



CALIBRE* Megarad 2081 Transparent Polycarbonate Resin

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).

Medical Grade

This product is a medical grade product which has been tested for US Pharmacopoeia XXIII Class VI and/or ISO 10993. If biocompatibility data is required, please contact us at CIG@styron.com.

US 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 Administrations regulations listed in Title 21 of the Code of Federal Regulations.

2002/72/EC Food Contact

The composition of this product has not been assessed for use in contact with food according to the EU-Directive 2002/72/EC.

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.

Animal Derived Components

This product contains additives synthesized from animal extracts, i.e., hydrolysis, etc. of animal fats and oils into fatty acids. For one additive, the supplier states that the animal extract comes from bovine (beef) sources. Only Category 3 materials as defined by Article 6 of European Parliament and Council Regulation (EC) No 1774/2002 (EUROPA- FOOD SAFETY – BSE) are used as raw materials for the animal derived component. The chemical products (fatty acids/glycerine) used in the manufacture of this raw material have been produced under conditions which are in compliance with the minimum conditions described below for the processing of rendered fats listed in Annex VI, Chapter III of the EU Regulation 1774/2002 as well as the EMEA guideline NfG/EMEA/410/01 Rev 2:

Process Conditions

1. Transesterification or hydrolysis at at least 200°C and at an appropriate corresponding pressure, for not less than 20 minutes (glycerol, fatty acids and fatty acid esters) or
2. Saponification with NaOH 12 M (glycerol and soap)
 - Batchprocess: at 95°C for three hours or
 - Continuous process: at 140°C for eight minutes or equivalent conditions

For the second additive, the supplier states that the animal extract comes from animals in the United States primarily from bovine (beef) sources although porcine (hog) or ovine (sheep) fat may also be used. Only Category 3 materials as defined by Article 6 of European Parliament and Council Regulation (EC) No 1774/2002 (EUROPA- FOOD SAFETY – BSE) are used as raw materials for the animal derived component. The supplier states that the animal derived component is processed according to the following:

- Annex VI, Chapter III of European Parliament and Council Regulation (EC) No 1774/2002 re. health rules concerning animal by-products not intended for human consumption.
- Section 6.4 of the "Note for Guidance on minimizing the risk of transmitting animal spongiform encephalopathy agents via human veterinary medicinal products" (EMEA/410/01 Rev. 2 - October 2003), adopted by the Committee for Proprietary Medicinal Product (CPMP) and by the Committee for Veterinary Medicinal Products (CVMP).
- European Council Decision 1999/534/EC ("Measures applying to the processing of certain animal waste to protect against transmissible spongiform encephalopathies"). The processing satisfies or exceeds the Decision's requirements for "rendered fats derived from ruminant waste" (glycerol, fatty acids, and esters) of hydrolysis (splitting) at 200 deg C at corresponding pressure for 20 minutes.
- Process Conditions: Hydrolysis 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 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.

Food Allergens

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

Materials from Genetically Modified Organisms

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

Kosher

This product is not made under Kosher/Halal conditions.

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.

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 1993, as amended (58 FR 8136).

REACH

This product is a: Preparation per art. 3(2)

1. Pre-registration information:

This product is in compliance with REACH. We will continue to market it after December 1, 2008.

2. Registration information:

All REACH relevant substances in this product will be registered within the relevant deadline.

3. Earliest planned registration deadline based on Styron substances in the products: 2010

4. Substances of Very High Concern (SVHC):

REACH is laying down specific communication and notification requirements for products containing >0.1% (w/w) of substances on the Candidate List in articles 7.2, 31.1(c) and 31.3(b) and in article 33 of the REACH legislation. The Candidate List of

substances of very high concern (SVHC) established in accordance with article 59(1) of substances potentially subject to the authorization procedure has been published for the first time at the ECHA website on October 28, 2008.

To fulfill the REACH communication requirements, the Styron Safety Data Sheets for products containing >0.1% (w/w) of a substance on the Candidate List will be updated without delay. Styron will proactively provide such updated Safety Data Sheets to all recorded customers within the Community (EU & EEA) currently purchasing concerned products. Any updates in the candidate list will be handled in the same way. Styron urges downstream users to ensure compliance with the requirements for communication and notification given in above listed articles of the REACH legislation.

For the most recent copy of the Safety Data Sheet, please contact the Styron Customer Information Group.

Tel.: +32 3 450 22 40 Email: CIG@styron.com

EU Directive 2002/95/EC (RoHS) as amended by 2008/385/EC

In response to your inquiry regarding the status of the above mentioned product, with respect to EU Parliament and Council Directive 2002/95/EC of January 27, 2003, incl. the subsequent amendments:

- Commission Decision 2005/618/EC (18.8.2005)
 - Regarding: Addition of maximum concentration values for certain substances as follows :
 - max. 0.1 wt% in homogenous materials for lead, mercury, hexavalent chromium, polybrominated biphenyls and polybrominated diphenyl ethers
 - max. 0.01 wt% in homogenous materials for cadmium
- Commission Decision 2005/717/EC (13.10.2005), Item 2:
 - Regarding: Exemption of DecaBDE in polymeric applications
 - This exemption was annulled by the European Court of Justice as of July 1, 2008 (01.04.2008)
- Commission Decision 2005/747/EC (21.10.2005)
 - Regarding: Exemptions for applications of lead and cadmium
- Commission Decision 2006/310/EC (21.04.2006)
 - Regarding: Exemption for applications of lead
- Commission Decision 2006/690/EC (12.10.2006)
 - Regarding: Exemptions for applications of lead
- Commission Decision 2006/691/EC (12.10.2006)
 - Regarding: Exemptions for applications of lead and cadmium
- Commission Decision 2006/692/EC (12.10.2006)
 - Regarding: Exemptions for applications of hexavalent chromium
- Commission Decision 2008/385/EC (14.01.2008)
 - Regarding: Exemptions for applications of lead and cadmium
- Directive 2008/35/EC of the European Parliament and of the Council (11.03.2008)
 - Regarding: Administrative provisions
- Commission Decision 2009/443/EC (10.06.2009)
 - Regarding: Exemptions for applications of lead, cadmium and mercury

This is to inform you that the above mentioned product, to the best of our knowledge, is not intentionally manufactured or formulated with the following substances listed in Article 4.1 of EU-Directive 2002/95/EC (RoHS):

- 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 EU-Directive 2002/95/EC as well as fulfilling the requirements of Commission Decision 2005/618/EC as specified above.

However, please be advised that we do not analyze for these substances on a regular basis.

EU Directive 2002/96/EC on Waste Electrical and Electronic Equipment (WEEE)

EU Directive 2002/96/EC (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. Hydrocarbons (HC) are also listed in Annex II, and are the basic constituents of this polymer.

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.

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>.

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.

Bisphenol A (BPA)

As supplied by Styron, 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.

Substances/Compounds

The above mentioned 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

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

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
- Dibenzo[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

Product Stewardship

Styron and its subsidiaries 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 Styron products—from the initial concept and research, to manufacture, use, sale, disposal and recycle of each product.

Customer Notice

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

Medical Applications Policy

NOTICE REGARDING MEDICAL APPLICATION RESTRICTIONS: Styron 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.

Styron requests that customers considering use of Styron products in medical applications notify Styron so that appropriate assessments may be conducted. Styron 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 Styron product is safe, lawful, and technically suitable for the intended use. **STYRON MAKES NO WARRANTIES, EXPRESS OR IMPLIED, CONCERNING THE SUITABILITY OF ANY STYRON PRODUCT FOR USE IN MEDICAL APPLICATIONS.**

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