

Statement

Product Regulatory Information Sheet

CAS	EC N°	REACH N°	CODE
8002-74-2	232-315-6	01-2119488076-30-0008	77243

PARASUR 150 SOLIDA

ORIGIN

The substance is a petroleum product obtained by the dewaxing solvent of the refining of lubricating oil and finalized by a purification (hydrogenation treatment).

REACH COMPLIANCE DECLARATION

This product meets requirements with European REACH (Regulation 1907/2006 and its subsequent amendments).

REACH RESTRICTION

This product does not contain any substance included in Annex XVII of REACH restrictions. Visit the link for more information.
<https://echa.europa.eu/es/substances-restricted-under-reach/-/dislist/details/0b0236e1807e2c14>

REACH SVHC

This product does not contain any substance considered of very high concern (SVHC) above 0.1%. In case of any modification about the status of this sentence, Cepsa Comercial Petróleo, SAU would inform accordingly in its Safety Data Sheets.
More over does not contained substances classified as CMR.

BSE - TSE / GMO

Regulations concerning BSE / TSE apply to animal derived products. This product is derived from non-animal based material and therefore no further certification is mandatory.

KOSHER / HALAL

The origin of this product is petrochemical. Manufactured at petrochemical dedicated facilities. No biological material, flesh or other parts of swine, are used as feedstock, catalyst or additive.

The product does not contain animal fats or animal derivatives. Animal material, vegetable or alcoholic beverages are not involved during the production of any of its component. Incidental contact is highly improbable.

Certificates are available upon request.

NANOPARTICLE

According to the REACH definition: Nanomaterials are chemical substances or materials whose particles are between 1 and 100 nanometres (nm) in size in at least one dimension, therefore the product does not meet the definition and does not contain nanoparticles.

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ROHS

This product complies with the new Directive (EU) 2015/863 amending Annex II of EU RoHS 2 (Directive 2011/65/EU) (which is known as RoHS 3) and its subsequent amendments up to the date of this document.

Content of heavy metals and restricted substances are shown in the Annex.

See table "Regulation for Restriction of Hazardous Substances"

ABSENCE OF SUBSTANCES

The substances listed in annex table (Substance absence) are not used as raw materials or additives. Thus the presence of those substances is highly unlikely.

Additionally Cepsa Comercial Petróleo, SAU does not routinely test for these substances in our products or include limits in product specifications.

See annexed "Substances absence"

METAL CONTENT

See annexed table "Metal Content".

CONFLICT MINERAL COMPLIANCE

Materials coming from conflict minerals are not used in its manufacture process, neither intentionally added.

Within the scope of this declaration, Conflict Minerals i.e. are: Tantalum, Tin, Tungsten and Gold, sourced from The Democratic Republic of Congo, Sudan, Uganda, Rwanda, Burundi, United Republic of Tanzania, Zambia, Angola or the Central African Republic.

MINERAL OILS

(MOAH, MOSH, POSH ...) are not added voluntarily in the manufacturing process, the product has traces due to the nature of its origin. Performed analysis of PAHs in specific samples.

PAHs analysis available upon request.

AROMATICS CONTENT

See annexed table, Aromatics Contents

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FOOD CONTACT

• Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 repealing Directives 80/590 / EEC and 89/109 / EEC, on materials and objects intended to enter in contact with food.

• Commission Regulation (EC) No 2023/2006 of December 22, 2006, on good manufacturing practices for materials and objects intended to come into contact with food.

• Commission Regulation (EC) No 1895/2005 of November 18, 2005 regarding the restriction on the use of certain epoxy derivatives in materials and objects intended to come into contact with food products.

• Commission Regulation (EU) No 10/2011 of January 14, 2011 on plastic materials and objects intended to come into contact with food. And its amendments up to the date of this document.

• F D A :

PART 175-Indirect food additives: Adhesives and components of coatings.

21CFR-Section- 175.105- Adhesives

21CFR Section- 175.300. Resinous and polymeric coatings

21CFR Section- 175.320. Resinous and polymeric coatings for polyolefin films

PART 176 -- Indirect food additives: Paper and Paperboard components.

21CFR Section-176.170 Components of paper and paperboard in contact with aqueous and fatty foods

21CFR Sec. 176.180 Components of paper and paperboard in contact with dry food.

21CFR 176.200 Defoaming agents used in coatings

21CFR 176.210 Defoaming agents used in the manufacture of paper and paperboard.

PART 178 -- Indirect food additives: Adjuvants, Production Aids, and Sanitizers. Subpart D -- Certain Adjuvants and Production Aids

21CFR Sec. 178.3710 Petroleum wax.

• B f R :

Complies with the recommendations for food contact materials of the Institute for Risk Assessment- (Bundesinstitut für Risikobewertung) – BfR

FOOD ADDITIVE

• Royal Decree 1601/2010 of November 26, 2010 Published in: "BOE" no. 305, of December 16, 2010, pages 103888 to 103893 (6 pages) approving the basic materials for the manufacture of chewing gum base gum or chewing gum.

See annexed table Purity criteria.

FOOD ADDITIVE - USA

FDA: Subchapter B -Food for Human consumption- Part 172 21 CFR-Section 172.886-FDA-Food additives permitted for direct addition to food for human consumption.

Section 172.886: Petroleum wax may be safely used in or on food.

See annexed table, Food Additive

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FOOD ALLERGENS

It does not contain allergens, substances or products that cause allergies or intolerances in accordance with the following legal provisions:

- Annex V of Royal Decree 1334/1999, of July 31, and its subsequent modifications.

- Annex II of Regulation 1169/2011 of October 25, 2011, on the food information provided to the consumer and its subsequent modifications.

- Directive 2000/13 / EC of the European Parliament and of the Council of March 20, 2000 and subsequent amendments.

FSSC 22000

When supplied and stored in liquid form, the recommended storage temperature is 10°C above the freezing point of the indicated product.

Under proper storage and handling conditions, 100 days for liquid paraffin waxes.

When supplied and stored in solid form, all products should be kept in a covered warehouse and well protected from heat, dust and light. Under such conditions they will withstand any ambient temperature. Solid paraffin waxes have a shelf life of 5 years under the above storage conditions.

COSMETIC COMPLIANCE REGULATION

Regulation (EC) No 1223/2009 of the European Parliament and of the Council of November 30, 2009 on cosmetic products (recast version).

EU PHARMACOPEIA COMPLIANCE

See annexed table EU Pharmacopeia: Monograph Hardparaffin (Purity Tests)

PHARMACOPEIA USA COMPLIANCE

See annexed table USP/US Monograph Paraffin

UK REACH

CEPSA Química has appointed an only representative to fulfill the registration of this substance as required by UK REACH, for which a Downstream User import notification have been submitted:

DUIN No: UK-20-0621962546-1-0000

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DUIN No: UK-20-0621962546-1-0000

KKDIK REGISTRATION

CEPSA Química has appointed an only representative to fulfill the registration of this substance as required by KKDIK Regulation (30105) of the Turkish Republic, for which a the pre-registration have been carried out:

Pre-registration number: 05-0000327509-61-0000

KKDIK REGISTRATION

CEPSA Química has appointed an only representative to fulfill the registration of this substance as required by KKDIK Regulation (30105) of the Turkish Republic, for which a the pre-registration have been carried out:

Pre-registration number: 05-0000327509-61-0000

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ANNEX

Aromatics content

Based on the anual analyses in Eurofin CRO these are the results

Parameter	Method	Result	Unit	Date
Benzene	GC-MS	<1	mg/kg	12/03/2021
Toluene	GC-MS	<1	mg/kg	12/03/2021
Ethylbenzene	GC-MS	<1	mg/kg	12/03/2021
Styrene	GC-MS	<1	mg/kg	12/03/2021
Xylene, m-, p-	GC-MS	<1	mg/kg	12/03/2021
Xylene, o-	GC-MS	<1	mg/kg	12/03/2021

Annex I, Plastics Food Contact Regulation 10/2011/EU

Specific requirements according to Annex I, Regulation (EU) No 10/2011

Parameter	Result	Unit	Limit
Viscosity at 100 °C	3,9	cSt	> 2,5
Average molecular weight	382	Da	>350
Content of hydrocarbons with Carbon number less than 25		% (w/w)	<40
Specific Migration Limit (SML)		mg/kg	0,05
Not to be used for articles in contact with fatty foods for which simulant D is laid down.			

Food Additive

The product complies with Subchapter B: Food for Human consumption- Part 172 21 CFR-Section 172.886-FDA-Food additives permitted for direct addition to food for human consumption. Section 172.886: Petroleum wax may be safely used in of on food.

Parameter	Method	Result	Unit	Limit	Date
280-289	UV-Absorption (FDA-21 CFR §172.886)	0.006	nm	< 0,15	12/03/2021
360-400	UV-Absorption (FDA-21 CFR §172.886)	0.001	nm	<0,02	12/03/2021
300-359	UV-Absorption (FDA-21 CFR §172.886)	0.003	nm	< 0,08	12/03/2021
290-299	UV-Absorption (FDA-21 CFR §172.886)	0.004	nm	< 0,12	12/03/2021

Metal content

Although not routinely analyzed, based on the analyses these are the results of a spot sample.

Parameter	Method	Result	Unit
Hg	ICP-MS	<0,01	mg/kg
Fe	ICP-MS	<5	mg/kg
Sn	ICP-MS	<1	mg/kg
Cr	ICP-MS	<0,1	mg/kg
As	ICP-MS	<0,1	mg/kg

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Cd	ICP-MS	<0,01	mg/kg
Pb	ICP-MS	<0,1	mg/kg
Cu	ICP-MS	<1	mg/kg

Pharmacopeia EU Monograph "Hardparafin"

Based on the anual analyses in Eurofin CRO these are the results

Parameter	Method	Result	Unit	Date
Sulphur	DIN EN ISO 20884	5.0	mg/kg	12/03/2021
Acidity or Alkalinity		Meets the requirements		12/03/2021
Polycyclic aromatic hydrocarbons		Meets the requirements		12/03/2021
Sulphates (EP 2.4.13)		<150	ppm	12/03/2021
Ash	775 °c DIN EN ISO 6245	<0.001	%	12/03/2021

USP/NF Farmacopeia Monografía "Paraffin"

Based on the anual analyses in Eurofin CRO these are the results

Parameter	Method	Result	Unit	Date
Limit of Polycyclic aromatic Hydrocarbons		Meets the requirements		12/03/2021
Limit of Sulphur compounds		Meets the requirements		12/03/2021
Alkalinity		Meets the requirements		12/03/2021
Acidity		Meets the requirements		12/03/2021
Readily carbonizable substances		Meets the requirements		12/03/2021

Parameter	Method	Result	Unit	Limit
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Regulation for Restriction of Hazardous Substances

In relation to the substances of the ROHS regulation, the information is detailed in the following table

Parameter	Limits
Cr	< 0,1%
Cd	< 0,01%
Hg	< 0,1%

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Pb	< 0,1%
Polybrominated biphenyls (PBB)	< 0,1%
Polybrominated diphenyl ethers (PBDE)	< 0,1%
Bis(2-Ethylhexyl) phthalate (DEHP)	< 0,1%
Benzyl butyl phthalate (BBP)	< 0,1%
Dibutyl phthalate (DBP)	< 0,1%
Diisobutyl phthalate (DIBP)	< 0,1%

Substances absence

Based on the composition and production process the presence of the following substances is considered unlikely.

Parameter

Persistent Organic Pollutants (COP) in accordance with Annexes A, B and C of the Stockholm Convention

Morpholine (CAS No.: 110-91-8 / Tetrahydro-1,4-oxazine, diethylene oximide) and / or its derivatives.

Substance of high concern (SVHC), contained in the candidate list "Candidate List". Published by ECHA in its decisions up to the date of publication of this document.

Nitrosamines

Formaldehyde and its derivatives

Phenol and its derivatives.

Dioxins or furans

Isocyanates and their derivatives.

Titanium Acetyl Acetone (TAA).

Benzonfenone and its derivatives (Benzophenone - CAS 119-61-9, 4-methylbenzophenone - CAS 134-84-9, 4-Hydroxybenzophenone - CAS 1137-42-4, etc.).

Post-consumer recycled waste

CMR substances (Carcinogenic, Mutagenic and Toxic for Reproduction), as well as substances and chemicals included in the Proposition 65 list.

Latex and / or Natural Rubbers

Bis (2,3-epoxypropyl) 2,2-bis (4-hydroxyphenyl) propane called "BADGE", 1895/2005 according to Regulation 1895/2005.

Novolac glycidyl ether, called "NOGE", according to Regulation 1895/2005.

Substances and / or Phytosanitary treatments, Pesticides or Pesticides (Fungicides, Disinfectants, Algaecides, Herbicides, Insecticide, Acaricide, Rodenticides, Phytoregulators ...)

Category of polybromodiphenylethers (PBDE)CAS 41318-75-6CAS 5436-43-1CAS 243982-82-3CAS 60348-60-9CAS 189084-64-8CAS 67888-98-6CAS 68631-49-2CAS 207122-15-4CAS 207122-16-5CAS 1163-19-5

Category of hexabromocyclododecanes (HBCDD)CAS 134237-50-6CAS 134237-51-7CAS134237-52-8

Category of tetrabromobisphenol A and derivativesCAS 79-94-7CAS 70156-79-5CAS 4162-45-2CAS 25327-89-3CAS 3072-84-2CAS 21850-44-2

Category of bromed phenols an derivateCAS 118-79-6CAS 615-58-7CAS 106-41-2CAS 608-33-3CAS 39635-79-5CAS 70156-79-5

Substances (PBT) or (mPmB - vPvB).

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Perfluorocarbons (PFCs)

Substances that deplete the ozone layer in accordance with the Montreal Protocol

Photo-initiators, including isopropyl-thioxanthone (ITX) and others

Other UV curing components

Triclosan

Category of new retarders of bromed flameCAS 126-72-7CAS 32588-76-4CAS

25495-98-1CAS 26040-51-7CAS 183658-27-7CAS 3296-90-0

Elamine

Acrylamide

Vinyl Chloride Monomers (CAS 45-01-4).

Polychlorinated biphenyls or polychlorinated biphenyls (PCBs or PCBs)

Akylphenols (eg propylphenol, butylphenol, amylphenol, heptylphenol, octylphenol, nonylphenol.

Perfluoroalkyl and polyfluoroalkyl substances (PFAS)

Halogens (F, Cl, Br; including salts, catalysts, monomers, additives, solvents, etc.)

Phthalates or their derivatives

Bisphenol or its derivatives (Bisphenol A, AP, AF, B, BP, C, E, F, G, M, S, P, PH, TMC and Z)

Anthraquinone

Substances that act on Estrogens (Xenohormones / Endocrine Disruptors)

Musk

Azodicarbonamide and Semicarbazide

Asbestos

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