



## Regulatory Affairs Product Information Data Sheet (RAPIDS)

Polypropylene grade

# DOMOLEN<sup>®</sup> 3248TC

- **FOOD APPROVALS**

**European Union**

**Regulation 1935/2004/EC**

This grade meets the relevant requirements of Regulation 1935/2004/EC, so far applicable for plastic raw materials, used for articles or components of articles intended to come into contact with food. This grade is a plastic raw material for which specific measures are adopted as foreseen in article 5 of Regulation 1935/2004/EC. For plastic materials and articles, specific measures are adopted through directive 2002/72/EC and amendments (see below).

**Directive 2002/72/EC**

The monomers and additives used to manufacture this grade are listed in Directive 2002/72/EC and its amendments (2004/1/EC, 2004/19/EC, 2005/79/EC, 2007/19/EC, 2008/39/EC, and 2009/975/EC), relating to plastic materials and articles intended to come into contact with foodstuffs, as implemented into the single members States Regulations. Some additives used to manufacture this grade are subject to a restriction, i.e. a specific migration limit (SML). The identity of substances with a restriction can be disclosed for testing purposes, upon special request and under maintaining secrecy.

For full compliance an overall migration limit of 60mg/kg resp. 10mg/dm<sup>2</sup> and specific migration limits apply to the final article intended to come in contact with food, which shall be measured from the finished food contact article by using real food or appropriate food simulants at the time/temperature conditions as applicable, according to the rules as specified in Directives 82/711/EC (as amended) and 85/572/EC. It is the responsibility of the convertor to check and confirm that the final article meets both the technical and regulatory requirements of the application.

**United States of America**

The base resin in this grade meets the FDA (Food and Drug Administration) requirements contained in the Code of Federal Regulations in 21 CFR 177.1520 (a) (3) (i) and (c) (3.1a). According to information received from all of our suppliers, all other ingredients used in this grade meet the requirements of their respective FDA regulations and 21 CFR 177.1520 (b). This grade meets the FDA criteria in 21 CFR 177.1520 for food contact applications 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.

- **Chemical Inventories**

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

<u>United States</u>	: Toxic Substances Control Act Inventory (TSCA)
<u>Canada</u>	: Domestic Substances List (DSL) – Non Domestic Substances List (NSDL)
<u>Europe</u>	: European Inventory of Existing Commercial Chemical Substances (EINECS) European List of Notified Chemical Substances (ELINCS)
<u>Australia</u>	: Australian Inventory of Chemical Substances (AICS)
<u>Korea</u>	: Korean Existing Chemicals List (ECL)
<u>Japan</u>	: Japanese Existing and New Chemical Substances (ENCS)

This grade has no special requirements under US TSCA (e.g. consent orders, test rules, 12 (b) requirements, etc.).

- **European Pharmacopoeia (EP)**

This product has not been tested for E.P.

- **US Pharmacopoeia (USP)**

This product has not been tested for E.P.

- **Drug Master File (DMF)**

This product is not listed in a DMF

- **Bovine Spongiform Encephalopathy (BSE) / Transmissible Spongiform Encephalopathy (TSE) / Animal Derived Material**

From information received from our suppliers we know this grade contains additives, which may be derived from materials (tallow) of animal (mainly ovine and bovine) origin. Tallow derivatives, used for the production of plastic materials, undergo a series of (thermal and chemical) process steps in which they are subjected to severe conditions. These conditions are more stringent as those described as "rigorous processes" by CPMP (Committee on Proprietary Medicinal Products) in the "note for guidance on minimizing the risk of transmitting TSE via medicinal products" dated 21st of September 1999. The process conditions also far exceed the requirements in annex II of the European directive 99/534/EC and 2000/6/EC.

To the best of our knowledge, these treatments ensure complete inactivation of any agents present in the tallow derivatives to be used in plastics materials. We therefore can state that this grade is considered safe to use with respect to BSE and TSE transmissions.

- **Toys (EN 71-3)**

This grade meets the requirements of the European Standard EN 71 "Safety of Toys", Part 3 (1994): "Migration of certain elements". None of the substances mentioned in EN 71-3 are intentionally introduced as additives or used during the manufacturing of the above-mentioned grade.

- **Phthalates in toys and childcare articles (Directive 2005/84/EC)**

The phthalates listed in the Annex of Directive 2005/84/EC are not intentionally added in the manufacture of or the formulation of this grade in a concentration above the given limits.

- **Phthalates**

The above-mentioned grade contains traces of a phthalate, originating from the used catalyst system. These traces are in full compliance with EC Directives 2007/19/EC and 2005/84/EC.

- **REACH (Regulation 1907/2006/EC)**

The substances, which are contained in this grade, and require registration, have been pre-registered by Domo Polypropylene B.V., or by our upstream suppliers. This grade does not contain the substances listed on the current (March 2010) REACH Annex XIV, Substances of Very High Concern (SVHC) candidate list, in a concentration above 0.1% (w/w).

- **Packaging and packing waste (Directive 94/62/EC)**

The chemical composition of this product meets the relevant requirements of Directive 92/62/EC (as amended) on packaging and packaging waste. The sum of the concentration Cd, Cr (VI), Hg and Pb in this product does not exceed 100 ppm. This grade can be recycled according to Directive 94/62/EC requirements.

- **Heavy metals (Directive 2000/53/EC)**

The chemical composition of this product meets the relevant requirements of Directive 2000/53/EC (as amended) on the end-of-life of vehicles (ELV). The concentration of Cr (VI), Hg, and Pb in this product does not exceed 0.1 wt.%, and the concentration of Cd does not exceed 0.01 wt.%

- **Restrictions on the use of certain hazardous substances in electrical and electronic equipment (Directive 2002/95/EC) - ROHS**

The chemical composition of this product meets the relevant requirements of Directive 2002/95/EC on Restriction of the use of certain Hazardous Substances in electrical and electronic equipment - RoHS. The concentration of Cr (VI), Hg, Pb, PBB, and PBDE in this product does not exceed 0.1 wt.%, and the concentration of Cd does not exceed 0.01 wt.%.

- **Waste Electrical & Electronic Equipment (Directive 2002/96/EC) - WEEE**

No ingredients are intentionally used in the manufacturing of or the formulation of this grade, which are subject to the selective waste requirements of Annex II of Directive 2002/96/EC on the waste of electrical & electronic Equipment - WEEE.

- **Coalition of Northeastern Governors (CONEG)**

The chemical composition of this product meets the relevant CONEG requirements as described in the "Toxics in Packaging" Model legislation, rev. 2004 (USA) on packaging and packaging components. The sum of the concentration Cd, Cr (VI), Hg and Pb in this product does not exceed 100 ppm.

- **SWITZERLAND “VOC-LENKUNGSABGABE”**

This product contains less than 3% VOC's of the substances in the positive lists of the above Regulations.

- **Composting – CEN Standard prEN 13432**

This raw material is not suitable for composting.

- **Energy Recovery – CEN Standard prEN 13431**

The calorific gain from this raw material in an energy recovery process is 24MJ/Kg.

- **Absence of substances and chemicals**

None the following substances are intentionally used in the manufacturing of or the formulation this grade.

Acrylamide

Allergens (as defined in Directive 2003/89/EC - Annex IIIa)

Antimony, Arsenic, Beryllium, Bismuth

Aromatic Amines (restricted in Directive 2002/61/EC)

Asbestos

Azocolorants (restricted in Directive 2002/61/EC)

Biocides (Pesticides, Herbicides, Insecticides)

Bisphenol A and its compounds (e.g. NOGE, BFDGE, BADGE)

Brominated flame retardants (e.g. PBB, PBDE)

Cadmium, Chromium (VI), Lead, Mercury

Chlorinated hydrocarbons, Chlorinated Paraffins (C10-C13)

Cobalt (II) chloride hexahydrate

Dioxines and furanes

Dimethyl fumate (DMF)

2-EHA, Ethoxyquin, ITX, Thiuram

Formaldehyde

Genetically modified organisms (GMO)

Gold, Indium, Nickel, Palladium

Melamine

Nanoparticles (i.e. TiO<sub>2</sub> nanoparticles, Silver nanoparticles, Carbon-nanotubes)

Natural rubbers, Latex

Octyl- or Nonylphenols or -phenoethoxylates, Tris nonylphenol phoshite (TNPP)

Ozone depleting substances (CFC's, HCFC's, Halons, CCl<sub>4</sub>, Trichloroethane, HBFC's)

Tert-butyl-4-hydroxyanisole (BHA) and 2,6-di-tert-butyl-p-cresol (BHT)

Triclosan

Organotin compounds

Pentachlorophenol (PCP)

Perfluorinated tensides - PFT (e.g. PFOA, PFOS)

Plasticisers (e.g. Adipates, Epoxidised Soya Bean Oil (ESBO))

Polychlorinated Bi- or Terphenyls (PCB/PCT)

Polycyclic aromatic hydrocarbons (PAH)

Radioactive substances

Selenium, Silver, Tellurium, Thorium

Semicarbazide

Silicones

UV-hardeners (e.g. ITX, Titanyl-acetylacetone)

Vinylchloride, Vinylidenechloride, PVC or PVDC

The absence of these substances has not been checked by tests.

The information provided in this document applies to the product mentioned above as it leaves the production facility of Domo Polypropylene B.V., and does not cover any additive, pigment, or any other third party material, subsequently included by the convertor.

Ultimately customers must make their own determination that their use of our product is safe, lawful (except as provided in the above certifications) and technically suitable in their intended applications. Because of possible changes in the law and in regulations, we recommend that customers continuing to use our product verify status every year from this date.

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For further information please contact: [polypropylene@domo.org](mailto:polypropylene@domo.org)

Not certified if printed

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