

EFSA's Concluding remarks - Review of EFSA Opinion

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This is a paper for discussion.

This does not represent the views of the Committee and should not be cited.

231. No reproductive or developmental toxicity studies performed with E 171 and considered sufficiently reliable with respect to their internal validity were identified from the published literature.

232. No maternal and developmental effects were observed up to 1,000 mg/kg bw per day, the highest dose tested, in a single rat developmental toxicity study with five different TiO₂ materials, TiO₂ Nanoparticles or TiO₂ containing a

fraction of nanoparticles (Warheit et al., 2015a) (Score: 4 for NSC).

233. In mice, the effects of TiO₂ nanoparticles <30 nm on the testis (decreased weight, decreased seminiferous tubule diameter, germ cell apoptosis) and sperm (decreased sperm counts and motility, increased percentage of abnormal spermatozoa) were observed in three studies (Khorsandi et al., 2016, 2017; Karimi et al., 2019) at doses ranging from 50 to 300 TiO₂ Nanoparticles /kg bw per day. The lowest dose at which the effects were observed was 50 mg TiO₂ Nanoparticles /kg bw per day (Karimi et al., 2019). In a mouse study by Lu et al. (2020), no effects were observed at the lowest dose tested, 10 mg/kg bw per day (Score: 4 for NSC). In rats, administration of TiO₂ Nanoparticles (21 nm) did not show effects at any dose level in a developmental toxicity study up to 1,000 mg/kg bw per day (Lee et al., 2019, Score: 3 for NSC).