

Safety Dossier on Ashwagandha root extract (KSM-66®)

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1. SUMMARY

The dossier presents a comprehensive overview of the safety and efficacy profile of Ashwagandha root extract, focusing primarily on KSM-66 Ashwagandha root extract and particularly its impact on liver health, thyroid health, reproductive health, and sex hormones. Additionally, it aims to clarify the nature of any reported adverse events associated with its use. The enclosed data covers a wide range of toxicity evaluations, including acute, subacute, chronic, reproductive, genotoxicity, and specific organ toxicity studies conducted across various biological models. Furthermore, it includes safety assessments derived from preclinical, animal, and human clinical studies.

The main objective of this safety dossier is to bring out the current evidence-based knowledge and understanding of the herb to academicians, researchers, healthcare providers, consumers, and policymakers, enabling them to make informed decisions that prioritize safety while recognizing and harnessing the potential benefits of herbal supplements within today's health landscape.

1.1. Scope of work

- Short description of Ashwagandha
- Description of KSM-66 Ashwagandha® root extract
- Description of published, under peer review, and ongoing toxicological studies, preclinical studies, human clinical studies, and veterinary clinical studies on KSM-66 Ashwagandha
- Description of studies demonstrating the safety of Ashwagandha root extract on the liver, thyroid, reproductive health, and during pregnancy.
- Global Demand and Post-Marketing Surveillance