

CALIBRE™ MEGARAD™ 2081 Transparent Polycarbonate Resin**Product Information****Allergens**

This product contains a raw material that is derived, in part, from soybeans.

Animal Derived Components

This product contains additives synthesized from animal extracts, i.e., hydrolysis, etc. of animal fats and oils into fatty acids. According to our raw material supplier, the tallow feedstock used to produce the animal-derived raw material comes primarily from bovine (beef) sources although porcine (hog) fat may also be used. Suppliers confirm they use healthy animals (age not specified) from the United States, Canada, and/or Mexico, and that the tallow-derived material has been produced in accordance with applicable FDA and USDA regulations, including 9CFR Part 94 which lists countries in which imports of live bovine and ovine animals and animal products are banned.

The tallow-derived component which is used in the manufacture of our supplier's raw material has been produced under harsh temperatures, pressures, and residence times. As a minimum, the process conditions are

- Hydrolysis step carried out at sustained temperature of at least 200°C at pressures of not less than 40 bar for a minimum time of 20 min and may also include hydrogenation of tallow at 200°C
- Distillation of fatty acids at temperatures greater than 420 deg F (215.6 deg C).

The above rigorous processes are equivalent to, or exceed, the recognized conditions for inactivating the BSE agent as defined in DIN EN ISO 22442-1:2008-03 Annex C section C.5 "Tallow Derivatives" which states

- a) Transesterification or hydrolysis at not less than 200°C for not less than 20 min under pressure (glycerol, fatty acids and fatty acid esters production);
- b) Saponification with sodium hydroxide solution, at a concentration of 12 mol/l (glycerol and soap production);
 - 1) batch process: at not less than 95°C for not less than 3 h;
 - 2) continuous process: at not less than 140°C, under pressure for not less than 8 min, or equivalent;
- c) Distillation at 200 °C.

These same processing conditions are also specified in various other regulatory controls, such as Commission Directive 98/16/EC dated 5th March 1998 as annexed to Council Directive 76/768/EEC, Regulation (EC) No. 1069/2009, Directive 2000/6/EC and Directive 2003/63/EC as amended by guidance note EMEA/410/01 Rev. 3 and endorsed by the Scientific Steering Committee (SSC) of the European Commission.

According to another supplier, the animal extract is sourced from animals in the EU region primarily from bovine (beef) sources. The chemical products (fatty acids and glycerine) are derived from tallow meeting EU Category 3 and have been produced under conditions which are in compliance with the minimum conditions described below for the processing of rendered fats listed in Annex XIII, Chapter XI of the EU Regulation 142/2011/EC. The requirements of EMA/410/01 Rev. 3 (2011/C 73/01), Chapter 6.4 are fulfilled. EU Regulation 1774/2002 has been replaced by the EU Regulations 1069/2009/EC of October 21, 2009 and 142/2011/EC of February 25, 2011.

Process Conditions in Regulation 142/2011/EC Annex XIII, Chapter XI:

1. Transesterification or hydrolysis at at least 200°C, under corresponding appropriate pressure, for 20 minutes (glycerol, fatty acids and fatty acid esters) or



2. Saponification with NaOH 12 M (glycerol and soap)

I. in a batch process: at 95°C for 3 hours; or

II. in a continuous process: at 140°C, 2 bars for 8 minutes; or

3. Hydrogenation at 160 deg C at 12 bars for 20 minutes.

Tallow derivatives manufactured from tallow under conditions as rigorous as these are considered unlikely to be infectious irrespective of geographical origin and the nature of the tissues from which they are derived.

Bisphenol A (BPA)

As supplied by Trinseo, this product typically contains levels below 50 ppm of the following substance:

- Bisphenol A CAS# 80-05-7

Please note that the amount of residual BPA present in the customer's end-use product will be dependent on the customer's production process and formulation and must, therefore, be determined based on the end-use product.

Conflict Minerals

Trinseo does not use conflict minerals in manufacturing its products. Conflict minerals are not necessary to the "functionality or production" of our products. Based on the information we have to date, we are not aware of any conflict minerals sourced from the DRC or adjoining countries in our supply chain.

Genetically Modified Organisms

This product contains an additive that may be derived from genetically modified organisms (GMOs).

Global Chemical Inventory Compliance

This product is a mixture, all of the ingredients are on or not required to be listed on the following Global Inventories: Australia - AICS (Australia Inventory of Chemical Substances), Canada - DSL (Domestic Substances List), China - IECSC (Inventory of Existing Chemical Substances in China), Europe - EINECS (European Inventory of Existing Chemical Substances)/ELINCS (European List of Notified Chemical Substances), Japan - ENCS (Existing and New Chemical Substances), Korea - KECL (Korean Existing Chemicals List), New Zealand - NZLoC (New Zealand Inventory of Chemicals) and U.S. - TSCA (Toxic Substances Control Act).

Heavy Metals & CONEG

The heavy metals Cadmium, Lead, Mercury and Hexavalent Chromium are not used in the formulation of this material.

Kosher

This product is not made under Kosher/Halal conditions.

Medical Grade

This product is a medical grade product. Components have been tested under United States Pharmacopoeia (USP) and/or ISO 10993 standards. If biocompatibility data is required, please contact us at CIG@trinseo.com.

Trinseo 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 Trinseo product is safe, lawful, and technically suitable for the intended use.



Phthalate Esters

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

- Butyl benzyl phthalate (BBP), CAS# 000085-68-7
- Diethyl hexyl phthalate (DEHP), CAS# 117-81-7
- Diethyl phthalate (DEP), CAS# 000084-66-2
- Diisobutyl phthalate (DIBP), CAS# 000084-69-5
- Di-iso-decyl phthalate (DIDP), CAS# 26271-40-0
- Di-isononyl phthalate (DINP), CAS# 28553-12-0
- Dimethyl phthalate, CAS# 131-11-3
- Di-n-butyl phthalate (DBP), CAS# 000084-74-2
- Di-n-hexyl phthalate (DnHP), CAS# 000084-75-3
- Di-n-octyl phthalate (DNOP), CAS# 117-84-0
- Dimethyl Phthalate (DMP), CAS# 131-11-3
- Bis(2-methoxyethyl) Phthalate (DMEP), CAS#117-82-8

Polynuclear Aromatic Hydrocarbons (PAHs)

This product is not intentionally manufactured or formulated with the following Polynuclear Aromatic Hydrocarbons (PAHs); however, we do not analyze for these specific substances or compounds.

- Acenaphthylene, CAS# 208-96-8
- Acenaphthene, CAS# 83-32-9
- Anthracene, CAS# 120-12-7
- Benzo[a]anthracene, CAS# 56-55-3
- Benzo[b]fluoranthene, CAS# 205-99-2
- Benzo[k]fluoranthene, CAS# 207-08-9
- Benzo[g,h,i]perylene, CAS# 191-24-2
- Benzo(j)fluoranthene (BjFA), CAS# 205-82-3
- Benzo(k)fluoranthene (BkFA), CAS# 207-08-9
- Benzo[a]pyrene, CAS# 50-32-8
- Benzo(a)pyrene (BaP), CAS# 192-97-2
- Chrysene, CAS# 218-01-9
- Coronene, CAS# 191-07-1
- Corannulene, CAS# 5821-51-2
- Dibenz[a,h]anthracene, CAS# 53-70-3
- Fluorene, CAS# 86-73-7



- Fluoranthene, CAS# 206-44-0
- Indeno[1,2,3-cd]pyrene, CAS# 193-39-5
- Naphthacene, CAS# 92-24-0
- Naphthalene, CAS# 91-20-3
- Pentacene, CAS# 84434-51-5
- Phenanthrene, CAS# 85-01-8
- Pyrene, CAS# 129-00-0
- Ovalene, CAS# 190-26-1
- Triphenylene, CAS# 217-59-4

Persistent Organic Pollutants (POPs)

In response to your request for information regarding chemicals listed by the Stockholm Convention on Persistent Organic Pollutants (POPs Treaty), the above mentioned product is not manufactured or formulated with the below substances which are currently listed in Annex A, B and C on the following website: <http://chm.pops.int/Convention/ThePOPs/tabid/673/language/en-US/Default.aspx>.

Substances/Compounds

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

- Alkylphenols (Octylphenol, CAS# 67554-50-1; Nonylphenol, CAS#s 104-40-5, 25154-52-3, 84852-15-3, 90481-04-2)
- Alkylphenol ethoxylates (octylphenol ethoxylated, CAS# 52623-95-7; nonylphenol ethoxylated, CAS # 9016-45-9)
- Arsenic, CAS# 7440-38-2
- Asbestos, CAS#s 12001-28-4, 12001-29-5, 1332-21-4, 17068-78-9, 14567-73-8, 77536-68-6
- Azocolorants
- Beryllium and its compounds
- Bisphenol A diglycidyl ethers "BADGE", CAS# 1675-54-3; Bisphenol F diglycidyl ethers "BFDGE", CAS# 54208-63-8
- Bromine or brominated compounds
 - Polybrominated biphenyl (PBB), CAS# 36355-01-8
 - Polybrominated biphenyloxides (PBBOs)
 - Polybrominated diphenyloxides (PBDOs) or Polybrominated diphenylethers (PBDEs):
Decabromodiphenyl ether (DBDE), CAS# 1163-19-5; Pentabromobidphenyl ether (PeBDPO), CAS# 32534-81-9; Octabromodiphenyl ether, CAS# 32536-52-0
- Butylated hydroxyanisole (BHA), CAS# 25013-16-5
- Cadmium and its compounds
- Chlorofluorocarbons (CFCs) and Hydrogenated ChloroFluroCarbons (HCFCs)
- Chlorinated paraffins, CAS # 63449-39-8, 61788-76-9

- Dioxins
- Dimethylfumarate, CAS# 624-49-7
- Epichlorohydrin, CAS# 106-89-8
- Formaldehyde, CAS# 50-00-0
- Natural Rubber Latex, CAS# 9006-04-6
- Lead and its compounds
- Mercury and its compounds
- Nickel and its compounds
- Organic tins (tetrabutyl tin, CAS# 1461-25-2; tributyl tin, CAS#. 688-73-3; triphenyl tin, CAS# 892-20-6)
- Pentachlorophenol, CAS# 87-86-5
- Perfluorooctanoic acid (PFOA), CAS# 335-67-1
- Perfluorooctane sulfonate (PFOS), CAS # 1763-23-1
- Polychlorinated biphenyls (PCBs), CAS# 1336-36-6
- Polychlorinated terphenyls (PCTs), CAS# 61788-33-8
- Polychlorinated naphthalenes (PCNs), CAS#s 70776-03-3, 1321-64-8, 1321-65-9, 1335-87-1, 1335-88-2, 32241-08-0
- Polyvinyl Chloride (PVC), CAS# 9002-86-2
- Radioactive Substances
- Trichloroethylene, CAS# 79-01-6 and Tetrachloroethylene, CAS# 127-18-4

North America Regulations

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.

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.

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, with the exception of Bisphenol A (BPA) (CAS# 80-05-7) listed under Batch 2 Challenge Substances. Please be advised that we do not analyze for these specific substances.

Please refer to the following link: <http://www.chemicalsubstanceschimiques.gc.ca/challenge-defi/index-eng.php>.

Clean Air Act

This product is not intentionally manufactured or formulated with Class I or II substances as defined under 40 CFR part 82 of the Clean Air Act of 1993, as amended (58 FR 8136).

Consumer Product Safety Improvement Act of 2008 (CPSIA)

This product is not intentionally 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.

FDA Food Contact Status

This product has not been evaluated for compliance with the U.S. Federal Food, Drug and Cosmetics Act or the U.S. Food and Drug Administration regulations listed in Title 21 of the Code of Federal Regulations. If food contact compliance is required, please contact us at FTNSTPS@trinseo.com

Europe Regulations

EU Food Contact

The composition of this product has not been assessed for use in contact with food according to the Commission Regulation (EU) 10/2011.

REACH/SVHC

For information regarding REACH and SVHC (Substances of Very High Concern), please contact FTNSTPS@trinseo.com.

RoHS

This is to inform you that the above mentioned product(s), to the best of our knowledge, is/are not intentionally manufactured or formulated with the following substances listed in Article 4(1) of the EU Directive 2011/65/EC (RoHS (amended by COMMISSION DELEGATED DIRECTIVE (EU) 2015/863 of 31 March 2015)):

- Heavy metals (like cadmium, hexavalent chromium, lead and mercury)
- Polybrominated Biphenyls (PBB)
- Polybrominated Diphenyl Ethers (PBDE)
- Bis(2-ethylhexyl) phthalate (DEHP)
- Butyl benzyl phthalate (BBP)
- Dibutyl phthalate (DBP)
- Diisobutyl phthalate (DIBP)

Therefore, the product(s) listed above is/are in compliance with the requirements of Article 4.1 of the EU Directive 2011/65/EC.

However, please be advised that we do not routinely analyze our materials for these substances.

WEEE

EU Directive 2012/19/EC (WEEE): Selective treatment of the waste (Article 8 and Annex VII). None of the substances listed in Annex VII are intentionally added or used in the formulation of this product. Hydrocarbons (HC) are also listed in Annex VII, and are the basic constituents of this polymer.



PRODUCT STEWARDSHIP

Trinseo and its affiliated companies have a fundamental concern for all who make, distribute, and use their 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 so that appropriate steps may be taken to protect employee and public health and our environment. The success of our product stewardship program rests with each and every individual involved with Trinseo products – from the initial concept and research, to manufacture, use, sale, disposal, and recycle of each product.

CUSTOMER NOTICE

Customers are responsible for reviewing their manufacturing processes and their applications of Trinseo products from the standpoint of human health and environmental quality to ensure that Trinseo products are not used in ways for which they are not suitable. Trinseo personnel are available to answer questions and to provide reasonable technical support. Trinseo product literature, including safety data sheets, should be consulted prior to the use of Trinseo products. Current safety data sheets are available from Trinseo.

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Trinseo requests that customers refer to Trinseo's Medical Application Policy <http://www.trinseo.com/medical.htm> before considering the use of Trinseo products in medical applications. The restrictions and disclaimers set forth in that policy are incorporated by reference.

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