Antimony intraperitoneal injection studies by NTP

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27. The Committee requested a summary of the NTP intraperitoneal study at the October meeting 2024, as it was potentially useful in a weight of evidence consideration with respect to toxicity of antimony.

28. Intraperitoneal injection studies using antimony potassium tartrate (purity>99.4%) were conducted in F344 rats and B6C3F1 mice (10/sex/group) (NTP, 1992). A 16-day range finding study used doses of 0, 1,500, 3,000, 6,000, 11,000 or 22,000 µg/kg bw/day in rats and 0, 6,000, 13,000, 25,000, 50,000, or 100,000 µg/kg bw/day in mice, administered as 12 injections given on consecutive weekdays. These correspond to doses of 0, 600, 1,200, 2,400, 4,400, or 8,800 µg Sb/kg bw/day in rats and 0, 2,400, 5,200, 10,000, 20,000, or 40,000 µg Sb/kg bw/day in mice. Mortality was observed in the high dose groups for both rats (3/20) and mice (20/20).

29. Liver lesions, characterised as necrosis and inflammation of the liver capsule, were observed in 7 of 10 mice given 20,000 µg Sb/kg bw/day (both sexes). These lesions were not observed in mice from the highest dose group that died prior to the end of the study. Liver necrosis and kidney degeneration were observed in the high dose male rats that died prior to the end of the study.

30. A 13-week intraperitoneal injection studies using antimony potassium tartrate doses of 0, 1,500, 3,000, 6,000, 12,000, or 24,000 µg/kg bw/day given 3 times per week, resulting in daily antimony doses of 0, 600, 1,200, 2,400, 4,800, or 9,600 µg Sb/kg bw/day. Mortality was observed in 4 of 10 male rats in the highest dose groups. A reduction in body weight was seen in both male (18%) and female (11%) rats from these groups. Relative liver weight was increased in male and female rats from all dose groups (maximum increase of 20% for males and 40% for females at 9600 µg Sb/kg bw/day). Dose-related increases in serum alanine aminotransferase and sorbitol dehydrogenase were also observed in male and female rats. Liver degeneration and necrosis were observed in male rats and in female rats. Kidney degeneration was also observed in the highest dose group in female rats (3/10). No clinical signs of toxicity or gross or microscopic changes were observed in mice exposed to antimony potassium tartrate in this study.