



May 5, 2005

Michael L. Koenig, Ph.D.
Interdisciplinary Scientist
Division of Over-the-Counter Drug Products
U.S. Food and Drug Administration
5600 Fishers Lane, HFD-560
Rockville, MD 20857
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RE: Ciba Specialty Chemicals Corporation Time and Extent Application for Triclosan USP, prepared to support its inclusion into the Monograph for Topical Acne Drug Products for Over-the-Counter Human Use – Clarification of Confidential Information Content.

Dear Dr. Koenig:

As discussed, the information provided in the aforementioned TEA is non-confidential except for the following items which are considered Confidential Business Information to Ciba Specialty Chemicals:

- Section 1.2.7 Method of Synthesis and Purification (Section title is non-confidential, section content is confidential).
- In Section 2.1.1 Amount of Active Ingredient Sold, Table 2: Volume (kg) of triclosan sold for acne products by country and/or geographical region and Table 3: Volume (kg) of triclosan sold continuously in individual selected countries by year (1999-2004) are confidential (Table titles are non-confidential, content of tables is confidential).
- In Section 2.2 Estimates of Number of Units Sold and Exposed Populations, Table 4: Estimation of units sold for six continuous years (1999-2004) in six geographic regions (millions of units) is confidential. Specifically, the individual country/region estimates of units sold by year in Table 4 are confidential; however, the yearly cumulative totals (e.g. 4.10 million units for 1999, 4.06 million units for 2000, 2.83 million units for 2004) and the cumulative 6 year total across all countries (21.48 million units) are non-confidential information.

Please feel free to contact me at (336) 801-2037 or via email at lisa.navarro@cibasc.com if you have any questions regarding this information.

Sincerely,

A handwritten signature in black ink that reads "Lisa Navarro". The signature is written in a cursive, flowing style.

Lisa Navarro, Ph.D., D.A.B.T.
Director, Product Safety & Regulatory Affairs
Home & Personal Care Business Line