Summary of Official Agencies Denoting Recognition and Suitability of Magnesium Silicate, Synthetic for use as a Food Additive

Background

The Magnesium Silicate, synthetic manufactured by The Dallas Group of America, Inc. carries the trade name MAGNESOL®. MAGNESOL® is a synthetic, hydrous, amorphous form of Magnesium Silicate in which the molar ratio of magnesium oxide to silicon dioxide is approximately 2:5. It is a white, odorless, tasteless powder that is insoluble in water and alcohol, but is readily decomposed by mineral acids. The pH of a 1 in 10 slurry is between 7.0 and 10.0.

MAGNESOL® has a very high surface area with numerous active sites and is widely used as an adsorbent to remove impurities from cooking oils. MAGNESOL® is placed in contact with the cooking oil for a sufficient length of time for soluble impurities to be adsorbed and trapped for removal by filtration.

MAGNESOL® can be used with almost any filtration system designed to separate particles from fluids. It may be used as a free flowing filter-precoat powder or as a powder trapped in a fibrous matrix (e.g. a filter pad).

MAGNESOL® XL is manufactured to conform, in all respects, with the specifications for Magnesium Silicate, synthetic as set forth in the:

1) U.S. Pharmacopoeia/National Formulary Ed. XVII
2) Food Chemicals Codex, Ed. Third (FCC)
3) The Joint Food and Agriculture Organization (FAO) World Health Organization (WHO) Expert Committee on Food Additives (JECFA)

The following data from these official compendia attest directly to the suitability of Magnesium Silicate, synthetic for the stated uses and by inference to the safe ingestion of the material.

1. Food Chemical Codex (FCC): "The Food and Drug Administration (FDA) will regard the specifications in the Food Chemicals Codex (FCC) as defining an appropriate food grade product. The Food Chemicals Codex was officially recognized by the FDA when the definitions and procedural and interpretive regulations under Federal Register Section 170.30, relating to eligibility of substances for classification as generally recognized as safe (GRAS), were revised and published in the Federal Register of June 25, 1971 (36 FR 12093)".

Food Chemicals Codex specifications have also been adopted, under certain conditions by:

- the National Health and Medical Research Council of Australia
- the Health Protection Branch of the Department of National Health and Welfare of Canada
- the Ministries of Agriculture, Fisheries, and Food of Great Britain
- the Department of Health (Food and Nutrition Branch) of New Zealand.

Under Functional Use in Foods, The Food Chemicals Codex specifically lists Magnesium Silicate in the categories of Anti-caking Agent and Filter Aid. Calcium Silicate, Cellulose (powdered), Diatomaceous Earth, and Perlite are also listed in the Filter Aid category.

2. **U.S. Pharmacopoeia/National Formulary (USP/NF):** "The goal of the U.S. Pharmacopoeia National Formulary (USP) (NF) is to provide monographs for all pharmaceutic ingredients used in drug dosage forms." Magnesium Silicate is listed in the NF under the category of Glidant and/or Anti-caking Agent.

3. **Food and Agriculture organization/World Health Organization:** In 1982, the Joint Food and Agriculture Organization (FAO)/World Health Organization (WHO) Expert Committee on Food Additives (JECFA) prepared the FAO Food and Nutrition Paper: "Specifications for Identity and Purity". This publication covered buffering agents, salts; emulsifiers, thickening agents, and stabilizers; flavoring agents, food colours, sweeting agents, and miscellaneous food additives. "The specifications for identity and purity appearing in this publication were prepared at the Twenty-sixth Session of the Joint FAO/WHO Expert Committee on Food Additives (Rome, 19-28 April 1982) for the substances which, in the consideration of the committee, adequate data were available. The specifications, for the identity and purity of the food additives established by JEFCA, are meant to identify the substance that has been subjected to biological testing to ensure the substance is of adequate degree of purity required for safe use in food and to reflect and encourage good manufacturing practice: Magnesium Silicate (synthetic) is listed on page 118 of the publication.

4. **U.S. Department of Agriculture:** In a letter to the Dallas Group, the United States Department of Agriculture (USDA) declares "... MAGNESOL® XL is chemically acceptable for use as a processing aid for filtering used fats and oils in establishments operating under the Federal meat and poultry inspection program." (see letter of 2-24-89 attached)

5. **U.S. Food and Drug Administration:** In letters to the Dallas Group, the United States Food and Drug Administration (FDA) declares "...concerning the use of synthetic magnesium silicate as an adsorbent filter aid for the removal of impurities from used cooking oil, ...your proposed use of magnesium silicate would appear to be generally recognized as safe." (see letters 9-19-85 and 11-14089 attached)