

1. DESIGNATION

Product name	: PROPYLENE GLYCOL
CAS No.	: 57-55-6
EC no.	: 200-338-0
Trade name	: RADIANOL 4710
Origin	: vegetable
Qualifications	: Ecocert; Halal.

2. Worldwide status

2.1. Registration status

Chemical inventories	: Listed on AICS, DSL, ECST, ENCS, IECSC, KECL, NZIoC, PICCS, TSCA, EC inventories.
Chem. inventories legend	: AICS = Australian Inventory of Chemical Substances DSL = Canadian Domestic Substances List ECST = Existing Chemical Substances Inventory of Taiwan ENCS = Japanese Existing and New Chemicals Substances List IECSC = Inventory of Existing Chemicals Substances in China KECL = Korean Existing Chemical List NZIoC = New Zealand Inventory of Chemicals PICCS = Philippine Inventory of Chemicals and Chemical Substances TSCA = USA Toxic Substances Control Act EC inventories = European Community inventories of chemicals (EINECS/ELINCS/NLP/REACH)
GADSL (automotive)	: This product does not contain any declarable substance; all listed substances are below the reportable threshold (0.1%w, unless otherwise specified). This statement includes all substances listed on the Reference List including the update of 2015.
IEC 62474 (electrotechnic)	: This product is containing no declarable substance above the reportable threshold. This statement includes all substances listed on the update released on July 15, 2015 (substance list D9.00).

2.2. Food and Feed Legislation

Suitability for use (food/feed)	: This product has not been manufactured or conditioned under the HACCP principles. Use or application in foodstuffs might be subject to regulatory limitations.
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2.3. Health and Beauty Legislation

INCI Name	: PROPYLENE GLYCOL
IFRA Transparency List	: Listed by CAS RN.

3. EUROPE EU MEMBER COUNTRIES

3.1. Legislative status

REACH registration No	: 01-2119456809-23
SVHC (Substances of Very High Concern)	: This product is free from any substance identified as "SVHC" (Substances of Very High Concern) which are referred to in the "candidate list" as published by ECHA in the context of the REACH Regulation (EC) No 1907/2006 above of the 0.1% w/w threshold. This statement

CN code (Goods code)	: includes all substances listed by ECHA including the update of January 12th, 2017. : 2905320000
EU Nanomaterials	: This product complies to the provisions of Article 16 of EU Regulation 1223/2009 about nanomaterials, as far as applicable; no 'nano' labelling is required. This product complies to the provisions of Article 18 of EU Regulation 1169/2011 about the List of ingredients, as far as applicable; no 'nano' labelling is required. This product is free of any declarable substance in nanoparticulate state according to the provisions of the French Decret 2012-232.
Electrical and Electronic Equipments (EEE)	: This product complies with the applicable limits defined in the EU Directive 2011/65 (RoHS Directive), as amended. This product complies with EU Directive 2012/19 (WEEE Directive), as far as applicable. The restricted substances (Lead, Mercury, Cadmium, Hexavalent chromium, Polybrominated biphenyls (PBB), Polybrominated diphenyl ethers (PBDE) and the four cited phthalates), if present, are below the defined maximum values.

3.2. Food and Feed Legislation

EU Regulation 1829/2003 (GMO), as amended	: This product is free of genetically modified organisms, in the following sense: > it does not contain or consist of GMOs > it is not produced from or contain ingredients produced from GMOs > it has not to be labelled according to Regulation (EC) 2003/1830 Proteins or (fragments of) DNA is not present. Consequently the product will be PCR negative when tested Cross-contamination (adventitious or technically unavoidable) in a proportion not higher than 0,9 per cent cannot be excluded.
EU Regulation 1881/2006 (contaminants), as amended	: This product complies to the specified limits, as far as applicable: > Dioxins and PCBs > Inherent plant toxins > Melamine and its structural analogues This compliance does not apply to foodstuffs for babies, infants and young children > Mycotoxins > Nitrate.
EU Pesticides residues	: This product complies with Regulation 396/2005/EC (as amended) on maximum residue levels of pesticides in or on food and feed, as far as applicable.
EU Regulation 68/2013 (Feed material)	: Listed as 13.11.1 - Propylene glycol [propane-1,2-diol]

3.3. Health and Beauty Legislation

INCI Name	: PROPYLENE GLYCOL
CosIng Description	: Propane-1,2-diol
CosIng Function	: HUMECTANTS; SKIN CONDITIONING; SOLVENTS; VISCOSITY CONTROLLING AGENTS
CosIng Pharm Eur	: propylenglycolum
Allergenic	: False
Is perfume?	: Yes
Animal testing	: This product complies to the provisions of Article 18 of EU Regulation 1223/2009 about animal testing, as amended. This product complies to EU Directive 2010/63 on the protection of animals used for scientific purposes, as far as applicable. This product complies to the latest ECHA guidance about animal testing requirements on the interface between REACH and the Cosmetics Regulation.
CMR substances	: Substances classified as carcinogenic, mutagenic or toxic for reproduction (CMR) in this

	context are listed under Part 3 of Annex VI to Regulation (EC) 1272/2008, as amended. This product complies to the provisions of Article 15 of Regulation (EC) 1223/2009 about CMR substances, as amended.
Cosmetic allergens	: This product is free of any allergen as defined in Regulation (EC) 1223/2009 as amended (Annex III reference numbers 45, 67, 69-92).
EU Pharma monograph	: Complies with the relevant product monograph of the European Pharmacopoeia; Monograph title: Propylene glycol.
Pharma pesticides	: This product is compliant with the limits on pesticides as defined in the Eur.Pharmacopoeia monograph 2.8.13.
EMA Residual solvents	: This product is in compliance with the consensus guideline CPMP/ICH/283/95 edited by EMA concerning the residual solvents. This product is manufactured without the use or intentional addition of any listed Class 1 solvent. This product complies with the concentration limit of any listed Class 2 solvent. This product is in line with the GMP requirements for any listed Class 3 solvent. This product is free from any listed Class 4 solvent.

3.4. Food contact status

EU Regulation 10/2011 (Annex I), as amended	: FCM 109 - (CAS 0000057-55-6) 1,2-propanediol
FC EU regulatory notices	: This product is in compliance with EC Regulation No 1935/2004 on materials and articles intended to come into contact with food, as far as it is concerned. This product is in compliance with EC Regulation No 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food, as far as it is concerned. The Directive 2002/72/EC of 6 August 2002 relating to plastic materials and articles intended to come into contact with foodstuffs as amended has been repealed by EU Regulation No 10/2011.
BfR Recommendations	: XIV. Plastics Dispersions; XXI. Commodities based on Natural and Synthetic Rubber; XXVIII. Cross-Linked Polyurethanes as Adhesive Layers for Food Packaging Materials; XXXIX. Commodities Based on Polyurethanes; XLI. Linear Polyurethanes for Paper Coatings; XLIV. Artificial Sausage Casings

4. UNITED STATES OF AMERICA and CANADA

4.1. Legislative status

HTS code	: 2905.32.0000
FDA Bioterrorism no. (Food facility registration)	: 10270599464
SARA 313	: This product or mixture is not known to contain a toxic chemical or chemicals in excess of the applicable de minimis concentration as specified in 40 CFR §372.38(a) subject to the reporting requirements of section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 and 40 CFR Part 372.
CA Prop 65	: California Proposition 65 - This product does not contain any substances known to the state of California to cause cancer, developmental and/or reproductive harm.

4.2. Food and Feed Legislation

FEMA No.	: 2940
CFR Title 21 - GRAS Substances (Direct food)	: Listed in 184.1666 - Propylene glycol

CFR Title 21 - GRAS Substances : Listed in 582.1666 - Propylene glycol
(Feed) 582.4666 - Propylene glycol

4.3. Health and Beauty Legislation

USP-NF monograph : Complies with the relevant product monograph of the USP-NF; Monograph title: Propylene Glycol.
US Pharma pesticides : This product is compliant with the limits on pesticides as defined in the US Pharmacopoeia monograph 561.
US Pharma residual solvents : This product is compliant with the limits for "residual solvents" as defined by the US Pharmacopoeia under "Organic volatile impurities" (chemical test <467> of the General Chapters). Class 1 solvents are not used nor added during manufacture; Class 2 solvents are below the stated concentration limits; Class 3 solvents are used below GMP / quality-based requirements and solvents listed under "Other Residual Solvents" are not used.

4.4. Food contact status

CFR Title 21 - Indirect Food : Listed in 175.300 - Resinous and polymeric coatings
Additives 175.320 - Resinous and polymeric coatings for polyolefin films
176.180 - Components of paper and paperboard in contact with dry food
176.210 - Defoaming agents used in the manufacture of paper and paperboard
177.1390 - Laminate structures for use at temperatures of 250 °F and above
177.1680 - Polyurethane resins
177.2420 - Polyester resins, cross-linked
177.2600 - Rubber articles intended for repeated use
177.2800 - Textiles and textile fibers
178.3300 - Corrosion inhibitors used for steel or tinplate

4.5. EPA status

Pesticides Inert Ingredients - Food : Listed in 180.910; Listed in 180.930
use
Pesticides Inert Ingredients - : Listed
Nonfood use
Pesticides Inert Ingredients - : Listed
Fragrance use

5. ASIA

5.1. Legislative status

No supplementary information available.

5.2. Food and Feed Legislation

Food facility registration (local) : Not applicable.

5.3. Health and Beauty Legislation

China IECIC 2015 : Listed (based on INCI name)
Japan JSQI (Quasi-Drug : Listed based on product's CAS RN.
Ingredients)

5.4. Food contact status

China GB 9685 (2008) : Listed based on product's CAS RN

6. OTHER REGIONS / COUNTRIES

6.1. Registration status

Swiss ChemO (SR 813.11) : This substance is not subject to the obligation to register pursuant to art.61 of the Chemicals Ordinance (ChemO).

6.2. Food and Feed Legislation

No supplementary information available.

6.3. Health and Beauty Legislation

No supplementary information available.

6.4. Food contact status

Swiss Ordinance (SR 817.023.21) : List of solvents (part A); List of additives (part A).
Annex 6