

## 1. DESIGNATION

Product name	: MONO- AND DIGLYCERIDES OF FATTY ACIDS
CAS No.	: 91052-47-0
EC no.	: 293-208-8
Trade name	: RADIAMULS MG 2914K
IUPAC name	: Glycerides, C16-18 (even numbered) mono-
Origin	: vegetable
Origin-source	: based on rapeseed and/or sunflower oil
Qualifications	: Non GMO; FSSC 22000; Kosher; Halal

## 2. Worldwide status

### 2.1. Registration status

Chemical inventories	: Compliant with ECST, ENCS, IECSC, KECL, NZIoC, EC inventories.
Chem. inventories legend	: 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 EC inventories = European Community inventories of chemicals (EINECS/ELINCS/NLP/REACH)

ECCN (Export control classification number) : This product is not a dual use item; an export control number is not applicable.

WADA (Doping substances) : Doping substances as defined by the World Anti-doping Agency are not produced nor added intentionally during the manufacturing process. This statement includes all substances mentioned in the Prohibited List of January 2021.

### 2.2. Food and Feed Legislation

INS number	: 471
JECFA Food Additive	: Listed as Mono- and Diglycerides; Complies with the relevant monograph of the Joint FAO/WHO Expert Committee on Food Additives (JECFA).

### 2.3. Health and Beauty Legislation

INCI Name	: GLYCERYL STEARATES
IFRA Transparency List	: Not listed.

## 3. EUROPE EU MEMBER COUNTRIES

### 3.1. Legislative status

REACH registration No	: 01-2119492308-31
SVHC (Substances of Very High)	: This product is free from any substance identified as "SVHC" (Substances of Very High)

Concern)	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 19th, 2021.
CN code (Goods code)	: 3404900000
BTI reference (Binding Tariff Information)	: BE BTI D.T.309.283
EU Regulation 428/2009 (Dual use), as amended	: This product is not listed as dual use item. Export authorisations are consequently not applicable.
EU Regulation 111/2005 (Drug precursors), as amended	: This product is not listed as drug precursor.
EU Regulation 2019/1148 (Explosives precursors)	: This product is not listed as explosive precursor.
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.
EU Nanomaterials	: 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.

### 3.2. Food and Feed Legislation

Food-Feed facility registration (local)	: 2.142.798.888
EU Food additive no.	: E 471 - MONO- AND DIGLYCERIDES OF FATTY ACIDS
EU Food additive status	: This product complies with Commission Regulation (EU) No 231/2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008. Annex II to Regulation (EC) No 1333/2008 (Community list of food additives approved for use in foods and conditions of use) is amended by Commission Regulation (EU) No 1129/2011. Annex III to Regulation (EC) No 1333/2008 (Community list of food additives approved for use in food additives, food enzymes and food flavourings, and their conditions) is amended by Commission Regulation (EU) No 1130/2011.
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"> <li>&gt; it does not contain or consist of GMOs</li> <li>&gt; it is not produced from or contain ingredients produced from GMOs</li> <li>&gt; it has not to be labelled according to Regulation (EC) 2003/1830</li> </ul> Cross-contamination (adventitious or technically unavoidable) in a proportion not higher than 0,9 per cent cannot be excluded Proteins or (fragments of) DNA is not present. Consequently the product will be PCR negative when tested.
EU Regulation 1881/2006 (Contaminants), as amended	: This product complies to the specified limits, as far as applicable: <ul style="list-style-type: none"> <li>&gt; Dioxins and PCBs</li> <li>&gt; Inherent plant toxins</li> <li>&gt; Melamine and its structural analogues</li> <li>&gt; Metals</li> <li>&gt; Mycotoxins</li> <li>&gt; Nitrate</li> </ul>

EU Regulation 1169/2011 (Annex II), as amended	<p>› Polycyclic aromatic hydrocarbons</p> <p>This compliance does not apply to foodstuffs for babies, infants and young children.</p> <p>: This product is free from the following substances or products causing allergies or intolerances:</p> <p>› Celery and products thereof</p> <p>› Cereals containing gluten, namely: wheat, rye, barley, oats, spelt, kamut or their hybridised strains, and products thereof</p> <p>› Crustaceans and products thereof</p> <p>› Eggs and products thereof</p> <p>› Fish and products thereof</p> <p>› Lupin and products thereof</p> <p>› Milk and products thereof (including lactose)</p> <p>› Molluscs and products thereof</p> <p>› 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</p> <p>› Peanuts and products thereof</p> <p>› Sesame seeds and products thereof</p> <p>› Soybeans and products thereof</p> <p>› Sulphur dioxide and sulphites at concentrations of more than 10 mg/kg</p> <p>› Mustard and products thereof.</p>
EU Food regulatory notices	<p>: 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).</p> <p>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.</p> <p>The Directive 2008/84/EC laying down specific purity criteria on food additives other than colours and sweeteners has been repealed by EU Regulation No 231/2012.</p>
EU Pesticides residues	<p>: 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.</p>

### 3.3. Health and Beauty Legislation

INCI Name	: GLYCERYL STEARATES
CosIng Description	: Octadecanoic acid, mono-, di- and triesters with 1,2,3-propanetriol
CosIng Function	: SKIN CONDITIONING - EMOLLIENT
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.
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).

### 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
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FC EU regulatory notices	<p>included), FCM 41 - glycerol, esters with acids, aliphatic, saturated, linear, with an even number of carbon atoms (C14-C18) and with acids, aliphatic, unsaturated, linear, with an even number of carbon atoms (C16-C18)</p> <p>: 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.</p> <p>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.</p> <p>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.</p>
BfR Recommendations	<p>: IX. Colorants for Plastics and other Polymers Used in Commodities;</p> <p>XXV. Hard Paraffins, Microcrystalline Waxes and Mixtures of these with Waxes, Resins and Plastics;</p> <p>XLIV. Artificial Sausage Casings;</p> <p>XXXVI. Paper and board for food contact.</p>

## 4. UNITED STATES OF AMERICA and CANADA

### 4.1. Legislative status

HTS code	: 3404.90.5150
CCL (Commerce control list)	: EAR99.
FDA Bioterrorism no. (Food facility registration)	: 18203949798; 15852376522
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.
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.

### 4.2. Food and Feed Legislation

Food Chemicals Codex	: Listed as Glyceryl Monostearate; Complies with the relevant monograph of the Food Chemical Codex (FCC).
CFR Title 21 - GRAS Substances (Direct food)	: Listed in 184.1 - Substances added directly to human food affirmed as generally recognized as safe (GRAS) 184.1324 - Glyceryl monostearate 184.1505 - Mono- and diglycerides
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 allergens (FALCPA)	: The 8 major food allergens identified by FALCPA are: milk, egg, fish, crustacean shellfish, tree nuts, wheat, peanuts and soybeans. This product is free from food allergens or proteins derived for food allergens as defined by FALCPA (Public Law 108-282).

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

#### **4.3. Health and Beauty Legislation**

#### **4.4. Food contact status**

CFR Title 21 - Indirect Food : Listed in 175.105 - Adhesives  
Additives 175.210 - Acrylate ester copolymer coating  
175.300 - Resinous and polymeric coatings  
176.200 - Defoaming agents used in coatings  
176.210 - Defoaming agents used in the manufacture of paper and paperboard  
177.2800 - Textiles and textile fibers

#### **4.5. EPA status**

Pesticides Inert Ingredients - Food : Not listed  
use  
Pesticides Inert Ingredients - : Not listed  
Nonfood use  
Pesticides Inert Ingredients - : Not listed  
Fragrance use

## **5. ASIA**

#### **5.1. Legislative status**

No supplementary information available.

#### **5.2. Food and Feed Legislation**

Food facility registration (local) : B11P1141105-019901

#### **5.3. Health and Beauty Legislation**

China IECIC 2015 : Listed (based on INCI name)  
Japan JSQI (Quasi-Drug : Not 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.69 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)