# Ponceau 4r lake

## Toxicological Data on the Unburnt Ingredient

[+ve, positive; -ve, negative; ?, equivocal
with, with metabolic activation; without, without metabolic activation]

In vivo

| Species | Test conditions | Endpoint | Results | Reference |
|---|---|---|---|---|
| Mouse, 6 males/dose group | Mice were given a single intraperitoneal injection at 0, 300, 600, 1200 or 2400 mg Ponceau 4R/kg bw. After 24 hours, bone marrow cells were examined for micronuclei. | Chromosome damage | -ve<br><br>(At the top dose, five of the six tested animals died.) | Hayashi *et al.*, 1988 |
| Mouse, 6 males/dose group | Mice were given intraperitoneal injections of 300 mg Ponceau 4R/kg bw daily for 4 days. 24 hours after the final dose, bone marrow cells were examined for micronuclei. | Chromosome damage | -ve | Hayashi *et al.*, 1988 |
| Mouse, 5/sex/dose group | Mice were given 0, 500, 1000 or 2000 mg Ponceau 4R/kg bw by gavage. Bone marrow cells were assessed for micronuclei after 24 hours (all doses) and 48 hours (top dose). | Chromosome damage | -ve | Honovar & Völkner, 2002 |
| Mouse [number, and sex not given in abstract] | The bone marrow cells of treated mice were examined for micronuclei [no further details given in brief report]. | Chromosome damage | -ve | Tarján & Kürti, 1982 |

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| Mouse | Ponceau 4R was administered to mice at "0.63 or 6.3 mg/kg" Brain cells were examined for chromosome aberration.<br><br>[This Russian study is very limited. The brain is an unusual organ to examine, and the route of exposure, duration, and presence of any controls cannot be clearly determined.] | Chromosome damage | -ve | Durnev *et al.*, 1995 |
| Mouse, 4 males/dose group | Mice were given a single intraperitoneal injection of 0, 4, 10 or 20 mg/kg bw. After 24 hours, bone marrow cells were examined for micronuclei.<br><br>[Poorly reported study, using unusually low doses.] | Chromosome damage | +ve<br><br>(at all dose levels) | Agarwal *et al.*, 1993 |
| Mouse [apparently 1 male/dose group] | Mice were given Ponceau 4R in intraperitoneal doses of 0, 200, 400 or 600 mg/kg bw/day for two days. Bone marrow cells were then assessed for micronuclei.<br><br>[Poorly reported study and very limited, using an inadequate number of animals. Concern for the validity of these findings is raised by results for other chemicals tested in this study.] | Chromosome damage | +ve | Vaidya & Godbole, 1978 |

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| Mouse, 4 males/dose group | Mice were given a single dose of Ponceau 4R by gavage at 0, 1, 20, 100 or 2000 mg/kg bw. Comet assay at 3, 6 or 24 hours in brain, lung, liver, kidney, stomach, colon, bladder and bone marrow. | DNA damage | +ve<br><br>(10 mg/kg bw: colon; 100 mg/kg bw: stomach, bladder; 2000 mg/kg bw: liver, kidney, lung.) | Tsuda *et al.*, 2001 |
| Mouse, 4 males/dose group | Mice were given a single oral dose of up to 2000 mg/kg bw. Comet assay at 3 and 24 hours in stomach, colon, liver, kidney, bladder, lung, brain and bone marrow. | DNA damage | +ve<br><br>(The lowest effective dose was 10 mg/kg bw in the colon, three hours after treatment.) | Kawaguchi *et al.*, 2001; Sasaki *et al.*, 2002a, 2002b |
| ICR (CD-1) Mouse, male, 4/dose group, 6 untreated controls | Mice were given 1 or 10 mg Ponceau 4R/kg bw by gavage, and sacrificed after three hours. Comet assay in brain, lung, liver, kidney, glandular stomach, colon, urinary bladder and bone marrow. | DNA damage | +ve<br><br>(colon in 10 mg/kg bw group) | Shimada *et al.*, 2010 |
| Fischer F344 rat, male, 4/dose group, 5 untreated controls | Rats were given Ponceau 4R at 10, 100 or 1000 mg/kg bw by gavage. Comet assay at 3, 6, 12 or 24 hours in brain, lung, liver, kidney, glandular stomach, colon, urinary bladder and bone marrow. | DNA damage | -ve | Shimada *et al.*, 2010 |
| Rat, 2 males/dose group | Rats were given a single dose of 0 or 300 mg/kg bw by gavage. After 2 and 15 hours, the liver was examined for evidence of DNA repair.<br><br>[Very limited study] | DNA damage | -ve | Kornbrust & Barfknecht, 1985 |

In vitro

| Test system | Test conditions | Endpoint | Activation status | Results | Reference |
|---|---|---|---|---|---|
| Mouse lymphoma L5178Y cells | Mutagenicity assay in which cells were treated with up to 1.5 mg Ponceau 4R/ml (with S9) or 10 mg/ml (without S9) for four hours. | Mutation | With and without S9 | -ve | Cameron *et al.*, 1987 |
| Chinese hamster lung fibroblasts | Following incubation [at unspecified concentrations, possibly up to 2 mg/ml] for 24 or 48 hours, cells were examined for polyploidy and chromosomal aberrations. | Chromosome aberration | Without [limited study] | +ve<br><br>(Weak +ve, chromo-some aberrations at 1 mg/ml. no effects on ploidy.) | Ishidate *et al.*, 1984 |
| Chinese hamster lung fibroblasts | Following incubation with Ponceau 4R at up to 2 mg/ml for 24 or 48 hours, cells were examined for polyploidy and chromosomal aberrations. | Chromosome aberration | Without [limited study] | -ve | Ishidate *et al.*, 1978, 1988 |
| Mammalian cells [not specified in citing source] | DNA repair assay [concentration tested not stated in citing source]. | DNA damage | Without [limited study] | -ve | Kornbrust & Barfknecht, 1985 |

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| *Salmonella typhimurium*, strains TA92, TA94, TA98, TA100, TA1535, TA1537 [and possibly TA2637] | Ames tests with Ponceau 4R at up to 5 mg/plate. | Mutation | With and without | -ve | Ishidate *et al.*, 1984 |
| *Salmonella typhimurium*, strains TA98, TA100, TA1535, TA1537 and TA1538 | Ames test with Ponceau 4R at up to 10 mg/plate. Also present was flavin mono-nucleotide, thought to increase liver enzyme capacity for breaking azo bonds. | Mutation | With | -ve | Cameron *et al.*, 1987 |
| *Salmonella typhimurium*, various strains | Various studies: Ames tests with Ponceau 4R, at up to 5 mg/plate. | Mutation | With and without | -ve | Fujita & Sasaki, 1993; Izbirak *et al.*, 1990 and several other earlier references cited in bibra, 1993 |
| *Salmonella typhimurium*, strains TA98, TA100, TA1535, TA1537, TA1538 | Ames test with Ponceau 4R [unspecified concentration]. | Mutation | With and without | -ve | Tarján & Kürti, 1982 |

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