

CALIBRE™ MEGARAD™ 2091 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 one supplier, the animal extract is sourced from animals exclusively in the United States primarily from bovine (beef) sources although porcine (hog) fat may also be used. The raw 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 raw material is compliant with EMEA guideline NfG/EMEA/410/01Rev. 3 and European Commission Regulation EC No 1069/2009 of February 25, 2011 implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive.

The supplier states that the animal derived component is derived from tallow which meets EU Category 3 and is processed according to the below process conditions:

- Hydrolysis step at sustained temperatures of over 450 deg F (232.2 deg C), using 700 psi (48.3 bar) pressure and a residence time of 3 hours.
- Distillation of fatty acids at temperatures greater than 420 deg F (215.6 deg C).

These rigorous processes comply with the recognized conditions for inactivating the BSE agent as defined by the EU Scientific Steering Committee in various opinions since March 1998, and as defined by other regulatory bodies.

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 EU Regulation 1774/2002 has been replaced by the EU Regulations 1069/2009/EC of October 21, 2009 and 142/2011/EC of February 25, 2011.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.

As per the supplier, fat derivatives emerging from hydrolysis of rendered fats do not fall under the scope of the EU Regulation 1774/2002. Products from further processing (e.g. hydrogenation, fractionation and distillation) are considered to be chemical products, not fat derivatives.

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.

Samples, representative of the above named product have been analysed for the presence of above named elements. These substances could not be detected. The sensitivity of the methods used for the analysis is 5 ppm.

Kosher

This product is not made under Kosher/Halal conditions.

Medical Grade

This product is a medical grade product which has been tested under ISO 10993. If biocompatibility data is required, please contact us at FTNSTPS@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>.

- Aldrin
- Alpha hexachlorocyclohexane
- Beta hexachlorocyclohexane
- Chlordane
- Chlordecone
- DDT
- Dieldrin
- Endrin
- Heptabromodiphenyl ether
- Heptachlor
- Hexabromobiphenyl
- Hexabromodiphenyl ether
- Hexachlorobenzene (HCB)
- Lindane
- Mirex
- Pentabromodiphenyl ether
- Pentachlorobenzene
- Perfluorooctane sulfonic acid, its salts
- Perfluorooctane sulfonyl fluoride
- Polychlorinated biphenyls (PCB)
- Polychlorinated dibenzofurans (PCDF)
- Polychlorinated dibenzo-p-dioxins (PCDD)
- Technical endosulfan and its related isomers
- Tetrabromodiphenyl ether
- Toxaphene

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 a chemical known to the State of California to cause cancer. Please refer to the MSDS for additional information.

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:

- Oxirane, methyl- (Propylene oxide, CAS# 75-56-9) listed under Batch 1 Challenge Substances
- 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

When used unmodified for the manufacture of food contact articles, this resin will comply with the U.S. Food and Drug Administration Food Additive Regulation 21 CFR 177.1580.

This resin is restricted to use with repeated use food contact articles and the food contact articles can have a maximum thickness of 3 mm, and a maximum use temperature of 100 degrees C.

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 product, to the best of our knowledge, is not intentionally manufactured or formulated with the following substances listed in Article 4(1) of the EU Directive 2011/65/EC (RoHS):

- Heavy metals (cadmium, hexavalent chromium, lead and mercury)
- Polybrominated Biphenyls (PBB)
- Polybrominated Diphenyl Ethers (PBDE)

Therefore, the product listed above is in compliance with the requirements of Article 4.1 of the EU Directive 2011/65/EC (amended by Directive 2014/76/EC of 13.03.14).

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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GENERAL NOTICE

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