ISO 9001 Registered
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MILLAD® 3988i
Regulatory Information Document

International Chemical Substances Approvals

	Millad® 3988	**Silane, dichlorodimethyl-, reaction products with silica**
US – TSCA	Listed	Listed
Europe* – ELINCS/ELINCS	Listed	Listed
Canadian – DSL	Listed	Listed
Australian – AICS	Listed	Listed
Korean – TCCL	Listed	Listed
Japanese – METI	Listed	Listed
Philippines – PICCS	Listed	Listed
China – Chemical Inventory	Listed	Listed
New Zealand – NZIoC	Listed	Listed
Switzerland	Listed	

*REACH Registration Status - Only substances included on EINECS can be pre-registered. Since **Millad® 3988** is listed on ELINCS it is not eligible for pre-registration, but will be automatically transferred to the REACH list at some point in the future. Other components in this product have been pre-registered by Milliken Europe as Milliken Chemical's OR.

International Approvals For Use In Plastics For Food Contact Applications

	Millad® 3988	**Silane, dichlorodimethyl-, reaction products with silica**
US – FDA	21CFR178.3295	FCN – 629
EU – 2002/72/EC; Section A	Listed	Listed
Japan, JHOSPA; Positive List	Listed	Listed
MERCOSUR Food Contact Positive List	Listed	Listed

- United States Food and Drug Administration (FDA): Food Additive Regulation 178.3295 Clarifying Agents for Polymers - Conditions A through H, maximum 0.40% by weight of the polymer (Millad® 3988).
- Europe: Food Contact Materials Directive 2002/72/EC (Section A) Product Reference Number 38879 (Millad® 3988). No restrictions and/or specifications.
    - Germany: BGA, April, 1994.

Milliken Chemical, A Division of Milliken & Company, 920 Milliken Road, M-209, Spartanburg, S.C. 29303
Phone: (864) 503-2200, Fax: (864) 503-2430

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- Italy: Ministero Dello Sanita, February 6, 1997
- France : Ministere de l'Economie des Finances et du Plan, July 11, 1995
- Belgium : Ministere des Affaires Sociales, de la Sante Publique et de l'Environment, July 18, 1995

- Canada, Health and Welfare Canada, Health Protection Branch: Food Packaging Materials and Incidental Additives Section, Chemical Evaluation Division, at levels up to 0.4% by weight, in polypropylene homopolymer and high propylene olefin copolymer- Letter of "No Objection" received, September, 1994 (Millad 3988).

- MERCOSUR Food Contact Positives List: Positive List of MERCOSUR for additives in propylene homopolymer and high propylene copolymer articles intended for use in contact with food, annex II, published March, 1996.

- Japan, JHOSPA: Positive list approval PL No. is G6-46 (Millad® 3988)

California Safe Drinking Water and Toxic Enforcement Act (Proposition 65)

- Although we have not analyzed for every chemical included on the California Safe Drinking Water and Toxic Enforcement Act Proposition 65 list, based upon a review of our process for the manufacture of this product, there should be no Proposition 65 listed chemicals present at regulated quantities in this product.

Product Origin

- We do not intentionally use any animal products in the manufacturing of our product or in the manufacturing process of this product.

- With regards to genetically modified organisms, sorbitol, crystalline and solutions are made by hydrogenation of starch hydrolysates from corn. Our Sorbitol supplier's policy is to procure its raw material corn from internationally approved crop sources. Because of their large scale, non-GM corn and GM corn cannot be segregated from one another. Consequently, their sorbitol, crystalline and solutions, may or may not be produced from GM corn. However, current industry consensus is that any DNA in the raw material stream is denatured, degraded or removed through successive processing steps including physical separation, heating, purification and filtration and most likely cannot be detected in measurable amounts in the sorbitol.

  As a conclusion, we can state that based on the above, it is safe to assume that any DNA is being destroyed or removed during the production process of the sorbitol. However, we cannot confirm that for the production of MILLAD® 3905 and MILLAD® 3988, we exclusively use sorbitol originating from corn that has not been genetically modified.

Heavy Metal Content

Chemical	Quantity	Chemical	Quantity
Antimony	<1.0ppm	Lead	<2.0ppm
Arsenic	<2.0ppm	Mercury	<0.07ppm

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Barium	<0.3ppm	Nickel	<0.5ppm
Cadmium	<0.2ppm	Selenium	<2.0ppm
Chromium	<0.3ppm	Zinc	2.31ppm
Copper	5.82ppm		

CONEG

This product is in full compliance with the CONEG (Congress of Northeastern Governors) Model legislation addressing the elimination of heavy metals in packaging and packaging components.

Specifically, Milliken Chemical certifies that:

A. MILLAD® 3988 contains no lead, cadmium, mercury or hexavalent chromium which has been intentionally introduced as an element during manufacture or distribution, and

B. The sum of the concentration levels of lead, cadmium, mercury and hexavalent chromium incidentally present in these products shall not exceed 100 parts per million by weight.

Hazardous Materials

Millad® 3988 does not contain any Class i or Class ii ozone depleting substances as defined by the Clean Air Act.

Millad® 3988 is not manufactured with BPA.

Millad® 3988 does not contain any Volatile Organic Compounds (VOCs)

Millad® 3988 is not classified as hazardous as defined by the Globally Harmonized System for Hazard Communications.

Allergens

Millad® 3988 does not contain any of the following known food allergens or others:

Peanuts, Milk, Fish, Tree Nuts, Soy Beans, Eggs, Shellfish, Wheat, or Natural Latex

Harmonized Tariff Code

- 2932.99--Aromatic heterocyclic compounds with oxygen hetero-atom(s) only

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NOTE: This document is intended solely for Milliken Chemical use in documenting MILLAD® 3988i regulatory approvals. No warranties as to accuracy or completeness are implied. Please contact your Milliken Chemical sales representative to receive the most up to date regulatory information.

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Created by: Regina Harper

Milliken Chemical, A Division of Milliken & Company, 920 Milliken Road, M-209, Spartanburg, S.C. 29303
Phone: (864) 503-2200, Fax: (864) 503-2430