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Industrial microbial enzyme safety: What does the weight-of-evidence indicate?

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10 **Abstract**

11 With the exception for the potential skin and eye irritating effects of some proteases, and the
12 well-documented potential for respiratory sensitization in case of work place exposure, enzymes
13 in general don't produce acute toxicity, dermal sensitization; genotoxicity, or repeated dose oral
14 toxicity. Acute inhalation, reproduction, chronic toxicity, and carcinogenicity are not relevant for
15 enzymes. Several hundred mutagenicity studies have been conducted on bacterial and
16 mammalian cells using a variety of enzymes. No positive findings were observed. > 225 90-day
17 studies have been performed and submitted to EFSA with no adverse findings, including in the
18 bone marrow. The data showing no adverse effects for enzyme preparations also confirms that
19 microbial metabolites and fermentation materials lack toxicity as well. Exposure to enzyme
20 products is also minimal as recommended use levels are low, generally < 0.1% (wt/wt). The
21 weight-of-evidence indicates that there are no concerns for oral toxicity of enzymes in general,

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