REPRODUCTION TOXICITY SCREENING TEST OF THE VULM 1457 SUBSTANCE

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The OECD 421 (1995) Reproduction/Development Toxicity Screening Test was used in preclinical screening of toxicity of the VULM 1457 original hypolipidemic from the group of ACAT inhibitors. The purpose of the test was to collect information on the effect of the substance on basic reproductive performance of male and female rats, and, in case of positive toxicity findings, to establish the region of adverse effects. VULM 1457 was administered *per os* in three dose groups – 30, 120 and 300 mg/kg, to rats of both sexes 14 days prior to mating and during the mating period, and to female rats during gestation and partum, until day 4 *post partum*. A vehicle was administered to animals in the control group. The animals were daily clinically examined. We evaluated the effect of the tested substance on gonadal functions of the animals, conception, course of pregnancy, partum, and on development of pups during the first four days of lactation. Conclusions of the evaluation of reproductive parameters of males, females and pups indicate that there were no significant differences between animals in the dose groups and the control group. Macroscopic investigations revealed no malformations in pups in neither dose group. The experiment was terminated by euthanasia, autopsy, and histopathological examination of reproductive organs of males and females in the highest dose group and the control group. The histopathological examinations revealed no negative effect of the VULM 1457 substance on parameters under study.

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