	-	-	10 (10)			
			1 (1)	-	0 (0)	-	0 (0)	-	-	-	0 (0)			
Urinary bladder	Hyperplasia, mucosal epithelium	-	10 (10)	8	2 (10)	9	1 (10)	10	(10)	8	(8)			
		+	0 (0)	0	0 (0)	0	0 (0)	0	(0)	0	(0)			
			10 (10)	8	2 (10)	9	1 (10)	10	(10)	8	(8)			
	Cellular infiltration, neutrophile, submucosa	-	0 (0)	0	0 (0)	0	0 (0)	0	(0)	1	(1)			
		+	10 (10)	8	2 (10)	9	1 (10)	10	(10)	9	(9)			
			0 (0)	0	0 (0)	0	0 (0)	0	(0)	1	(1)			
Testis	Atrophy, seminiferous tubule, focal	-	9 (9)	-	2 (2)	-	1 (1)	-	-	-	-	10 (10)		
		+	1 (1)	-	0 (0)	-	0 (0)	-	-	-	-	0 (0)		
			9 (9)	-	2 (2)	-	1 (1)	-	-	-	9 (9)			
Prostate:	Cellular infiltration, lymphocyte, interstitium	-	1 (1)	-	0 (0)	-	0 (0)	-	-	-	-	1 (1)		
		+	9 (9)	-	2 (2)	-	1 (1)	-	-	-	9 (9)			
			1 (1)	-	0 (0)	-	0 (0)	-	-	-	1 (1)			
Pituitary	Cyst, Rathke's pouch, anterior lobe	-	10 (10)	-	2 (2)	-	1 (1)	-	-	-	-	9 (9)		
		+	0 (0)	-	0 (0)	-	0 (0)	-	-	-	1 (1)			
			10 (10)	-	2 (2)	-	1 (1)	-	-	-	9 (9)			
Adrenal	Vacuolization, zona fasciculata	-	9 (9)	8	2 (10)	8	1 (9)	9	(9)	4	(4)			
		+	1 (1)	0	0 (0)	1	0 (1)	1	(1)	5	(5)			
		++	0 (0)	0	0 (0)	0	0 (1)	0	(1)	1	(6)			

- : Not examined; - : Negative; + : Slight; ++ : Moderate; TK : Terminal kill; FP : Failed to cause pregnancy, killed at the termination; UC : Animal with unsuccessful copulation, killed at the termination; T : Total
 * : Significantly different from control at 5% level of probability
 The organs of the heart, lung, liver, pancreas, stomach, intestine, kidney, urinary bladder, testis, epididymis, seminal vesicle, prostate, pituitary, thyroid, parathyroid, adrenal, thymus, spleen, bone marrow, lymph node and brain were examined from animals of the control and 600 mg/kg groups, and UC and FP animals. The skin from an animal of the 150 mg/kg group, which had a macroscopic skin lesion, was also examined.
 : The liver with diaphragmatic nodule from one animal was examined.

-22-
243-

Study No. 95-047

Table 17 - 1 Incidence of histopathological findings of female rats treated orally with isocyanuric acid in the combined repeat dose and reproductive/developmental toxicity screening test

Organ : Findings	Degree	0		10		40		150		600	
		TK (1)	TK NP (1)	TK UC KL (1)	TK UC KL (1)	TK UC KL (1)	TK UC KL (1)	TK UC KL (1)	TK UC KL (1)	TK UC KL (1)	TK UC KL (1)
Kidney : Degeneration, fatty, proximal tubular epithelium	++	0 (0)	8 (2)	8 (1)	8 (1)	9 (1)	9 (1)	1 (1)	1 (1)	0 (0)	0 (0)
Degeneration, vacuolar, proximal tubular epithelium	-	10 (10)	8 (2)	8 (1)	8 (1)	9 (1)	9 (1)	1 (1)	1 (1)	2 (2)	2 (2)
Necrosis, tubular epithelium	-	10 (10)	8 (2)	8 (1)	8 (1)	9 (1)	9 (1)	0 (0)	0 (0)	5 (5)	5 (5)
Mineralization, cortex	-	10 (10)	8 (2)	8 (1)	8 (1)	9 (1)	9 (1)	0 (0)	0 (0)	1 (1)	1 (1)
Cellular infiltration, neutrophils, medulla	-	10 (10)	8 (2)	8 (1)	8 (1)	9 (1)	9 (1)	0 (0)	0 (0)	2 (2)	2 (2)
Dilatation, distal tubule, focal/multifocal	-	9 (9)	8 (2)	8 (1)	8 (1)	8 (1)	8 (1)	1 (1)	1 (1)	10 (10)	10 (10)
Dilatation renal tubule, diffuse	-	10 (10)	8 (2)	8 (1)	8 (1)	9 (1)	9 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Basophilic tubules	+	9 (9)	7 (2)	7 (1)	7 (1)	6 (1)	6 (1)	1 (1)	1 (1)	0 (0)	0 (0)
Hyperplasia, tubular epithelium	-	10 (10)	8 (2)	8 (1)	8 (1)	9 (1)	9 (1)	0 (0)	0 (0)	3 (3)	3 (3)
Fibrosis	-	10 (10)	8 (2)	8 (1)	8 (1)	9 (1)	9 (1)	0 (0)	0 (0)	7 (7)	7 (7)
Cast hyaline/proteinous/granular	+	10 (10)	7 (2)	7 (1)	7 (1)	8 (1)	8 (1)	0 (0)	0 (0)	0 (0)	0 (0)
Heart : Myocardial degeneration/fibrosis, focal	-	9 (9)	2 (2)	1 (1)	1 (1)	1 (1)	1 (1)	0 (0)	0 (0)	10 (10)	10 (10)
Lung : Inflammatory cell infiltration, focal	-	10 (10)	2 (2)	0 (0)	0 (0)	1 (1)	1 (1)	0 (0)	0 (0)	10 (10)	10 (10)
Edema, alveolar	+	10 (10)	1 (1)	1 (1)	1 (1)	1 (1)	1 (1)	0 (0)	0 (0)	10 (10)	10 (10)
Hemorrhage	+	10 (10)	2 (2)	0 (0)	0 (0)	1 (1)	1 (1)	0 (0)	0 (0)	10 (10)	10 (10)

Not examined: - : Negative; + : Slight; ++ : Moderate; +++ : Marked; TK : Terminal Kill; NP : Non-pregnant; UC : Animal with unsuccessful copulation; KL : Killed because all pups died after delivery; I : Total; ++ : Significantly different from control at 5% level of probability; * : Significantly different from control at 1% level of probability; - : Not examined.

Table 17 - 2 Incidence of histopathological findings of female rats treated orally with isocyanuric acid in the combined repeat dose and reproductive/developmental toxicity screening test

Organ	Findings	Degree	Dose (mg/kg) 0		10		40			150		600	
			Fate No. of animals	TK (T)	TK NP (T)	TK UC	KL (T)	TK KL (T)	TK KL (T)				
Lung	Mineralization, artery	-	9 (9)	-	2 (2)	-	1 (1)	1 (2)	-	1 (1)	10 (10)		
		+	1 (1)	-	0 (0)	-	0 (0)	0 (0)	-	0 (0)	0 (0)		
	Metaplasia, osseous	-	10 (10)	-	2 (2)	-	1 (1)	1 (2)	-	1 (1)	8 (8)		
Liver	Degeneration, fatty, hepatocyte, periporlal	+	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)	9 (9)	1 (1)	8 (8)		
		++	0 (0)	0 (0)	0 (0)	0 (0)	1 (2)	0 (0)	0 (0)	0 (0)	2 (2)		
	Necrosis, focal	-	10 (10)	7 (7)	2 (2)	7 (7)	1 (1)	1 (1)	9 (9)	1 (1)	9 (9)		
Pancreas	Proliferation, ductule	+	2 (2)	-	0 (0)	-	0 (0)	0 (0)	-	0 (0)	1 (1)		
		-	8 (8)	-	2 (2)	-	1 (1)	1 (2)	-	1 (1)	9 (9)		
	Hypertrophic foci, acinar cell	-	10 (10)	-	2 (2)	-	1 (1)	1 (2)	-	1 (1)	9 (9)		
Stomach	Hyperplasia, squamous, forestomach	+	0 (0)	-	0 (0)	-	0 (0)	0 (0)	-	0 (0)	10 (10)		
		-	10 (10)	-	2 (2)	-	1 (1)	1 (2)	-	0 (0)	0 (0)		
	Erosion, glandular stomach	++	0 (0)	-	0 (0)	-	0 (0)	1 (1)	-	0 (0)	10 (10)		
Urinary bladder	Hyperplasia, mucosal epithelium	+	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	9 (9)	1 (1)	6 (6)		
		-	10 (10)	8 (8)	2 (2)	8 (8)	1 (1)	1 (1)	9 (9)	0 (0)	4 (4)		
	Pituitary : Cyst, Rathke's pouch, anterior lobe	+	1 (1)	-	0 (0)	-	0 (0)	0 (0)	-	0 (0)	10 (10)		
Adrenal	Vacuolization, zona fasciculata	+	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)	3 (3)		
		++	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)	1 (4)		
	Hyperplasia, nodular, cortical cell	++	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1)	9 (9)	1 (1)	10 (10)		
Thymus	Atrophy, cortical	+	2 (2)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	3 (3)		
		-	8 (8)	6 (6)	2 (2)	8 (8)	1 (1)	0 (0)	9 (9)	1 (1)	5 (5)		
	Hemorrhage	+	0 (0)	1 (1)	0 (0)	0 (0)	0 (0)	1 (1)	0 (0)	0 (0)	2 (5)		
Skin	Cellular infiltration, neutrophile, focal	-	-	-	-	-	-	-	-	-	0 (0)		
		+	-	-	-	-	-	-	-	-	1 (1)		

- : Not examined; - : Negative; + : Slight; ++ : Moderate; TK : Terminal kill; NP : Non-pregnant; UC : Animal with unsuccessful copulation; KL : Killed because all pups died after delivery; T : Total
 The organs of the heart, lung, liver, pancreas, stomach, intestine, kidney, urinary bladder, ovary, uterus, vagina, mammary gland, pituitary, thyroid, parathyroid, adrenal, thymus, spleen, bone marrow, lymph node and brain were examined from animals of the control and 600 mg/kg groups, and NP, UC and KL animals.
 * : Animal with macroscopic skin lesions

-245-

Study No. 95-047

Table 1 8 Reproduction results of rats treated orally with isocyanuric acid in the combined repeat dose and reproductive/developmental toxicity screening test

	Dose (mg/kg)	0	10	40	150	600
No. of pairs mated		10	10	10	10	10
No. of pairs with successful copulation		10	10	9	10	10
Copulation index (%)		100	100	90	100	100
Pairing days until copulation(days, Mean±S.D.)		2.0±0.9	2.2±1.2	2.7±0.9	3.0±1.9	2.3±0.9
No. of pregnant females		10	8	9	10	10
Fertility index (%)		100	80	100	100	100
No. of corpora lutea (Mean±S.D.)		18.4±1.4	18.5±2.7	18.4±1.8	17.7±1.8	18.5±1.9
No. of implantation sites (Mean±S.D.)		17.8±1.8	17.4±1.3	17.1±1.2	16.2±3.6	16.8±1.2
Implantation index (%. Mean±S.D.)		96.7±4.8	94.8±8.5	93.2±7.4	90.6±17.3	91.6±10.1
No. of pregnant females with parturition		10	8	9	10	10
Gestation length (days, Mean±S.D.)		22.5±0.5	22.9±0.4	22.9±0.6	22.4±0.5	22.7±0.5
No. of pregnant females with live pups		10	8	9	10	10
Gestation index (%)		100	100	100	100	100
No. of pregnant killed ^{a)}		0	0	1	1	0
No. of pregnant females with live pups on day 4		10	8	8	9	10

Copulation index = (No. of pairs with successful copulation/No. of pairs mated) ×100

Fertility index = (No. of pregnant animals/No. of pairs with successful copulation) ×100

Gestation index = (No. of females with live pups/No. of living pregnant females) ×100

a) : All pups died after delivery, killed during the study for pathological examination

Table 19

Litter results of female rats treated orally with isocyanuric acid in the combined repeat dose and reproductive/developmental toxicity screening test

Dose (mg/kg)	0	10	40	150	600
No. of pups born	16.8± 2.3	15.4± 1.2	16.1± 1.3	14.1± 5.2	15.4± 2.2
Delivery index (%)	94.1± 6.8	89.0±10.2	94.3± 6.2	88.1±25.4	91.6±10.2
No. of pups alive on day 0 of lactation					
Total	16.6± 2.2	14.8± 1.9	15.0± 2.3	11.9± 6.4	15.1± 2.0
Male	8.6± 2.8	6.6± 2.4	9.0± 2.8	5.8± 3.9	7.2± 2.4
Female	8.0± 2.8	8.1± 2.6	6.0± 1.7	6.1± 4.3	7.9± 2.6
Live birth index (%)	98.9± 2.4	95.7± 7.5	92.9±10.7	86.9±30.9	98.2± 4.1
Sex ratio (Male/Female)	1.10	0.81	1.46	1.04	0.95
No. of pups alive on day 4 of lactation					
Total	16.5± 2.2	14.8± 1.9	12.8± 5.2	13.1± 5.1	14.0± 1.7
Male	8.5± 2.9	6.6± 2.4	7.8± 3.7	6.4± 3.5	7.0± 2.2
Female	8.0± 2.8	8.1± 2.6	5.0± 2.7	6.7± 3.9	7.0± 1.8
Viability index (%)	99.4± 1.9	100 ± 0	86.2±32.8	99.4± 1.9	93.3± 9.4
Body weight of live pups (g)					
on day 0					
Male	7.0± 0.4	7.6± 0.7	7.1± 0.6	7.3± 0.9	6.9± 0.8
Female	6.8± 0.6	7.0± 0.7	6.7± 0.4	6.8± 0.8	6.6± 0.7
on day 4					
Male	11.1± 1.8	11.9± 2.3	11.5± 1.7	12.0± 2.5	10.0± 2.3
Female	10.7± 1.8	11.3± 2.2	11.2± 1.6	11.3± 2.4	9.8± 2.1

Delivery index = (No. of pups born / No. of implantation sites) x 100

Live birth index = (No. of live pups on day 0 / No. of pups born) x 100

Viability index = (No. of live pups on day 4 / No. of live pups on day 0) x 100

Sex ratio = Total No. of male pups / Total No. of female pups

Each value is expressed as Mean ± SD., except sex ratio

Table 20 Incidence of external findings of rats treated orally with isocyanuric acid in the combined repeat dose and reproductive/developmental toxicity screening test

Findings	Dose (mg/kg)	10	40	124	150	600
External	No. of pups examined	123	145	124	154	
No. of pups with external anomalies ^a	1	0	0	1	0	
(Mean \pm S.D. of individual litter percentages)	(0.6 \pm 1.9)	(0)	(0)	(0.7 \pm 2.1)	(0)	
External anomalies ^a	1	0	0	1	0	
Vestigial tail	1	0	0	1	0	
(Mean \pm S.D. of individual litter percentages)	(0.6 \pm 1.9)	(0)	(0)	(0.7 \pm 2.1)	(0)	

Table 21 Incidence of visceral findings of rats treated orally with isocyanuric acid in the combined repeat dose and reproductive/developmental toxicity screening test

Findings	Dose (mg/kg)	0	10	40	150	600
Visceral	No. of pups examined	167	123	142	123	151
	No. of pups with visceral anomalies ^a	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
	No. of pups with visceral variations ^a	5 (3.1±4.5)	2 (1.7±3.2)	3 (2.2±6.7)	6 (4.2±8.3)	4 (2.8±4.8)
	Visceral variations ^a					
	Thymic remnant in neck	1 (0.6±1.8)	2 (1.7±3.2)	3 (2.2±6.7)	6 (4.2±8.3)	4 (2.8±4.8)
	Persistent left umbilical artery	3 (2.0±4.4)	0 (0)	0 (0)	0 (0)	0 (0)
	Dilatation of renal pelvis	1 (0.6±1.8)	0 (0)	0 (0)	0 (0)	0 (0)

a : No. of pups (Mean ± S.D. of individual litter percentages)

FOREWORD

INTRODUCTION

ISOCYANURIC ACID
CAS N°: 108-80-5

SIDS Initial Assessment Report

for

9th SIAM

(France, June 29-July 1, 1999)

Chemical Name: Isocyanuric acid
CAS No: 108-80-5
Sponsor Country: Japan

National SIDS Contact Point in Sponsor Country:

Mr. Kazuhide Ishikawa
Ministry of Foreign Affairs, Japan

HISTORY:

SIDS Testing Plan were reviewed in SIDS Review Process, where the following SIDS Testing Plan was agreed:

no testing ()

testing (X) Water solubility, Vapour pressure, Octanol/water partition coefficient,
Stability in water Biodegradation

Chronic toxicity to daphnia

Combined repeat dose and reproductive toxicity,

Chromosomal aberration test in vitro

Deadline for circulation: March 31, 1999

Date of Circulation: March 30, 1999

(To all National SIDS Contact Points and the OECD Secretariat)