

# Product Stewardship Bulletin

## HE649T

A product of Viva Energy Polymers Pty Ltd.

### Food Contact Status : European Union

This product complies with the relevant requirements of Regulation 1935/2004/EC (Framework Regulation), applicable to intermediate materials (e.g. plastic powders, plastic granules or plastic flakes).

This product complies with the relevant requirements of Regulation 2023/2006/EC (GMP), applicable to intermediate materials (e.g. plastic powders, plastic granules or plastic flakes).

This product complies with the relevant requirements of Regulation 10/2011/EC (PIM) as amended, applicable to intermediate materials (e.g. plastic powders, plastic granules or plastic flakes).

The monomers and additives used to produce this product are listed in the Union List of Authorized Substances of Regulation 10/2011/EC and subsequent amendments.

EU Regulation 10/2011/EC specifies 10 mg/dm<sup>2</sup> as the maximum overall migration (OML) from the finished plastic food contact material or article. The OML and SMLs (when applicable) should be determined according to the requirements specified in EU Regulation 10/2011/EC and subsequent amendments. The OML and SML determinations are the responsibility of the manufacturer of the finished plastic food contact material or article. In addition, we remind you that the manufacturers of the finished food contact material or article must verify that the finished material or article, manufactured according to good manufacturing practices, does not modify the organoleptic properties of the food.

### SML Components

The following information concerns the chemical substance(s) used in the manufacture of and/or formulation of this product, which have specific migration limits (SMLs) listed in Commission Regulation (EU) 10/2011, and its amendments:

95360; 1,3,5-tris(3,5-di-tert-butyl-4-hydroxybenzyl)-1,3,5-triazine-2,4,6(1H,3H,5H)-trione; SML = 5 mg/kg  
38560; 2,5-bis(5-tert-butyl-2-benzoxazolyl)thiophene; SML = 0.6 mg/kg

This product contains traces of a substance which is regulated with a specific migration limit (SML) in EU (Commission Regulation 10/2011; Annex II) and its amendments:

Aluminium : SML = 1 mg/kg (expressed as Aluminium)

### Dual Use Additives

This product contains one or more Dual Use Additives as defined in Regulation 10/2011/EC.

- E 470a Calcium salts of fatty acids
- E 470a Sodium salts of fatty acids
- E 470b Magnesium salts of fatty acids

- E 471 Mono and diglycerides of fatty acids
- E 570 Stearic Acid

## Food Contact Status : United States

The base resin in this product meets the FDA requirements contained in the Code of Federal Regulations in 21 CFR 177.1520(a)(1)(i) and (c)1.1a.

This product may also contain adjuvant substances that may be safely used in polymers used for the manufacture of articles that come into direct contact with food. According to our information, the substances used in this product meet the requirements of their respective FDA regulations and 21 CFR 177.1520(b).

This product meets the FDA criteria in 21 CFR 177.1520 for food contact applications, including cooking, listed under conditions of use A through H in 21 CFR 176.170(c), Table 2, and can be used in contact with all food types as listed in 21 CFR 176.170(c), Table 1.

## Allergen Statements : General

This product contains no identified allergenic materials including:

Cereals containing gluten or products of these, wheat or wheat products  
Dairy or dairy products, egg or egg products  
Peanut or peanut products, soybean or soybean products  
Tree nut or tree nut products, seed or seed products Fish or fish products, shellfish or shellfish products  
Phenylalanine, tartrazine  
Sugar, monosaccharides or disaccharides, modified corn starch, yeast  
Preservatives, artificial colour, artificial flavour, sulphur dioxide or sulphites

No identified allergenic materials are present in the manufacturing facility and the product is manufactured in dedicated equipment.

## Allergen Statements : Food Allergen European Regulation 1169/2011

The food ingredients listed in Annex II of Regulation (EU) No 1169/2011, are not used in the manufacture of or formulation of this product. However, this product has not been tested for these substances.

## Biomedical Policy

This product(s) may not be used in:

(1) U.S. FDA Class III, Health Canada Class IV, and/or European Class III Medical Devices; or (2) applications involving permanent implantation into the body.

Prior written approval for each specific product and application must be given by Viva Energy Polymers before this product(s) is used in any:

(1) U.S. FDA Class I, Health Canada Class I, and/or European Union Class I Medical Devices; (2) U.S. FDA Class II, Health Canada Class II or Class III, and/or European Union Class II Medical Devices; (3) film, overwrap and/or product packaging that is considered a part or component of one of the aforementioned Medical Devices; or (4) packaging in direct contact with a pharmaceutical active ingredient and/or dosage

form that is intended for inhalation, injection, intravenous, nasal, ophthalmic (eye), digestive, or topical (skin) administration.

All references to U.S. FDA, Health Canada, and European Union regulations include other country's equivalent regulatory classifications.

Viva Energy Polymers may further prohibit or restrict the sale of its products into certain applications. For further information, please contact [polymers-enquiries@vivaenergy.com.au](mailto:polymers-enquiries@vivaenergy.com.au).

## **Animal Based Raw-Materials (BSE/TSE)**

Components derived from animal sources are not used in the manufacture or formulation of this product.

## **Tallow**

Tallow derived components are not used in the manufacture or formulation of this product.

## **Halal Certification**

We do not certify our resins to be HALAL or in compliance with HALAL requirements.

This product is not manufactured from, nor does it contain any animals, animal products or by-products.

## **Kosher Certification**

We do not certify our resins to be Kosher or in compliance with Kosher requirements.

This product is not manufactured from, nor does it contain any animals, animal products or by-products.

## **Epoxy Derivatives**

The materials BADGE, BFDGE or NOGE are not intentionally added in this product as referenced in Commission Regulation 1895/2005/EC, on the use of certain epoxy derivatives in materials and articles intended to come into contact with foodstuffs as plasticizers, additives or raw materials.

## **Halogenated Compounds**

Halogenated compounds are not used in the manufacture or the formulation of this product. However, this product has not been tested for these chemical materials.

## **Latex**

No materials containing latex or natural rubber are used in the manufacturing, handling and packaging processes for this product.

## **Medical : European Pharmacopeia (EP)**

This product does not meet the EP requirements for 3.1.3, Polyolefins - 7th Edition of European Pharmacopeia.

## **Medical : USP Class VI**

This product has not been tested for USP Class VI.

## US CONEG

Based on the available documentation provided by our raw material suppliers, this product complies with the CONEG Model Legislation for requirements regarding the defined limit for the sum of heavy metals (lead, mercury, cadmium and hexavalent chromium).

## End of Life Vehicle

To the best of our knowledge, based on the available documentation from raw materials suppliers, we deem that this product complies with the directive 2000/53/EC and its following amendments as concerns the defined limit(s) of heavy metals.

## Restriction of Hazardous Substances in Electric and Electronic Equipment (RoHS)

RoHS Regulation refers to electrical and electronic equipment and not specifically to plastic raw materials. However, based on the available documentation from raw materials suppliers, this product complies with the requirements of the Directives 2002/95/EC and 2011/65/EU, as amended, concerning the limits of cadmium, lead, mercury, hexavalent chromium, polybrominated biphenyls (PBB), polybrominated diphenyl ethers (PBDE), bis(2-ethylhexyl)phthalate (DEHP), butyl benzyl phthalate (BBP), Dibutyl phthalate (DBP) and diisobutyl phthalate (DIBP).

## Perfluorinated Chemicals (PFCs)

Perfluorinated Chemicals (PFCs), including Per- and Polyfluoroalkyl Substances (PFASs), including Perfluorooctane sulfonate (PFOS); CAS# 1763-23-1 and Perfluorooctanoic acid (PFOA); CAS# 335-67-1 are not intentionally used in the manufacture or the formulation of this product. However, this product has not been tested for these chemical materials.

## Conflict Minerals

Viva Energy Australia does not knowingly purchase raw materials containing the minerals cassiterite, columbite-tantalite, gold, tantalum, tin, tungsten, or wolframite that directly or indirectly finance or benefit armed groups in the Democratic Republic of the Congo ("DRC") and adjoining countries. Such minerals are defined as "Conflict Minerals". The DRC and adjoining countries are presently defined as Angola, Burundi, Central African Republic, DRC, the Republic of Congo, Rwanda, South Sudan, Tanzania, Uganda, and Zambia.

## Nanomaterials

Nanomaterials (defined as natural, incidental or manufactured materials containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm - 100 nm) are not used in the manufacture of or the formulation of this grade. However, this product has not been tested for these chemical substances.

## Other Chemicals

The chemical materials listed below are not intentionally used in the manufacture or the formulation of this product. However, this product has not been tested for these chemical materials.

- 2-(2H-1, 2, 3-Benzotriazol-2-yl)-4,6-di-tert-butylphenol; (Benzotriazole); CAS# 3846-71-7;
- 2,4,4-trichloro-2-hydroxydiphenyl ether; (Triclosan); CAS# 3380-34-5;

- 2,4,6-Tri-tert-butylphenol; (2,4,6-TTBP); CASRN: 732-26-3
- 2-mercaptobenzothiazole; MBT; CAS# 149-30-4;
- Acrolein; (propenal); (CAS# 107-02-8);
- Acrylamide; CAS# 79-06-1;
- Acrylonitrile; CAS 107-13-1
- Aromatic amines;
- Asbestos;
- Azo Dyes and Pigments;
- Decabromodiphenylether; (DecaBDE); CAS 1163-19-5
- Polyaromatic Hydrocarbons - PAHs:
  - 1,2-dihydro-acenaphthene; (CAS# 83-32-9);
  - 9H-Fluorene; (CAS# 86-73-7);
  - Acenaphthylene; (CAS# 208-96-8);
  - Anthracene; (CAS# 120-12-7);
  - Benz(a)anthracene; (CAS# 56-55-3);
  - Benzo(a)pyrene; (CAS# 50-32-8);
  - Benzo(b)fluoranthene; (CAS# 205-99-2);
  - Benzo(e)pyrene; (CAS# 192-97-2);
  - Benzo(ghi)perylene; (CAS# 191-24-2);
  - Benzo(j)fluoranthene; (CAS# 205-82-3);
  - Benzo(k)fluoranthene; (CAS# 207-08-9);
  - Dibenzo(a,h)anthracene; (CAS# 53-70-3)
  - Chrysene; (CAS# 218-01-9);
  - Dibenz(a,h)anthracene; (CAS# 53-70-3);
  - Fluoranthene; (CAS# 206-44-0);
  - Indeno(1,2,3-cd)pyrene; (CAS# 193-39-5);
  - Naphthalene; (CAS# 91-20-3);
  - Phenanthrene; (CAS# 85-01-8);
  - Pyrene; (CAS# 129-00-0);
- Benzophenone; CAS RN 119-61-9;
- BPA and other Bisphenols including B, C, E, F, G, M, P, S, T and Z;
- Bisphenol A; (BPA); CAS# 80-05-7;
- Bisphenol A diglycidyl ether; (BADGE); CAS# 1675-54-3;
- Bisphenol F diglycidyl ether; BFDGE; CAS# 2095-03-6;
- Butylated hydroxyanisole; (BHA); CAS# 121-00-6 & 25013-16-5;
- Butylated hydroxytoluene; (BHT); CAS# 128-37-0

- Chlorinated flame retardants;
- Chlorinated paraffins;
- Cyanuric acid; (Isocyanuric Acid or CYA); CAS# 108-80-5;
- Dimethyl fumarate; (DMF); CAS# 624-49-7;
- Dioxins;
- Epichlorohydrin; (ECH); CAS# 106-89-8;
- Fluorocarbons;
- Fluorotelomers
- Formaldehyde; CAS# 50-00-0;
- Gold(Au); CAS# 7440-57-5;
- Halogenated Flame Retardants
- Hexachlorobutadiene; CASRN: 87-68-3
- Melamine; (1,3,5-Triazine-2,4,6-triamine); CAS# 108-78-1;
- Nickel; CAS# 7440-02-0;
- Nonylphenol; CAS# 25154-52-3;
- Nonylphenol ethoxylates;
- Novolac glycidyl ether;
- Nitrites
- Organotin compounds;
- Oxo-degradation additives
- Oxo-degradable plastic
- Pesticides;
- Perchlorate; CAS 14797-73-0
- Pentachlorothiophenol (PCTP); CASRN: 133-49-3
- Phenol, isopropylated phosphate (3:1); (PIP (3:1)); CASRN: 68937-41-7
- Plasticizers:
  - DINCH; 1,2-Cyclohexanedicarboxylic acid, 1,2-diisononyl ester; CASRN: 166412-78-8;
  - DEHA; Bis(2-ethylhexyl) adipate; CASRN: 103-23-1;
  - BTHC; Butyryl tri-n-hexyl citrate; CASRN: 82469-79-2;
  - TOTM; Tris(2-ethylhexyl)benzene-1,2,4-tricarboxylate; CASRN: 3319-31-1;
  - DINP; Diisononyl Phthalate; CASRN: 28553-12-0;
  - DEHP; di(2-ethylhexyl) phthalate
  - DOP; di-octyl phthalate; CASRN: 117-81-7;
  - DIDP; di-iso-decyl phthalate; CASRN: 26761-40-0;
  - DBP; di-butyl phthalate; or DNBP; di-n-butyl phthalate; CASRN 84-74-2;
  - BBP; butyl benzyl phthalate; CASRN 85-68-7;

- DNOP; di-n-octyl phthalate; CASRN: 117-84-0;
- Glycerides, castor-oil mono-, hydrogenated, acetates; CASRN: 736150-63-3;
- Polybrominated biphenyls; (PBBs);
- Polybrominated diphenyl ethers; (PBDEs);
- Polybrominated terphenyls; (PBTs);
- Polychlorinated biphenyls; (PCBs);
- Polychlorinated naphthalenes; (PCNs);
- Polychlorinated terphenyls; (PCTs);
- Polystyrene;
- Polyvinyl chloride; (PVC); CAS# 9002-86-2;
- Polyvinylidene chloride; CARN 9002-85-1; PVdC;
- Radioactive substances;
- Styrene monomer; CAS# 100-42-5;
- tert-butylhydroquinone; CAS RN 1948-33-0; TBHQ
- Toluene; CAS 108-88-3
- Tris-nonylphenol phosphite; (TNPP); CAS# 26523-78-4;
- Vinyl chloride monomer; CAS RN 75-01-4; VCM
- Hydrofluorocarbon; HFCs

## California Proposition 65

This material does not contain listed substance(s) known to the State of California to cause cancer, birth defects, or other reproductive harm that would require warning under the California Proposition 65 State Drinking Water and Toxic Enforcement Act as outlined by the California Office of Environmental Health Hazard Assessment. However, this product has not been tested for the presence of listed chemical substances.

## Ozone Depleting Substances : United States

Materials listed in the Clean Air Act Amendments of 1990 (Class I, CFCs and Class II, HCFCs, Halons and the solvents, carbon tetrachloride and 1,1,1-trichloroethane) are not intentionally used in the production of this product.

## Ozone Depleting Chemicals (ODCs) : Montreal Protocol

ODCs listed in the Montreal Protocol are not used in the manufacture of or formulation of this product.

## Phthalates

Polyolefins do not require the use of plasticizers (such as phthalates) to make them soft and flexible. Viva Energy Polymers does not add phthalates to its polyolefin products as plasticizers. However, traces of phthalates may be present in some products as impurities from the catalytic system.

## REACH Information

Under the EC Regulation REACH this product is classified as a preparation. If this product is purchased from any supplier, which is not established in the European Union, the importer into the European Economic Area (EEA) is responsible for compliance with the requirements of REACH.

## REACH Substances of Very High Concern (SVHC)

This product does not contain any of the Annex XIV substances on the Authorisation list or Annex XIV candidate chemicals proposed to be Substances of Very High Concern for Authorisation (List as of June 14, 2023) above the 0.1 % threshold as stated in REACH (Article 57, Regulation No. 1907/2006) determined either through (i) non-use of the substance, (ii) mass balance calculation, or (iii) specific testing. The current list of all SVHCs can be found at ECHA website link listed below:

<https://www.echa.europa.eu/candidate-list-table>

## REACH Annex XVII of Regulation No. 1907/2006

This product does not contain chemicals in excess of the conditions of restriction as listed (as of December 17, 2022) in Annex XVII of the REACH Regulation 1907/2006 - Restrictions on the manufacturing, placing on the market and use of certain dangerous substances, mixtures and articles.

## Global Chemical Control Regulations

All ingredients in this product are in compliance with the following chemical inventories:

See Section 15, of the SDS (Safety Data Sheet) for Global Chemical Inventories.

## Global Toy Regulations

CEN EN Standards refer to safety of toys and not specifically to plastic raw materials. According to the information provided by our raw material suppliers, we deem this product should comply with the requirements of CEN standards EN71-3 / EN71-9 (as amended) as applicable to plastic raw materials (pellets, powder, flakes). However, this product has not been tested according to these CEN Standards.

We have reviewed Standard Consumer Safety Specification of Toy Safety: ASTM F-963-2017. It appears that Section 4.3.5 applies to paints or similar coatings, and accessible parts of toys, and section 8.3 describes corresponding testing protocol. Metal elements mentioned in Section 4.3.5 are not intentionally used in the production or formulation of this product.

Should you have any further questions please do not hesitate to contact us at [polymers-enquiries@vivaenergy.com.au](mailto:polymers-enquiries@vivaenergy.com.au).

Certified by,

*Robert Moran*

### **Robert Moran**

Technical and Sustainability Manager – Polymers and Chemicals  
Viva Energy Australia Pty Ltd



## **Disclaimer**

Information in this document is accurate to the best of our knowledge at the date of publication. The document is designed to provide users general information for safe handling, use, processing, storage, transportation, disposal and release and does not constitute any warranty or quality specification, either express or implied, including any warranty of merchantability or fitness for any particular purpose. Users shall determine whether the product is suitable for their use and can be used safely and legally.

In addition to any prohibitions of use specifically noted in this document, Viva Energy may further prohibit or restrict the sale of its products into certain applications. For further information, please contact a Viva Energy representative.