



Effective Date: 01/23/2017

REGULATORY INFORMATION PACKET

DOW™ HDPE 25455N

HIGH DENSITY POLYETHYLENE

Product Manufacturer

This product is manufactured by The DOW Chemical Company in Midland, MI U.S.A.

Manufacturing Facility Certifications

ISO 9001:2008 Certificate Midland, MI, USA.

Chemical Inventories

Please see SDS for chemical inventory listings.

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.

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.

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.

China Food Contact Compliance (GB9685-2008)

This product complies with China GB 9685-2008, Hygienic Standards for Uses of Additives in Food Containers and Packaging Materials and the supplementary positive lists of resins and additives for food contact materials; extended food contact certification letter for this product.

US FDA Drug Master File (DMF)

This product is listed under FDA Drug Master File 22316.



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 (mollusks), crustaceans, tree nuts, mustard, celery, sesame, lupine, animal or vegetable proteins, caffeine, monosodium glutamate (MSG), colorants (including carmine and cochineal), corn, wheat, barley, rye, triticale, gluten, mushrooms, yams, and/or phenylalanine and its derivatives. 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.

US Pharmacopeia (USP)

This product has been assessed under U.S. Pharmacopoeia, (Class VI) Plastic.

European Pharmacopoeia (EPHC)

This product complies with the compositional requirements of the European Pharmacopoeia, 8th Edition (including current supplements), Paragraph 3.1.3. "Polyolefines". However, be aware that tests have not been performed as specified in this Monograph.

China Food Contact Compliance (GB9685-2008)

This product complies with China GB 9685-2008, Hygienic Standards for Uses of Additives in Food Containers and Packaging Materials and the supplementary positive lists of resins and additives for food contact materials.

Japan Hygienic Olefin and Styrene Plastics Association (JHOSPA)

This product is not currently registered under the Japan Hygienic Olefin and Styrene Plastics Association (JHOSPA) for use in food contact packaging applications.

India Standard for Contact with Food, Pharmaceuticals, or Drinking Water

The composition of this product has not been assessed for use in contact with foodstuff, pharmaceutical, or drinking water applications under the Indian Standards.

Latin America MERCOSUR Food Contact Status

The composition of this product has not been assessed for use in contact with food according to MERCOSUR GMC Resolution No. 32/07 and/or Resolution No. 02/12.

Animal Derived Components (BSE/TSE)

One or more ingredients used to manufacture this product may have been 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).

Furthermore, only Category 3 materials or equivalent as defined by Article 10 of European Parliament and Council Regulation (EC) No 1069/2009 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.

Plant Derived Components

This product may contain one or more additive(s)/substance(s) synthesized from plant extracts, i.e. hydrolysis, etc. of plant oils into fatty acids and/or their derivatives, as per information from our raw material suppliers.

Kosher

One or more of the raw materials used in the manufacture of this product may have originated in whole or in part from animal sources. If used, 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.

Halal

This product is not Halal certified. Please note that one or more of the raw materials used in the manufacture of this product may have originated in whole or in part from animal sources. This raw material has been chemically altered from its original structure prior to addition to the manufacturing process for making this product and is therefore considered synthetic.

REACH 173 Substances (January 12, 2017)

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 that would require reporting under this regulation. Current information can be found at the ECHA website.

EU Directive 2011/65/EU Restriction of Hazardous Substances (RoHS)

This product complies with the requirements of Article 4.1 of EU Directive 2011/65/EU (RoHS 2), as amended (Directive (EU) 2015/863 inclusive). It is not intentionally manufactured or formulated with cadmium, hexavalent chromium, lead, mercury, polybrominated biphenyls



(PBB), polybrominated diphenyl ethers (PBDE), Bis(2-ethylhexyl) phthalate (DEHP), Butyl benzyl phthalate (BBP), Dibutyl phthalate (DBP), or Diisobutyl phthalate (DIBP).

Heavy Metals (ELV Directive 2000/53/EC)

Coalition of Northeastern Governors (CONEG)

This product conforms to the Coalition of Northeastern Governors (CONEG) and European Directive. Any incidental levels of lead, cadmium, hexavalent chromium, and mercury do not exceed 100 ppm total.

European Directive (94/62/EC) Packaging and Packaging Waste

EU Directive 2012/19/EU Waste Electrical & Electronic Equipment (WEEE)

This product conforms to 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.

EU Directive 2012/19/EU on WEEE: Selective treatment of the waste (Annex VII). None of the substances listed in Annex VII are intentionally added or used in the formulation of this product with the following exception. This product is a hydrocarbon; however, liquid hydrocarbons are not present in this product.

European Regulation (EC) No. 1895/2005 (BADGE, BFDGE, NOGE)

The resin manufacturer does not use 2,2-bis(4-hydroxyphenyl) propane bis (2,3- epoxypropyl) ether (BADGE), bis(hydroxyphenyl)methane bis(2,3-epoxypropyl) ethers (BFDGE) or novolac glycidyl ethers (NOGE) in the manufacture or formulation of this product.

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 as of the effective date of this regulatory datasheet.

Conflict Materials (Dodd-Frank Wall Street Reform and Consumer Protection Act)

This product is not intentionally manufactured or formulated with the listed conflict minerals as per Section 1502 of the Dodd-Frank Wall Street Reform and Consumer Protection Act; however, we do not analyze for these specific substances or compounds.

- Columbite-Tantalite – refined into Tantalum (Ta) (CAS # 7440-25-7)
- Cassiterite – refined into Tin (Sn) (CAS # 7440-31-5)
- Wolframite – refined into Tungsten (W) (CAS # 7440-33-7)
- Gold (Au) (CAS # 7440-57-5)



We are disclosing the above information, to the best of our knowledge based upon data from our raw material suppliers. We believe this information to be accurate and reliable as of the effective date of this Regulatory Data Sheet.

Ozone Depleting Chemicals (ODCs)

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).

Phthalates

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

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.

Additional Substance Information

This product is not intentionally manufactured or formulated with the following substances or compounds; however, we do not analyze for these substances or compounds.

- 2-Mercaptobenzothiazole (MBT)
- Aflatoxin-like compounds
- Aldehydes
- Azoxy compounds
- Bis(2-ethylhexyl) Adipate (DEHA)
- Bisphenol compounds, incl. but not limited to: BPA, BPB, BPC, BPE, BPF, BPS, and BPZ
- Butylated Hydroxyanisole (BHA)
- Butylated Hydroxytoluene (BHT)
- Dioxins and similar compounds
- Endocrine Disruptors (proven by the industry)
- Epoxy Resin
- Formaldehyde
- Halogenated (Brominated or chlorinated) or phosphorous based flame retardants
- Isocyanate
- Melamine
- Natural rubber latex, dry natural rubber, or synthetic latex
- Nitroso compounds
- Novolac Glycidyl Ethers (NOGE)
- Organic phosphates
- Perfluorooctane Sulfonate (PFOS)
- Phthalates / Phthalate esters
- Plasticizers



Polybrominated Biphenyls (PBB's)
Polybrominated Diphenyl Ethers (PBDEs)
Polybrominated Terphenyls (PBTs)
Polychlorinated Biphenyls (PCBs)
Polycyclic aromatic hydrocarbon (PAH)
Polyurethane
Polyvinyl Chloride (PVC)
Polyvinylidene Chloride (PVDC)
Tris-nonylphenol Phosphite (TNPP)

Sterilization Methods

| | |
|--------------|----------------------------|
| E-beam/Gamma | (gamma may cause toxicity) |
| EtO | (possibly used) |
| Autoclave | No information available |

Shelf Life and Expiration Date

Eldon James has tight controls on inventory, so finished products are manufactured and sold quickly. Consequently, raw materials are stored for a relatively short time before use in the manufacturing process. Eldon James cannot commit to a shelf life on products, but we stand by the quality and use of new raw materials. Resin manufacturers usually make no commitment on shelf life. Eldon James does not make any claims regarding Expiration Date because our customers use our products in many different applications and conditions. Eldon James cannot make any assessment or claims regarding expiration. Each individual condition and application must be tested by the customer to determine the limits of each product, material, and use.

Use of this Regulatory Information Data Sheet

The information provided as requested is intended to be used for informational purposes only. The information is provided on a without prejudice basis and should not be viewed as giving technical advice, instruction, or otherwise. The information is furnished free of charge and is based on supplier knowledge and understanding. Eldon James Corporation makes no representation or warranty as to the completeness or accuracy of the information contained herein. It is intended for use by persons having technical skill, at their own discretion and risk, who will make their own determination as to its suitability for their purposes prior to use. As with any material, evaluation of any compound under end-use conditions prior to specification is essential. Ultimately, customers must make their own determination that use of this product is safe, lawful, and technically suitable for their intended applications.