

Cambridge Isotope Laboratories, Inc. **isotope.com** 

## Research Use of CIL Products

CIL manufactures highly pure research biochemicals that are produced for research applications. As a service to our customers, some of these materials have been tested for the presence of *S. aureus, P. aeruginosa, E. coli, Salmonella sp.,* aerobic bacteria, yeast, and mold, as well as the presence of endotoxin in the bulk material by taking a random sample of the bulk product. Subsequent aliquots are not retested. Presence of endotoxin is assessed by determining endotoxin content following established protocols and standardized limulus amebocyte lysate (LAL) reagents. These tests are provided at no charge for any materials listed in our catalog or website that are designated as "MPT" in the item product number (e.g., DLM-349-MPT).

CIL is able to provide microbiological testing for other products. Depending on the compound and the quantity ordered, an additional charge may apply.

Please note that microbiological-tested products are not guaranteed to be sterile and pyrogen-free when received by the customer, and microbiological testing does not imply suitability for any desired use. If the product must be sterile and pyrogenfree for a desired application, CIL recommends that the product be packaged or formulated into its ultimate dose form by the customer or appropriate local facility. The product should always be tested by a qualified pharmacy/facility prior to actual use. CIL research products are labeled "For Research Use Only. Not for use in diagnostic procedures." Persons intending to use CIL products in applications involving humans are responsible for complying with all applicable laws and regulations including but limited to the US FDA, other local regulatory authorities, and institutional review boards concerning their specific application or desired use.

It may be necessary to obtain approval for using these research products in humans from the US FDA or the comparable governmental agency in the country of use. CIL will provide supporting information, such as lot-specific analytical data and test method protocols, to assist medical research groups in obtaining approval for the desired use.

CIL will allocate a specific lot of a product to customers who are starting long-term projects requiring large amounts of material. Benefits from this type of arrangement include experimental consistency arising from use of only one lot, no delay in shipments, and guaranteed stock. Please note that some CIL products have a specific shelf life and cannot be held indefinitely. If interested, please contact your sales manager for further details.