

1. DESIGNATION

Product name	: MEDIUM CHAIN TRIGLYCERIDES
CAS No.	: 73398-61-5
EC no.	: 277-452-2
Trade name	: RADIA 7102K
IUPAC name	: Glycerides, mixed decanoyl and octanoyl
Qualifications	: GRAS (self affirmation); RSPO (available on request); Pharma type; Kosher; Halal.

2. Worldwide status

2.1. Registration status

Chemical inventories	: Compliant with AICS, DSL, ECST, ENCS, IECSC, INSQ, KECL, NZIoC, PICCS, TECI, TSCA, EC inventories.
Chem. inventories legend	: AICS = Australian Inventory of Chemical Substances DSL = Canadian Domestic Sustances List ECST = Existing Chemical Substances Inventory of Taiwan ENCS = Japanese Existing and New Chemicals Substances List IECSC = Inventory of Existing Chemicals Substances in China INSQ = Mexico National Inventory of Chemical Substance KECL = Korean Existing Chemical List NZIoC = New Zealand Inventory of Chemicals PICCS = Philippine Inventory of Chemicals and Chemical Substances TECI = Thailand FDA Existing Chemicals Inventory TSCA = USA Toxic Substances Control Act EC inventories = European Community inventories of chemicals (EINECS/ELINCS/NLP/REACH)

2.2. Food and Feed Legislation

Suitability for use (food/feed)	: This product is suited for use in foodstuffs (food grade), as the principles of general food laws including HACCP are applied. This includes the steps of sourcing, manufacturing and distribution carried out under the responsibility of Oleon NV.
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2.3. Health and Beauty Legislation

INCI Name	: CAPRYLIC/CAPRIC TRIGLYCERIDE
Cosmetic Ingredient Review (CIR)	: The safe use as cosmetic ingredient has been assessed by the CIR Expert Panel under ingredient reference(s) Caprylic/Capric Triglyceride.
IFRA Transparency List	: Listed by CAS RN.
ICH Q3C (Residual solvents)	: This product is in compliance with the current version of ICH guideline Q3C on residual solvents.

3. EUROPE EU MEMBER COUNTRIES

3.1. Legislative status

REACH registration No	: 01-2119492306-35
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 includes all substances listed by ECHA including the update of January 15th, 2019.
CN code (Goods code)	: 3824999299
ABPR (Animal By-Product Regulations)	: This product is not derived from nor contains any animal (by-)product and the ABP Regulations are consequently not relevant.
Electrical and Electronic Equipments (EEE)	: This product complies with the applicable limits defined in the EU Directive 2011/65 (RoHS Directive), as amended. 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. This product complies with EU Directive 2012/19 (WEEE Directive), as far as applicable.

3.2. Food and Feed Legislation

Food-Feed facility registration (local)	: 2.142.798.888
EU Food additive no.	: f - Fit for use in foodstuffs
EU Food additive status	: This product has no E-number. The Commission Regulation (EU) No 231/2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 does not apply.
EU Regulation 1829/2003 (GMO), as amended	: This product is free of genetically modified organisms, in the following sense: <ul style="list-style-type: none"> > it does not contain or consist of GMOs > it has not to be labelled according to Regulation (EC) 2003/1830 > it is not produced from or contain ingredients produced from GMOs.
EU Regulation 1881/2006 (contaminants), as amended	: This product complies to the specified limits, as far as applicable: <ul style="list-style-type: none"> > Polycyclic aromatic hydrocarbons This compliance does not apply to foodstuffs for babies, infants and young children.
EU Regulation 1169/2011 (Annex II), as amended	: This product is free from the following substances or products causing allergies or intolerances: <ul style="list-style-type: none"> > Celery and products thereof > Cereals containing gluten, namely: wheat, rye, barley, oats, spelt, kamut or their hybridised strains, and products thereof > Crustaceans and products thereof > Eggs and products thereof > Fish and products thereof > Lupin and products thereof > Molluscs and products thereof > Milk and products thereof (including lactose) > Mustard and products thereof > Nuts, namely: almonds (<i>Amygdalus communis</i> L.), hazelnuts (<i>Corylus avellana</i>), walnuts (<i>Juglans regia</i>), cashews (<i>Anacardium occidentale</i>), pecan nuts (<i>Carya illinoensis</i>)

	(Wangenh.) K. Koch), Brazil nuts (<i>Bertholletia excelsa</i>), pistachio nuts (<i>Pistacia vera</i>), macadamia or Queensland nuts (<i>Macadamia ternifolia</i>), and products thereof
	> Peanuts and products thereof
	> Sesame seeds and products thereof
	> Soybeans and products thereof
	> Sulphur dioxide and sulphites at concentrations of more than 10 mg/kg.
EU Food regulatory notices	: This product complies with Article 25 of the national French regulation on Dietetic and Dietary Products (Arrêté du 20 juillet 1977), as amended. This product has been subject neither to irradiation neither to ionizing treatment. Consequently, it has not to be labelled as such according to EU Regulation 1169/2011 (Annex VI; Part A; pt.3). The Directive 2000/13/EC relating to the labelling, presentation and advertising of foodstuffs as amended has been repealed by EU Regulation No 1169/2011.
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.

3.3. Health and Beauty Legislation

INCI Name	: CAPRYLIC/CAPRIC TRIGLYCERIDE
CosIng Description	: Decanoic acid, ester with 1,2,3-propanetriol octanoate; Glycerides, mixed decanoyl and octanoyl
CosIng Function	: MASKING; PERFUMING
Allergenic	: False
Is perfume?	: No
BSE/ TSE Restriction	: This product is not derived from nor contains any animal (by-)product and BSE/TSE issues are consequently not relevant.
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).
Pharma pesticides	: This product is compliant with the limits on pesticides as defined in the Eur.Pharmacopoeia monograph 2.8.13.
EMA regulatory notices	: The EMA guideline for residual solvents (CHMP/ICH/82260/2006) is aligned with the worldwide ICH guideline Q3C. Please refer to section 2.3 of this document.

3.4. Food contact status

EU Regulation 10/2011 (Annex I), as amended	: FCM 9 - acids, C2-C24, aliphatic, linear, monocarboxylic from natural oils and fats, and their mono-, di- and triglycerol esters (branched fatty acids at naturally occurring levels are included)
FC EU regulatory notices	: 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. 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.

This product is in compliance with Article 11 of EC Directive 94/62 as amended, regarding concentration levels of heavy metals present in packaging.

BfR Recommendations : XLIV. Artificial Sausage Casings.

4. UNITED STATES OF AMERICA and CANADA

4.1. Legislative status

HTS code : 3824.99.4140

FDA Bioterrorism no. (Food facility registration) : 14453884412

California Proposition 65 : This product is manufactured without the use or intentional addition of any substance known to the state of California to cause cancer, developmental and/or reproductive harm.

Animal By-Products CFR : This product is not derived from nor contains any animal (by-)product and 9CFR94.18 or 21CFR189.5 are consequently not relevant.

CONEG Packaging Legislation : This product complies with the legislation about Toxics in Packaging Clearinghouse (TPCH), as far as applicable. The four listed heavy metals (mercury, lead, cadmium and hexavalent chromium) are not intentionally introduced as element during manufacturing nor during distribution and are, if present, below the 100ppm limit.

4.2. Food and Feed Legislation

Food Chemicals Codex : The Food Chemical Codex (FCC) does not hold any relevant monograph.

CFR Title 21 - Prohibited in human food : Contains OPS - This product is free from any listed substance prohibited from use in human food

US Food regulatory notices : This product has been subject neither to irradiation neither to ionizing treatment. Consequently, it has not to be labelled as such according to 21 CFR §179.26.

CFR Title 21 - Prohibited in animal food or feed : Contains OPS - This product is free from any listed substance prohibited from use in animal food or feed

4.3. Health and Beauty Legislation

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).

4.4. Food contact status

CFR Title 21 - Indirect Food Additives : Listed in 175.300 - Resinous and polymeric coatings
177.2800 - Textiles and textile fibers

4.5. EPA status

Pesticides Inert Ingredients - Food use : Listed in 180.910

Pesticides Inert Ingredients - Nonfood use : Listed

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) : B11P1120307-003585

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)

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 additives (part A).
(Annex 6)