

Addendum 7-1. Macroscopic examinations of dams - individual findings

		continued		
Sex	Exp.group (µg/kg/day)	Animal No.	Fate	Macroscopic findings
		21	ta	No abnormalities detected
		22	ta	No abnormalities detected
		23	fd	Glandular stomach
				Blackish region of mucosa (spotty, multiple)
				Adrenal
				Enlargement (bilateral)
		24	ta	No abnormalities detected
		25	ta	No abnormalities detected
Female	5	26	ia-pd	Mammary gland
				Poorly developed
		27	ia-pd	Mammary gland
				Poorly developed
		28	ta	No abnormalities detected
		29	ta	No abnormalities detected
		30	ta	No abnormalities detected

ta, terminal autopsy; ia-pd, dam all her pups were dead; fd, found dead.

Addendum 7-1. Macroscopic examinations of dams - individual findings

continued

Sex	Exp.group (µg/kg/day)	Animal No.	Fate	Macroscopic findings
		31	ta	No abnormalities detected
		32	ta	No abnormalities detected
		33	ta	No abnormalities detected
		34	ta	No abnormalities detected
		35	ia-pd	Kidney Pale (bilateral)
Female	50			Spleen Enlargement Mammary gland Poorly developed
		36	ta	No abnormalities detected
		37	ta	No abnormalities detected
		38	ta	No abnormalities detected
		39	ta	No abnormalities detected
		40	ta	No abnormalities detected

ta, terminal autopsy; ia-pd, dam all her pups were dead.

Addendum 7-2. Macroscopic examinations of offspring at 3 months after birth - individual findings

Sex	Exp.group	Animal No.	Fate	Macroscopic findings
		103	ta	No abnormalities detected
		106	ta	No abnormalities detected
		108	ta	No abnormalities detected
		113	ta	No abnormalities detected
		116	ta	No abnormalities detected
		119	ta	No abnormalities detected
		122	ta	No abnormalities detected
		126	ta	Kidney
Female	Vehicle control			Pelvic dilatation (bilateral)
		130	ta	No abnormalities detected
		132	ta	No abnormalities detected
		135	ta	No abnormalities detected
		136	ta	No abnormalities detected
		140	ta	No abnormalities detected
		141	ta	Uterus
		144	ta	Nodule (cervix, ϕ 2 mm)
			ta	No abnormalities detected

ta, terminal autopsy.

Addendum 7-2. Macroscopic examinations of offspring at 3 months after birth - individual findings

continued

Sex	Exp.group (µg/kg/day)	Animal No.	Fate	Macroscopic findings
		148	ta	No abnormalities detected
		153	ta	No abnormalities detected
		156	ta	No abnormalities detected
		158	ta	No abnormalities detected
		161	ta	No abnormalities detected
Female	0.5	163	ta	No abnormalities detected
		168	ta	No abnormalities detected
		169	ta	No abnormalities detected
		174	ta	No abnormalities detected
		178	ta	No abnormalities detected
		179	ta	No abnormalities detected

ta, terminal autopsy.

Addendum 7-2. Macroscopic examinations of offspring at 3 months after birth - individual findings
continued

Sex	Exp.group (µg/kg/day)	Animal No.	Fate	Macroscopic findings
		183	ta	No abnormalities detected
		186	ta	No abnormalities detected
		187	ta	No abnormalities detected
		188	ta	No abnormalities detected
		192	ta	No abnormalities detected
		196	ta	No abnormalities detected
Female	5	197	ta	No abnormalities detected
		200	ta	No abnormalities detected
		203	ta	No abnormalities detected
		205	ta	No abnormalities detected
		207	ta	No abnormalities detected
		211	ta	no abnormalities detected
		215	ta	No abnormalities detected

ta, terminal autopsy.

Addendum 7-2. Macroscopic examinations of offspring at 3 months after birth - individual findings
continued

Sex	Exp.group (µg/kg/day)	Animal No.	Fate	Macroscopic findings
		216	ta	No abnormalities detected
		221	ta	No abnormalities detected
		222	ta	No abnormalities detected
		225	ta	No abnormalities detected
		228	ta	No abnormalities detected
		231	ta	No abnormalities detected
		234	ta	No abnormalities detected
		239	ta	No abnormalities detected
		240	ta	No abnormalities detected
Female	50	246	ta	Kidney Enlargement (right) Pelvic dilatation (bilateral) Ureter Dilatation (right)
		247	ta	No abnormalities detected
		249	ta	No abnormalities detected
		253	ta	No abnormalities detected
		255	ta	No abnormalities detected
		257	ta	No abnormalities detected
		259	ta	No abnormalities detected

ta, terminal autopsy.

Addendum 7-3. Macroscopic examinations of offspring at 7 months after birth - individual findings

Sex	Exp.group	Animal No.	Fate	Macroscopic findings
		102	ta	No abnormalities detected
		107	ta	Subcutis
				Mass (right inguina, ϕ 10 mm)
		110	ta	No abnormalities detected
		115	ta	No abnormalities detected
		120	ta	No abnormalities detected
Female	Vehicle control	121	ta	No abnormalities detected
		123	ta	No abnormalities detected
		127	ta	No abnormalities detected
		128	ta	No abnormalities detected
		134	ta	No abnormalities detected
		137	ta	No abnormalities detected
		139	ta	No abnormalities detected

ta, terminal autopsy.

Addendum 7-3. Macroscopic examinations of offspring at 7 months after birth - individual findings

continued

Sex	Exp.group (µg/kg/day)	Animal No.	Fate	Macroscopic findings
		218	ta	Ovary
				Small (bilateral)
		219	ta	No abnormalities detected
		226	ta	No abnormalities detected
		227	ta	No abnormalities detected
		232	ta	No abnormalities detected
		233	ta	No abnormalities detected
		238	ta	No abnormalities detected
Female	50	241	ta	Ovary
				Small (bilateral)
		245	ta	Sternum
				Deformity
		251	ta	No abnormalities detected
		252	ta	No abnormalities detected
		258	ta	Ovary
				Small (bilateral)

ta, terminal autopsy.

Addendum 7-4. Macroscopic examinations of offspring at 12 months after birth - individual findings

Sex	Exp.group	Animal No.	Fate	Macroscopic findings
		501	ta	No abnormalities detected
		502	ta	No abnormalities detected
		503	ta	No abnormalities detected
		504	ta	No abnormalities detected
		505	ta	No abnormalities detected
		506	ta	No abnormalities detected
		507	fd	Glandular stomach Blackish region of mucosa (multiple, spotty) Testis Dark reddish change (left) Cerebrum Hydrocephalus Spleen Small
		508	ta	Hindlimb Tylosis (bilateral)
		509	ta	No abnormalities detected
		510	ta	Kidney Calculi (left, whitish, granular) Pelvic dilatation (left) Hindlimb Tylosis (right)
Male	Vehicle control	511	ta	No abnormalities detected
		512	ta	No abnormalities detected
		513	ta	No abnormalities detected
		514	ta	No abnormalities detected
		515	ta	No abnormalities detected
		516	ta	Testis Enlargement (right) Epididymis Whitish region (right, caput, ϕ 4 mm) Auricle Thickening (right)
		517	ta	No abnormalities detected
		518	ta	Auricle Thickening (right)
		519	ta	No abnormalities detected
		520	ta	No abnormalities detected

ta, terminal autopsy; fd, found dead.

Animal No.507 was found dead at 33 days old. The animal showed no abnormality in clinical signs before dead.

Addendum 7-4. Macroscopic examinations of offspring at 12 months after birth - individual findings
continued

Sex	Exp.group (µg/kg/day)	Animal No.	Fate	Macroscopic findings
Male	0.5	521	ta	No abnormalities detected
		522	ta	No abnormalities detected
		523	ta	No abnormalities detected
		524	ta	No abnormalities detected
		525	ta	No abnormalities detected
		526	ta	No abnormalities detected
		527	ta	No abnormalities detected
		528	ta	No abnormalities detected
		529	ta	No abnormalities detected
		530	ta	No abnormalities detected
		531	ta	No abnormalities detected
		532	ta	No abnormalities detected

ta, terminal autopsy.

Addendum 7-4. Macroscopic examinations of offspring at 12 months after birth - individual findings
continued

Sex	Exp.group (µg/kg/day)	Animal No.	Fate	Macroscopic findings
Male	5	533	ta	No abnormalities detected
		534	ta	No abnormalities detected
		535	ta	No abnormalities detected
		536	ta	No abnormalities detected
		537	ta	No abnormalities detected
		538	ta	Kidney Cyst (left, 5×8 mm)
		539	ta	Kidney Pelvic dilatation (right)
		540	ta	No abnormalities detected
		541	ta	No abnormalities detected
		542	ta	Kidney Pelvic dilatation (right)
		543	ta	Hindlimb Tylosis (left)
		544	ta	No abnormalities detected
		545	ta	No abnormalities detected
		546	ta	No abnormalities detected

ta, terminal autopsy.

Addendum 7-4. Macroscopic examinations of offspring at 12 months after birth - individual findings
continued

Sex	Exp.group (µg/kg/day)	Animal No.	Fate	Macroscopic findings
Male	50	547	ta	No abnormalities detected
		548	ta	No abnormalities detected
		549	ta	No abnormalities detected
		550	ta	No abnormalities detected
		551	ta	Epididymis Whitish region (left, caput, φ 4 mm)
		552	ta	No abnormalities detected
		553	ta	Kidney Cyst (left, multiple, φ 2-7 mm)
		554	ta	No abnormalities detected
		555	ta	Kidney Pelvic dilatation (right)
		556	ta	No abnormalities detected
		557	ta	No abnormalities detected
		558	ta	Hindlimb Tylosis (bilateral)
		559	ta	No abnormalities detected
		560	ta	No abnormalities detected
		561	ta	Cerebrum Partial defect of cortex (3×7 mm) Adrenal Dark reddish region (right, φ 5 mm) Enlargement (right)
		562	ta	No abnormalities detected
		563	ta	Kidney Calculi (bilateral, whitish, granular)
		564	ta	Kidney Calculi (right, whitish, granular)

ta, terminal autopsy.

Addendum 7-4. Macroscopic examinations of offspring at 12 months after birth - individual findings
continued

Sex	Exp.group	Animal No.	Fate	Macroscopic findings
		101	ta	Mammary gland Well-developed
		104	ta	Vagina Cyst (2 cysts, ϕ 2 mm, ϕ 6 mm) Pituitary gland Enlargement Hindlimb Tylosis (bilateral) Mammary gland Secretion
		105	ta	Mammary gland Secretion
		109	ta	Ovary Small (bilateral)
		111	ta	No abnormalities detected
		112	ta	No abnormalities detected
		114	ta	Ovary Small (bilateral) Mammary gland Well-developed
Female	Vehicle control	117	ta	No abnormalities detected
		118	ta	No abnormalities detected
		124	ta	Ovary Small (bilateral)
		125	ta	Pituitary gland Blackish region (ϕ 1 mm) Enlargement Mammary gland Secretion
		129	ta	No abnormalities detected
		131	ta	Ovary Cyst (bilateral, multiple, ϕ 1-2 mm) Hindlimb Tylosis (left) Mammary gland Well-developed
		133	ta	No abnormalities detected
		138	ta	No abnormalities detected

ta, terminal autopsy.

**Addendum 7-4. Macroscopic examinations of offspring at 12 months after birth - individual findings
continued**

Sex	Exp.group	Animal No.	Fate	Macroscopic findings
		142	fd	Pituitary gland Nodule (dark reddish, 6×6×12 mm) Mammary gland Well-developed
		143	ta	No abnormalities detected
Female	Vehicle control	145	ta	Uterus Polyp (right horn, 2×2×6 mm)
		146	ta	Ovary Small (bilateral) Mammary gland Secretion

ta, terminal autopsy; fd, found dead.

Animal No.142 was found dead at 323 days old.

The animal showed clinical signs before dead; decreased locomotor activity, slow respiration, hypothermia, lacrimation, reddish tears, nasal hemorrhage, decrease feces, anorexia, cloudy urine and side position.

Addendum 7-4. Macroscopic examinations of offspring at 12 months after birth - individual findings
continued

Sex	Exp.group (µg/kg/day)	Animal No.	Fate	Macroscopic findings
Female	0.5	147	ta	Ovary Small (bilateral) Mammary gland Secretion
		149	ta	Pituitary gland Enlargement Mammary gland Secretion
		150	ta	No abnormalities detected
		151	ta	Pituitary gland Blackish region (1×2 mm) Mammary gland Secretion
		152	ta	Pituitary gland Enlargement Mammary gland Secretion
		154	ta	Ovary Small (bilateral) Pituitary gland Nodule (dark reddish, 5×6×7 mm) Thyroid Enlargement Mammary gland Secretion
		155	ta	Ovary Small (bilateral) Pituitary gland Nodule (dark reddish, 6×7×10 mm) Mammary gland Secretion
		157	ta	Lung Atelectasis of middle lobe of right lung
		159	ta	Mammary gland Secretion
		160	ta	Uterus Cyst (left horn, φ 1 mm) Mammary gland Well-developed

ta, terminal autopsy.

Addendum 7-4. Macroscopic examinations of offspring at 12 months after birth - individual findings

continued

Sex	Exp.group (µg/kg/day)	Animal No.	Fate	Macroscopic findings
Female	0.5	162	ta	Hindlimb Tylosis (right) Mammary gland Secretion
		164	ta	Ovary Cyst (left, φ 3 mm)
		165	ta	No abnormalities detected
		166	ta	Ovary Small (bilateral)
		167	ta	Hindlimb Tylosis (right) Mammary gland Secretion
		170	ta	Ovary Small (bilateral) Mammary gland Secretion
		171	ta	Ovary Cyst (right, φ 2 mm) Mammary gland Secretion
		172	ta	Mammary gland Secretion
		173	ta	Ovary Small (bilateral) Mammary gland Secretion
		175	ta	No abnormalities detected
		176	ta	Mammary gland Secretion
		177	ta	No abnormalities detected
		180	ta	Pituitary gland Dark reddish region (φ 2 mm)

ta, terminal autopsy.

Addendum 7-4. Macroscopic examinations of offspring at 12 months after birth - individual findings

continued

Sex	Exp.group (µg/kg/day)	Animal No.	Fate	Macroscopic findings
Female	5	181	ta	Pituitary gland Nodule (dark reddish, φ 8 mm) Mammary gland Well-developed
		182	ta	No abnormalities detected
		184	ta	Mammary gland Well-developed
		185	ta	Lung Dark reddish region (left lung, 6×8 mm) Forestomach Edematous change of wall Recessed region of mucosa (multiple, 2×5 mm, 2×6 mm, 3×6 mm) Ovary Small (bilateral) Pituitary gland Nodule (dark reddish, 8×10×12 mm)
		189	ta	Subcutis Mass (right inguina, 12×20×27 mm)
		190	ta	No abnormalities detected
		191	ta	Pituitary gland Nodule (φ 2 mm) Mammary gland Well-developed
		193	ta	Pituitary gland Enlargement
		194	ta	Ovary Small (bilateral) Pituitary gland Enlargement Mammary gland Secretion
		195	ta	No abnormalities detected
		198	ta	Mammary gland Well-developed
		199	ta	No abnormalities detected
		201	ta	Pituitary gland Nodule (φ 3 mm) Mammary gland Well-developed
		202	ta	Hindlimb Tylosis (left) Mammary gland Well-developed
		204	ta	No abnormalities detected

ta, terminal autopsy.

Addendum 7-4. Macroscopic examinations of offspring at 12 months after birth - individual findings
continued

Sex	Exp.group (µg/kg/day)	Animal No.	Fate	Macroscopic findings
		206	ta	Ovary Small (bilateral)
		208	ta	Ovary Cyst (left, φ2.5 mm) Mammary gland Secretion
Female	5	209	ta	No abnormalities detected
		210	ta	No abnormalities detected
		212	ta	No abnormalities detected
		213	ta	No abnormalities detected
		214	ta	Uterus Polyp (right horn, 3×3×15 mm) Hindlimb Tylosis (right)

ta, terminal autopsy.

Addendum 7-4. Macroscopic examinations of offspring at 12 months after birth - individual findings
continued

Sex	Exp.group (µg/kg/day)	Animal No.	Fate	Macroscopic findings
Female	50	217	ta	Pituitary gland Enlargement Mammary gland Secretion
		220	ta	No abnormalities detected
		223	ta	Hindlimb Tylosis (right) Mammary gland Secretion
		224	ta	Ovary Small (left)
		229	ta	Pituitary gland Blackish region (ϕ 3 mm)
		230	ta	Ovary Small (bilateral)
		235	ta	No abnormalities detected
		236	ta	No abnormalities detected
		237	ta	Ovary Small (bilateral) Mammary gland Secretion
		242	ta	No abnormalities detected
		243	ta	Hindlimb Tylosis (left) Subcutis Mass (right inguina, ϕ 20 mm, 20×20×30 mm)
		244	ta	No abnormalities detected
		248	ta	Mammary gland Secretion
		250	ta	Ovary Small (bilateral)
		254	ta	Mammary gland Secretion
		256	ta	No abnormalities detected
		260	ta	No abnormalities detected
261	ta	No abnormalities detected		

ta, terminal autopsy.



**ENVIRONMENT DIRECTORATE
JOINT MEETING OF THE CHEMICALS COMMITTEE AND
THE WORKING PARTY ON CHEMICALS, PESTICIDES AND BIOTECHNOLOGY**

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**Task Force on Endocrine Disrupters Testing and Assessment (EDTA) of the
Test Guidelines Programme**

**FINAL SUMMARY REPORT OF THE MEETING OF THE VALIDATION MANAGEMENT GROUP
FOR MAMMALIAN TESTING**

4-5 April 2006, Washington, DC, USA

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