

CONCEPTRIA TESTING & RESULTS

In order to be labeled as “Fertility Friendly,” lubricants must be cleared by the FDA through extensive testing to ensure safety for sperm, oocytes, and embryos. Tests on Conceptria were performed by three different laboratories in the United States.

Conceptria underwent testing to confirm its effects in the following ways:

Osmolality Determination – The molecular balance of the substance.

Conceptria was determined to have an osmolality of 331 mOsm/kg, within range of the osmolality of semen (260–380 mOsm/kg) – **Passed**.

Vaginal Irritation – Microscopic evaluations of vaginal tissues after exposure to the substance.

Conceptria was considered a “nonirritant to vaginal tissue,” demonstrating “macroscopically normal” observations in both the control and the tested samples – **Passed**.

Penile Irritation – How the substance interacts with the penis.

Conceptria was considered a “nonirritant to the penile mucosal tissue,” demonstrating “macroscopically normal” observations in both the control and the tested samples – **Passed**.

Cytotoxicity – Damage to cells caused by the substance.

Conceptria was shown to have slight cytotoxicity when compared to the control, but was within appropriate ranges – **Passed**.

Acute Systemic Toxicity – Assess the toxicity levels within the body after exposure to the substance

“No evidence of systemic toxicity” from Conceptria – **Passed**.

Endotoxin titer and interference screening – Ensures the substance is non-toxic and safe for human use.

The test was performed twice, both times with a resulting endotoxin value of <0.5 EU/mL – **Passed**.

Dermal Contact Sensitization – Measures allergic reactions to the substance following repeated exposure.

Conceptria demonstrated no reaction and was declared a “non-sensitizer” – **Passed**.

Embryo Development – How an embryo develops from a single cell after exposure to the substance.

The test was performed with 42 control embryos and 42 embryos exposed to Conceptria. All 84 embryos showed the same development within 24 and 96 hours, demonstrating no negative impact from the lubricant – **Passed**.

Sperm Motility – How the substance affects the movement speed of sperm.

The test was performed twice and both times the sperm tested with Conceptria showed no negative impact to motility when compared with the control – **Passed**.

Lubricant Barrier Testing – How well sperm can penetrate the substance.

The test was performed twice and both times the sperm “penetrated and completely migrated into” Conceptria – **Passed**.