



NATPET

Regulatory Compliance Product Declaration (RCPD)

Teldene® H12ML-MG

A product of National Petrochemical Industrial Company **NATPET**

Dear Customer,

The following is in response to your request for regulatory compliance for the product listed above. The attached Regulatory Compliance Product Declaration (RCPD) details the regulatory status of this product.

National Petrochemical Industrial Company **NATPET** response to regulatory requests with a standardized regulatory compliance product declaration document (RCPD) which summarizes the global regulatory status of a product including global food contact status, REACH registration, Substances of Very High Concern (SVHC), SML & OML Components, Dual-Use Additives and Biocompatibility test results if applied.

Please note that compliance with these regulations should not be interpreted to guarantee that the product, will, in fact, perform in a particular application. Your technical service representative can help you determine that the characteristics of the product are compatible with the desired conditions of use.

If we can be of any further assistance, please do not hesitate in contacting us.


Best Regards,


Neaz Ahmed

Manager Product Application

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REACH (Regulation (EC) No. 1907/2006) of December 18, 2006 and Amendments

This product is REACH compliant and the monomer (propylene) used for this product is registered (**01-2119447103-50-0144**) under REACH regulation. For EU customers we appointed **Steptoe & Johnson LLP** as EU only representative (OR) to fulfil REACH obligation. 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, you may contact our OR through the email: eSDS3@steptoe.com

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 (**Latest list as of Jan 16, 2020**) 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>

Global Food Contact Status:

European Union (EU)

- The product is in compliance with the revised regulation of 10/2011 and issued as 2019/1338.
- This product complies with the relevant requirements of Regulation 1935/2004/EC (Framework Regulation) as 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) and as amended, applicable to intermediate materials (e.g. plastic powders, plastic granules or plastic flakes).
- 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.

Specific Migration Limit (SML) & Overall Migration Limit (OML)

EU regulation 10/2011/EC specifies 10mg/dm² 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 & make sure it does not modify the organoleptic properties of the food.

SML Components

This product contains one or more components with Specific Migration Limits (SMLS):

Ref.	SML Substance	CAS No.	Limit	Unit
39815	9,9-bis (methoxymethyl)-9H-fluorene	182121-12-6	0.05	mg/kg
39090	N, N-bis(2-hydroxyethyl) alkyl (C8-C18) amine	-	1.2	mg/kg
39120	N, N-bis(2-hydroxyethyl) alkyl (C8-C18) amine hydrochlorides*	-	1.2	mg/kg

* Expressed as tertiary ammine excluding HCL

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 471: Mono- and di-glycerides of fatty acids

United States (FDA)

The base resin of this product complies with FDA directive 21 CFR 177-1520 (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 21 CFR 177.1520 (b). The grade is in compliance of the food contact requirement, including cooking, under conditions of A through H in 21 CFR 176.170(c), Table 2 and can be used in contact of all food types listed in 21 CFR 176.170(c), Table 1.

China Food Contact

- 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.
- GB4806.1-2016 “Food Contact Material & Articles General Safety Requirement”
This product complies with relevant requirements of GB4806.1-2016 - Food Contact Material & Articles General Safety Requirement, as applicable to Plastic Resins.
- GB4806.6-2016 “National Food Safety Standard: Food Contact Resins”
The base resin in this product complies with the specifications established in GB4806.6-2016, “National Food Safety Standard: Food Contact Resins, Appendix A.1, Serial Number 74, resin type: PP.” No monomer(s) with SMLs are present in this base resin.
- GB9685-2016 “National Food Safety Standard: Additives for use in Food Contact Materials and Articles”
The additives used in this product comply with the requirement of “GB9685-2016 National Food Safety Standard: Additives for use in Food Contact Materials and Articles” and relevant approval announcements.

Please note that some additives could have migration (SML, SML (T)) and/or Maximum Residual (QM) restrictions applicable to final food contact articles, the identities of which may or may not be disclosed in this document.

MOSH, MOAH & POSH

- POSH : Polyolefin Oligomeric Saturated Hydrocarbons
- MOSH: Mineral Oil Saturated Hydrocarbons
- MOAH: Mineral Oils Aromatic Hydrocarbons

Mineral oil saturated hydrocarbons (MOSH) are paraffins and naphthenes. Mineral oil aromatic hydrocarbons (MOAH) are highly alkylated mono- and/or polyaromatic hydrocarbons from mineral oil.

Teldene products do not fall under MOSH, MOAH nor POSH hydrocarbons. Moreover, all NATPET products are in compliance with the revised European Union regulation of food contact and FDA.

Biocompatibility Test Results:

European Pharmacopeia (EP)

Biological reactivity evaluations have been performed on representative samples of this product, more specifically ISO 10993-part 4 (Tests for interactions with blood); ISO 10993-part 5 (Tests for In Vitro Cytotoxicity); ISO 10993-part 10 (Skin Sensitization Tests) and USP Class VI <88> (Intracutaneous reactivity Test); ISO 10993-part 11 and USP Class VI <88> (Systemic Injection Test). These ISO 10993 and USP tests may fit the bio-compatibility requirements of certain sections of European Pharmacopeia. The grade is also tested as per EU 3.1.3 & 3.1.6, and the result reflects that the grade is in compliance to the regulation. Despite this, the manufacturer of a medical device, made with this product, must still evaluate the medical device to show that it fully meets the requirements of the applicable sections of EP.

Results provided by Seller are intended to be representative in nature only and are not to be construed as a guarantee of future product performance. Seller makes no warranty, express or implied by virtue of disclosing pass/fail status.

Drug Master File (DMF)

Information on this product is not listed in a DMF.

US Pharmacopeia (USP)

Biological reactivity evaluations have been performed on representative samples of this product, more specifically ISO 10993-part 4 (Tests for interactions with blood); ISO 10993-part 5 (Tests for In Vitro Cytotoxicity); ISO 10993-part 10 (Skin Sensitization Tests) & USP Class VI <88> (Intracutaneous reactivity Test); ISO 10993-part 11, USP Class VI <88> (Systemic Injection Test) and USP 661.1 (Plastic Materials of Construction) . Despite this, the manufacturer of a medical device, made with this product, must still evaluate the medical device to show that it fully meets the requirements of the applicable sections of USP.

Bovine Spongiform Encephalopathy (BSE)/Transmissible Spongiform Encephalopathy (TSE)/"Mad Cow":

- Tallow derived materials used in this product compliance to the requirements of the regulations 1223/2009/EC, 1069/2009/EC and 142/2011/EC.
- 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).

Tallow

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

Halal

We do not issue halal certificate for our resins.

Kosher

We do not issue kosher certificate for our resins.

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.

ICH Harmonized Guideline for Elemental impurities

The elemental impurities of class 1, 2, 3 listed in latest version of guideline Q3D are not intentionally used in the manufacturing or formulation of this product. However, this product has not been tested for these substances.

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

VDA 270

Representative samples of this product have been tested as per the standard, VDA 270 "Determination of the odor characteristics of trim materials in motor vehicles". Accordingly, the odor characteristic of this product is classified as Grade 2 (not perceptible) on the evaluation scale.

UL Flammability

Representative samples of this product have been tested as per standard UL 94-HB and verified as compliance to the standard.

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 & Toxic Enforcement Act of 1986, Proposition 65, May, 2018

Chemicals mentioned in the list of proposition 65 are not directly used in the manufacture of or formulation of this product and are not expected to be present. However, this product has not been tested for those chemical substances.

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.

Global Automotive Declarable Substance List (GADSL)

The monomer, the base resin and the additives used in the formulation of this product are not listed in the aforementioned Global Automotive Declarable Substance List. The phthalate plasticizers that have been listed in the GADSL are not intentionally used by NATPET in the manufacture or formulation of this product.

Phthalates

NATPET does not use any plasticizers in the resins it supplies. Polyolefin 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.

Persistent Organic Pollutants (POP) – Regulation 1342/2014/EU amending regulation 850/2004/EC

The chemical substances listed in the Annex I of the regulation 1342/2014/EU that require selective waste management are not used in the manufacture or formulation of this product and are expected not to be present. However, this product has not been tested for these chemical substances.

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.

Plasticizers and Epoxy Derivatives Under 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.

Nanomaterials

NANOMATERIALS (defined as a natural, incidental or manufactured material, 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 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:

Substance	CAS No.	Substance	CAS No.
Acenaphthylene	208-96-8	Perfluorochemicals (PFCs)	-----
Acrylamide	79-06-1		
Acrolein (propenal)	107-02-8	Perfluorooctanoic acid (PFOA)	335-67-1
Anthracene	120-12-7	Perfluorooctane sulfonate (PFOS)	1763-23-1
Aromatic Amines	-----	Peroxide	-----
Asbestos	-----	Phenanthrene	85-01-8
Azo Dyes and Pigments	-----	Polybrominated Biphenyls (PBBs)	-----

Benzene	71-43-2	Polybrominated Diphenyl Ethers	-----
Benz(a)anthracene	56-55-3	(PBDEs)	
Benzo(a)pyrene	50-32-8	Polybrominated Terphenyls (PBTs)	-----
Benzo(b)fluoranthene	205-99-2	Polychlorinated Biphenyls (PCBs)	-----
Benzo(e)pyrene	192-97-2	Polychlorinated Naphthalenes (PCNs)	-----
Benzo(ghi)perylene	191-24-2	Polychlorinated Terphenyls (PCTs)	-----
Benzo(j)fluoranthene	205-82-3	Polycyclic Aromatic Hydrocarbons (PAHs)	-----
Benzo(k)fluoranthene	207-08-9	Polystyrene	-----
Benzophenone	119-61-9		
Bisphenol A and other derivatives of Bisphenol	80-05-7	Polyvinyl Chloride (PVC)	9002-86-2
Bisphenol A diglycidyl ether (BADGE)	1675-54-3	Polyvinylidene chloride (PVDC)	9002-85-1
Bisphenol F diglycidyl ether (BFDGE)	2095-03-6	Pyrene	129-00-0
Butylated hydroxyanisole (BHA)	121-00-6	Silicone	-----
Butylated hydroxytoluene (BHT)	128-37-0	Styrene monomer	100-42-5
Chlorinated paraffins	-----	Sulfur di-oxide	7446-09-5
Chrysene	218-01-9	Sulfide or sulfide derivatives	-----
Crystal Violet	548-62-9	Tin oxide (SnO ₂)	8062-08-6
Cyanuric acid	108-80-5	Titanium Acetylacetonate	17501-79-0
Dibenz(a,h)anthracene	53-70-3	Tris-nonylphenol phosphite (TNPP)	26523-78-4
Diisohexyl phthalate	71850-09-4	Tris (4-nonylphenyl, branched and linear) phosphite (TNPP) with ≥ 0.1% W/W of 4 nonylphenol, branched and linear (4-NP)	-----
Dimethyl fumarate (DMF)	624-49-7		
Dioxins	-----		
Epichlorohydrin	106-89-8		
Fluoranthene	206-44-0	Vinyl Chloride Monomer	75-01-4
Fluorene	86-73-7	Wolframite; Tungsten (W)	1332-08-7
Fluorocarbons	-----	1,2-dihydro-acenaphthene	83-32-9
Fluorotelomers	-----	2-(2H-1, 2, 3-Benzotriazol-2-yl)-	3846-71-7
Formaldehyde	50-00-0	4,6-di-tert-butylphenol (Benzotriazole)	
Formaldehyde in specific conditions could be formed during the resin processing (see MSDS)			
GMO	-----	2-Benzyl-2-dimethylamino-4'-morpholinobutyrophenone	119313-12-1
Gold (Au)	7440-57-5	2-Mercaptobenzothiazole (Benzothiazole-2-thiol or MBT)	149-30-4
Halogenated flame retardants	-----	2-Methoxyethyl acetate	110-49-6
Hindered phenols	-----	2-methyl-1-(4-methylthiophenyl)-2-morpholinopropan-1-one	71868-10-5
Indeno (1,2,3-cd) pyrene	193-39-5	83846-86-0	
Isopropylthioxanthane (ITX)	86-0	2,3,3,3-tetrafluoro-2-(heptafluoropropoxy) propanoic acid, its salts and its acyl halides (covering any of their individual isomers and combinations thereof)	
Melamine (1,3,5-Triazine-2,4,6-triamine)	108-78-1		
Naphthalene	91-20-3		
Nonylphenol	25154-52-3		
Nonylphenol ethoxylates	-----		
Novolac glycidyl ether	-----		
Organo-tin Compounds	-----	2,4 pentadione (Acetylacetone)	123-54-6
Perfluorobutane sulfonic acid (PFBS) and its salts	-----	2,4,4'-trichloro-2'-hydroxydiphenyl ether (Triclosan)	3380-34-5
		4-tert-butylphenol (PTBP)	98-54-4
		9H-fluorene	86-73-7

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)

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.

Switzerland "VOC-LENKUNGSABGABE"

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

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.

Restriction of Hazardous Substances in Electric and Electronic Equipment (RoHS) – Directive 2011/65/EU, and Commission Delegated Directive (EU) 2015/863.

At the light of our acknowledge,

- PBDE
- Lead
- PBB
- Mercury
- Chromium (VI)
- 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.

Waste Electrical and Electronic Equipment (WEEE) – Directive 2012/19/EU – Annex VII

The chemical substances (PCB, PCT, Hg, asbestos, CFC, HCFC, HFC, ceramic fibers, brominated flame retardants) requiring selective waste treatment are not used in the manufacture or formulation of this product. However, this product has not tested for these chemical substances.

Global Chemical Control Regulations

The substances used in the manufacture and formulation of this product including the base resin are listed in the following chemical inventories:

Country/Region	Inventory
Australia	AICS
Canada	DSL
China	IECSC
Japan	ENCS
Korea	KECI
New Zealand	NZIoC
Philippines	PICCS
United States of America	TSCA
Taiwan	TCSCA

*Please consult with your NATPET representative to understand volume approvals.

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

Users are advised to review the applicable Safety Data Sheet before handling the product. Before using this product user should make their own independent determination that the product is suitable for the intended use and can be used safely and legally.

NATPET MAKES NO WARRANTY, EXPRESS OR IMPLIED, INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OTHER THAN AS SEPARATELY AGREED TO BY THE PARTIES IN A CONTRACT.

Teldene is the registered trademark owned and used by NATPET.