

**EXPERT PANEL CONSENSUS STATEMENT REGARDING  
THE GENERALLY RECOGNIZED AS SAFE (GRAS) STATUS  
OF AQUANOVA® WSQ5% (Q405) AND WSQ22% (Q1022),  
WATER-SOLUBLE FORMULATIONS OF COENZYME Q10  
CONTAINING POLYSORBATE 80, FOR USE IN FOODS**

June 30, 2004

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RECOGNIZED AS SAFE (GRAS) STATUS OF AQUANOVA<sup>®</sup> WSQ5% (Q405) AND  
WSQ22% (Q1022), WATER-SOLUBLE FORMULATIONS OF COENZYME Q<sub>10</sub>  
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## **INTRODUCTION**

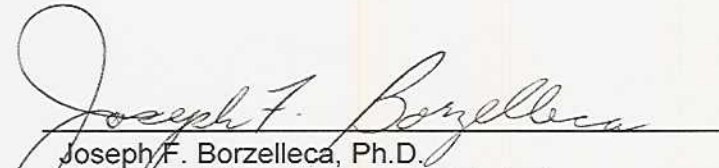
At the request of a consortium of three companies, Kyowa Hakko USA, Inc., AQUANOVA<sup>®</sup> German Solubilisate Technologies (AGT) GmbH, and WILD Flavors, Inc., an Expert Panel (the "Panel") of independent scientists, qualified by their relevant national and international experience and scientific training to evaluate the safety of food ingredients, was specially convened to conduct a critical and comprehensive evaluation of the available pertinent data and information, and determine whether, under the conditions of intended use as an ingredient in traditional foods, Aquanova<sup>®</sup> WSQ5% (Q405) and WSQ22% (Q1022) would be Generally Recognized as Safe (GRAS), based on scientific procedures. Aquanova<sup>®</sup> WSQ5% (Q405) and WSQ22% (Q1022) are food-grade water-soluble formulations of coenzyme Q<sub>10</sub> (CoQ<sub>10</sub>), containing polysorbate 80. The CoQ<sub>10</sub> composition ranges from 4.8 to 5.2% and 20.0 to 24.0% for Aquanova<sup>®</sup> WSQ5% (Q405) and WSQ22% (Q1022), respectively. The Panel consisted of the below-signed qualified scientific experts: Joseph F. Borzelleca, Ph.D. (Medical College of Virginia), John Doull, Ph.D., M.D. (University of Kansas Medical Center), and W. Gary Flamm, Ph.D (Flamm Associates). *Curricula vitae* evidencing the Panel members' qualifications for evaluating the safety of food ingredients are provided in Attachment 1.

The Panel, independently and collectively, critically examined a comprehensive package of publicly available scientific information and data compiled by CANTOX Health Sciences International from the literature and other published sources through February 2004. In addition, the Panel evaluated other information deemed appropriate or necessary, including data and information provided by members of the consortium. The Panel reviewed information pertaining to the method of manufacture and product specifications, analytical data, intended use-levels in specified food products, consumption estimates for all intended uses, and comprehensive literature on the safety of Aquanova<sup>®</sup> WSQ5% (Q405) and WSQ22% (Q1022) and its individual components.

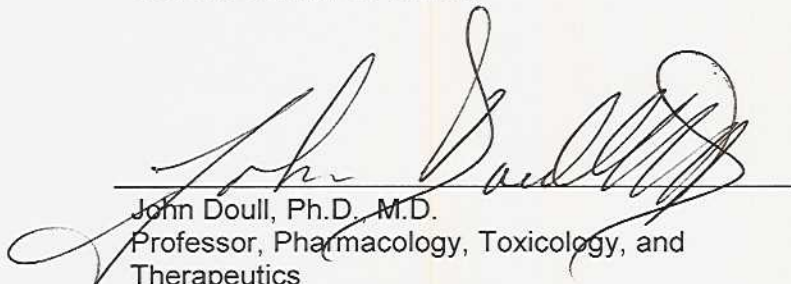
Following independent, critical evaluation of such data and information, the Panel unanimously concludes that under the conditions of intended use in traditional foods described herein, Aquanova<sup>®</sup> WSQ5% (Q405) and WSQ22% (Q1022), water-soluble formulations of CoQ<sub>10</sub>, containing polysorbate 80, meeting appropriate food-grade specifications, are GRAS based on

## CONCLUSION


We, the Expert Panel, have, independently and collectively, critically evaluated the data and information summarized above and conclude that Aquanova® WSQ5% (Q405) and WSQ22% (Q1022), water-soluble formulations of coenzyme Q<sub>10</sub> containing polysorbate 80, meeting appropriate food-grade specifications is Generally Recognized as Safe (GRAS) based on scientific procedures under the conditions of intended use in foods specified herein.

  
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