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### ACCEPTED MANUSCRIPT

# Safety evaluation of a mixture of the human-identical milk oligosaccharides 2'-fucosyllactose and difucosyllactose

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Abbreviations: 2-AA, 2-aminoanthracene; 2'-FL, 2'-fucosyllactose; 2'-FL/DFL, 2'-fucosyllactose / difucosyllactose mixture; 2-NF, 2-nitroflourine; 4-NQO, 4-nitroquinoline-1-oxide; 9-AA, 9-aminocacridine; AAALAC, Assessment and Accreditation of Laboratory Animal Care; ANOVA, analysis of variance; ARRIVE, Animal Research: Reporting of *In Vivo* Experiments; AST, aspartate aminotransferase; BaP, benzo[a]pyrene; bw, body weight; CBPI, cytokinesis block proliferative index; DFL, difucosyllactose; EMA, European Medicines Agency; EPA, United States Environmental Protection Agency; FDA, United States Food and Drug Administration; FOS, fructooligosaccharide; Fuc, fucose; Gal, galactose; GD, gestation day; Glc, Glucose; GLP, Good Laboratory Practice; GRAS, Generally Recognized as Safe; HCD, historical control data; HiMO, human-identical milk oligosaccharide; HMO, human milk oligosaccharide; IF, infant formula; LD, lactation day; LNnT, lacto-N-neotetraose; LUC, large unstained cells; MCH, mean cell hemoglobin; MCHC, mean cell hemoglobin concentration; MCV, mean cell volume; MoE, margin of exposure; NOAEL, no-observed-adverse-effect-level; OECD, Organisation for Economic Co-operation and Development; PND, postnatal day; PT, prothrombin time; RBC, red

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