ISO 9001 Registered
RC 14001 Registered

MILLIKEN®

Millad® NX8000
Regulatory Information Document

International Chemical Substances Approvals (Clarifying Agent)

- United States (TSCA)
- Europe* (ELINCS)
- Korea (ECL)
- Australia (AICS)
- New Zealand (NZIoC)
- China (IECSC)
- Japan
- Canada (DSL)

*REACH Registration Status - Only substances included on EINECS can be pre-registered. Since the clarifying agent in **Millad® NX8000** was listed on ELINCS, it was not eligible for pre-registration. It has been transferred to the REACH list, and our Only Representative is working to complete the final registration. Other components in this product have been pre-registered by Milliken Europe as Milliken Chemical's OR and will be registered at the appropriate time.

International Approvals For Use In Plastics For Food Contact Applications

- United States Food and Drug Administration (FDA): FCN 825
  Bis(4-propylbenzylidene) propyl sorbitol for use as a clarifying agent at a level not to exceed 5000 parts per million (0.50% wt.) by weight in polypropylene homopolymer and high-propylene olefin copolymers. The polymers containing the clarifier will be used in the form of film and molded articles and are intended to contact all food types under Conditions of Use A ("High temperature heat-sterilized (e.g., over 100 deg.C)") through H ("Frozen or refrigerated storage).
  The components of the AE package are approved by the United States Food and Drug Administration as Indirect Food Additives used in food contact substances.

  Europe: Bis(4-propylbenzylidene) propyl sorbitol- is listed in COMMISSION REGULATION (EC) No 975/2009 of 19 October 2009 amending Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with foodstuffs – Annex III Reference No.38550. The clarifying agent is listed with an SML of 5 mg/kg (including the sum of its hydrolysis products). The components of the AE package are already listed in the Plastics Directive and allow for use in polypropylene food contact articles in all food types.

- Canada: Submitted a request to the Health Products and Food Branch (HPFB) of Health Canada for the use of Bis(4-propylbenzylidene) propyl sorbitol- in food contact applications.

- MERCOSUR: Food Contact Positive List - Bis(4-propylbenzylidene) propyl sorbitol

- China: GB 9685 Hygienic Standards for uses of Additives in Food Containers and Packaging Materials - "Positive List" of Additives: Nominated for provisional listing.
  The components of the AE package are included on GB 9685 Hygienic Standards for uses of Additives in Food Containers and Packaging Materials provisional list.

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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.

Heavy Metal Content

Chemical	Quantity	Chemical	Quantity
Antimony	<10ppm	Lead	<10ppm
Arsenic	<10ppm	Mercury	< 8ppm
Barium	<10ppm	Nickel	<10ppm
Cadmium	<10ppm	Selenium	<10ppm
Chromium	<10ppm	Zinc	<10ppm
Copper	<10ppm		

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:

- Millad® NX8000 contains no lead, cadmium, mercury or hexavalent chromium which has been intentionally introduced as an element during manufacture or distribution, and

- 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® NX8000 does not contain any Class i or Class ii ozone depleting substances as defined by the Clean Air Act.

- Millad® NX8000 is not manufactured with Bisphenol A or Phthalates*

- Millad® NX8000 does not contain any Volatile Organic Compounds (VOCs)

- Millad® NX8000 is not classified as hazardous as defined by the Globally Harmonized System for Hazard Communications.

***** We have not specifically analyzed for the presence of these chemicals, however, none are intentionally added during the manufacturing process.

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Product Origin

With regards to genetically modified organisms, one of the raw materials used in the manufacture of the clarifying agent, in MILLAD® NX8000, is derived from corn. Our raw material supplier's policy is to procure its 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 raw material 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 raw material.

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 raw material. However, we cannot confirm that for the production of the clarifying agent in MILLAD® NX8000, we exclusively use raw materials originating from corn that has not been genetically modified.

Kosher Status

We do not intentionally use any animal products in the manufacturing process of Millad® NX8000

Harmonized Tariff Code

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

NOTE: This document is intended solely for Milliken Chemical use in documenting MILLAD® NX8000 regulatory approvals. No warranties as to accuracy or completeness are implied. Please contact contact your Milliken Chemical sales representative to receive the most up to date regulatory information.

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