



<u>Clarification on Pharmco's Disclaimer</u> <u>All Chemical Products</u>

All Pharmco product labels and Certificate of Analysis include a disclaimer that states the following:

"For Industrial or Lab Use Only. Not intended as an active substance in Food or Drug. Not to be considered a Medical Device. Not intended for use as a Disinfectant as defined by the EPA."

These disclaimers are required by different Federal Agencies with regulatory powers over chemicals. Each statement is intended to fulfill each agency's requirements for Pharmco and is not intended to limit or prevent the use of our chemicals for end use application by our customers.

The appropriateness for use of our chemicals for any application is the sole discretion of our customers.

- For Industrial or Lab Use Only: These are not consumer, retail products. They are intended for use in industry
 or research not retail outlets or personal use. The term industry or industrial does not imply a low grade or use.
 It includes such diverse markets as Pharmaceutical, Biotechnology, Life Sciences, Flavor & Fragrance,
 Cosmetic, Research & Development, University, Hospital/Clinical and General Industrial Applications.
- 2.) <u>Not intended as an active substance in Food or Drug</u>: These products are not to be sold as an active substance. These products are not to be sold or used as food. While some products (pure alcohol) have nutritional value, no products are to be sold for this purpose. These products are not drugs and should not be considered drug substances. They should not be sold or used as a drug. Pharmco has not registered any product with the FDA as an active and does not intend to do so. These products are for excipient use only. These statements in no way imply that the chemicals cannot be used in food or drugs only not used as an active in food or drug.
- 3.) <u>Not to be considered a Medical Device</u>: These products are not manufactured under strict FDA conditions for Medical Device Manufacturing and are not sold as medical devices. Pharmco has not registered these products as Medical Devices and does not intend to do so.
- 4.) <u>Not intended for use as a Disinfectant as defined by the EPA</u>: These products are not manufactured with the intent to be used as disinfectants as defined by the EPA. Pharmco has conducted no microbial studies on these products. Pharmco has not registered these products with the EPA and does not intend to do so.

Approved by: Paul DiMarco, Vice President Quality Management

Date: 11/29/01 PD Rev. 2.0