

## Regulatory Data Sheet



### Polyethylene 17450N High Density

#### **Global Chemical Inventory Compliance**

All components of this product are on the following Inventory Lists or are exempt:

Country	Inventory	Y/N
Europe	EINECS	Yes
Europe	ELINCS	-
Canada	DSL	Yes
Canada	NDSL	-
United States	TSCA	Yes

Country	Inventory	Y/N
Australia	AICS	Yes
China	IECS	Yes
Japan	ENCS	Yes
Korea	KECI	Yes
New Zealand	NZIoC	Yes
Philippines	PICCS	Yes

#### **US FDA Food Contact Status**

When used unmodified and processed in accordance with Good Manufacturing Practices (GMP) for food contact applications, this resin will comply with the U.S. Food and Drug Administration's food additive regulation at 21 CFR 177.1520(c), paragraph 3.2a, under the Federal Food, Drug, and Cosmetic Act. This product may be used to produce articles or components of articles used in contact with food to all food types described in Table 1 and Conditions of Use A-H described in Table 2 of U.S. FDA's regulation at 21 CFR § 176.170(c). The preceding statement refers to regulatory requirements only, not to the product's physical utility. It is the responsibility of the article producer or food packager to determine that the article is suitable for its intended use.

#### **US FDA Drug Master File (DMF)**

Please contact Dow's Customer Information Group for more information (DowCIG@Dow.com).

#### **US Pharmacopoeia (USP)**

Please contact Dow's Customer Information Group for more information (DowCIG@Dow.com).

#### **European Commission Regulation (EU) No 10/2011 (Food Contact)**

The composition of this product complies with the requirements for use in contact with food of European Commission Regulation (EU) No 10/2011, including any subsequent amendments that are in force prior to the effective date of this Regulatory Data Sheet. Contact Dow at FGLREGL@dow.com to obtain a detailed food contact compliance letter for the individual European Countries and information about the imposed migration requirement.

#### **European Pharmacopoeia (EPHC)**

Please contact Dow's Customer Information Group for more information (CIGEUROPE@Dow.com).

#### **Canadian Food Contact (HPFB or CFIA)**

Although this product has been granted Canadian Health Products and Food Branch (HPFB) No Objection Status, it is the responsibility of the end user to consult HPFB before using this product in a food contact or pharmaceutical packaging application.



WORLDWIDE PARTNER

## **RDS - Polyethylene 17450N High Density**

### **Animal Derived Components**

This product contains one or more additive(s)/substance(s) synthesized from animal extracts, i.e. hydrolysis, etc. of animal fats (tallow) into fatty acids. The manufacturing process of the fatty acids includes a multi-step chemical treatment involving high temperatures, high pressures, and long residence times. These processing conditions greatly exceed the requirements as specified in Section 6.4 of the "Note for Guidance on minimizing the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products" (EMA/410/01 Rev. 3 – July 1, 2011), adopted by the European Commission and published in the Official Journal of the European Union March 5, 2011 (2011/C 73/01). Further, only Category 3 materials or equivalent as defined by Article 6 of European Parliament and Council Regulation (EC) No 1774/2002 are used as raw materials for the fatty acids. Thus, the tallow derivatives (irrespective of the geographical origin according to the Note for Guidance) used in the manufacturing of this product are therefore considered compliant with the EMA Note for Guidance referenced above.

### **Food Allergens**

To the best of our knowledge, there are no raw materials, including additives, that have their origin in peanuts, soybeans, milk, eggs, fish, shellfish, tree nuts, mustard, celery, sesame, and/or wheat or gluten. No sulfates or sulfites are used in the synthesis of this material. This evaluation is based on information provided by our raw material and additive suppliers for the presence of the allergen-stimulating substances shown above. Therefore, although we believe this product to be free of the specified known allergy stimulating food substances, we cannot guarantee this.

### **Materials from Genetically Modified Organisms**

To the best of our knowledge, there are no raw materials, including additives, that have been derived from genetically modified organisms (GMO). This is based on information from our additive suppliers. Therefore, although we believe this product to be GMO free, we cannot guarantee it at this time.

### **Kosher**

One or more of the raw materials used in the manufacture of this product originated in whole or in part from animal sources. The animal sourced raw material(s) have been chemically altered from their original structure and have undergone significant chemical processing, and is/are therefore considered synthetic. Because of this modification and processing, kosher compliance is claimed for the above product containing the raw material(s) of animal origin.

### **REACH**

For information on Dow and the European Union regulation for Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), visit our website, [www.reach.dow.com](http://www.reach.dow.com).

This product is not manufactured or formulated with any of the Substances of Very High Concern (SVHC) as per the candidate list that was current as of the effective date of this regulatory datasheet. Current information can be found at the ECHA website. [http://echa.europa.eu/chem\\_data/authorisation\\_process/candidate\\_list\\_table\\_en.asp](http://echa.europa.eu/chem_data/authorisation_process/candidate_list_table_en.asp). Please contact Dow's Customer Information Group for more information ([CIGEUROPE@Dow.com](mailto:CIGEUROPE@Dow.com)).

### **EU Directive 2011/65/EU (RoHS)**

This product complies with the requirements of Article 4.1 of EU Directive 2011/65/EU (RoHS). It is not intentionally manufactured or formulated with cadmium, hexavalent chromium, lead, mercury, polybrominated biphenyls (PBB), or polybrominated diphenyl ethers (PBDE).

EU Directive 2002/95/EC, as amended, will be repealed effective January 3, 2013.



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### **EU Directive 2002/96/EC on Waste Electrical and Electronic Equipment (WEEE), latest amended by EU Directive 2008/34/EC**

EU Directive 2002/96/EC on WEEE: Selective treatment of the waste (Article 6.1 and Annex II). None of the substances listed in Annex II are intentionally added or used in the formulation of this product.

### **Heavy Metals, EU 94/62/EC and Coalition of Northeastern Governors (CONEG)**

This product conforms to the Coalition of Northeastern Governors (CONEG) and the European Directive 94/62/EC, as amended, on Packaging and Packaging Waste, Article 11. Any incidental levels of lead, cadmium, hexavalent chromium, and mercury do not exceed 100 ppm total.

### **ASTM F963 - Standard Consumer Safety for Toy Safety**

This product is not formulated with antimony, arsenic, barium, cadmium, chromium, mercury, lead or selenium. To the best of our knowledge, it does not contain these substances above the limits set in ASTM F 963-95, Section 4.3.5.2., Table 1.

### **Consumer Product Safety Improvement Act of 2008 (CPSIA)**

This product is not manufactured or formulated with lead, di-(2-ethylhexyl)phthalate (DEHP), dibutyl phthalate (DBP), or benzyl butyl phthalate (BBP). To the best of our knowledge, it does not contain these materials above the limits set in the Consumer Product Safety Improvement Act of 2008, Title 1, Sections 101 and 108.

### **Canadian Environmental Protection Act Challenge Substances**

This product is not intentionally manufactured or formulated with the Batch Lists of Canadian Environmental Protection Agency (CEPA) Challenge Substances released as of the effective date of this document. However, we do not analyze for these specific substances.

(<http://www.chemicalsubstanceschimiques.gc.ca/challenge-defi/index-eng.php>)

### **Bisphenol A**

This product is not manufactured or formulated with Bisphenol A (CAS# 80-05-7).

### **Natural Rubber or Latex**

This product is not intentionally manufactured or formulated with natural rubber or natural latex; however, we do not analyze for these specific substances or compounds.

### **Phthalates**

The above mentioned product is not intentionally manufactured or formulated with phthalate esters; however, we do not analyze for these specific substances or compounds.

### **Halogenated Flame Retardants**

This product is not intentionally manufactured or formulated with halogenated or phosphorous based flame retardants; however, we do not analyze for these specific substances or compounds.



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### **Fluorotelomers, Perfluorooctanoic acid (PFOA) and Derivatives**

This product is not intentionally manufactured or formulated with Fluorotelomers, Perfluorooctanoic acid (PFOA), or Perfluorooctane sulfonate (PFOS); however, we do not analyze for these specific substances or compounds.

### **Residual Volatile Organic Compounds (VOC)**

The residual volatiles in this product are a maximum of 1500 ppm of straight chain aliphatic hydrocarbons. Limited laboratory data has indicated that approximately 50% of the residual volatiles are emitted during film processing.

### **Clean Air Act**

This product is not manufactured or formulated with Class I or II substances as defined under 40 CFR part 82 of the Clean Air Act of 1990, as amended (58 FR 8136).

### **California Proposition 65 (Safe Drinking Water and Toxic Enforcement Act of 1986)**

This product contains no listed substances known to the State of California to cause cancer, birth defects or other reproductive harm, at levels which would require a warning under the statute.

### **Product Stewardship**

The Dow Chemical Company and its subsidiaries ("Dow") has a fundamental concern for all who make, distribute, and use its products, and for the environment in which we live. This concern is the basis for our Product Stewardship philosophy by which we assess the safety, health, and environmental information on our products and then take the appropriate steps to protect employee and public health and our environment. The success of our product stewardship program rests with each and every individual involved with Dow products—from the initial concept and research, to manufacture, use, sale, disposal and recycle of each product.

### **Customer Notice**

Dow strongly encourages its customers to review both their manufacturing processes and their applications of Dow products from the standpoint of human health and environmental quality to ensure that Dow products are not used in ways for which they are not intended or tested. Dow personnel are available to answer your questions and to provide reasonable technical support. Dow product literature, including safety data sheets, should be consulted prior to use of Dow products. Current safety data sheets are available from Dow.

### **Medical Applications Policy**

NOTICE REGARDING MEDICAL APPLICATION RESTRICTIONS: Dow will not knowingly sell or sample any product or service ("Product") into any commercial or developmental application that is intended for:

- long-term or permanent contact with internal bodily fluids or tissues. "Long-term" is contact which exceeds 72 continuous hours;
- use in cardiac prosthetic devices regardless of the length of time involved ("cardiac prosthetic devices" include, but are not limited to, pacemaker leads and devices, artificial hearts, heart valves, intra-aortic balloons and control systems, and ventricular bypass-assisted devices);
- use as a critical component in medical devices that support or sustain human life; or
- use specifically by pregnant women or in applications designed specifically to promote or interfere with human reproduction.

Dow requests that customers considering use of Dow products in medical applications notify Dow so that appropriate assessments may be conducted. Dow does not endorse or claim suitability of its products for specific medical applications. It is the responsibility of the medical device or pharmaceutical manufacturer to determine that the Dow product is safe, lawful, and technically suitable for the intended use. **DOW MAKES NO WARRANTIES, EXPRESS OR IMPLIED, CONCERNING THE SUITABILITY OF ANY DOW PRODUCT FOR USE IN MEDICAL APPLICATIONS.**

### **Disclaimer**

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