



## Hyperform® HPN-20E Regulatory Information Document

### International Chemical Substance Approvals

All the components of Hyperform® HPN-20E are compliant with the chemical inventory requirements in the following countries:

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

\*REACH Registration Status - Only substances included on EINECS can be pre-registered. Since the nucleator component in **Hyperform® HPN-20E** 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

- United States: All components are compliant with the United States Food and Drug Administration (FDA): Food Contact Substance Notification for the use of Hyperform® HPN-20E as a nucleating agent, at a maximum level of 0.35 percent in all polyolefins in contact with all food types, under Conditions of Use A through H, as described in Table 2 of 21CFR 176.170.
- Canada: "Letter of no Objection" received from the Health Products and Food Branch (HPFB) of Health Canada when Cyclohexanedicarboxylic acid, calcium salt (1:1), (1R,2S)-rel is used as a nucleating agent or clarifying agent at a level not to exceed 0.25% by weight in all polyolefins. The polymers in which this substance will be used are intended to contact all food types under conditions ranging from high temperature heat-sterilized (100°C) through frozen and refrigerated storage: ready prepared foods intended to be reheated in container at time of use.
- Europe: Food Contact Materials Directive 2002/72/EC, amended for the fifth time by 2008/39/EC. As this product is a blend, both components are included in the directive. According to Commission Directive 2005 / 79 / EC (§1.2 b) Zinc Stearate is listed under Reference Number 89040 with an SML of 25 mg/kg of food. The nucleator component is listed under Reference Number 45703 with a limitation of 5 mg/kg of food.



- Japan: Japan Hygienic Olefin And Styrene Plastics Association (JHOSPA) has issued a certificate for Hyperform® HPN-20E which is approved for food contact at levels up to 2500 parts per million (ppm) in polyethylene and polypropylene resins.
- MERCOSUR: Food Contact Positive List - All of the components of Hyperform® HPN-20E are present on the MERCOSUR Positive List for food contact.

### 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 Hyperform® HPN-20E.

### Product Origin/ Kosher Status

No animal products are used in the components or manufacturing process of Hyperform® HPN-20E.

### Heavy Metal Content

Chemical	Detection Limit	Quantity	Chemical	Detection Limit	Quantity
Antimony	4 ppm	<4ppm	Lead	4 ppm	<4 ppm
Arsenic	5 ppm	<5ppm	Mercury	No Data	No Data
Cadmium	0.6 ppm	<0.6ppm	Selenium	5 ppm	<5 ppm
Chromium	2.6 ppm	<2.6ppm			

### 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:

- Hyperform® HPN-20E contains no lead, cadmium, mercury or hexavalent chromium which has been intentionally introduced as an element during manufacture or distribution.
- 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



*ISO 9001 Registered*  
*RC 14001 Registered*

Hyperform® HPN-20E does not contain any Class i or Class ii ozone depleting substances as defined by the Clean Air Act.

Hyperform® HPN-20E is not manufactured with BPA.

Hyperform® HPN-20E does not contain any Volatile Organic Compounds (VOCs)

Hyperform® HPN-20E is not classified as hazardous as defined by the Globally Harmonized System for Hazard Communications.

### **Allergens**

Hyperform® HPN-20E 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

### **Other Regulatory Compliance**

The zinc stearate used in Hyperform® HPN-20E is produced from plant-based Stearic Acid which does not contain any known genetically modified organisms (GMOs). The nucleator component, Hyperform® HPN-20, is derived from synthetically produced industrial materials.

### **Harmonized Tariff Code**

3824.90

NOTE: This document is intended solely for Milliken Chemical use in documenting Hyperform® HPN-20E 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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