H28E-00 is an antistated, controlled rheology polypropylene homopolymer designed for injection molding applications that require improved impact characteristics. It meets the requirements of the U.S. Food and Drug Administration as specified in 21CFR 177.1520.

## **Typical Properties**<sup>1</sup>

	Values		ASTM	
	<b>English Units</b>	SI Units	Method	
Resin	0			
Density	_	0.9086 g/cc	D792	
Melt Flow Rate 230°C/2.16 kg	_	28 g/10 min	D1238	
Injection Molded Samples				
Tensile Strength (2 in/min)			D638	
@ Yield	4,990 psi	34.4 MPa		
@ Break	2,190 psi	15.1 MPa		
Elongation (2 in/min)			D638	
@ Yield	11.5 %	11.5 %		
@ Break	291 %	291 %		
Flexural Modulus			D790A	
1% Secant	194,700 psi	1,342 MPa		
Notched Izod Impact Strength			D256	
@ 23 C	0.55 ft-lbf/in	2.91 kJ/m <sup>2</sup>		
Hardness			D2240	
Rockwell R	95.7	95.7		
Deflection Temperature			D648	
@ 66 psi (455 kPa)	197 F	91.8 C		
Gloss at 60 ° angle	91.3	91.3	D2457	

<sup>1</sup> Typical properties will vary and are not to be used for specifications.

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#### **Regulatory Information**

The product and uses described herein may require global product registrations and notifications for chemical inventory listings, or for use in food contact or medical devices. For further information, please refer to the Regulatory Position Statement (RPS) online at <u>www.ineos-op.com</u>, or call + 1-800-527-5419.

#### Health and Safety Information

The product described herein may require precautions in handling and use because of toxicity, flammability, or other consideration. The Material Safety Data Sheet (MSDS) contains the available product health and safety information for this material and can be found at **www.ineos-op.com**. Before using any material, a customer is advised to consult the MSDS for the product under consideration for use.

The Material Safety Data Sheet for this product contains shipping descriptions and should be consulted, before transportation, as a reference in determining the proper shipping description. If the material shipped by INEOS O&P is altered or modified, different shipping descriptions may apply and the MSDS of the original material should not be used.

For additional information, samples, pricing and availability, please contact:

#### INEOS Olefins & Polymers, USA

Marina View Building 2600 South Shore Boulevard Suite 500 League City, Texas 77573 Phone: +1 281 535 6600 Fax: +1 281 535 6764 Customer Service: +1 800 527 5419 Tech Service: +1 800 338 0489 www.ineos-op.com

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# H28E-00

CAS # 9003-07-0

Regulatory Position Statement

## Food Contact Clearances

January 2019

#### US FDA Compliance (21 CFR 2019)

Under 21 CFR 177.1520(c) 1.1a, this resin may be safely used in articles or components of articles intended for use in contact with food. All adjuvants used in the manufacture of this resin are cleared for use in 21 CFR 170-189 by specific citation, generally recognized as safe (GRAS), prior sanctioned or under a specific Food Contact Notification (FCN). No further restrictions apply to the finished polymer.

### EU Food Contact Compliance - Commission Regulation (EU) No 10/2011

As dispatched from our plant, the monomers and additives of this INEOS product meet the relevant requirements of Commission Regulation (EU) No 10/2011 as amended under the Framework Regulation EU 1935/2004. Please send an email to Product Stewardship\* if you need an EU Declaration of Compliance.

#### Health Canada, Health Products and Food Branch "No Objection" Letter

A Letter of No Objection (LONO) under File Number KS11060207 is available for this product. Further restrictions may apply. Please contact Product Stewardship for details.

# China's Hygienic Standards for Uses of Additives in Food Containers and Packaging Materials (GB 4806-2016 and GB 9685-2016)

As dispatched from our plant, this product meets relevant requirements laid down in GB 4806-2016 and GB 9685-2016. As the conversion process can affect migration, only the converter can guarantee to the food packager that any limit is not exceeded.

#### MERCOSUR

Please be advised that the monomers and additive(s) used in this product conform to the requirements and listings of MERCOSUR/ GMC/RES N° 02/12 and RES N° 32/07.

## **Regulations/Directives Applicable to End Use Articles**

This product conforms to the substance limits and prohibition requirements of the following:

- EU Cosmetic Regulation (EC) No 1223/2009
- Consumer Product Safety Improvement Act (CPSIA) of 2008/Lead and Phthalates in Toys
- EU Safety of Toys EN 71-3:2013
- RoHS 2, Directive 2011/65/EU, as amended by 2015/863/EU
- WEEE EU 2012/19/EU

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# H28E-00

## CAS # 9003-07-0 Regulatory Position Statement

#### U.S. Pharmacopeial Convention (USP)

This resin has not been tested under the criteria specified in the United States Pharmacopoeia, nor that specified by ISO 10993 for biological testing of materials. This resin is not intentionally formulated with aluminum, arsenic, cadmium, lead, mercury, cobalt, nickel, chromium, titanium, vanadium, zinc, and/or zirconium. We do not test for ingredients not intentionally added. Please contact us for additive information if needed for USP 661.2 testing.

#### European Pharmacopoeia

All additives in this product are listed as approved in European Pharmacopoeia 3.1.3, "Polyolefins".

#### CONEG/EU Directive 94/62/EC/Heavy Metals

The regulated metals – lead, mercury, cadmium, and hexavalent chromium – are not intentionally added during the manufacturing process. Testing for heavy metals – cadmium, chromium, lead and mercury - resulted in a total for all metals detected of < 2 ppm, compared to the CONEG requirement of < 100 ppm. The result for incidental lead concentration was less than the detection limit of 0.1 ppm.

### **Other Regulations/Directives**

#### California Proposition 65

No substance listed on California's Proposition 65 chemicals listing, known to the State of California to cause cancer or reproductive toxicity, is intentionally added in the manufacture of this product.

#### Canada (WHMIS, Toxic Substances and Chemical Management Plan)

None of the chemicals on WHMIS, Canada's *Prohibition of Certain Toxic Substances* list or the Canadian Chemical Management Plan are intentionally added as raw materials to this product.

#### EU Commission Regulation (EC) No 1895/2005

This Regulation does not apply to our product because our products are not manufactured with any of the following substances:

- (a) 2,2-bis(4-hydroxyphenyl)propane bis(2,3-epoxypropyl) ether, hereinafter referred to as 'BADGE' (CAS No 001675-54-3), and some of its derivatives;
- (b) bis(hydroxyphenyl)methane bis(2,3-epoxypropyl)ethers, hereinafter referred to as 'BFDGE' (CAS No 039817-09-9);
- (c) other novolac glycidyl ethers, hereinafter referred to as 'NOGE'.

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# H28E-00 CAS # 9003-07-0 Regulatory Position Statement

#### RECYCLING

The recycling code shown to the right applies to the resin only. It may not apply to products manufactured from this resin. Recycling codes for finished articles must be determined by the manufacturer on a case by case basis.



#### GMP, FSMA and EU Commission Regulation (EC) No 2023/2006

INEOS O&P USA maintains an ISO 9001 system that corresponds to the requirements of FSMA and EC No 2023/2006 and addresses good manufacturing practice for materials intended to come into contact with food. US FDA regulations do not specifically address good manufacturing practices (GMP) for food contact materials. A copy of the current certificate is available online at <u>ISO Certificate.pdf</u>.

### REACH

Please refer to our REACH statement online at <u>REACH SVHCs</u> covering REACH registration issues, CoRAP and SVHCs.

#### **GLOBAL INVENTORY STATUS**

Country	Inventory	<i>Y/N</i>	Country	Inventory	Y/N
United States	TSCA This product has been verified with a status of "active" on the TSCA inventory prior to Feb 7, 2018.	Y	Japan	ENCS (METI) ISHL	Y
European Union	EINECS	Y	New Zeal	and NZIoC	Y
China	IECSC	Y	Korea	KECI	Y
Canada	DSL	Y	Philippine	es PICCS	Y
Australia	AICS	Y	Taiwan	NECI	Y

## Drug Master File

#### Drug Master File(s)

This product is filed with the FDA in INEOS Drug Master File 3720. A letter of authorization for the FDA to access our file on your behalf is available upon request.

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### Substances of Concern to Our Customers

Based on knowledge of our raw materials and information from our suppliers, we can state that none of the substances of concern to our customers listed below are intentionally added to this product. We do not conduct routine analytical testing for the presence of these substances in our products.

<u>Genetically Modified Organisms (GMO)</u> Because of the multitude of crop sources used, our suppliers of plant-based additives are unable to certify that their products are 100% GMO-free.

• 3-MCPD (3-monochloropropane)	• Melamine		
Alkyphenols and Ethoxylates	Methylisothiazolinone (MI / MIT) & Methylchloroisothiazolinone (MCI / CMIT)		
• Allergens or allergen derivatives <sup>1</sup>	• Microbeads		
• Animal Derived Material/TSE/BSE <sup>2</sup>	Nanoparticles		
• Antimicrobial agents/Biocides/Fungicides/ Pesticides (Substances identified as such and used	• N-Ethyl-toluenesulfonamide (Ortho/Para)		
for such purpose)	• Nonylphenol ethoxylates (NPEs)		
• Asbestos	Organotin Compounds		
Azo dyes/ Colorants/Pigments	Ozone Depleting Chemicals (ODCs)		
• Azodicarbonamide	PAHs (Polycyclic Aromatic Hydrocarbons)		
• Benzophenones	Parabens and PABA		
• Benzoate Preservatives (BHA, TBHQ)	Pentanoic acid		
• Bisphenols (e.g., A, F, S)	Perfluoroalkyl substituted phosphate ester acids		
• Carboxymethylcellulose	<ul> <li>Perfluorinated and polyfluorinated compounds, including their acid, salts and pre- cursors such as PFCs, PFAs and PFASs, PFNs, PFOs and PFOA and PFCAs</li> </ul>		
• CITES Appendix (I, II, III)	Persistent Organic pollutants (POPs) EU No 757/2010 Annex I amending EC No 850/2004		
• Conflict Minerals (columbite-tantalite (coltan, niobium, tantalum), cassiterite (tin), gold, and wolframite (tungsten) <sup>3</sup>	• Phthalates <sup>4</sup> (e.g., BBP, BDP, DBP, DCP, DCHP, DEHP, DEP, DiBP, DiDP, DiNP, DMP, DnHP, DnOP, DiiHP)		
Cocamide diethanolamide	Photoinitiators (e.g., ITX)		

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# H28E-00

# CAS # 9003-07-0 Regulatory Position Statement

• Decabromodiphenyl ether (Deca)	Delvaerbate 20		
• Diethanolamine salts of mono- and bis-	• Polysorbate 80		
• Dimethyl/Methyl Fumarate (DMF)	<ul> <li>Polyhalogenated Organo Compounds (PCBs, PCTs and Ugilec)</li> </ul>		
• Dioxins	• PVC		
• Flame Retardants (e.g. Brominated,	Radioactive Substances		
Halogenated, Phosphorous- or Nitrogen- based, Chlorinated, etc.)	• REACH Annexes XIV and XVII		
• Formaldehyde	• Red List (Living Future bldg. materials list)		
• Fragrances	• Short Chain Chlorinated paraffins (SCCPs)		
• GADSL	• Silica		
• Halogens (fluorine, chlorine, bromine, iodine, astatine)	• Silicone		
HAPs (Hazardous Air Pollutants) Section     112(b) of the US Clean Air Act	Solvents, residual solvents		
• Heavy Metals (As, Ba, Cd, Cr, Hg, Pb, Sb, Se)	• State Lists – including Maine, Massachusetts,		
International Council for Harmonisation	Minnesota, Vermont, Washington		
(ICH) Q3D Elemental Impurities	• SVHCs (Please refer to our REACH statement		
• "Intelligent packaging" materials	online at www.ineos-op.com covering REACH registration issues, CoRAP and SVHCs.)		
IUCN Red List of Threatened Species	• Triclosan (2,4,4' –trichloro-2'-hydroxy-		
Jatropha Oil	diphenyl ether)		
• Latex	• Tris (Nonylphenyl) phosphite (TNPP)		
• Materials banned by Lacey Act of 1900			

<sup>1</sup> from such things as pigments, fragrances, artificial sweeteners (e.g. aspartame), almonds, Brazil nuts, cashews, corn, hazelnuts, macadamia nuts, pecans, pine nuts, pistachios and walnuts; peanuts, lupine, soy/soybeans, peas, carmine/cochineal, milk, lecithin, eggs, fish, shellfish/crustacea or mollusks, tree nuts, celery, sesame seeds, mustard or mustard seeds, diacetyl, glutamites, glutamic acid, MSG or hydrolyzed vegetable proteins, nitrites or sulfites, or gluten from the grains of the following cereals: barley; oats; rye; triticale; or wheat

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# H28E-00 CAS # 9003-07-0 Regulatory Position Statement

<sup>2</sup> No animal-derived products are intentionally used as components of, or in the manufacture of, this product.

<sup>3</sup> INEOS O&P USA (INEOS O&P) is not a publicly traded company so is not subject to the SEC reporting requirements of the Dodd-Frank Wall Street Reform and Consumer Protection Act.

As with most polypropylene grades, including grades from other producers, this resin may contain trace levels of phthalates. If needed, please contact Product Stewardship for further information.

For further information, please see our website <u>www.ineos-op.com</u> or contact me in Product Stewardship:

As agent for INEOS O&P USA,

Carolyn Runsder

\*Email: carolyn.ramsden@ineos.com Phone: 281-535-6729

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# PRODUCT DATA SHEET

**Product:** 568616C

**Description:** White PP Concentrate

Form: Pellets

Letdown Ratio: 50:1

Base Resin Carrier: Polypropylene Homopolymer

**Pigment Loading:** 50 %

**Melt Index Range:** 12 - 28 g/10 min

**FDA Compliance\*:** 21 CFR 177.1520 (c) 1.1a 21 CFR 178.2010 21 CFR 178.3297 \*When used at levels not to exceed 32% of the final article.

The properties and suggested applications listed above are provided for informational purposes only. They do not imply a warranty of performance. The Customer is responsible for determining if the material is suitable for the application in the molded or extruded form.

04-2019



# PRODUCT DATA SHEET

## HS035/20F

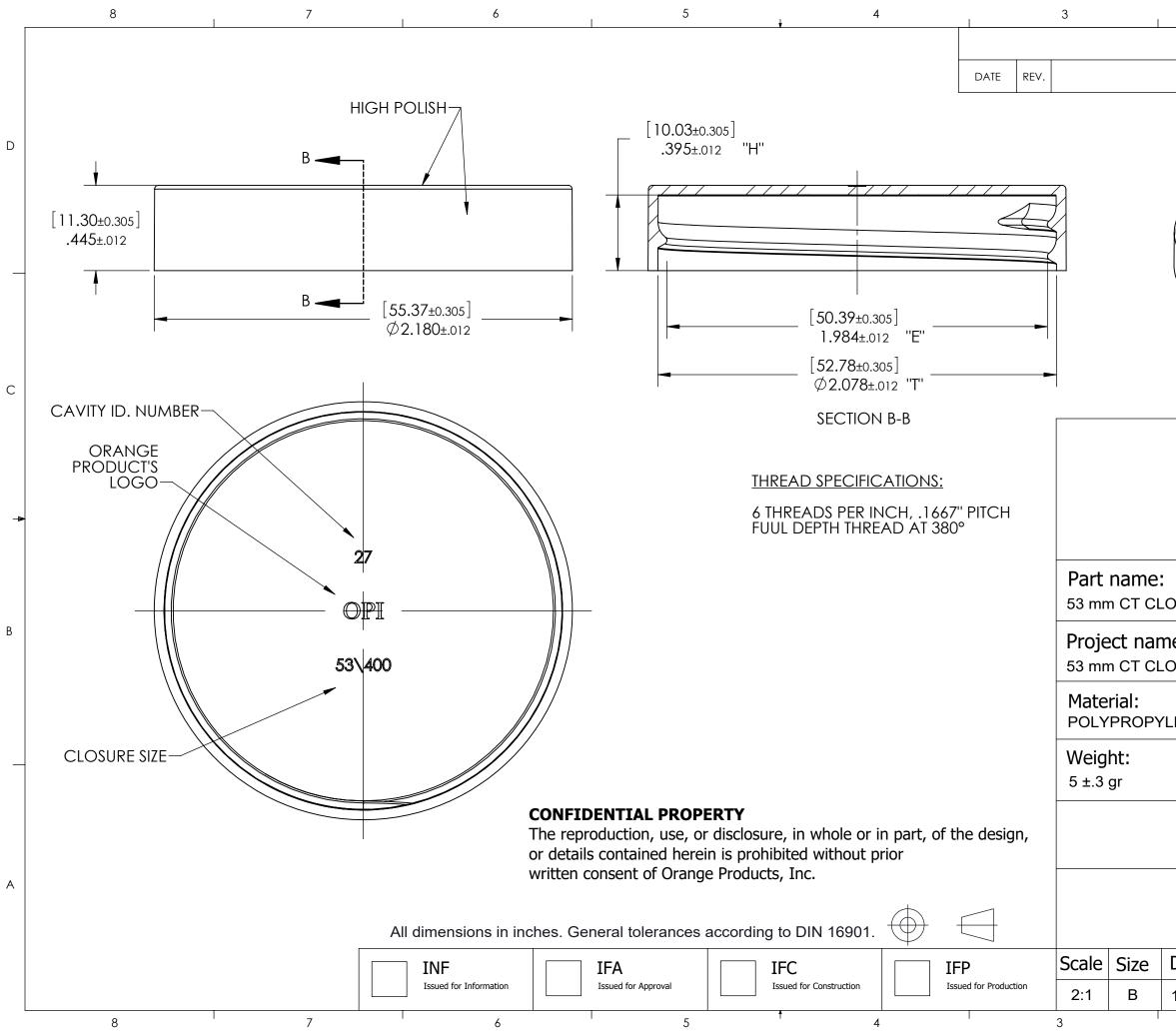
- HS035/20F is a one-piece, polystyrene backed, induction heat seal with an ethylene vinyl acetate based sealant layer that gives a tamper evident bond to Polyethylene (PE), Polypropylene (PP). Polyester (PET), Polystyrene (PS), Vinyl (PVC) and glass containers.
- Available with standard or custom print.

### Typical Product Attributes

Construction				
		SI (μm)	US (Mils)	
Polystyrene Foam White Paper Aluminum Foil Heat Seal		508,0 71,1 8,9 38,1-76,2	20.0 2.8 0.35 1.5-3.0	
Thickness Tolerance Minimum Width Width Tolerance		± 10% 25,4 mm ± 1,6 mm	± 10% 1.0 in ± 0.0625 in	
Properties				
Oxygen Transmission (O <sub>2</sub> TR) Water Vapor Transmission (WVTR)	Essentially Zero Essentially Zero			
Regulatory Compliance				
FDA Compliance Drug Master File (DMF) Other Compliances Safety Data Sheet (SDS) Statement	<ul> <li>21 CFR 177.1640 Polystyrene and rubber-modified polystyrene.</li> <li>21 CFR 177.1350 Ethylene-vinyl acetate copolymers.</li> <li>21 CFR 177.1210 Closures with sealing gaskets for food containers.</li> <li>21 CFR 176.180 Components of paper and paperboard in contact with dry foods.</li> <li>21 CFR 176.170 Components of paper and paperboard in contact with aqueous and fatty foods.</li> <li>21 CFR 176.170 Components of paper and paperboard in contact with aqueous and fatty foods.</li> <li>21 CFR 176.170 Components of paper and paperboard in contact with aqueous and fatty foods.</li> <li>002518</li> <li>USFDA Food Allergen Guidelines   California Proposition 65 Labeling Requirements   Limitations of Heavy Metals in Packaging per CONEG &amp; EU 94/62/EC, Article 11</li> <li>Safety Data Sheets (SDS) are not required for articles as defined in 29 CFR 1910.1200, the OSHA Hazard Communication Standard (HazCom). This product is an article as defined by HazCom and is not considered to be, or to contain, a hazardous chemical based on evaluations made by our company.</li> </ul>			
Please note that construction does not reflect adhesive or resin bonding layers, if present.				

Revision Number: 3 Revised Date: 2018-05-29

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