Regulatory Compliance Product Declaration (RCPD)

Teldene® H12ML

Product Manufacturer

This product is manufactured by National Petrochemical Industrial Company (***NATPET)***.

REACH (Regulation (EC) No. 1907/2006)

This product is defined as a preparation under REACh. All components of this preparation as supplied in the European Union are compliant with the registration requirements of REACh, and we have the intentions to proceed with the registration of these substances, or to procure substances only from suppliers from which confirmation has been received that the suppliers are aware of their REACh requirements, that they have pre-registered and/or will timely register their substances, and that they will supply the relevant Safety Data Sheets (SDS) with REACh registration numbers as soon as the registrations occur. All members of the supply chain are affected by REACh, and we recommend that you seek additional advice, in the event that you need further clarification concerning your own obligations related to the REACh legislation.

Substances of Very High Concern (SVHC)

This product does not contain any of the Annex XIV candidate chemicals proposed to be Substances of Very High Concern **(List as of December 17, 2015)** 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 can be found at the following link to the ECHA website:

http://echa.europa.eu/web/guest/candidate-list-table

Food Contact

European Union (EU):

- *This product complies with relevant requirements of Regulation EU 10/2011 (PIM) and its subsequent amendments, applicable to intermediate materials (i.e. Plastic powders, plastic granules or plastic flakes).*
- *The monomer and additives of this product are listed in the union list of authorized substances of EU regulation 10/2011/EC and subsequent amendments.*
- *This product does not contain monomers or additives which have SMLs, as specified by Regulation 10/2011/EC.*
- *EU regulation 10/2011/EC specifies 10mg/dm^2 as the maximum overall migration (OML) from the finished plastic food contact material or article. The OML and SML determinations are the responsibility of the manufacturer of finished plastic food contact material or article. We would like to remind that the finished food contact material or article manufacturer must follow the GMP and make sure it does not modify the organoleptic properties of the food.*

- *This product contains one or more Dual Use Additives as defined in Regulation 10/2011/EC.*
- *The product is in compliance with the revised regulation 1282/2011.*
- *The product is in compliance with the relevant requirements of regulation 1935/2004/EC.*
- *This product complies with the relevant requirements of regulation 2023/2006/EC (GMP).*
- *The product is in compliance with the revised regulation of 10/2011 and issued as 1183/2012.*

United States:
The base resin of this product complies with FDA directive 21 CFR177.1520 (a)(1)(i) and (c)1.1a. Best of our knowledge, all other ingredients used in this product meet the requirements of their respective FDA regulations and 21CFR177.1520 (b). The grade is in compliance of the food contact requirement, including cooking, under conditions of A through H in 21CFR176.170(c), Table 2 and can be used in contact of all food types listed in 21 CFR 176.170(c), Table 1.

China:
GB9693-1988 "Hygienic standard for polypropylene resin used as food packaging material":
This product complies with the requirements of GB9693-1988 of less than or equal to 2 per cent of N-hexane extract.
GB9685-2008 "The Hygienic Standards for Uses of Additives in Food Containers and Packaging Materials":
All additives in this product comply with the requirements of GB9685-2008. However there is a substance used in this product for which a Specific Migration Limit (SML) has been established in GB9685-2008. We want to remind you that this specification applies to the final articles as defined in GB9685-2008 section 2.5.

Tallow
Tallow derived additives may be used in the manufacture of this product.

Bovine Spongiform Encephalopathy (BSE)/Transmissible Spongiform Encephalopathy (TSE)/"Mad Cow":
STATEMENT ON THE USE OF TALLOW DERIVATIVES FOR FOOD CONTACT PLASTICS (AS AGREED UPON BY APME (NOW PLEUR) MEMBER COMPANIES)
The concerns relative to BSE/TSE in the context of plastics materials used in contact with food are linked to the use of additives of animal origin: tallow derivatives. These products (fatty acids, fatty alcohols, metallic soaps, fatty amines, fatty amides, fatty acid esters, glycerin) are incorporated into plastics as lubricants, slip agents, anti-static agents as well as emulsifiers, anti-oxidants or corrosion inhibitors. They are primarily extracted from tissues of ovine or bovine origin. The tallow derivatives used for the production of our plastics materials undergo a series of severe process steps during manufacture:
Normally, pre-treatment of tallow and/or animal fat with strong acids Hydrolytic cleavage at temperatures above 200 °C, under pressure, for more than 20 minutes, yielding glycerin and fatty acids Trans-esterification of the fatty acids with methanol at temperatures above 200 °C, under pressure, for more than 20 minutes, yielding fatty acid methyl ester. Reduction of fatty acid methyl esters with hydrogen at temperatures above 200 °C, under high pressure, for more than 20 minutes, yielding fatty alcohols. According to the revised opinion of the EU Scientific Steering Committee on the Safety of Tallow (June 2001) and the recommendation for inactivation of TSE included (among others) in the Commission Directive 2000/6/EC following the latest amendment 1223/2009/EC, in the updated report of APAG of April 2001 and also in the Regulation 1069/2009/EC and 142/2011/EC, the above-mentioned treatments do ensure a complete inactivation of any TSE/BSE agent regardless of the source and type of material. The additional exposure of the plastic materials to temperatures ranging from 150 °C to 300 °C during 30 seconds up to several minutes, both at the

compounding step and in the final conversion process, represents an additional safety factor ensuring the complete protection of people's health in respect of TSE/BSE for plastic materials used in contact with food.

The tallow derived raw materials used in this product fulfill the requirements laid down in the Note for Guidance, EMA/410/01,rev.3, part 6.4 (Tallow Derivatives). Our suppliers declare that the tallow derivatives are Category 3 materials and are manufactured under the conditions given in the aforementioned Note for Guidance.

Kosher

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

Food Allergens

European Union:

The food ingredients listed in the Annex II of European Directive 1169/2011/EC, are not used in the manufacture of or formulation of this product. However, this product has not been tested for these substances.

United States:

Major food allergens (crustacean shellfish, eggs, fish, milk, peanuts, soy, tree nuts, and wheat) as specified in the Food allergen Labelling and Consumer Protection Act (FALCPA) of 2004 are not used in the manufacture of or formulation of this product. However, this product has not been tested for these substances.

Biocides

The active substances listed in the Annex I of the biocidal products regulation, EU 528/2012, are not used in the manufacture of or formulation of this product. However, this product has not been tested for these chemical substances.

European Pharmacopeia (EP)

This product cannot be certified for compliance to EP requirements.

Drug Master File (DMF)

Information on this product is not listed in a DMF.

US Pharmacopeia (USP)

This product cannot be certified for USP.

Latex

"Natural rubber latex", "dry natural rubber", "synthetic latex" or "rubbers that contains natural rubber" are not used in the manufacture of or the formulation of this product.

Heavy metals (ELV Directive 2000/53/EC and its following amendments, final amendment 2013/28/EU)

The quantity (statistically evaluated) of Cd, Pb, Cr(VI), Hg present in this grade is deemed below the limits given in Annex II (Note) of the Decision 2013/28/EU of May 17th 2013 Directive which establishes:

- 0.1% Lead
- 0.1% Chromium
- 0.1% Mercury
- 0.01% Cadmium

Coalition of Northeastern Governors (CONEG)
Cadmium, chromium (VI), lead and mercury are not used in the manufacture of or the formulation of this product. In addition, this product meets the CONEG requirements of less than 100 ppm for total incidental cadmium, chromium, lead and mercury.

European Union (EU) Directive - Packaging and Packaging Waste - 94/62/EC (as amended)
Cadmium, chromium (VI), lead and mercury are not used in the manufacture of or the formulation of this product. This product meets the 94/62/EC requirements of less than 100 ppm for total incidental cadmium, chromium (VI), lead and mercury. In addition, this product has the potential to be recycled according to these requirements.

California's Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65)
Chemicals mentioned in the list of proposition 65 are not directly used in the manufacture of or formulation of this product; however, there may be traceability of DBP and DEHP, because both are impurities in di-isobutyl phthalate (DIBP), which is a minor component of the catalyst system used to make the base resin in this product. Calculated estimates confirmed by testing of several resins indicate a potential total residual phthalate (all phthalates) content of less than 10-15 ppm (parts per million). Further testing with food simulants, per general conditions of use as established in European Union Regulation 10/2011/EC did not detect any phthalate migration at a detection sensitivity of 20 ppb (parts per billion) (0.02 parts per million or 0.02 mg/kg). A worst case estimate of the amount of DBP or DEHP that could potentially migrate from the resin is calculated to be less than 10 ppb (parts per billion) each. Under Proposition 65, DBP has a maximum allowable dose level (MADL) of 8.7 micrograms per day. The DEHP MADL for intravenous exposure is 4200 (adults), 600 (infant boys, age 29 days- 24 mos.) and 210 (neonatal infant boys, age 0-28 days) and for oral exposure is 410 (adults), 58 (infant boys, age 29 days- 24 mos.) and 20 (neonatal infant boys, age 0-28 days), all values in micrograms per day. DEHP has a no significant risk level (NSRL) of 310 micrograms per day. It is the responsibility of the California business owner to develop his or her own regulatory compliance plan.

Ozone Depleting Chemicals (ODCs)
European Union:
The ozone-depleting substances (ODS), listed in the Annexes I & II of the Regulation (EC) No 1005/2009 of 16 September 2009, are not intentionally used in the manufacture of or formulation of this product.

United States:
The ozone depleting substances (ODS), listed in the US Clean Air Act of 1990 Title VI, class I (CFC's) and class II (HCFC's Halons and the solvents, carbon tetrachloride and methyl chloroform) are not intentionally used in the manufacture of this product.

Toy Regulations
CEN standard for toys refer to safety of toys and not specifically to plastic resins. However on the basis of information from raw material suppliers for our resins we deem this product complies with the requirements of CEN Standard EN71.3/EN71.9 (as amended) but the product has not been tested according to the CEN standards.

Phthalates

NATPET does not use any plasticizers in the resins it supplies. Polyolefins do not require the use of plasticizers to make them soft and flexible. Those phthalate plasticizers that have been associated with potential health issues are not intentionally used by NATPET in the manufacture of or formulation of its resins. However, traces of phthalates may be present in some products as impurities in the catalyst system.

Cosmetic regulation 1223/2009/EC

The EU regulation 1223/2009/EC applies to cosmetic products and it does not apply to the polymer resins. However, we confirm that any of the substances listed in the Annex II of the regulation 1223/2009/EC is not used in the manufacture or formulation of this product. However, this product has not been tested for these chemical substances.

Other Chemicals

The chemical substances listed below are not used intentionally in the manufacture or the formulation of this product and are not expected to be present. However, this product has not been tested for these chemical substances:

2-(2H-1, 2, 3-Benzotriazol-2-yl)-4,6-di-tert-butylphenol (Benzotriazole); CAS number 3846-71-7);

2-Mercaptobenzothiazole (Benzothiazole-2-thiol or MBT), CAS number 149-30-4;

Acrylamide, CAS number 79-06-1;

Acrolein (propenal), CAS number 107-02-8;

Aromatic Amines;

Asbestos;

Azo Dyes and Pigments;

Benzene; CAS number 71-43-2;

Benzophenone, CAS number 119-61-9;

Bisphenol A, CAS number 80-05-7;

Butylated hydroxyanisole (BHA), CAS number 121-00-6 and 25013-16-5;

Butylated hydroxytoluene (BHT), CAS number 128-37-0;

Crystal Violet, CAS number 548-62-9;

Chlorinated paraffins;

Cyanuric acid, CAS number 108-80-5;

Dioxins;

Epichlorohydrin, CAS number 106-89-8;

Formaldehyde, CAS number 50-00-0;

>>Formaldehyde in specific conditions could be formed during the resin processing (see MSDS)

Fluorocarbons;

Fluorotelomers;

Gold (Au), CAS number 7440-57-5;

Halogenated flame retardants;

GMO;

Hindered phenols;

Isopropylthioxanthane (ITX), CAS number 83846-86-0;

Melamine, CAS number 108-78-1;

Nonylphenol, CAS number 25154-52-3;

Organo-tin Compounds;

Peroxide;

Perfluorochemicals (PFCs);

Perfluorooctanoic acid (PFOA), CAS number 335-67-1;

Perfluorooctane sulfonate (PFOS), CAS number 1763-23-1;

Polybrominated Biphenyls (PBBs);

Polybrominated Diphenyl Ethers (PBDEs);

Polybrominated Terphenyls (PBTs)

Polychlorinated Biphenyls (PCBs);

Polychlorinated Naphthalenes (PCNs);

Polychlorinated Terphenyls (PCTs);

Polycyclic Aromatic Hydrocarbons (PAHs):
1,2-dihydro-acenaphthene (CAS# 83-32-9);
acenaphthylene (CAS# 208-96-8);
9H-fluorene (CAS# 86-73-7);
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);
chrysene (CAS# 218-01-9);
dibenz(a,h)anthracene (CAS# 53-70-3);
fluoranthene (CAS# 206-44-0);
fluorene (CAS# 86-73-7);
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);

Polystyrene;

Polyvinyl Chloride (PVC), CAS number 9002-86-2;

Polyvinylidene chloride (PVDC), CAS number 9002-85-1;

Silicone

Styrene monomer, CAS number 100-42-5;

Sulfur di-oxide, CAS number 7446-09-5;

Sulfide or sulfide derivatives

Tris-nonylphenol phosphite (TNPP), CAS No. 26523-78-4;

Tin oxide (SnO_2), CAS number 8062-08-6;

Vinyl Chloride, CAS number 75-01-4;

Nanomaterials

NANOMATERIALS (insoluble or bio-persistent and intentionally manufactured materials with one or more external dimensions, or an internal structure, on the scale from 1 to 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

Regulation (EC) N.1895/2005

BADGE, NOGE and BFDGE are not used in the manufacture of or the formulation of this product according to requirement of Regulation N.1895/2005.

Dimethyl Fumarate (DMF) - EU Commission Decision 2009/251/EC

Dimethyl fumarate [2-butenedioic acid (2E)-, dimethyl ester] (DMF) (CAS#: 624-49-7) is not used in the manufacture of or formulation of this product. However, we do not test this product for DMF.

Triclosan(2,4,4'-trichloro-2'-hydroxydiphenyl ether)-Commission Decision of 19 March 2010-(2010/169/EU)

Triclosan (2,4,4'-trichloro-2'-hydroxydiphenyl ether) CAS. N.3380-34-5 is not used in the manufacture of or formulation of this product. However, this product has not been tested for this substance.

Conflict Minerals (Dodd-Fran Wall Street Reform and Consumer Protection Act – September,2010)

Conflict minerals, which include columbite-tantalite (also known as coltan) [source for tantalum], cassiterite [source for tin], gold, wolframite [source for tungsten] or their derivatives are not intentionally used in the manufacture of or formulation of this product. However, we do not test this product for these substances.

Rhode Island Air Toxics

To the best of our knowledge the chemicals in the list of Rhode Island Air Toxics mentioned as HAP are not used in the manufacturing or formulation of this product. However, this product has not been tested for these chemical substances.

Switzerland "VOC-LENKUNGSABGABE"

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

Restriction of Hazardous Substances in Electric and Electronic Equipment (RoHS) – Directive 2011/65/EU, as amended.

At the light of our acknowledge,

- PBDE
- PBB
- Chromium (VI)
- Lead
- Mercury
- Cadmium are not used nor intentionally added in the production of the resin.

The incidental sum of their concentrations does not exceed the limits established by Decision 2011/65/EU.

Composting - CEN Standard EN 13432

This product is not suitable for composting.

Energy Recovery - CEN Standard EN 13431

The calorific gain from polypropylene in an energy recovery process is 24 MJ/kg.

Disclaimer

The information in this document is, to the best of our knowledge, true and accurate at the time and date of issue. However, information in this document may be updated periodically due to changes in the laws and regulations, or for other reasons, therefore we cannot guarantee that the status of this product will remain unchanged. Hence, users are expected to regularly visit our website www.natpet.com to obtain the most current information on this product

Before using this product users should make their own independent determination that the product is suitable for the intended use and can be used safely and legally.

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