Appendix O - *In vivo* genotoxicity study from OECD dossier (OECD, 2016)

The evaluation of the study has been performed according the approach set in Appendix D

Test system/Test object	Dose/Route	Information on the characteristics of the test substance	Scoring for nanoscale considerations (dispersion and/or confirmation of internal exposure), assigned according to Appendix E	Result	Reliability/ Comments	Relevance of the result	Reference authors_year
Female Wistar rats Investigation of DNA adducts in lung tissue after 2 years inhalation exposure in a carcinogenicity study. ^{32}P post-labelling assay	7.5 mg/m^3 for the first 4 months, then dose was increased to 15 mg/m^3 for 4 months. Afterwards, dose was reduced to 10mg/m^3 (due to toxicity) for 16 months. **Inhalation** (whole body exposure chamber); 18h/day, 5 days/week for 2 years	TiO_2NPs (P25), anatase/rutile, 15-24 nm	Aerosol dispersion technique to generate TiO_2 aerosol Dispersion not assessed as criteria are not applicable to inhalation studies	After 2 years exposure to TiO_2 NPs, the levels of lung DNA adducts were not increased	Reliability: 5 Reliability not evaluated as the study is considered not relevant for oral risk assessment	Low Investigation on site of contact effects after inhalational exposure	Gallagher et al. 1994

The ccWG Genotoxicity noted that under the NANOGENOTOX project also *in vivo* studies were performed, however the provided information (Documentation provided to EFSA No. 9) was considered preliminary and not sufficient to evaluate the reliability and the relevance of these studies.