

**G028
Cresols**

Results of Testing

Chemical Name	CAS No.	Study Code/Type	Protocol/Guideline	Species	Exposure	Dose/Concentration	No. per Group	Results	Reference
<i>p</i> - Cresol	106-44-5	HECTOXTRFM Morphological transformation study	40 CFR 795.285 (modified)	mice, BALB/C-3T3 cells	<i>in vitro</i>	0.81-15.0 nL/mL	Not applicable	<i>p</i> -Cresol produced a dose-related increase in the number of foci/plate over the entire concentration range. The test material induced cell transformation that was significantly elevated when compared to the controls.	53 FR 27564; 7/21/88 OTS0517694
<i>p</i> - Cresol	106-44-5	HEGTOXCHRM Mammalian cytogenicity study	40 CFR 798.5375 (modified)	Chinese hamster ovary cells (CHO)	<i>in vitro</i>	10, 50, 250, 500, 749, 999 µg/mL	Not applicable	The test materials did not induce chromosomal aberrations either in the presence or absence of metabolic activation.	53 FR 27564; 7/21/88 OTS0517691
<i>p</i> - Cresol	106-44-5	HEGTOXCHRM Rodent dominant lethal assay	40 CFR 798.5450 (modified)	mice	gavage	0, 100, 275, 550 mg/kg bw	25/group	The treatment had no adverse effects with respect to number of early and late resorptions, and live implants, indicating that the test compound did not induce dominant lethal mutations in male germ cells of mice under the conditions of this assay.	54 FR 30460; 7/20/89 OTS0529223
<i>p</i> - Cresol	106-44-5	HEGTOXMUTA Sex-linked recessive lethal assay	40 CFR 798.5275 (modified)	<i>Drosophila melanogaster</i>	oral (dietary), 3 d	0, 60, 300, 600 µg/mL	200-300/group	The treatment did not increase the frequency of sex-linked recessive lethal mutations, indicating that the test substance was not mutagenic in <i>Drosophila</i> under the conditions of this assay.	54 FR 14861; 4/13/89 OTS0529221
<i>p</i> - Cresol	106-44-5	HEGTOXMUTA Mutagenicity study	40 CFR 798.5375 (modified)	mouse L5178Y TK +/-	<i>in vitro</i>	6.39-818 µg/mL (nonactivated) 0.128-40.9 µg/mL (activated)	Not applicable	None of the treatments caused increased mutant frequencies greater than 2-fold over the solvent control mutant frequency. The test materials were considered to have no genotoxic effects and were nonmutagenic either in the presence or absence of metabolic activation.	53 FR 27564; 7/21/88 OTS0517693
<i>p</i> - Cresol	106-44-5	HERTOXTERA Developmental toxicity	40 CFR 798.4900	rabbits	oral (gavage), days 6-18 of gestation	0, 5.0, 50.0, 100.0 mg/kg/d	14 pregnant females	There were no treatment-related deaths, abortions, or early deliveries. Clinical signs of toxicity (audible respiration and ocular discharge) were observed at 50 and 100 mg/kg/day. At 50 and 100 mg/kg/day hypoactivity was observed. For <i>p</i> -cresol only, observations included gasping, cyanosis, and audible labored and rapid respiration. There were no treatment-related effects on food consumption or incidence of any malformations.	53 FR 27564; 7/21/88 OTS0517695
<i>p</i> - Cresol	106-44-5	HERTOXTERA Developmental toxicity	40 CFR 798.4900	rats	oral (gavage), days 6-15 of gestation	0, 30.0, 175.0, 450.0 mg/kg/d	25 pregnant females	At 450 mg/kg/day, there was a significant reduction in maternal body weight gain during the dosing period. At 450 mg/kg/day, clinical signs of toxicity were hypoactivity, ataxia, tremors, twitches, prone positioning, audible respiration, and peroral wetness. Fetal body weights per litter were reduced at 450 mg/kg/day. There were no significant changes in the incidence of any individual malformations for any dose group.	53 FR 27564; 7/21/88 OTS0517695

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Chemical Name	CAS No.	Study Code/Type	Protocol/Guideline	Species	Exposure	Dose/Concentration	No. per Group	Results	Reference
<i>p</i> -Cresol	106-44-5	HERTOXTERE 2-Generation reproduction study	40 CFR 798.4900 (modified)	rats	gavage	0, 30, 175, 450 mg/kg bw/day	25/sex/ generation/ group	No treatment related reproductive effects were observed in this 2-generation gavage study. The NOEL's for parental animals and offspring were 30 and 175 mg/kg bw/day, respectively.	54 FR 52449; 12/21/89 OTS0529224
<i>m</i> -Cresol	108-39-4	HECTOXTRFM Morphological transformation study	40 CFR 795.285 (modified)	mice, BALB/C-3T3 cells	<i>in vitro</i>	6.0-72.0 nL/mL	Not applicable	<i>m</i> -Cresol was evaluated for its ability to induce cell transformation. Results indicated that the test material did not produce significant increases in the number of transformed loci, with or without activation.	53 FR 51134; 12/20/88 OTS0517698
<i>m</i> -Cresol	108-39-4	HECTOXTRFM Morphological transformation study	40 CFR 795.285 (modified)	mice, BALB/C- 3T3 cells	<i>in vitro</i>	0.57-48.0 nL/mL	Not applicable	Results indicated that the test material did not induce cell transformation, with or without activation.	53 FR 27564; 7/21/88 OTS0517694
<i>m</i> -Cresol	108-39-4	HEGTOXCHRM Mammalian cytogenicity study	40 CFR 798.5375 (modified)	Chinese hamster ovary cells (CHO)	<i>in vitro</i>	10, 50, 250, 500, 749, 999 µg/mL	Not applicable	The test materials did not induce chromosomal aberrations either in the presence or absence of metabolic activation.	53 FR 27564; 7/21/88 OTS0517691
<i>m</i> -Cresol	108-39-4	HEGTOXCHRM Mammalian bone marrow cytogenicity study	40 CFR 798.5385 (modified)	mice	gavage	0, 96, 329, 960 mg/kg	5/sex/group	The treatment did not increase the frequency of chromosomal aberrations, indicating that <i>m</i> -cresol was not clastogenic in mice under the conditions of this assay.	54 FR 7093; 2/16/89 OTS0529219
<i>m</i> -Cresol	108-39-4	HEGTOXDNAF Unscheduled DNA synthesis	40 CFR 798.5550 (modified)	rat, primary hepatocytes	<i>in vitro</i>	0.251-10.0 µg/mL	Not applicable	The test material showed no evidence of unscheduled DNA synthesis (UDS).	53 FR 27564; 7/21/88 OTS0517692
<i>m</i> -Cresol	108-39-4	HEGTOXMUTA Mutagenicity study	40 CFR 798.5375 (modified)	mouse L5178Y TK +/-	<i>in vitro</i>	6.39-818 µg/mL (nonactivated) 0.128-40.9 µg/mL (activated)	Not applicable	None of the treatments caused increased mutant frequencies greater than 2-fold over the solvent control mutant frequency. The test materials were considered to have no genotoxic effects and were nonmutagenic either in the presence or absence of metabolic activation.	53 FR 27564; 7/21/88 OTS0517693
<i>m</i> -Cresol	108-39-4	HERTOXTERA Developmental toxicity	40 CFR 798.4900	rats	oral (gavage), days 6- 15 of gestation	0, 30.0, 175.0, 450.0 mg/kg/d	25 pregnant females	At 450 mg/kg/day, there was a significant reduction in maternal body weight gain during the dosing period. At 450 mg/kg/day, clinical signs of toxicity were hypoactivity, ataxia, tremors, twitches, prone positioning, audible respiration, and peroral wetness. There were no significant changes in the incidence of any individual malformations for any dose group.	53 FR 27564; 7/21/88 OTS0517695
<i>m</i> -Cresol	108-39-4	HERTOXTERA Developmental toxicity	40 CFR 798.4900	rabbits	oral (gavage), days 6- 18 of gestation	0, 5.0, 50.0, 100.0 mg/kg/d	14 pregnant females	There were no treatment-related deaths, abortions, or early deliveries. Clinical signs of toxicity (audible respiration and ocular discharge) were observed at 50 and 100 mg/kg/day. There were no treatment-related effects on food consumption or incidence of any malformations.	53 FR 27564; 7/21/88 OTS0517695

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<i>m</i> -Cresol	108-39-4	HERTOXTERE 2-Generation reproduction study	40 CFR 798.4900 (modified)	rats	gavage	0, 30, 175, 450 mg/kg bw/day	25/sex/ generation/ group	No treatment related reproductive effects were observed in this 2-generation gavage study. The NOEL's for parental animals and offspring were 30 and 175 mg/kg bw/day, respectively.	54 FR 52449; 12/21/89 OTS0529224
<i>o</i> -Cresol	95-48-7	HECTOXTRFM Morphological transformation study	40 CFR 795.285 (modified)	mice, BALB/C- 3T3 cells	<i>in vitro</i>	7.5-45 µL/mL	Not applicable	The test material was found not to produce increased transformed foci, with or without activation. Cytotoxicity ranged from 7.2 to 87.8% over the test concentration range.	53 FR 37643; 9/27/88 OTS0517697
<i>o</i> -Cresol	95-48-7	HEGTOXCHRM Rodent dominant lethal assay	40 CFR 798.5450 (modified)	mice	gavage	0, 75, 250, 750 mg/kg bw	25/group	The treatment had no adverse effects with respect to number of early and late resorptions, and live implants, indicating that the test compound did not induce dominant lethal mutations in male germ cells of mice under the conditions of this assay.	54 FR 30460; 7/20/89 OTS0529223
<i>o</i> -Cresol	95-48-7	HEGTOXCHRM Mammalian cytogenicity study	40 CFR 798.5375 (modified)	Chinese hamster ovary cells (CHO)	<i>in vitro</i>	10, 50, 250, 500, 749, 999 µg/mL	Not applicable	The test materials did not induce chromosomal aberrations either in the presence or absence of metabolic activation.	53 FR 27564; 7/21/88 OTS0517691
<i>o</i> -Cresol	95-48-7	HEGTOXMUTA Sex-linked recessive lethal assay	40 CFR 798.5275 (modified)	<i>Drosophila melanogaster</i>	oral (dietary), 3 d	0, 100, 500, 1000 µg/mL	150/group	The treatment did not increase the frequency of sex-linked recessive lethal mutations, indicating that the test substance was not mutagenic in <i>Drosophila</i> under the conditions of this assay.	54 FR 14861; 4/13/89 OTS0529221
<i>o</i> -Cresol	95-48-7	HERTOXTERA Developmental toxicity	40 CFR 798.4900	rabbits	oral (gavage), days 6- 18 of gestation	0, 5.0, 50.0, 100.0 mg/kg/d	14 pregnant females	There were no treatment-related deaths, abortions, or early deliveries. Clinical signs of toxicity (audible respiration and ocular discharge) were observed at 50 and 100 mg/kg/day. At 50 and 100 mg/kg/day hypoactivity was observed. There were no treatment-related effects on food consumption or incidence of any malformations.	53 FR 27564; 7/21/88 OTS0517695
<i>o</i> -Cresol	95-48-7	HERTOXTERA Developmental toxicity	40 CFR 798.4900	rats	oral (gavage), days 6- 15 of gestation	0, 30.0, 175.0, 450.0 mg/kg/d	25 pregnant females	At 450 mg/kg/day, there was a significant reduction in maternal body weight gain during the dosing period. At 450 mg/kg/day, clinical signs of toxicity were hypoactivity, ataxia, tremors, twitches, prone positioning, audible respiration, and peroral wetness. There were no significant changes in the incidence of any individual malformations for any dose group.	53 FR 27564; 7/21/88 OTS0517695
<i>o</i> -Cresol	95-48-7	HERTOXTERE 2-Generation reproduction study	40 CFR 798.4900 (modified)	rats	gavage	0, 30, 175, 450 mg/kg bw/day	25/sex/ generation/ group	No treatment related reproductive effects were observed in this 2-generation gavage study. The NOEL's for parental animals and offspring were 30 and 175 mg/kg bw/day, respectively.	54 FR 52449; 12/21/89 OTS0529224