

Summary of Non-Clinical Bench Performance Testing

Study Information

Title: Toxicological Evaluation of RiteWipe™

Study Director: Third Party Laboratory

Testing Facility: Third Party Laboratory

Study Summary

The toxicological evaluation was conducted to assess the acute and chronic safety of RiteWipe™. The study followed guidelines recommended by the U.S. Consumer Product Safety Commission (CPSC), European Union (EU) Council Directives, and FDA toxicological testing and risk assessment guidance. The evaluation focused on identifying hazards, assessing dose-response, exposure, and characterizing risk for individual ingredients and the product as a whole.

A. Study Importance:

This study evaluates the safety profile of RiteWipe™. The assessment ensures that the product meets safety standards for acute and chronic use, confirming its suitability for consumer use.

B. Key Aspects:

Ingredient Profile: The evaluation includes a detailed analysis of each ingredient, including its function, toxicity data, and compliance with safety standards.

Acute Toxicity Data: Assessment of the product's safety in single-dose exposure scenarios.

Chronic Toxicity Data: Evaluation of the product's safety in multiple-dose exposure scenarios over extended periods.

Standards Compliance: The study follows guidelines from CPSC, EU Council Directives, and FDA, ensuring compliance with regulatory requirements.

C. Study Results:

The study determined that RiteWipe™ presents the lowest possible levels of acute and chronic toxic hazards with normal use. The product's Margin of Safety (MOS) for a child with accidental oral exposure varied from a low of 344 to as high as 89773, with a weighted average MOS of 12403. The MOS is a ratio that compares the no observed adverse effect level (NOAEL) of a substance to its estimated exposure level, providing a quantitative measure of safety. Typically, an MOS of 100 or more is considered safe, meaning that the exposure level would need to be increased 100 times to potentially cause harmful effects. The MOS scores for RiteWipe™ far exceed this threshold, indicating a high level of safety. Additionally, three ingredients are FDA Generally Recognized as Safe (GRAS).

D. Conclusion:

The toxicological evaluation of RiteWipe™ demonstrates that the product is safe for consumer use, presenting the lowest possible levels of acute and chronic toxic hazards. The findings support the product's safety for its intended use by a certified toxicologist, ensuring compliance with regulatory standards and enhancing consumer confidence. The MOS scores indicate that the product has a substantial safety margin, meaning it is highly unlikely to cause harm under normal usage conditions.