

TOXICOLOGY REPORT ON THE INGREDIENTS OF BIO-SCIENCE TM-100

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Summary and Conclusions

The published, peer reviewed scientific literature on the toxicity of the components of TM-100 is scant. The information that does exist in the scientific literature would indicate the individual components have low orders of relative animal and human toxicity. Mild skin irritation is the one potential result of exposure to TM-100. The applicators/users of TM-100 would appear to be the population that faces the greatest exposure potential.

In order to have an enzyme added to the GRAS list, the requestor must provide to the FDA health, safety and environmental data including: Details on the identity of the enzyme, enzyme class, specific information on the enzyme synthesis process; complete toxicological data on the enzyme system including tests to determine the oral lethal dose and the inhalation lethal dose tests of at least two species; chronic tests involving feeding for two years complete with biochemical and histopathological analysis; metabolic tests to determine absorption, distribution and fate in the body; cancer tests and interaction tests to determine any dietary restrictions; and most recently environmental impact assessment (EIA) data must also be provided to the FDA. The FDA will then evaluate the toxicological data and information and if applicable they will conclude that a material is classified as Generally Recognized as Safe (GRAS). The fact that five of the five components of TM-100 are on the GRAS list is an indication of the safety and relatively low toxicological concern of TM-100.

It should also be noted that there are no detectable residual components following the proper application and use of TM-100 that were determined to present sufficient exposure for association with adverse toxicological effects in humans.