



NATPET

Regulatory Compliance Product Declaration (RCPD)

Teldene® H03ML

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

P.O. Box 31469

Yanbu 41912, Saudi Arabia

: +966 14 324 6066

: +966 14 324 6036

: nahmed@natpet.com

: mmahbob@natpet.com

: www.natpet.com

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Version: 10.0

Reason: Revised to accommodate regulatory updates

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 **RCL Ireland** 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: glloyd@regsl.co.uk

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 January 23, 2024) 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>

Global Food Contact Status:

European Union (EU)

- 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 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.

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 and make sure it does not modify the organoleptic properties of the food.

SML Components

This product may contain the below component within Specific Migration Limit (SMLs), but not added intentionally in the manufacture of or the formulation of this product:

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

- This product contains traces of a substance which is regulated with a specific migration limit in EU (Commission Regulation 10/2011; Annex II). Migration tests showed a migration level significantly below the SML, thus exceeding this SML under foreseeable conditions of use involving food contact is not expected. SML = 1 mg/kg (expressed as Aluminium). This product may contain minor trace levels of other metals, which are regulated with

a specific migration limit in EU (Commission Regulation 10/2011 as amended; Annex II). These metals are not intentionally added but may be present as impurity of the raw materials used. Migration tests on representative polyolefin samples showed a migration level below the SMLs, thus exceeding these SMLs under foreseeable conditions of use involving food contact is not reasonably expected.

- **Annex IV, Part 6 - Genotoxicity**

In accordance with the requirements of Regulation 10/2011/EC (PIM), Annex IV, part 6, this product does not contain genotoxic substances which would migrate from a final material at a level exceeding 0.15 ppb in food or food simulant.

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

United States (FDA)

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 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, these substances used in this product meet the requirements of their respective FDA regulations, FCNs, and 21 CFR 177.1520(b). However, due to limitations of one ingredient, this product can only be used in certain applications as follows:

- For FILMS ONLY, 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, as described in 21 CFR 176.170(c), Table 2, and can be used in contact with all food types as described in 21 CFR 176.170(c), Table 1.
- For MOULDED OR EXTRUDED PARTS ONLY, this product meets the FDA criteria in 21 CFR 177.1520, for articles that contact food, EXCEPT for articles used for packing or holding food during cooking. This product can be used under conditions of use C through G, as described in 21 CFR 176.170(c), Table 2, and in contact with food types II, III, IV, V, VII-A and IX, as described in, 21 CFR 176.170(c), Table 1.

China Food Contact

- 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.
- General Remarks:
GB4806.1-2016 "Food Contact Materials & Articles -General Safety Requirement" Clause 8.4, requires only the manufacturer of the finished plastic food contact article to declare compliance with OML specification. Final plastic food contact articles may have additional compliance requirements and are the responsibility of the manufacturer of the finished plastic food article.

Japan

Food Contact Positive Lists by Japan's Ministry of Health, Labour and Welfare (MHLW) issued on April 28th, 2020 and effective on June 1st, 2020. The base resin of this product is listed in the Positive List of Base Polymers. The additives used in this product are listed in the Positive List of Additives authorized for use in the Base Resin of this product.

South America:**MERCOSUR**

- This product contains only monomers and/or polymers listed in Part 1 of the Annex, of MERCOSUR GMC RES. No. 2/12, Positive list of monomers and polymers to be used in packaging in contact with food.
- This product contains only additives included in Table 1, of the MERCOSUR GMC RES. No. 39/19, Positive list of additives to be used in packaging in contact with food.
- This product contains one or more components with LMEs (Specific Migration Limits).
- This product complies with the relevant requirements of MERCOSUR GMC Resolution RES Nº 03/92, General Criteria of Packaging and Food Equipment in Contact with Foods.
- The manufacturers of the final article must verify that the final article does not exceed overall migration limits that apply to the finished food packaging material.

ANVISA

- The base polymer of this product is listed in Annex II – Positive List of Polymers and Resins for Plastic Packaging and Equipment in Contact with Foodstuff of Resolution No. 56, 16 November 2012, as amended.
- This product contains only additives listed in Resolution RDC No.: 326, December 3, 2019. However, this product contains one or more components with LMEs.

Biocompatibility Test Results:**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 compliance to USP requirements.

Animal Based Raw-Materials (BSE/TSE)**Bovine Spongiform Encephalopathy (BSE)/Transmissible Spongiform Encephalopathy (TSE)/"Mad Cow":**

Tallow derived materials are not used intentionally in the formulation of this product. Hence, this regulation does not apply.

Tallow

Tallow is not used intentionally in the formulation of our product, but this product has not been tested for the presence of Tallow.

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 the presence of 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 the presence of 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 the presence of these chemical substances.

Genetically Modified Organisms (GMO)

Additives derived from Genetically Modified Organisms (GMO's) are not intentionally used in the manufacture of or formulation of this product.

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), and 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, 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, December 29, 2023

The substances listed in California Proposition 65 list (December 29, 2023) are not used intentionally in the manufacture of or formulation of this product. However, this product has not been tested for the presence of these 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 or formulation 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

Phthalates are not used in the manufacture of or the formulation of this product. However, this product has not been tested for phthalates.

Persistent Organic Pollutants (POP)

- The chemical materials listed in the below mentioned regulation are not used 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 materials.
- Compounds covered under Commission Regulation (EU) EC No.: 2019/1021, and as amended on Persistent Organic Pollutants (POPs).

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, this product has not been tested for the presence of 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 product. However, this product has not been tested for the presence of these chemical substances.

Other Chemicals

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

Substance	CAS No.	Substance	CAS No.
Acenaphthylene	208-96-8	Perfluorochemicals (PFCs)	-----
Acrylamide	79-06-1	Perfluorooctanoic acid (PFOA)	335-67-1
Acrolein (propenal)	107-02-8	Perfluorooctane sulfonate (PFOS)	1763-23-1
Anthracene	120-12-7	Peroxide	-----
Aromatic Amines	-----	Phenanthrene	85-01-8
Asbestos	-----	Polybrominated Biphenyls (PBBs)	-----
Azo Dyes and Pigments	-----	Polybrominated Diphenyl Ethers (PBDEs)	-----
Benzene	71-43-2	Polybrominated Terphenyls (PBTs)	-----
Benz(a)anthracene	56-55-3	Polychlorinated Biphenyls (PCBs)	-----
Benzo(a)pyrene	50-32-8	Polychlorinated Naphthalenes (PCNs)	-----
Benzo(b)fluoranthene	205-99-2	Polychlorinated Terphenyls (PCTs)	-----
Benzo(e)pyrene	192-97-2	Polycyclic Aromatic Hydrocarbons (PAHs)	-----
Benzo(ghi)perylene	191-24-2	Polystyrene	-----
Benzo(j)fluoranthene	205-82-3	Polyvinyl Chloride (PVC)	9002-86-2
Benzo(k)fluoranthene	207-08-9	Polyvinylidene chloride (PVDC)	9002-85-1
Benzophenone	119-61-9	Pyrene	129-00-0
Bisphenol A and other derivatives of Bisphenol	80-05-7	Silicone	-----
Bisphenol A diglycidyl ether (BADGE)	1675-54-3	Styrene monomer	100-42-5
Bisphenol F diglycidyl ether (BFDGE)	2095-03-6	Sulfur di-oxide	7446-09-5
Butylated hydroxyanisole (BHA)	121-00-6	Sulfide or sulfide derivatives	-----
Butylated hydroxytoluene (BHT)	128-37-0	Tin oxide (SnO ₂)	8062-08-6
Chlorinated paraffins	-----	Titanium Acetylacetonate	17501-79-0
Chrysene	218-01-9	Tris-nonylphenol phosphite (TNPP)	26523-78-4
Crystal Violet	548-62-9	Tris (4-nonylphenyl, branched and linear) phosphite (TNPP) with ≥ 0.1% W/W of 4 nonylphenol, branched and linear (4-NP)	-----
Cyanuric acid	108-80-5	Vinyl Chloride Monomer	75-01-4
Dibenz(a,h)anthracene	53-70-3	Wolframite; Tungsten (W)	1332-08-7
Diisohexyl phthalate	71850-09-4	1,2-dihydro-acenaphthene	83-32-9
Dimethyl fumarate (DMF)	624-49-7	2-(2H-1, 2, 3-Benzotriazol-2-yl)-4,6-di-tert-butylphenol (Benzotriazole)	3846-71-7
Dioxins	-----	2-Benzyl-2-dimethylamino-4'-morpholinobutyrophenone	119313-12-1
Epichlorohydrin	106-89-8	2-Mercaptobenzothiazole (Benzothiazole-2-thiol or MBT)	149-30-4
Fluoranthene	206-44-0		
Fluorene	86-73-7		
Fluorocarbons	-----		
Fluorotelomers	-----		
Formaldehyde	50-00-0		
Formaldehyde in specific conditions could be formed during the resin processing (see MSDS)			
GMO	-----		
Gold (Au)	7440-57-5		
Halogenated flame retardants	-----		
2-Methoxyethyl acetate	110-49-6		

Indeno (1,2,3-cd) pyrene	193-39-5	2-methyl-1-(4-methylthiophenyl)	71868-10-5
Isopropylthioxanthane (ITX)	83846-86-0	-2-morpholinopropan-1-one	
Melamine (1,3,5-Triazine-2,4,6-triamine)	108-78-1	2,3,3,3-tetrafluoro-2-	-----
Naphthalene	91-20-3	(heptafluoropropoxy) propanoic	
Nonylphenol	25154-52-3	acid, its salts and its acyl halides	
Nonylphenol ethoxylates	-----	(covering any of their individual	
Novolac glycidyl ether	-----	isomers and combinations thereof)	
Organo-tin Compounds	-----	2,4 pentadione (Acetilacetone)	123-54-6
		2,4,4'-trichloro-2'-hydroxydiphenyl ether	3380-34-5
Perfluorobutane sulfonic acid (PFBS)	-----	(Triclosan)	
and its salts		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 the presence of 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, this product has not been tested for the presence of 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)

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).

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.

CEN Standard EN 13432:2004

This product is not suitable for composting.

Energy Recovery - CEN Standard EN 13431:2004

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, 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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