



# Toxicological profile for Hydrocarbon resin

***This ingredient has been assessed to determine potential human health effects for the consumer. It was considered not to increase the inherent toxicity of the product and thus is acceptable under conditions of intended use.***

## **1. Name of substance and physico-chemical properties**

### **1.1. IUPAC systematic name**

Not applicable.

### **1.2. Synonyms**

(C8-C16)Cyclodiene resin, hydrogenated; Naphtha (petroleum), light steam-cracked, debenzenized, polymers, hydrogenated; Polycyclopentadiene (ChemIDplus); Homopolymer of cyclopentadiene (CosIng); Petroleum hydrocarbon resins (cyclopentadiene-type), hydrogenated (FDA, 2021a)

### **1.3. Molecular formula**

Unspecified (ChemIDplus)

### **1.4. Structural Formula**

Not applicable.

### **1.5. Molecular weight (g/mol)**

No data available to us at this time.

### **1.6. CAS registration number**

68132-00-3

## **1.7. Properties**

### **1.7.1. Melting point**

(°C): No data available to us at this time.

### **1.7.2. Boiling point**

(°C): No data available to us at this time.

### **1.7.3. Solubility**

No data available to us at this time.

### **1.7.4. pKa**

No data available to us at this time.

### **1.7.5. Flashpoint**

(°C): No data available to us at this time.

### **1.7.6. Flammability limits (vol/vol%)**

No data available to us at this time.

#### *1.7.7. (Auto)ignition temperature*

(°C): No data available to us at this time.

#### *1.7.8. Decomposition temperature*

(°C): No data available to us at this time.

#### *1.7.9. Stability*

Stable at normal temperatures and pressure

#### *1.7.10. Vapor pressure*

No data available to us at this time.

#### *1.7.11. log Kow*

No data available to us at this time.

## **2. General information**

### **2.1. Exposure**

Polycyclopentadiene (CAS RNs 68132-00-3, 25568-84-7) is used as a viscosity controlling agent in cosmetics in the EU. As taken from CosIng (undated).

Polycyclopentadiene (CAS RN 68132-00-3) is listed as an ingredient in a home maintenance product (at 15-25%) by the CPID.

### **2.2. Combustion products**

No data available to us at this time.

### **2.3. Ingredient(s) from which it originates**

No data available to us at this time.

## **3. Status in legislation and other official guidance**

Petroleum hydrocarbon resins (cyclopentadiene-type), hydrogenated (CAS RN 68132-00-3) is listed as an indirect additive used in food contact substances and is covered under 21 CFR 175.105 (Indirect food additives: adhesives and components of coatings) and 177.1520 (Olefin polymers) (FDA, 2022a,b).

Results of 90-day subchronic oral toxicity studies in rats and dogs were used to derive an acceptable daily intake for humans of 1.80-2.25 mg/kg bw/day (Edwards et al. 1992).

Naphtha (petroleum), light steam-cracked, debenzenezed, polymers, hydrogenated (CAS RN 68132-00-3) are pre-registered under REACH ("envisaged registration deadline 30 November 2010") (ECHA).

Naphtha (petroleum), light steam-cracked, debenzenezed, polymers, hydrogenated (CAS RN 68132-00-3) are listed in the US EPA Toxic Substances Control Act (TSCA) inventory and are fully exempt from reporting under the 2020 Chemical Data Reporting (CDR) rule. The Chemical Data

Reporting (CDR) Rule requires companies that manufacture (including import) certain chemicals at certain volumes in the U.S. to report to EPA every four years through its CDR.

The TSCA inventory and 2020 CDR Full Exempt list are available at [https://sor.epa.gov/sor\\_internet/registry/substreg/searchandretrieve/searchbylist/search.do](https://sor.epa.gov/sor_internet/registry/substreg/searchandretrieve/searchbylist/search.do)

Naphtha (petroleum), light steam-cracked, debenzene, polymers, hydrogenated (CAS RN 68132-00-3) are not classified for packaging and labelling under Regulation (EC) No. 1272/2008 (ECHA, 2022).

Naphtha (petroleum), light steam-cracked, debenzene, polymers, hydrogenated (CAS RN 68132-00-3) are included on the New Zealand Inventory of Chemicals and may be used as single component chemicals under an appropriate group standards (NZ EPA, 2006).

Naphtha, petroleum, light steam cracked, debenzene, polymers, hydrogenated (CAS RN 68132-00-3) "poses no unreasonable risk to human health based on Tier I assessment under the NICNAS IMAP assessment framework" and "data available on the function of the chemical indicate that it may be used in cosmetics but only at low concentrations" (AICIS, 2015).

#### **4. Metabolism/Pharmacokinetics**

##### *4.1. Metabolism/metabolites*

No data available to us at this time.

##### *4.2. Absorption, distribution and excretion*

No data available to us at this time.

##### *4.3. Interactions*

No data available to us at this time.

#### **5. Toxicity**

##### *5.1. Single dose toxicity*

No data available to us at this time.

##### *5.2. Repeated dose toxicity*

The results of 90-day subchronic oral toxicity studies in the rat and dog were used to derive an acceptable daily intake for humans of 1.80 to 2.25 mg/kg bw/day (Edwards et al. 1992).

##### *5.3. Reproduction toxicity*

An oral teratology and 2-generation reproduction study in the rat gave negative results (Edwards et al. 1992).

##### *5.4. Mutagenicity*

There was no evidence of mutagenicity in an Ames test or a mouse micronucleus assay (Edwards et al. 1992).

## **5.5. Cytotoxicity**

No data available to us at this time.

## **5.6. Carcinogenicity**

There was no evidence of carcinogenicity in a 2-year skin painting study in mice (Edwards et al. 1992).

## **5.7. Irritation/immunotoxicity**

Hydrocarbon resin has little or no skin irritation or sensitization potential. It does have the potential to irritate but not permanently damage the eye and, at high concentrations, produce respiratory irritation (Edwards et al. 1992).

## **5.8. All other relevant types of toxicity**

No data available to us at this time.

## **6. Functional effects on**

### **6.1. Broncho/pulmonary system**

No data available to us at this time.

### **6.2. Cardiovascular system**

No data available to us at this time.

### **6.3. Nervous system**

No data available to us at this time.

### **6.4. Other organ systems, dependent on the properties of the substance**

No data available to us at this time.

## **7. Addiction**

JTI is not aware of any information that demonstrates that this ingredient has any addictive effect.

## **8. Burnt ingredient toxicity**

No data available to us at this time.

## **9. Heated/vapor emissions toxicity**

Aerosol from heated tobacco stick(s) containing Hydrocarbon Resin was tested in aerosol chemistry and a battery of in vitro test(s). Under the test conditions and within the sensitivity and specificity of the bioassay(s), the activity of the total particulate matter (TPM) and/or gas vapor phase (GVP) were not increased by the addition of this ingredient when compared to TPM and/or GVP from reference combustible cigarettes. The table below provides the highest tested level(s) and specific endpoint(s):

Endpoint	Tested level (mg/stick)	Reference
Aerosol chemistry	0.79	Labstat International Inc. (2020a) Labstat International Inc. (2021a)
In vitro genotoxicity	0.79	Labstat International Inc. (2020b) Labstat International Inc. (2021b)
In vitro cytotoxicity	0.79	Labstat International Inc. (2020b) Labstat International Inc. (2021b)

## 10. Ecotoxicity

### 10.1. Environmental fate

The Ecological Categorization Results from the Canadian Domestic Substances List simply state that naphtha (petroleum), light steam-cracked, debenzene, polymers, hydrogenated (CAS RN 68132-00-3) are persistent in the environment.

Data accessed December 2014 on the OECD website:  
<http://webnet.oecd.org/CCRWeb/Search.aspx>

### 10.2. Aquatic toxicity

“Hydrocarbon resins are used to modify polymer products to achieve desired functional properties for a diverse range of products. These complex hydrocarbon-based mixtures are typically poorly soluble in water. However, resins may leach lower-molecular-weight monomers or impurities upon contact with water, thus posing a potential hazard to the aquatic environment. The bioavailability and toxicity of leachable constituents of four solid and three liquid resins were evaluated by analyzing water-accommodated fractions prepared with each resin, using biomimetic solid phase microextraction (SPME) techniques. Liquid resins exhibited concentrations of bioavailable constituents that were sufficiently elevated to cause acute toxicity to the aquatic organism *Daphnia magna*. All solid resins exhibited lower bioavailable concentrations of leachable constituents that were unlikely to pose an aquatic toxicity concern. Since observed toxicity of both resin types was generally consistent with bioavailable concentrations determined using SPME fiber measurements, it is concluded that this approach provides a convenient in vitro screening tool that can help reduce the use of animal testing in environmental hazard assessment of complex hydrocarbon-based substances”.

As taken from Woods RW et al. 2007. Ecotoxicol Environ Saf. 66(2), 159-68. PubMed, 2010 available at <http://www.ncbi.nlm.nih.gov/pubmed/16469379>

The Ecological Categorization Results from the Canadian Domestic Substances List simply state that naphtha (petroleum), light steam-cracked, debenzene, polymers, hydrogenated (CAS RN 68132-00-3) are not inherently toxic to aquatic organisms and are of low ecotoxicological concern. Data accessed December 2014 on the OECD website:

<http://webnet.oecd.org/CCRWeb/Search.aspx>

### **10.3. Sediment toxicity**

No data available to us at this time.

### **10.4. Terrestrial toxicity**

No data available to us at this time.

### **10.5. All other relevant types of ecotoxicity**

The Ecological Categorization Results from the Canadian Domestic Substances List simply state that naphtha (petroleum), light steam-cracked, debenzene, polymers, hydrogenated (CAS RN 68132-00-3) are not bioaccumulative in the environment.

Data accessed December 2014 on the OECD website:  
<http://webnet.oecd.org/CCRWeb/Search.aspx>

## **11. References**

- AICIS (2015). Australian Government Department of Health. Australian Industrial Chemicals Introduction Scheme. Inventory Multi-Tiered Assessment and Prioritisation (IMAP) Tier I. Health record for naphtha, petroleum, light steam cracked, debenzene, polymers, hydrogenated (CAS RN 68132-00-3). Dated 3 July 2015. Available at <https://www.industrialchemicals.gov.au/chemical-information/search-assessments?assessmentcasnumber=68132-00-3>
- ChemIDplus. Available at <https://chem.nlm.nih.gov/chemidplus/>
- CosIng. Cosmetic substances and ingredients database. Record for polycyclopentadiene (CAS RNs 68132-00-3, 25568-84-7). Undated, Available at <https://ec.europa.eu/growth/tools-databases/cosing/>
- CPID (undated). Consumer Product Information Database. Record for polycyclopentadiene (CAS RN 68132-00-3). Available at <https://www.whatsinproducts.com/>
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- ECHA (undated). European Chemicals Agency. Information on chemicals. Record for naphtha (petroleum), light steam-cracked, debenzene, polymers, hydrogenated. Available at: <https://echa.europa.eu/information-on-chemicals/pre-registered-substances/>
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- FDA (2022a). US Food and Drug Administration. Indirect Additives Used in Food Contact. Last updated 25 May 2022. Available at <https://www.cfsanappexternal.fda.gov/scripts/fdcc/index.cfm?set=IndirectAdditives>
- FDA (2022b). US Food and Drug Administration. Electronic Code of Federal Regulations (eCFR) Title 21. Current as of 16 June 2022. Available at <https://www.ecfr.gov/cgi-bin/ECFR?page=browse>
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- Labstat International Inc. (2020b) Determination of Mutagenic Response (Ames), Cytotoxic Response (NRU) and Genotoxic Response (ivMN) of Mainstream Aerosol Total Particulate

Matter (TPM) and Mainstream Gas Vapor Phase (GVP) of Heat-not-burn Products.Biological Activity Test Report(s).

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- Labstat International Inc. (2021b). Determination of Mutagenic Response (Ames), Cytotoxic Response (NRU) and Genotoxic Response (ivMN) of Mainstream Aerosol Total Particulate Matter (TPM) and Mainstream Gas Vapor Phase (GVP) of Heat-not-burn Products. Biological Activity Test Report(s).
- NZ EPA (2006). New Zealand Environmental Protection Authority. Inventory of Chemicals (NZIoC). Record for naphtha (petroleum), light steam-cracked, debenzene, polymers, hydrogenated (CAS RN 68132-00-3). Added to inventory 1 December 2006. Accessed April 2020. Available at <https://www.epa.govt.nz/database-search/new-zealand-inventory-of-chemicals-nzioc/view/15176>
- OECD. Organisation for Economic Co-operation and Development. The Global Portal to Information on Chemical Substances (eChemPortal). Naphtha (petroleum), light steam-cracked, debenzene, polymers, hydrogenated. Accessed December 2014. Available at <http://webnet.oecd.org/CCRWeb/Search.aspx>
- US EPA CDR (Chemical Data Reporting) 2020 Full Exempt list. Available at [https://sor.epa.gov/sor\\_internet/registry/substreg/searchandretrieve/searchbylist/search.do](https://sor.epa.gov/sor_internet/registry/substreg/searchandretrieve/searchbylist/search.do)
- US EPA TSCA inventory. Available at [https://sor.epa.gov/sor\\_internet/registry/substreg/searchandretrieve/searchbylist/search.do](https://sor.epa.gov/sor_internet/registry/substreg/searchandretrieve/searchbylist/search.do)
- Woods RW, Letinski DJ, Febbo EJ, Dzamba CL, Connelly MJ and Parkerton TF (2007). Assessing the aquatic hazard of commercial hydrocarbon resins. Ecotoxicol. Environ. Saf. 66(2), 159-68. PubMed, 2010 available at <http://www.ncbi.nlm.nih.gov/pubmed/16469379>

## **12. Other information**

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## **13. Last audited**

June 2022

**Opinion of the Scientific Panel on food additives, flavourings, processing aids and materials in contact with food (AFC)  
on a request related to**

**a 13<sup>th</sup> list of substances for food contact materials**

**Question N° EFSA-Q-2005-229, EFSA-Q-2006-074, EFSA-Q-2005-111,  
EFSA-Q-2006-138, EFSA-Q-2006-022, EFSA-Q-2006-058, EFSA-Q-  
2004-057, EFSA-Q-2004-056, EFSA-Q-2005-228, EFSA-Q-2006-075**

**Adopted on 29 November 2006**

**SUMMARY**

Within the general task of evaluating substances intended for use in materials in contact with food according to the Regulation (EC) No.1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with foodstuffs, the AFC Panel evaluated the following substances:

Ref. No.:	19180
Name of the substance:	Isophthalic acid dichloride
CAS number:	99-63-8
Classified in list:	3
Restriction:	5 mg/kg food (expressed as isophthalic acid)
Ref. No.:	26305
Name of the substance:	Vinyltriethoxysilane
CAS number:	78-08-0
Classified in list:	3
Restriction:	0.05 mg/kg of food Only to be used as a surface treatment agent
Ref. No.:	48960
Name of the substance:	9,10-dihydroxy stearic acid and its oligomers
CAS number:	
Classified in list:	3
Restriction:	5 mg/kg food
Ref. No.:	53670
Name of the substance:	Ethylene glycol bis[3,3-bis(3-tert-butyl-4-hydroxyphenyl)butyrate]
CAS number:	32509-66-3
Classified in list:	2

Restriction:	TDI = 0.1 mg/kg bw
Ref. No.:	60025
Name of the substance:	Hydrogenated homopolymers and/or copolymers made of 1-decene and/or 1-dodecene and/or 1-octene
CAS number:	-
Classified in list:	3
Restriction:	None
Ref. No.:	72081/10
Name of the substance:	Petroleum Hydrocarbon Resins (hydrogenated)
CAS number:	-
Classified in list:	3
Restriction:	None
Ref. No.:	77732
Name of the substance:	Polyethylene glycol (EO=1-30, typically 5) ether of butyl 2-cyano 3-(4-hydroxy-3-methoxyphenyl) acrylate
CAS number:	-
Classified in list:	3
Restriction:	0.05 mg/kg of food Only for the requested use in PET
Ref. No.:	77733
Name of the substance:	Polyethyleneglycol (EO=1-30, typically 5) ether of butyl-2-cyano-3-(4-hydroxyphenyl) acrylate
CAS number:	-
Classified in list:	3
Restriction:	0.05 mg/kg food. Only for the requested use in PET
Ref. No.:	79985
Name of the substance:	Poly(ethylene propylene)glycol tridecyl ether
CAS number:	61725-89-1 and 65150-81-4
Classified in list:	3
Restriction:	0.05 mg/kg food To be used only in PTFE items sintered at high temperatures
Ref. No.:	95858
Name of the substance:	Waxes, paraffinic, refined, derived from petroleum based or synthetic hydrocarbon feedstocks
CAS number:	-
Classified in list:	3
Restriction:	0.05 mg/food Not to be used for articles in contact with fatty foods.

## KEYWORDS

Food Contact Materials, Plastics, Monomers, Additives, REF. No 19180, CAS No 99-63-8, Isophthalic acid dichloride, REF. No 26305, CAS No 78-08-0, Vinyltriethoxysilane, REF. No 48960, 9,10-dihydroxy stearic acid and its oligomers, REF. No 53670, CAS No. 32509-66-3, Ethylene glycol bis[3,3-bis(3-tert-butyl-4-hydroxyphenyl)butyrate], REF. No 60025, Hydrogenated homopolymers and/or copolymers made of 1-decene and/or 1-dodecene and/or 1-octene, REF. No 72081/10, Petroleum Hydrocarbon Resins (hydrogenated), REF. No 77732, Polyethylene glycol (EO=1-30, typically 5) ether of butyl 2-cyano 3-(4-hydroxy-3-methoxyphenyl) acrylate, REF. No 77733, Polyethyleneglycol (EO=1-30, typically 5) ether of butyl-2-cyano-3-(4-hydroxyphenyl) acrylate, REF. No 79985, CAS No 61725-89-1 and 65150-81-4, Poly(ethylene propylene)glycol tridecyl ether, REF. No 95858, Waxes, paraffinic, refined, derived from petroleum based or synthetic hydrocarbon feedstocks.

## BACKGROUND

Before a substance is authorised to be used in food contact materials and is included in a positive list EFSA's opinion on its safety is required. This procedure has been established in Articles 8 and 9 of the Regulation (EC) No. 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food<sup>1</sup>.

## TERMS OF REFERENCE

The EFSA is required by Article 10 of Regulation (EC) No. 1935/2004 of the European Parliament and of the Council on materials and articles intended to come into contact with food to carry out risk assessments on the risks originating from the migration of substances from food contact materials into food and deliver a scientific opinion on:

1. new substances intended to be used in food contact materials before their authorisation and inclusion in a positive list;
2. substances which are already authorised in the framework of Regulation (EC) No. 1935/2004 but need to be re-evaluated.

## ASSESSMENT

Within this general task the Scientific Panel on food additives, flavourings, processing aids and materials in contact with food (AFC) evaluated the following substances used in food contact materials.

The substances examined are listed in ascending order of their Reference Number (REF No.), with their chemical name, Chemical Abstract Number (CAS No.) and classification

<sup>1</sup> This Regulation replaces Directive 89/109/EEC of 21 December 1988, OJ L 40, 11.2.1989, P.38

according to the “SCF list”. (Since in the past the evaluation of substances used in food contact materials was undertaken by the Scientific Committee on Food (SCF), the same system of classification into a “SCF list” is retained for uniformity purposes). The definitions of the various SCF lists and the abbreviations used are given in the appendix.

The studies submitted for evaluation followed the SCF guidelines for the presentation of an application for safety assessment of a substance to be used in food contact materials prior to its authorisation ([http://ec.europa.eu/food/fs/sc/scf/out82\\_en.pdf](http://ec.europa.eu/food/fs/sc/scf/out82_en.pdf))

<b>Ref. No.:</b>	<b>19180</b>
<b>Name of the substance:</b>	<b>Isophthalic acid dichloride</b>
<b>CAS number:</b>	99-63-8
<b>Document reference:</b>	SDS EFSA/AFC/FCM/552-Rev.IA/19180 of September 2006
<b>General information:</b>	According to the petitioner isophthalic acid dichloride is used as a co-monomer for the production of polystercarbonate polymers. The polymer is used in single and repeated use applications. The maximum amount used in polyester carbonate polymers is 20%.
<b>Previous evaluations (by SCF or AFC):</b>	None (new substance)
<b>Available data used for this evaluation:</b>	
<b>Non-toxicity data:</b>	<ul style="list-style-type: none"> <li>- Data on identity</li> <li>- Data on physical/chemical properties</li> <li>- Data on use</li> <li>- Data on authorisation</li> <li>- Data on hydrolysis in water</li> <li>- Data on residual content of the substance</li> <li>- Information on the possible formation of chlorine containing substances in poly(ester carbonate) polymers</li> </ul>
<b>Toxicity data:</b>	<ul style="list-style-type: none"> <li>- None, complete hydrolysis to authorised substances</li> </ul>
<b>Evaluation:</b>	<p>Isophthalic acid dichloride hydrolyses rapidly and completely either in the plastic or in the first contact with food to isophthalic acid (REF No 19150) and hydrochloric acid (REF No. 59990), which have both been authorised for the manufacture of plastics intended to come into contact with food, with a restriction of 5 mg/kg food and no specific restriction respectively (Directive 2002/72/EC).</p> <p>Due to hydrolysis the specific migration of isophthalic acid dichloride in food simulant is not relevant. The residual content of the monomer in polycarbonate was determined. The residual content of isophthalic acid dichloride plus isophthalic acid expressed as isophthalic acid was &lt;60 mg/kg plastic. Based on the residual content the worst case migration for isophthalic acid dichloride was calculated to be &lt; 1.1 mg/kg food. Information was provided on the possible formation of chlorine containing substances during the polymerisation. Due to the alkaline polymerisation conditions no formation of organic chlorinated substances is foreseeable.</p>
<b>Conclusion:</b>	Based on the above-mentioned data the substance is classified:
<b>SCF_List:</b>	<b>3</b>

<b>Restriction:</b>	<b>5 mg/kg food (expressed as isophthalic acid)</b>
<b>Remark for Commission:</b>	None
<b>Needed data or information</b>	None
<b>References:</b>	<ul style="list-style-type: none"> <li>- Unpublished data submitted by the petitioner in September 2005 and May 2006.</li> <li>- Commission Directive 2002/72/EC of 6 August 2002 relating to plastic materials and articles intended to come into contact with foodstuffs  <a href="http://europa.eu.int/comm/food/food/chemicalsafety/foodcontact/2002-72_en.pdf">http://europa.eu.int/comm/food/food/chemicalsafety/foodcontact/2002-72_en.pdf</a> </li> </ul>

<b>Ref. No.:</b>	<b>26305</b>
<b>Name of the substance:</b>	<b>Vinyltriethoxysilane</b>
<b>CAS number:</b>	78-08-0
<b>Document reference:</b>	SDS EFSA/AFC/FCM/711-Rev.0A/26305 of November 2006
<b>General information:</b>	According to the petitioner vinyltriethoxysilane (VTEO) is used as a coupling agent on inorganic materials (fillers) which are blended into polymers, acting as an adhesion promoter, crosslinker and/or surface modifier. Percentage of use is 0.1-1 % w/w filler. VTEO may also be used for the preparation of different polymers, destined for general use.
<b>Previous evaluations (by SCF or AFC):</b>	None (new substance)
<b>Available data used for this evaluation:</b>	
<b>Non-toxicity data:</b>	<ul style="list-style-type: none"> <li>- Data on the identity and physical and chemical properties,</li> <li>- hydrolysis studies,</li> <li>- data on the intended use and authorisation,</li> <li>- quantification of migrateable oligomers,</li> <li>- determination of residual content</li> <li>- worst case calculation of specific migration</li> </ul>
<b>Toxicity data</b>	<ul style="list-style-type: none"> <li>- Bacterial reversion assays with vinyltriethoxysilane (VTEO);</li> <li>- Tk<sup>+</sup>/- assay in mouse lymphoma cells with VTEO;</li> <li>- HPRT assay in CHO cells with vinyltrimethoxysilane (VTMO);</li> <li>- Chromosomal aberrations in CHO cells with VTMO;</li> <li>- Micronucleus test in mouse peripheral blood with VTMO</li> </ul>

<b>Evaluation:</b>	<p>Specific migration of VTEO in food simulants was not determined but worst case migration was calculated on the basis of the residual content. To this aim, the residual amount of VTEO in a worst case sample (filler treated with 1% VTEO) was determined by a properly validated analytical method (hexane extraction and Gas Chromatographic/Mass Spectrometric analysis). No residual amount of VTEO was detected with a detection limit of 1.16 µg VTEO/g filler. The calculated worst case migration was found to be lower than 31 µg/kg food.</p> <p>Migration of non-volatile oligomers and reaction products, determined by ethanol extraction, was in the range of untreated samples.</p> <p>Hydrolysis studies in gastric juice simulants showed complete hydrolysis of VTEO after 1 hour at 37°C to insoluble polysiloxanes and ethanol.</p> <p>Vinyltriethoxysilane (VTEO) was non-mutagenic in bacterial reversion tests and in the forward mutation assay in mouse lymphoma cells, which detects clastogenic effects as well as gene mutations. No further toxicity data on VTEO are available.</p> <p>However, as VTEO and VTMO (vinyltrimethoxysilane) hydrolyse completely in body fluids forming identical polysiloxanes, it is considered appropriate to read across from the genotoxicity studies performed on VTMO.</p> <p>In studies in cultured mammalian cells, VTMO was negative in a limited forward mutation test at the HPRT locus, while it increased the incidence of structural chromosomal aberrations, both with and without exogenous metabolism. The clastogenic potential of VTMO <i>in vivo</i> was assessed in the micronucleus test in mouse peripheral blood: in this study VTMO, administered at doses close to the LD50, provided negative results, indicating that the clastogenic activity of VTMO observed <i>in vitro</i> is not expressed <i>in vivo</i>. Based on the negative results of the studies on VTEO, and the fact that genotoxicity of VTMO is not expressed <i>in vivo</i>, it is concluded that VTEO does not raise concern for genotoxicity.</p>
<b>Conclusion:</b>	Based on the above-mentioned data the substance is classified:
<b>SCF_List:</b>	3
<b>Restriction:</b>	<b>0.05 mg/kg of food</b> <b>Only to be used as a surface treatment agent</b>
<b>Remark for Commission:</b>	Only method of analysis for the determination of the residual monomer on the treated surface (QMA) is provided.
<b>Needed data or information</b>	None

<b>References:</b>	Unpublished data provided by the petitioner in August 2006
<b>Ref. No.:</b>	<b>48960</b>
<b>Name of the substance:</b>	<b>9,10-dihydroxy stearic acid and its oligomers</b>
CAS number:	
Document reference::	EFSA/AFC/FCM/504-Rev.IIC/48960 of November 2006
<b>General information:</b>	According to the petitioner 9,10-dihydroxystearic acid and its oligomers is a defined mixture of monomer, dimer, trimer and tetramer of 9,10-dihydroxystearic acid derived from natural fats and oils. The ammonium salt of the substance is used as an emulsifier for the polymerisation of PVC.
<b>Previous evaluations (by SCF or AFC):</b>	The substance was first evaluated by the EFSA/AFC Panel in 2003 (EFSA/AFC, 2003) and it was classified in List 7 with the following request for additional data: <ul style="list-style-type: none"> <li>- Specification of the actual substance.</li> <li>- Information on the actual substance used for the determination of the solubility.</li> <li>- Confirmation whether iso-octanol or iso-octane is used in the determination of the solubility.</li> <li>- Confirmation of the detection limit (<math>\mu\text{g}/\text{dm}^2</math>) supported by convincing chromatograms to establish the detection limit.</li> <li>- Data on the actual amount of 9,10-dihydroxystearic acid recovered from simulants to which the substance has been added at a relevant concentration and stored for 10 d at 40°C, in accordance with the Note for Guidance.</li> <li>- Detailed data to evaluate the reliability of the migration results presented</li> <li>- A complete chromosomal aberration assay in mammalian cells including data without metabolic activation (S9).</li> </ul>
<b>Available data used for this evaluation:</b>	
Non-toxicity data:	<ul style="list-style-type: none"> <li>- Data on identity</li> <li>- Data on physical/chemical properties including Log Po/w values</li> <li>- Data on use and authorisation</li> <li>- Data on migration from PVC</li> <li>- Data on residual amount of 9,10-dihydroxystearic acid in PVC.</li> </ul>

<b>Ref. No.:</b>	<b>48960</b>
<b>Name of the substance:</b>	<b>9,10-dihydroxy stearic acid and its oligomers</b>
Toxicity data:	<ul style="list-style-type: none"> <li>- Gene mutation assay in bacteria.</li> <li>- Gene mutation assay in mammalian cells.</li> <li>- Chromosomal aberration assay in cultured mammalian cells (incomplete, data only with S9).</li> <li>- A complete chromosomal aberration assay in mammalian cells including data without metabolic activation (S9)</li> <li>- Micronucleus assay in bone marrow cells of the mouse</li> <li>- 90-day oral toxicity study with reversibility in rats</li> <li>- Bioavailability study</li> </ul>
<b>Evaluation:</b>	<p>Migration of 9,10-dihydroxystearic acid from two PVC samples containing 0.03 and 0.07% of the test substance was determined. Migration from the sample containing 0.03 % of the substance was not detectable in aqueous food simulants and was 63 µg/kg in 100% ethanol. From the sample containing 0.07% of the substance migration after a contact period of 10 days at 40°C into water, 3% acetic acid, 15% ethanol and 100% ethanol of 9,10-dihydroxystearic acid was found to be &lt;16, 27, 27 and 216 µg/kg respectively. A second set of migration data, including proper validation, was provided using the sample with 0.03% of 9,10-dihydroxystearic acid. Results confirmed earlier findings. Migration in 3% acetic acid, 10% ethanol and 95% ethanol was 12, 14 and 42 µg/kg respectively.</p> <p>The test substance was negative in the two requested gene mutation assays (in bacteria and in mammalian cells). The results of the two chromosomal aberration assays with S9 mix are not in agreement and the results of the only one study including exposure without S9 remains equivocal. However, the <i>in vivo</i> micronucleus assay was negative. Based on the available genotoxicity data the substance is considered as non genotoxic.</p> <p>An oral 90-day study has been performed. The doses used were up to 1000 mg/kg b.w/day. The usual monitored parameters were not significantly modified by the treatment at any dose. A no-observed-adverse-effect-level (NOAEL) greater than 1000 mg/kg bodyweight/day, the highest dose level tested, can be foreseen on the basis of this study.</p> <p>The toxicokinetic study indicates a low bioavailability of 9,10-dihydroxystearate after oral administration and suggests a rapid metabolism of 9,10-dihydroxystearate. These data demonstrate the absence of a potential for bioaccumulation.</p>
<b>Conclusion:</b>	Based on the above-mentioned data the substance is classified

<b>Ref. No.:</b>	<b>48960</b>
<b>Name of the substance:</b>	<b>9,10-dihydroxy stearic acid and its oligomers</b>
<b>SCF list:</b>	<b>3</b>
<b>Restriction</b>	<b>5 mg/kg food</b>
Needed data or information	None
Remark for Commission:	None
<b>References:</b>	<ul style="list-style-type: none"> <li>- Unpublished data submitted by the petitioner</li> <li>- EFSA/AFC opinion on a 1<sup>st</sup> list of substances for food contact materials, adopted on the 1<sup>st</sup> October 2003 <a href="http://www.efsa.eu.int/science/afc/afc_opinions/195_en.html">http://www.efsa.eu.int/science/afc/afc_opinions/195_en.html</a></li> </ul>

<b>Ref. No.:</b>	<b>53670</b>
<b>Name of the substance:</b>	<b>Ethylene glycol bis[3,3-bis(3-tert-butyl-4-hydroxyphenyl)butyrate]</b>
CAS number:	32509-66-3
Document reference:	EFSA/AFC/FCM/749-Rev.IA/53670 of November 2006
<b>General information:</b>	According to the petitioner ethylene glycol bis[3,3-bis(3-tert-butyl-4-hydroxyphenyl)butyrate] is intended to be used as a long term antioxidant in the manufacture of plastics. Maximum percentage in formulation is 0.115%.
<b>Previous evaluations (by SCF or AFC):</b>	<p>The substance was first evaluated by the SCF in 1998 (SCF, 1998) and it was allocated a TDI of 0.1 mg/kg bw on the basis of the following toxicity studies:</p> <p>acute oral toxicity data; 90-day oral rat study; 16-week oral rat study (after in utero exposure); 90-day oral dog study; 2-year oral dog study; 2.5 year oral rat study (combined chronic/carcinogenicity study); one-generation reproduction study with rats; three negative mutagenicity studies.</p> <p>REMARK for Commission: No method of analysis is available for the enforcement of an SML.</p>
<b>Available data used for this evaluation:</b>	
Non-toxicity data:	<ul style="list-style-type: none"> <li>- Data on identity</li> <li>- Data on physical/chemical properties</li> <li>- Data on use</li> <li>- Data on authorisation</li> </ul>

<b>Ref. No.:</b>	<b>53670</b>
<b>Name of the substance:</b>	<b>Ethylene glycol bis[3,3-bis(3-tert-butyl-4-hydroxyphenyl)butyrate]</b>
	<ul style="list-style-type: none"> <li>- Data on migration</li> <li>- Data on residual content of the substance</li> </ul>
Toxicity data	This aspect has been evaluated by the SCF (SCF, 1998)
<b>Evaluation:</b>	<p>An adequate method of analysis has been provided by the petitioner.</p> <p>Specific migration tests were performed on a LDPE containing 0.115% of the antioxidant. Tests were performed by total immersion in 3% acetic acid, 10% ethanol, 95% ethanol and iso-octane for 10 days 40°C and 2 days 20°C (iso-octane). Specific migration of ethylene glycol bis[3,3-bis(3-tert-butyl-4-hydroxyphenyl)butyrate] was found to be not detectable in the aqueous simulants and in 95% ethanol, with a detection limit for these simulants of 0.46 mg/kg food. In iso-octane, specific migration was found to be 0.20 mg/kg food. The method is properly described. Recovery experiments showed that the substance is stable in 10% ethanol, 95% ethanol and iso-octane, under the test conditions applied. In 3% acetic acid, recovery was found to be &lt;43%, due to acid catalysed hydrolysis.</p>
<b>Conclusion:</b>	Based on the previous evaluation by the SCF (SCF, 1998) and the currently provided analytical data the substance remains classified in:
<b>SCF List:</b>	<b>2</b>
<b>Restriction:</b>	<b>TDI = 0.1 mg/kg bw</b>
Remark for Commission:	FRF is applicable
Needed data or information	None
<b>References:</b>	<ul style="list-style-type: none"> <li>- Unpublished data submitted by the petitioner on 19/09/2006</li> <li>- Scientific Committee on Food, opinion on an additional list on monomers and additives for food contact materials (expressed on 10 December 1998)</li> </ul> <p><a href="http://europa.eu.int/comm/food/fs/sc/scf/out20_en.pdf">http://europa.eu.int/comm/food/fs/sc/scf/out20_en.pdf</a></p>

<b>Ref. No.:</b>	<b>60025</b>
<b>Name of the substance:</b>	<b>Hydrogenated homopolymers and/or copolymers made of 1-decene and/or 1-dodecene and/or 1-octene</b>
CAS number:	-
Document reference:	EFSA/AFC/FCM/755-Rev.IA/60025
<b>General information:</b>	According to the petitioner homopolymers and/or copolymers made

<b>Ref. No.:</b>	<b>60025</b>
<b>Name of the substance:</b>	<b>Hydrogenated homopolymers and/or copolymers made of 1-decene and/or 1-dodecene and/or 1-octene</b>
	of 1-decene and/or 1-dodecene and/or 1-octene (PAOs) are added to polypropylene to improve the polymer's desirable properties, such as melting point, crystallization rate, and optical properties. Average molecular mass of the PAOs ranges from 450-7000 Daltons depending on the type of PAOs. The substance is intended to be used in propylene homopolymers and copolymers in contact with aqueous, acidic, and low-alcohol (up to 10% ethanol) foods under all temperature conditions. Maximum amount of PAOs use in polypropylene is 10%.
<b>Previous evaluations (by SCF or AFC):</b>	None (new substance)
<b>Available data used for this evaluation:</b>	
Non-toxicity data:	<ul style="list-style-type: none"> <li>- Data on identity</li> <li>- Data on physical and chemical properties</li> <li>- Data on the intended use and authorisation of the substance</li> <li>- Data on migration of the substance</li> <li>- Data on the residual content of the substance</li> </ul>
Toxicity data	<ul style="list-style-type: none"> <li>- gene mutation in bacteria</li> <li>- chromosomal aberrations in cultured mammalian cells</li> <li>- <i>in vivo</i> mouse bone marrow micronucleus studies</li> <li>- subchronic (90-day) oral toxicity studies in rats</li> <li>- acute oral toxicity studies in rats</li> <li>- predictions on absorption, distribution, metabolism and excretion based on the SCF opinion on hydrogenated poly-1-decene</li> </ul>
<b>Evaluation:</b>	<p>The migration of PAOs with low viscosity from a polypropylene sample containing the maximum foreseeable amount of PAOs has been determined into 10% ethanol and using the contact conditions of 2 hours at 66°C followed by 238 hours at 40°C. The migration was not detectable at the level of 0.2 mg/kg. The calculated worst case migration of the main impurities are &lt; 0.014 mg/kg for the monomers 1-octene, 1-decene 1-dodecene and &lt;0.00085 mg/kg for organic chlorides assuming that the organic chlorides migrate at levels proportional to that of the PAOs.</p> <p>The PAOs tested did not induce mutagenicity in bacteria and did not induce chromosome aberrations in cultured mammalian cells. Moreover, representative compounds for the group did not induce</p>

<b>Ref. No.:</b>	<b>60025</b>
<b>Name of the substance:</b>	<b>Hydrogenated homopolymers and/or copolymers made of 1-decene and/or 1-dodecene and/or 1-octene</b>
	<p>micronucleus formation in the bone marrow of mice treated according to OECD-guidelines with high doses. Therefore, the tested substance is thus considered as non-genotoxic. In adequate 90-day oral feeding studies in rats, only marginal effects on some clinical chemistry parameters (not dose related) were observed. The NOAEL was 20000 mg/kg in food (approximately 1200 mg/kg bw/day). NOAELs of more than 1000 mg/kg bw/day were also observed in four 28-day studies with different representatives of polyalphaolefins. Due to a poor gastrointestinal absorption of structurally related compounds including poly-1-decene which is an authorised food additive (Commission, 2003) evaluated by the SCF in 2001 (SCF, 2001) only a low potential for bioaccumulation is predicted for the polyalphaolefins.</p> <p>Based on the toxicological data provided there are no safety concerns.</p>
<b>Conclusion:</b>	
<b>SCF List:</b>	<b>3</b>
<b>Restriction:</b>	<b>None</b>
Remark for Commission:	<p>Migration in fatty foods may exceed the overall migration limit</p> <p>Specifications:</p> <ul style="list-style-type: none"> <li>- Minimum viscosity (at 100°C) = 3.8 cSt</li> <li>- Average Mw&gt;450 Dalton</li> </ul>
Needed data or information	None
<b>References:</b>	<ul style="list-style-type: none"> <li>- Unpublished data submitted by the petitioner in February and September 2006</li> <li>- Commission Directive of the European Parliament and of the Council of 22 December 2003, amending Directive 95/2/EC on food additives other than colours and sweeteners</li> <li>- <a href="http://eur-lex.europa.eu/LexUriServ/site/en/oj/2004/l_024/l_02420040129en00580064.pdf">http://eur-lex.europa.eu/LexUriServ/site/en/oj/2004/l_024/l_02420040129en00580064.pdf</a></li> <li>- Scientific Committee on Food opinion on hydrogenated poly-1-decene, 11 July 2001 <a href="http://europa.eu.int/comm/food/fs/sc/scf/out95_en.pdf">http://europa.eu.int/comm/food/fs/sc/scf/out95_en.pdf</a></li> </ul>

<b>Ref. No.:</b>	<b>72081/10</b>
<b>Name of the substance:</b>	<b>Petroleum Hydrocarbon Resins (hydrogenated)</b>
<b>CAS number:</b>	-
<b>Document reference:</b>	EFSA/AFC/FCM/96-Rev.VIA/72081/10 of September 2006
<b>General information:</b>	According to the petitioner the petroleum hydrocarbon resins (hydrogenated) are used as a polymeric additive mainly in polyethylene and polypropylene but also in adhesives to improve processability, gas/vapour permeability, transparency, stiffness, sealing and adhesion properties.
<b>Previous evaluations (by SCF or AFC):</b>	<p>The substance was first evaluated in 1998 (SCF 1998) on the basis of three mutagenicity studies (performed with the hydrogenated hydrocarbon resin) but was classified in SCF_List 7 on the basis of inadequate migration data. (Needed: In first instance, migration data on the polymeric additive; explanation why the residual amount of the hydrogenated monomers and unpolymerisable components are rather high (in the product), more information on specification, i.e. information on hydrogenation, purification and viscosity of final product).</p> <p>The substance was again evaluated in 2000 (SCF 2000). Because of the high migration to be expected in fatty food the substance was again classified in SCF_List 7, requesting in first instance reduction of the residues of the hydrogenated monomers and non-polymerisable components (by technical processing).</p> <p>In the 3rd evaluation (SCF, 2002), an accumulation study with a representative sample of hydrocarbon resins was requested.</p> <p>In the 4<sup>th</sup> evaluation (EFSA, 2005), based on the data from an accumulation study and the package of toxicological studies available a restriction of 5 mg/kg food was proposed.</p>
<b>Available data used for this evaluation:</b>	
<u>Non-toxicity data:</u>	- See SCF 1998, 2000 and 2003
<u>Toxicity data:</u>	<ul style="list-style-type: none"> <li>- See SCF 1998, 2000, 2003 and EFSA 2005</li> <li>- Pharmacokinetic modelling of the accumulation data on a representative sample of hydrocarbon resins</li> </ul>
<b>Evaluation:</b>	Considering the high migration from a PP with 10% resin into olive oil and 95% ethanol (51 mg/kg and 11.6 mg/kg respectively) the potential accumulation of Petroleum hydrocarbon resins (hydrogenated) in man was re-evaluated using new data from a pharmacokinetic modelling of a bio-accumulation study in rats. The study was performed with [ <sup>3</sup> H]-labelled polycyclopentadiene (REF No 76680) as a representative sample of hydrocarbon resins.

	<p>Following the administration of 14 daily oral doses of 10 mg [<sup>3</sup>H]-polycyclopentadiene/kg, only a low amount of [<sup>3</sup>H]-labelled material was distributed into the tissues (0.69%) with the highest concentrations in liver and mesenteric lymph nodes. The terminal elimination of [<sup>3</sup>H]-material from tissues was slow, particularly from fat and mesenteric lymph nodes. According to the pharmacokinetic modelling of the bio-accumulation study the steady state levels of [<sup>3</sup>H]-polycyclopentadiene would have been attained in mesenteric lymph nodes and in fat after approximately 55 and 80 days of daily dosing, respectively. Based on the estimates of model parameters the dissipation half-lives of most tissues were in the range of 3.6 – 5.9 days, but longer for mesenteric lymph nodes (10.8 days) and for abdominal fat (18.1 days). Based on the pharmacokinetic modelling, the absence of toxicity in the 90-day study and low oral absorption, the accumulation potential of polycyclopentadiene is considered to be negligible. Based on these results and considering the absence of genotoxicity and adverse effects in the 90-day oral rat study (including an in utero exposure phase) up to 1800 mg/kg bw/d (SCF, 2003) the Panel noted that also without a specific restriction for petroleum hydrocarbon resins (hydrogenated) in food the margin of safety with regard to possible adverse effects in man would be large.</p>
<b>Conclusion:</b>	Based on the above-mentioned data the substance is classified:
<b>SCF List:</b>	<b>3</b>
<b>Restriction:</b>	<b>None</b>
<b>Remark for Commission:</b>	<ul style="list-style-type: none"> <li>Migration in fatty foods may exceed overall migration limit</li> <li>Specifications: Petroleum hydrocarbon resins, hydrogenated are produced by the catalytic or thermal polymerisation of dienes and olefins of the aliphatic, alicyclic and monobenzenoid arylalkene types from distillates of cracked petroleum stocks with a boiling range not greater than 220°C, as well as the pure monomers found in these distillation streams, subsequently followed by distillation, hydrogenation and additional processing</li> </ul> <p>Properties</p> <p>Viscosity: &gt; 3 Pa.s at 120 °C.</p> <p>Softening point &gt; 95 °C as determined by ASTM Method E 28-67.</p> <p>Bromine number &lt; 40 (ASTM D1159).</p> <p>The color of a 50% solution in toluene &lt; 11 on the Gardner scale</p> <p>Residual aromatic monomer ≤ 50 ppm</p> <p>These specifications cover also the substances:</p> <ul style="list-style-type: none"> <li>- polycyclopentadiene hydrogenated,</li> <li>- dicyclopentadiene-indene-styrene-alpha.methylstyrene-</li> </ul>

	<p>vinyltoluene-isobutylene, copolymer, hydrogenated</p> <ul style="list-style-type: none"> <li>- alpha-Methylstyrene-styrene, copolymer, hydrogenated</li> <li>- alpha-Methylstyrene-vinyltoluene, copolymer, hydrogenated</li> </ul>
<u>Needed data or information:</u>	
<b>References:</b>	<p>Unpublished data submitted by the petitioner.</p> <p>SCF (1998 and 2000): Opinion of the Scientific Committee on Food on the 11th additional list of monomers and additives for food contact materials (expressed on 19 October 2000)  <a href="http://ec.europa.eu/comm/food/fs/sc/scf/out76_en.pdf">http://ec.europa.eu/comm/food/fs/sc/scf/out76_en.pdf</a></p> <p>SCF (2003): Opinion of the Scientific Committee on Food on the 21st additional list of monomers and additives for food contact materials (expressed on 5 March 2003)  <a href="http://ec.europa.eu/comm/food/fs/sc/scf/out172_en.pdf">http://ec.europa.eu/comm/food/fs/sc/scf/out172_en.pdf</a></p> <p>EFSA (2005) Opinion of the Scientific Panel on food additives, flavourings, processing aids and materials in contact with food (AFC) on a request related to a 9<sup>th</sup> list of substances for food contact materials (adopted on 29 June 2005)  <a href="http://www.europa.eu/science/afc/afc_opinions/1056_en.html">http://www.europa.eu/science/afc/afc_opinions/1056_en.html</a></p>

<b>Ref. No.:</b>	<b>77732</b>
<b>Name of the substance:</b>	Polyethylene glycol (EO=1-30, typically 5) ether of butyl 2-cyano 3-(4-hydroxy-3-methoxyphenyl) acrylate
CAS number:	-
Document reference:	<i>EFSA/AFC/FCM/353-Rev.I/77732 of November 2006</i>
<b>General information:</b>	The test substance is a non-defined mixture. It is intended to be used as an additive in PET plastics at typically 2,000 mg/kg. Its function is to act as a light absorber to protect the packaged food or beverage.
<b>Previous evaluations (by SCF or AFC):</b>	None
<b>Available data used for this evaluation:</b>	
Non-toxicity data:	<ul style="list-style-type: none"> <li>- Data on identity and purity</li> <li>- Data on physical and chemical properties</li> <li>- Data on the intended use and authorisation</li> <li>- Data on hydrolysis in food simulants</li> </ul>

<b>Ref. No.:</b>	<b>77732</b>
<b>Name of the substance:</b>	Polyethylene glycol (EO=1-30, typically 5) ether of butyl 2-cyano 3-(4-hydroxy-3-methoxyphenyl) acrylate
	<ul style="list-style-type: none"> <li>- Migration data for the test substance and for two hydrolysis products, one of which is also an impurity in the test substance</li> <li>- Calculation by mathematical modelling, of the migration levels expected for a dimeric impurity</li> </ul>
<b>Toxicity data:</b>	<ul style="list-style-type: none"> <li>- Gene mutation in bacteria</li> <li>- <i>In vitro</i> mammalian cell gene mutation test</li> <li>- <i>In vitro</i> chromosome aberration test</li> </ul>
<b>Evaluation:</b>	The test substance hydrolyses in aqueous media. Migration of the test substance, as such or monitored via its hydrolysis product polyethoxylated (typically n=6) vanillin, was not detectable with a detection limit of 5 to 9 microg/kg into all simulants. Specific migration of butyl cyanoacetate (an impurity in the test substance and also a hydrolysis product) was detectable at 2.7 microg/kg using worst-case conditions of test. Specific migration of the dimer was estimated using verified migration modelling to be 1 microg/kg.
	Polyethylene glycol (EO=1-30, typically 5) ether of butyl 2-cyano 3-(4-hydroxy-3-methoxyphenyl) acrylate was consistently negative in <i>in vitro</i> genotoxicity studies performed under appropriate quality control.
<b>Conclusion:</b>	Based on the above-mentioned data the substance is classified:
<b>SCF_List:</b>	3
<b>Restriction:</b>	<b>0.05 mg/kg food.</b> <b>Only for the requested use in PET</b>
Remark for Commission:	None
Needed data or information	None
<b>References:</b>	Unpublished data provided by the petitioner, April 2004 and July 2006.

<b>Ref. No.:</b>	<b>77733</b>
<b>Name of the substance:</b>	<b>Polyethyleneglycol (EO=1-30, typically 5) ether of butyl-2-cyano-3-(4-hydroxyphenyl) acrylate</b>
CAS number:	-
Document reference:	<i>EFSA/AFC/FCM/354-Rev.I/77733 of November 2006</i>
<b>General information:</b>	The test substance is a non-defined mixture. It is intended to be used as an additive in PET plastics at typically 2,000 mg/kg. Its

<b>Ref. No.:</b>	77733
<b>Name of the substance:</b>	<b>Polyethyleneglycol (EO=1-30, typically 5) ether of butyl-2-cyano-3-(4-hydroxyphenyl) acrylate</b>
	function is to act as a light absorber to protect the packaged food or beverage.
<b>Previous evaluations (by SCF or AFC):</b>	None
<b>Available data used for this evaluation:</b>	
Non-toxicity data:	<ul style="list-style-type: none"> <li>- Data on identity and purity</li> <li>- Data on physical and chemical properties</li> <li>- Data on the intended use and authorisation</li> <li>- Data on hydrolysis in food simulants</li> <li>- Migration data for the test substance and for two hydrolysis products, one of which is also an impurity in the test substance</li> <li>- Calculation by mathematical modelling, of the migration levels expected for a dimeric impurity</li> </ul>
Toxicity data:	<ul style="list-style-type: none"> <li>- Gene mutation in bacteria</li> <li>- <i>In vitro</i> mammalian cell gene mutation test</li> <li>- <i>In vitro</i> chromosome aberration test</li> </ul>
<b>Evaluation:</b>	<p>The test substance hydrolyses in aqueous media. Migration of the test substance, as such or monitored via its hydrolysis product polyethoxylated (typically n=5) hydroxybenzaldehyde, was not detectable with a detection limit of 5 to 9 microg/kg into all simulants. Specific migration of butyl cyanoacetate (an impurity in the test substance and also a hydrolysis product) was detectable at 3.9 microg/kg using worst-case conditions of test. Specific migration of the dimer was estimated using verified migration modelling to be 1.3 microg/kg.</p> <p>Polyethylene glycol (EO=1-30, typically 5) ether of butyl 2-cyano 3-(4-hydroxyphenyl) acrylate was consistently negative in <i>in vitro</i> genotoxicity studies performed under appropriate quality control.</p>
<b>Conclusion:</b>	Based on the above-mentioned data the substance is classified:
<b>SCF List:</b>	3
<b>Restriction:</b>	<b>0.05 mg/kg food.</b> <b>Only for the requested use in PET</b>
Remark for Commission:	None
Needed data or information	None

<b>Ref. No.:</b>	<b>77733</b>
<b>Name of the substance:</b>	<b>Polyethyleneglycol (EO=1-30, typically 5) ether of butyl-2-cyano-3-(4-hydroxyphenyl) acrylate</b>
<b>References:</b>	Unpublished data provided by the petitioner, April 2004 and July 2006.

<b>Ref. No.:</b>	<b>79985</b>
<b>Name of the substance:</b>	<b>Poly(ethylene propylene)glycol tridecyl ether</b>
CAS number:	61725-89-1 and 65150-81-4
Document reference:	SDS EFSA/AFC/FCM 549-Rev.IA/79985 of September 2006
<b>General information:</b>	According to the petitioner poly(ethylene propylene)glycol tridecyl ether is used as a wetting agent and to improve the stability of polytetrafluorothylene (PTFE) in aqueous dispersion during transport and storage. Maximum addition level is 10% in aqueous PTFE dispersions. The food contact material is glass cloth or metal substrates coated with PTFE. The food contact materials are intended to be used with all types of food at all temperatures under conditions of repeat brief contact e.g. conveyor belts, cooking pans. The substance is not expected to be present in the final food contact material as final materials are sintered at high temperatures above the decomposition temperature of the substance. The decomposition products are also expected to burn off during this process.
<b>Previous evaluations (by SCF or AFC):</b>	None (new substance)
<b>Available data used for this evaluation:</b>	
Non-toxicity data:	<ul style="list-style-type: none"> <li>- Identity of the substance</li> <li>- Chemical and physical properties</li> <li>- Intended use</li> <li>- Authorisation of the substance</li> <li>- Overall migration tests from coatings to water, 10% ethanol, 95% ethanol, iso-octane and MPPO</li> <li>- Determination of the residual content in coatings</li> <li>- Calculation of worst case migration assuming 100% migration of residual content</li> <li>- Information on the sintering temperature and conditions of the test samples</li> <li>- Supporting documents on the analytical method like a calibration curve and typical chromatograms of sample extracts</li> <li>- Data on the presence and identity of any decomposition and/or reaction product of the substance in a final article, manufactured under conditions of minimum and maximum sintering</li> </ul>

<b>Ref. No.:</b>	<b>79985</b>
<b>Name of the substance:</b>	<b>Poly(ethylene propylene)glycol tridecyl ether</b> temperatures.
Toxicity data:	- Gene mutation in bacteria on tridecyl alcohol (CAS No. 27458-92-0)
<b>Evaluation:</b>	<p>The substance has two trade names and CAS No's because there are two different manufacturers but the additive is essentially the same with slightly different average ratios of ethylene oxide and propylene oxide and alcohol branching.</p> <p>The average molecular mass of the substance is 960/970 D. The fraction with MW below 1000D is 56%.</p> <p>Thermogravimetric analysis performed under conditions of manufacture of the food contact material (including the final sintering stage at 410°C) shows that the substance indeed decomposes during the sintering process.</p> <p>Overall migration in water, 10% ethanol, 95% ethanol, iso-octane from test samples consisting of aluminium foil coated on both sides with a PTFE dispersion containing 6% of the additive ranged from 0.9 – 3.6 mg/kg food.</p> <p>Specific migration tests have not been performed.</p> <p>The residual level of poly(ethylene propylene)glycol tridecyl ether in PTFE coatings was found to be 4 mg/kg polymer. The average worst case migration was calculated taking into account the lifetime of a conveyor belt and a coated pan and the total amount of food in contact with the article under real use conditions. For the conveyor belt and the coated pan the average migration was 0.01µg/kg and 0.07µg/kg food respectively. Calculation of the worst case migration was found to be 0.012 mg/6dm<sup>2</sup>. This does not take into account a reduced migration upon repeated use.</p> <p>The presence and identity of the decomposition and/or reaction products of the substance in a sample equivalent to a final article, sintered at 380°C and 420°C was determined. No volatile components were found in the sample extracts. The main components in the extracts were low molecular weight oligomers of poly(ethylene propylene)glycol tridecyl ether. Additional components present at lower levels were also oligomeric ethoxylate, presumably oxidized/degraded starting surfactant. Worst case migration of these oxidized by-products is calculated to be less than 1 µg/kg food or &lt;1 µg/6 dm<sup>2</sup>, taking into account repeated use contact.</p> <p>Two of the monomers for this additive, REF No. 17020 ethylene oxide and REF No. 24010 propylene oxide, have been authorized for the manufacture of plastics intended to come into contact with</p>

<b>Ref. No.:</b>	<b>79985</b>
<b>Name of the substance:</b>	<b>Poly(ethylene propylene)glycol tridecyl ether</b> food, with a restriction of 1 mg/kg in the final article (Directive 2002/72/EC). The third monomer, tridecyl alcohol, is not listed in the positive list of authorised substances of the above mentioned Directive. For the two different branched isomers of tridecyl alcohol, CAS No. 68526-86-3 and 27458 -92-0, which are used by the two manufacturers, only limited genotoxicity data are available; just one negative gene mutation study in bacteria with one of the isomers (CAS No 27458 -92-0). Considering the high temperature at which the final item is sintered, the monomers are not likely to be present in the final product. Therefore no further toxicity data are deemed necessary for the monomers. In addition, the substance polyethyleneglycol tridecyl ether phosphate, REF No. 79600, has been evaluated by EFSA in 2004 (EFSA, 2004) and a SML of 5 mg/kg was assigned.
<b>Conclusion:</b>	Based on the above-mentioned data the substance is classified:
<b>SCF List:</b>	<b>3</b>
<b>Restriction:</b>	<b>0.05 mg/kg food</b> <b>To be used only in PTFE items sintered at high temperatures</b>
Remark for Commission:	Only a method for the determination of the residual content is available.
Needed data or information	None
<b>References:</b>	<ul style="list-style-type: none"> <li>- Unpublished data submitted by the petitioner in September 2005 and May 2006</li> <li>- Commission Directive 2002/72/EC of 6 August 2002 relating to plastic materials and articles intended to come into contact with foodstuffs <a href="http://europa.eu.int/comm/food/food/chemicalsafety/foodcontact/2002-72_en.pdf">http://europa.eu.int/comm/food/food/chemicalsafety/foodcontact/2002-72_en.pdf</a></li> <li>- EFSA, Opinion of the Scientific Panel on food additives, flavourings, processing aids and materials in contact with food (AFC) on a request from the Commission related to a 6th list of substances for food contact materials, adopted on 8/12/2004 <a href="http://www.efsa.eu.int/science/afc/afc_opinions/768_en.html">http://www.efsa.eu.int/science/afc/afc_opinions/768_en.html</a></li> </ul>

<b>Ref. No.:</b>	<b>95858</b>
<b>Name of the substance:</b>	<b>Waxes, paraffinic, refined, derived from petroleum based or synthetic hydrocarbon feedstocks</b>
CAS number:	-
Document reference:	EFSA/AFC/FCM/758-Rev.0A/95858 of November 2006.
<b>General information:</b>	According to the petitioner waxes, paraffinic, refined, derived from petroleum based or synthetic hydrocarbon feedstocks are intended for use as lubricants in all kinds of polymers in amounts up to 3 %. The finished materials are intended for long term storage of food at ambient temperatures. Paraffin waxes are not intended for articles in contact with fatty foods.
<b>Previous evaluations (by SCF or AFC):</b>	None
<b>Available data used for this evaluation:</b>	
Non-toxicity data:	<ul style="list-style-type: none"> <li>- Data on identity</li> <li>- Data on physical/chemical properties</li> <li>- Data on use</li> <li>- Data on authorisation</li> <li>- Data on migration in aqueous food simulants</li> <li>- Data on residual content</li> </ul>
Toxicity data	<ul style="list-style-type: none"> <li>- Gene mutation in bacteria</li> <li>- <i>In vitro</i> mammalian cell gene mutation test</li> <li>- <i>In vitro</i> chromosome aberration test</li> </ul>
<b>Evaluation:</b>	Migration from LDPE manufactured with and without a wax representing the lower range of the specification was tested into water, 3% acetic acid and 10 % ethanol for 10d/40°C by total immersion. No detectable migration related to the wax was found at a detection limit of 15 microg/kg. Actual content of the waxes in the sample used for migration testing was determined to be 2.4%. Analytical methods are properly described and validated. (DMSO) extracts of paraffinic waxes did not show mutagenic potential in bacteria and in mammalian cells and it did not induce chromosome aberrations <i>in vitro</i> . Therefore, based on the three performed <i>in vitro</i> tests there is no evidence for a genotoxic potential of the tested extracts of paraffinic waxes.
<b>Conclusion:</b>	Based on the above-mentioned data the substance is classified:
<b>SCF_List:</b>	<b>3</b>
<b>Restriction:</b>	<b>0.05 mg/kg food</b> <b>Not to be used for articles in contact with fatty foods.</b>

<b>Ref. No.:</b>	<b>95858</b>
<b>Name of the substance:</b>	<b>Waxes, paraffinic, refined, derived from petroleum based or synthetic hydrocarbon feedstocks</b>
Remark for Commission:	Specifications: - Average molecular weight not less than 350 - Viscosity at 100°C min 2.5 cSt - Content of hydrocarbons with carbon number less than 25, not more than 40%(w/w).
Needed data or information	
<b>References:</b>	Unpublished data submitted by the petitioner in July 2006.

## SCIENTIFIC PANEL MEMBERS

Fernando Aguilar, Herman Autrup, Sue Barlow, Laurence Castle, Riccardo Crebelli, Wolfgang Dekant, Karl-Heinz Engel, Nathalie Gontard, David Gott, Sandro Grilli, Rainer Gürtler, John Christian Larsen, Jean-Charles Leblanc, Catherine Leclercq, François Xavier Malcata, Wim Mennes, Maria Rosaria Milana, Iona Pratt, Ivonne Rietjens, Paul Tobback, Fidel Toldrá.

## ACKNOWLEDGEMENTS

The Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food wishes to thank Mona-Lise Binderup, Jean-Claude Lhuguenot, Karla Pfaff, Tjoena Siere, Alida Stolker and Detlef Wölfle for their contribution to the draft opinion.

## LIST OF ABBREVIATIONS:

bw	Body weight
D	Dalton
FRF	Fat (consumption) Reduction Factor
MW	Molecular weight
NOAEL	No observed adverse effect level
OECD	Organisation for Economic Co-operation and Development
PAO	Poly alpha-olefin
PTFE	Polytetrafluoroethylene
QMA	Maximum permitted quantity of the substance in the finished material or article expressed as mg per dm <sup>2</sup> of the surface in contact with food
SML	Specific migration limit
TDI	Tolerable daily intake

## APPENDIX

### DEFINITION OF THE SCF LISTS

The classification into a SCF\_List is a tool used for tackling authorisation dossiers and do not prejudice the management decisions that will be taken on the basis of the scientific opinions of the AFC Panel and in the framework of the applicable legislation

**List 0** Substances, e.g. foods, which may be used in the production of plastic materials and articles, e.g. food ingredients and certain substances known from the intermediate metabolism in man and for which an ADI need not be established for this purpose.

**List 1** Substances, e.g. food additives, for which an ADI (=Acceptable Daily Intake), a t-ADI (=temporary ADI), a MTDI (=Maximum Tolerable Daily Intake), a PMTDI (=Provisional Maximum Tolerable Daily Intake), a PTWI (=Provisional Tolerable Weekly Intake) or the classification "acceptable" has been established by this Committee or by JECFA.

**List 2** Substances for which this Committee has established a TDI or a t-TDI.

**List 3** Substances for which an ADI or a TDI could not be established, but where the present use could be accepted.  
Some of these substances are self-limiting because of their organoleptic properties or are volatile and therefore unlikely to be present in the finished product. For other substances with very low migration, a TDI has not been set but the maximum level to be used in any packaging material or a specific limit of migration is stated. This is because the available toxicological data would give a TDI, which allows that a specific limit of migration or a composition limit could be fixed at levels very much higher than the maximum likely intakes arising from present uses of the additive.  
Depending on the available toxicological studies a restriction of migration into food of 0.05 mg/kg of food (3 mutagenicity studies only) or 5 mg/kg of food (3 mutagenicity studies plus 90-day oral toxicity study and data to demonstrate the absence of potential for bio-accumulation in man) may be allocated.

**List 4** **(for monomers)**  
**4A** Substances for which an ADI or TDI could not be established, but which could be used if the substance migrating into foods or in food simulants is not detectable by an agreed sensitive method.

**4B** Substances for which an ADI or TDI could not be established, but which could be used if the levels of monomer residues in materials and articles intended to come into contact with foodstuffs are reduced as much as possible.

**List 4** **(for additives)**  
Substances for which an ADI or TDI could not be established, but which could be used if the substance migrating into foods or in food simulants is not detectable by an agreed sensitive method.

**List 5** Substances that should not be used.

**List 6** Substances for which there exist suspicions about their toxicity and for which data are lacking or are insufficient.  
The allocation of substances to this list is mainly based upon similarity of structure with that of chemical substances already evaluated or known to have functional groups that indicate carcinogenic or other severe toxic properties.

**6A** Substances suspected to have carcinogenic properties. These substances should not be detectable in foods or in food simulants by an appropriate sensitive method for each substance.

**6B** Substances suspected to have toxic properties (other than carcinogenic). Restrictions may be indicated.

**List 7** Substances for which some toxicological data exist, but for which an ADI or a TDI could not be established. The required additional information should be furnished.

**List 8** Substances for which no or only scanty and inadequate data were available.

**List 9** Substances and groups of substances which could not be evaluated due to lack of specifications (substances) or to lack of adequate description ( groups of substances ).  
Groups of substances should be replaced, where possible, by individual substances actually in use. Polymers for which the data on identity specified in "SCF Guidelines" are not available.

**List W** "Waiting list". Substances not yet included in the Community lists, as they should be considered "new" substances, i.e. substances never approved at national level. These substances cannot be included in the Community lists, lacking the data requested by the Committee.

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**SECTION 1. IDENTIFICATION**

Product name : Plastolyn(TM) R1140 Hydrocarbon Resin

Product code : 1140, P2725801, E2725801, P27258SP, P272580Q, P272580B

**Manufacturer or supplier's details**

Company name of supplier : Eastman Chemical Company

Address : 200 South Wilcox Drive  
Kingsport TN 37660-5280

Telephone : (423) 229-2000

Emergency telephone : CHEMTREC: +1-800-424-9300, +1-703-527-3887 CCN7321

**Recommended use of the chemical and restrictions on use**

Recommended use : Plastic additive

Restrictions on use : None known.

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**SECTION 2. HAZARDS IDENTIFICATION****GHS classification in accordance with 29 CFR 1910.1200**

Combustible dust

**GHS label elements**

Signal Word : Warning

Hazard Statements : If small particles are generated during further processing, handling or by other means, may form combustible dust concentrations in air.

Precautionary Statements : **Disposal:**  
P501 Dispose of contents/ container to an approved waste disposal plant.

**Other hazards**

None known.

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**SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**

Substance / Mixture : Mixture

**Components**

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Chemical name	CAS-No.	Concentration (% w/w)
hydrocarbon resin	68132-00-3	> 99
antioxidant	proprietary	< 1

**SECTION 4. FIRST AID MEASURES**

If inhaled : Move to fresh air.  
Treat symptomatically.  
If symptoms persist, call a physician.

In case of skin contact : Wash off with soap and water.  
If symptoms persist, call a physician.  
Cool skin rapidly with cold water after contact with molten material.  
Do not peel solidified product off the skin.  
Burns must be treated by a physician.

In case of eye contact : In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

If swallowed : Seek medical advice.

Most important symptoms and effects, both acute and delayed : The molten product can cause serious burns.

Notes to physician : Treat symptomatically.

**SECTION 5. FIRE-FIGHTING MEASURES**

Suitable extinguishing media : Water spray  
Dry chemical  
Carbon dioxide (CO2)

Unsuitable extinguishing media : Do not use a solid water stream as it may scatter and spread fire.

Specific hazards during fire fighting : Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.

Hazardous combustion products : No hazardous combustion products are known

Further information : Minimize dust generation and accumulation.

Special protective equipment for fire-fighters : Wear an approved positive pressure self-contained breathing apparatus in addition to standard fire fighting gear.

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### SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

- : Wear appropriate personal protective equipment.  
Local authorities should be advised if significant spillages cannot be contained.

Environmental precautions : Avoid release to the environment.

Methods and materials for containment and cleaning up : Sweep up and shovel into suitable containers for disposal.

---

### SECTION 7. HANDLING AND STORAGE

Advice on protection against fire and explosion : Minimize dust generation and accumulation.

Advice on safe handling : Wash thoroughly after handling.  
Use only in area provided with appropriate exhaust ventilation.  
Minimize dust generation and accumulation.

Conditions for safe storage : Keep tightly closed.

---

### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Ingredients with workplace control parameters

Contains no substances with occupational exposure limit values.

**Engineering measures** : Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.

#### Personal protective equipment

Respiratory protection : Use respiratory protection unless adequate local exhaust ventilation is provided or exposure assessment demonstrates that exposures are within recommended exposure guidelines. Wear respiratory protection when its use is identified for certain contributing scenario.

Hand protection

Remarks : Wear suitable gloves. When handling hot material, use heat resistant gloves.

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Eye protection	:	Safety glasses Wear a face shield when working with molten material.
Skin and body protection	:	Wear suitable protective clothing.
Protective measures	:	Ensure that eye flushing systems and safety showers are located close to the working place.
Hygiene measures	:	Handle in accordance with good industrial hygiene and safety practice.

---

**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

Appearance	:	pellets
Color	:	colorless
Odor	:	odorless
Odor Threshold	:	not determined
pH	:	No data available
Softening point	:	282 °F / 139 °C
Melting point/range		No data available
Boiling point/boiling range	:	No data available
Flash point	:	> 392 °F / > 200 °C Method: Seta closed cup
Evaporation rate	:	not determined
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapor pressure	:	not determined
Relative vapor density	:	No data available
Relative density	:	0.98 (77 °F / 25 °C)
Solubility(ies)		

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Water solubility : negligible  
Partition coefficient: n-octanol/water : No data available  
Autoignition temperature : not determined  
Decomposition temperature : Thermal stability not tested. Low stability hazard expected at normal operating temperatures.  
Viscosity  
Viscosity, dynamic : not determined  
Viscosity, kinematic : 6,632.65 mm<sup>2</sup>/s (248 °F / 120 °C)  
Explosive properties : No data available  
Oxidizing properties : No data available

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**SECTION 10. STABILITY AND REACTIVITY**

Reactivity : None reasonably foreseeable.  
Chemical stability : Stable under normal conditions.  
Possibility of hazardous reactions : Stable  
Conditions to avoid : Minimize dust generation and accumulation.  
Incompatible materials : Strong oxidizing agents  
Hazardous decomposition products : Carbon monoxide  
Carbon dioxide (CO<sub>2</sub>)

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**SECTION 11. TOXICOLOGICAL INFORMATION****Acute toxicity**

Not classified based on available information.

**Product:**

Acute oral toxicity : Remarks: No data available  
Acute inhalation toxicity : Remarks: No data available  
Acute dermal toxicity : Remarks: No data available

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**Skin corrosion/irritation**

Not classified based on available information.

**Serious eye damage/eye irritation**

Not classified based on available information.

**Respiratory or skin sensitization****Skin sensitization**

Not classified based on available information.

**Respiratory sensitization**

Not classified based on available information.

**Germ cell mutagenicity**

Not classified based on available information.

**Carcinogenicity**

Not classified based on available information.

**IARC** No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

**OSHA** No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

**NTP** No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

**Reproductive toxicity**

Not classified based on available information.

**STOT-single exposure**

Not classified based on available information.

**STOT-repeated exposure**

Not classified based on available information.

**Aspiration toxicity**

Not classified based on available information.

**Information on likely routes of exposure****Product:**

Inhalation	: Remarks: None known.
Skin contact	: Remarks: The molten product can cause serious burns.
Eye contact	: Remarks: The molten product can cause serious burns.
Ingestion	: Remarks: None known.

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**SECTION 12. ECOLOGICAL INFORMATION****Ecotoxicity**

No data available

**Persistence and degradability**

No data available

**Bioaccumulative potential**

No data available

**Mobility in soil**

No data available

**Other adverse effects**

No data available

**SECTION 13. DISPOSAL CONSIDERATIONS****Disposal methods**

Waste from residues : Dispose of in accordance with local regulations.

**SECTION 14. TRANSPORT INFORMATION****International Regulations****IATA-DGR**

Not regulated as a dangerous good

**IMDG-Code**

Not regulated as a dangerous good

**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code**

Not applicable for product as supplied.

**Domestic regulation****49 CFR**

Not regulated as a dangerous good

**SECTION 15. REGULATORY INFORMATION****EPCRA - Emergency Planning and Community Right-to-Know****CERCLA Reportable Quantity**

This material does not contain any components with a CERCLA RQ.

**SARA 304 Extremely Hazardous Substances Reportable Quantity**

This material does not contain any components with a section 304 EHS RQ.

**SARA 302 Extremely Hazardous Substances Threshold Planning Quantity**

This material does not contain any components with a section 302 EHS TPQ.

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**SARA 311/312 Hazards**

  : Combustible dust

**SARA 313**                   : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

**California Prop. 65**

This product does not contain any chemicals known to the State of California to cause cancer, birth, or any other reproductive defects.

**The ingredients of this product are reported in the following inventories:**

TCSI                           : On the inventory, or in compliance with the inventory

TSCA                           : All substances listed as active on the TSCA inventory

AICS                           : On the inventory, or in compliance with the inventory

DSL                           : All components of this product are on the Canadian DSL

ENCS                           : On the inventory, or in compliance with the inventory

ISHL                           : On the inventory, or in compliance with the inventory

KECI                           : On the inventory, or in compliance with the inventory

NZIoC                        : On the inventory, or in compliance with the inventory

PICCS                        : On the inventory, or in compliance with the inventory

IECSC                        : On the inventory, or in compliance with the inventory

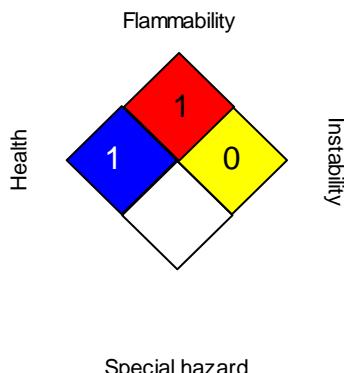
**TSCA list**

No substances are subject to a Significant New Use Rule.

No substances are subject to TSCA 12(b) export notification requirements.

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**SECTION 16. OTHER INFORMATION****Further information**

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Date of first issue: 09/06/2016**NFPA 704:****HMIS® IV:**

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "\*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

**Full text of other abbreviations**

AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

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The information provided in this Material Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

US / Z8

## 1. Identification

<b>Product identifier</b>	<b>R-1095S</b>
<b>Other means of identification</b>	None.
<b>Recommended use</b>	Hydrogenated cycloaliphatic hydrocarbon resin which has been developed specifically as a tackifier for commonly used elastomers in adhesives.
<b>Recommended restrictions</b>	None known.
<b>Manufacturer/Importer/Supplier/Distributor information</b>	
<b>Manufacturer</b>	Resinall Corp
<b>Address</b>	302 N. Water Street Severn, NC 27877
<b>E-Mail</b>	sds@ergon.com
<b>Hours of Operation</b>	8:00 a.m. - 5:00 p.m. (U.S. Eastern Time)
<b>Emergency Number</b>	1-800-634-6475
<b>CHEMTREC</b>	1-800-424-9300

## 2. Hazard(s) identification

<b>Physical hazards</b>	Not classified.
<b>Health hazards</b>	Not classified.
<b>Environmental hazards</b>	Not classified.
<b>OSHA defined hazards</b>	Combustible dust
<b>Label elements</b>	
<b>Hazard symbol</b>	None.
<b>Signal word</b>	Warning
<b>Hazard statement</b>	May form combustible dust concentrations in air.
<b>Precautionary statement</b>	
<b>Prevention</b>	Prevent dust accumulation to minimize explosion hazard. Keep away from heat/sparks/open flames/hot surfaces. - No smoking. Keep container tightly closed. Ground/bond container and receiving equipment. Observe good industrial hygiene practices.
<b>Response</b>	Take off contaminated clothing and wash before reuse. In case of fire: Use appropriate media to extinguish.
<b>Storage</b>	Store away from incompatible materials.
<b>Disposal</b>	Dispose of waste and residues in accordance with local authority requirements.
<b>Hazard(s) not otherwise classified (HNOC)</b>	None known.
<b>Supplemental information</b>	Not applicable.

## 3. Composition/information on ingredients

### Mixtures

Chemical name	Common name and synonyms	CAS number	%
HYDROGENATED DEBENZENIZED LIGHT STEAM-CRACKED NAPHTHA POLYMERS		68132-00-3	>99
STABILIZER	Proprietary		<1

All concentrations are in percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume.

## 4. First-aid measures

<b>Inhalation</b>	Move to fresh air. Call a physician if symptoms develop or persist.
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<b>Skin contact</b>	Wash off with soap and water. Get medical attention if irritation develops and persists.
<b>Eye contact</b>	Do not rub eyes. Rinse with water. Get medical attention if irritation develops and persists.
<b>Ingestion</b>	Rinse mouth. Get medical attention if symptoms occur.
<b>Most important symptoms/effects, acute and delayed</b>	Dusts may irritate the respiratory tract, skin and eyes.
<b>Indication of immediate medical attention and special treatment needed</b>	Treat symptomatically.
<b>General information</b>	Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

## 5. Fire-fighting measures

<b>Suitable extinguishing media</b>	Water fog. Foam. Dry chemical powder. Carbon dioxide (CO <sub>2</sub> ). Apply extinguishing media carefully to avoid creating airborne dust. Avoid high pressure media which could cause the formation of a potentially explosive dust-air mixture.
<b>Unsuitable extinguishing media</b>	Do not use water jet as an extinguisher, as this will spread the fire.
<b>Specific hazards arising from the chemical</b>	Explosion hazard: Avoid generating dust; fine dust dispersed in air in sufficient concentrations and in the presence of an ignition source is a potential dust explosion hazard. During fire, gases hazardous to health may be formed. Carbon monoxide and carbon dioxide.
<b>Special protective equipment and precautions for firefighters</b>	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
<b>Fire fighting equipment/instructions</b>	In case of fire and/or explosion do not breathe fumes. Move containers from fire area if you can do so without risk.
<b>Specific methods</b>	Use standard firefighting procedures and consider the hazards of other involved materials.
<b>General fire hazards</b>	May form combustible dust concentrations in air.

## 6. Accidental release measures

<b>Personal precautions, protective equipment and emergency procedures</b>	Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Use only non-sparking tools. Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Wear appropriate protective equipment and clothing during clean-up. Use a NIOSH/MSHA approved respirator if there is a risk of exposure to dust/fume at levels exceeding the exposure limits. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8 of the SDS.
<b>Methods and materials for containment and cleaning up</b>	Eliminate all ignition sources (no smoking, flares, sparks, or flames in immediate area). Take precautionary measures against static discharge. Use only non-sparking tools. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Collect dust using a vacuum cleaner equipped with HEPA filter. Stop the flow of material, if this is without risk.
	Large Spills: Wet down with water and dike for later disposal. Shovel the material into waste container. Following product recovery, flush area with water.
	Small Spills: Sweep up or vacuum up spillage and collect in suitable container for disposal.
	Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS. Avoid discharge into drains, water courses or onto the ground.

## Environmental precautions

## 7. Handling and storage

<b>Precautions for safe handling</b>	Minimize dust generation and accumulation. Avoid significant deposits of material, especially on horizontal surfaces, which may become airborne and form combustible dust clouds and may contribute to secondary explosions. Routine housekeeping should be instituted to ensure that dusts do not accumulate on surfaces. Dry powders can build static electricity charges when subjected to the friction of transfer and mixing operations. Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres. Keep away from heat/sparks/open flames/hot surfaces. - No smoking. Explosion-proof general and local exhaust ventilation. Avoid prolonged exposure. Wear appropriate personal protective equipment. Observe good industrial hygiene practices.
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**Conditions for safe storage, including any incompatibilities** Keep containers tightly closed in a dry, cool and well-ventilated place. Store away from incompatible materials (see Section 10 of the SDS). Maximum storage temperature 49 °C.

## 8. Exposure controls/personal protection

### Occupational exposure limits

The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit. At this time, the other constituents have no known exposure limits.

#### US. OSHA Table Z-3 (29 CFR 1910.1000)

Components	Type	Value	Form
DUST	TWA	5 mg/m3	Respirable fraction.
		15 mg/m3	Total dust.
		50 mppcf	Total dust.
		15 mppcf	Respirable fraction.

#### US. ACGIH Threshold Limit Values

Components	Type	Value	Form
DUST	TWA	3 mg/m3	Respirable particles.

### Biological limit values

### Appropriate engineering controls

No biological exposure limits noted for the ingredient(s).

Explosion-proof general and local exhaust ventilation. Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level. If engineering measures are not sufficient to maintain concentrations of dust particulates below the Occupational Exposure Limit (OEL), suitable respiratory protection must be worn.

### Individual protection measures, such as personal protective equipment

<b>Eye/face protection</b>	Goggles/face shield are recommended.
<b>Skin protection</b>	
<b>Hand protection</b>	Wear appropriate chemical resistant gloves. Nitrile or butyl rubber gloves are recommended.
<b>Other</b>	Wear appropriate clothing to prevent any possibility of skin contact with solutions containing 10% or more of this chemical.
<b>Respiratory protection</b>	When workers are facing concentrations above the exposure limit they must use appropriate certified respirators.
<b>Thermal hazards</b>	Wear appropriate thermal protective clothing, when necessary.

**General hygiene considerations** When using, do not eat, drink or smoke. Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

## 9. Physical and chemical properties

### Appearance

Solid.

### Physical state

Solid - May be molten liquid.

### Form

Powder. Flakes.

### Color

Clear to Whitish

### Odor

Mild Odor

### Odor threshold

Not available.

### pH

Not available.

### Melting point/freezing point

194 - 212 °F (90 - 100 °C)

### Initial boiling point and boiling range

> 500 °F (> 260 °C)

### Flash point

>= 375.1 °F (>= 190.6 °C) Cleveland Open Cup

### Evaporation rate

Not available.

### Flammability (solid, gas)

Not available.

## Upper/lower flammability or explosive limits

<b>Flammability limit - lower (%)</b>	Not available.
<b>Flammability limit - upper (%)</b>	Not available.
<b>Explosive limit - lower (%)</b>	Not available.
<b>Explosive limit - upper (%)</b>	Not available.
<b>Vapor pressure</b>	nil @ 200°F
<b>Vapor density</b>	0 @ 77°F
<b>Relative density</b>	Not available.
<b>Solubility(ies)</b>	
<b>Solubility (water)</b>	Negligible
<b>Partition coefficient (n-octanol/water)</b>	Not available.
<b>Auto-ignition temperature</b>	Not available.
<b>Decomposition temperature</b>	Not available.
<b>Viscosity</b>	Not available.
<b>Other information</b>	
<b>Explosive properties</b>	Not explosive.
<b>Oxidizing properties</b>	Not oxidizing.
<b>Percent volatile</b>	0 %
<b>Specific gravity</b>	1.038 @ 77°F

## 10. Stability and reactivity

<b>Reactivity</b>	The product is stable and non-reactive under normal conditions of use, storage and transport
<b>Chemical stability</b>	Material is stable under normal conditions.
<b>Possibility of hazardous reactions</b>	No dangerous reaction known under conditions of normal use.
<b>Conditions to avoid</b>	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. Contact with incompatible materials. Minimize dust generation and accumulation.
<b>Incompatible materials</b>	Strong oxidizing agents.
<b>Hazardous decomposition products</b>	No hazardous decomposition products are known.

## 11. Toxicological information

### Information on likely routes of exposure

<b>Inhalation</b>	Dust may irritate respiratory system. Prolonged inhalation may be harmful.
<b>Skin contact</b>	Dust or powder may irritate the skin.
<b>Eye contact</b>	Dust may irritate the eyes.
<b>Ingestion</b>	May cause discomfort if swallowed.
<b>Symptoms related to the physical, chemical and toxicological characteristics</b>	Dusts may irritate the respiratory tract, skin and eyes.

### Information on toxicological effects

<b>Acute toxicity</b>	Not expected to be acutely toxic.
<b>Skin corrosion/irritation</b>	Prolonged skin contact may cause temporary irritation.
<b>Serious eye damage/eye irritation</b>	Direct contact with eyes may cause temporary irritation.

### Respiratory or skin sensitization

<b>Respiratory sensitization</b>	Not a respiratory sensitizer.
<b>Skin sensitization</b>	This product is not expected to cause skin sensitization.

**Germ cell mutagenicity** No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.

**Carcinogenicity** Not classifiable as to carcinogenicity to humans.

**IARC Monographs. Overall Evaluation of Carcinogenicity**

Not listed.

**OSHA Specifically Regulated Substances (29 CFR 1910.1001-1052)**

Not regulated.

**US. National Toxicology Program (NTP) Report on Carcinogens**

Not listed.

**Reproductive toxicity** This product is not expected to cause reproductive or developmental effects

**Specific target organ toxicity** Not classified.

**- single exposure**

**Specific target organ toxicity** Not classified.

**- repeated exposure**

**Aspiration hazard** Not an aspiration hazard.

**Chronic effects** Prolonged inhalation may be harmful.

## 12. Ecological information

**Ecotoxicity** The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

**Persistence and degradability** No data is available on the degradability of this product.

**Bioaccumulative potential** No data available.

**Mobility in soil** No data available.

**Other adverse effects** No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

## 13. Disposal considerations

**Disposal instructions** Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Dispose of contents/container in accordance with local/regional/national/international regulations.

**Local disposal regulations**

Dispose in accordance with all applicable regulations.

**Hazardous waste code**

The waste code should be assigned in discussion between the user, the producer and the waste disposal company.

**Waste from residues / unused products** Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

**Contaminated packaging**

Since emptied containers may retain product residue, follow label warnings even after container is emptied. Empty containers should be taken to an approved waste handling site for recycling or disposal.

## 14. Transport information

**DOT**

**UN number** UN3257

**UN proper shipping name** Elevated temperature liquid, n.o.s. (HYDROGENATED DEBENZENIZED LIGHT STEAM-CRACKED NAPHTHA POLYMERS)

**Transport hazard class(es)**

**Class** 9

**Subsidiary risk** -

**Label(s)** 9

**Packing group** III

**Environmental hazards**

**Marine pollutant** No

**Special precautions for user** Read safety instructions, SDS and emergency procedures before handling.

**Special provisions** IB1, T3, TP3, TP29

**Packaging exceptions** None

**Packaging non bulk** None

**Packaging bulk** 247

**IATA**

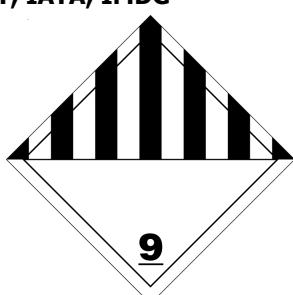
<b>UN number</b>	UN3257
<b>UN proper shipping name</b>	Elevated temperature liquid, n.o.s. (HYDROGENATED DEBENZENIZED LIGHT STEAM-CRACKED NAPHTHA POLYMERS)
<b>Transport hazard class(es)</b>	
<b>Class</b>	9
<b>Subsidiary risk</b>	-
<b>Packing group</b>	Not available.
<b>Environmental hazards</b>	No
<b>ERG Code</b>	9L
<b>Special precautions for user</b>	Read safety instructions, SDS and emergency procedures before handling.
<b>Other information</b>	
<b>Passenger and cargo aircraft</b>	Forbidden
<b>Cargo aircraft only</b>	Forbidden

**IMDG**

<b>UN number</b>	UN3257
<b>UN proper shipping name</b>	ELEVATED TEMPERATURE LIQUID, N.O.S. (HYDROGENATED DEBENZENIZED LIGHT STEAM-CRACKED NAPHTHA POLYMERS)
<b>Transport hazard class(es)</b>	
<b>Class</b>	9
<b>Subsidiary risk</b>	-
<b>Packing group</b>	III
<b>Environmental hazards</b>	
<b>Marine pollutant</b>	No
<b>EmS</b>	F-A, S-P
<b>Special precautions for user</b>	Read safety instructions, SDS and emergency procedures before handling.

**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code**

**DOT; IATA; IMDG**

**Further information**

If the product is shipped at temperatures below 212°F (100°C), it is not regulated for transport by ground, air or vessel.

## 15. Regulatory information

**US federal regulations** This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard 29 CFR 1910.1200.

**TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)**

Not regulated.

**CERCLA Hazardous Substance List (40 CFR 302.4)**

Not listed.

**SARA 304 Emergency release notification**

Not regulated.

**OSHA Specifically Regulated Substances (29 CFR 1910.1001-1052)**

Not regulated.

## **Superfund Amendments and Reauthorization Act of 1986 (SARA)**

### **SARA 302 Extremely hazardous substance**

Not listed.

### **SARA 311/312**

#### **Hazardous chemical**

Yes

#### **Classified hazard categories**

Combustible dust

### **SARA 313 (TRI reporting)**

Not regulated.

## **Other federal regulations**

### **Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List**

Not regulated.

### **Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)**

Not regulated.

### **Safe Drinking Water Act (SDWA)**

Not regulated.

## **US state regulations**

### **California Proposition 65**

California Safe Drinking Water and Toxic Enforcement Act of 2016 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins. For more information go to [www.P65Warnings.ca.gov](http://www.P65Warnings.ca.gov).

## **International Inventories**

<b>Country(s) or region</b>	<b>Inventory name</b>	<b>On inventory (yes/no)*</b>
Australia	Australian Inventory of Chemical Substances (AICS)	Yes
Canada	Domestic Substances List (DSL)	Yes
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	Yes
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	Yes
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	Yes
Korea	Existing Chemicals List (ECL)	Yes
New Zealand	New Zealand Inventory	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	Yes
Taiwan	Taiwan Chemical Substance Inventory (TCSI)	Yes
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	Yes

\*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

## **16. Other information, including date of preparation or last revision**

**Issue date** 10-29-2018

**Revision date** 01-06-2022

**Version #** 02

**Further information** Refer to NFPA 654, Standard for the Prevention of Fire and Dust Explosions from the Manufacturing, Processing, and Handling of Combustible Particulate Solids, for safe handling.

**NFPA ratings**  
Health: 1  
Flammability: 1  
Instability: 0

**Disclaimer**

The information provided in this Safety Data Sheet is correct to the best of our knowledge information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text. The information in the sheet was written based on the best knowledge and experience currently available.

**Revision information**

Fire-fighting measures: Specific hazards arising from the chemical  
Ecological information: Ecotoxicity