PRENATAL DEVELOPMENTAL TOXICITY STUDY OF [POLY (HEXAMETHYLENEBIGUANIDE), HYDROCHLORIDE] (PHMB) IN NEW ZEALAND WHITE RABBITS

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Abstract: PHMB [Poly (HexaMethyleneBiguanide), hydrochloride], CAS n° 32289-58-0; is a cationic disinfectant commercially available as a 20%-hydrochloric solution mainly used in water treatment and surface disinfection, as well as for skin disinfection in humans and animals, preservative for cosmetics (Directive 76/768/CEE), contact lenses solution, food-processing industry. Its effects (100, 300 and 1000 mg/L of active substance, purity 99.07%) on pregnant female rabbits and their developing foetuses (OECD 414), resulting from daily exposure via drinking water, from the day of implantation, i.e. 5th day of gestation, throughout their gestation period, up to 29\textsuperscript{th} day, i.e. one day prior to parturition, have been assessed. No evidence of maternal toxicity was observed in pregnant rabbits exposed to PHMB whatever the dose. Uterine observation parameters in PHMB-treated females were found to be comparable to those of the control group. The litters’ size was 24, 21 and 22 respectively for 100, 300 and 1000 mg/L versus 20 in control group. Evaluation of foetuses for different parameters such as body weights, external abnormalities, visceral abnormalities and skeletal abnormalities did not reveal any alterations which could be attributed to exposure to PHMB. Conclusions: No maternal toxicity, embryotoxicity or fetotoxicity was observed at and upto the dose of 1000 ppm. PHMB [Poly (HexaMethyleneBiguanide), hydrochloride] at the doses of 100 ppm, 300 ppm and 1000 ppm is not teratogenic. The “No-Observed-Adverse-Effect-Level (NOAEL)” of PHMB [Poly (HexaMethyleneBiguanide), hydrochloride] for maternal toxicity, fetotoxicity and teratogenicity is greater than 1000 mg/L.