

Chignolo d'Isola, 10 April 2019

Subject: Food Contact Declaration: RADILON® S HS 105 M NT.-

Dear Customer,

The material grade named as follow:

RADILON® S HS 105 M NT

in accordance to the below mentioned provisions and based on its composition, can be considered as suitable to be used as intended in food contact materials or articles in compliance with the currently laws and regulation in force.

The above mentioned material grades contain the following substances, which are:

➤ **subject to restrictions in food contact:**

| FCM substance No | Ref. No | CAS No | Name | Restrictions and/or Specifications ¹ |
|------------------|----------------|-------------|-------------|---|
| 212 | 14200 41480 | 000105-60-2 | Caprolactam | SML (T) = 15 mg/Kg |

➤ **recognized as “Dual-Use Additive”²:**

E 470 a | Sodium, potassium, calcium salts of fatty acids

No further substances (raw materials and/or intentionally added additives), which are subject to restrictions in food contact, are contained in the above mentioned material grade.

Migration of the above listed substances, as well as concerns the overall migration, depends on several factors, as thickness of the article in contact with food (or with a proper food simulant), surface to volume ratio, conditions of use (contact time and temperature) and the type of food, as well. **It is therefore responsibility of the producer of the final article to guarantee its compliance with food contact applications under actual or foreseeable conditions of use, and to check it on a regular basis.** In

¹ Annex I – Table 1, Columns 8, 9 and 10 of the **Commission Regulation (EU) N. 10/2011**: SML(T), (Total) Specific Migration Limit, given in mg of substance *per* Kg of food or simulant. Global Migration Limit (to be checked on the finished article): 10 mg/dm² or 60 mg/Kg food.

² **Commission Regulation (EU) N. 1333/2008** (OJ L 354, 31.12.2008) – Annex I, II and III; **European Council and Parliament Directive N. 95/2/EC** (OJ L 61, 18.3.1995) – Annex V.

RADICI NOVACIPS SPA

Sede Amministrativa, Legale e Unità Operativa:
Via Bedeschi, 20 IT - 24040 CHIGNOLO D'ISOLA (BG)
Ph. +39 035 4991311 Fax +39 035 994386
www.radicigroup.com
info.plastics@radicigroup.com

Unità Operativa:
Via Provinciale, 1331
IT - 24020 VILLA D'OGNA (BG)
Tel. +39 0346 22453
Fax +39 0346 23730

Cap Soc. Euro 15.000.000 int. vers.
C.F./P. IVA 00917130163
VAT IT 00917130163
R.E.A. Bergamo N°187124
Reg. Imp. Bergamo 00917130163

Società soggetta alla attività di direzione e coordinamento, ex art. 2497 c.c. e seguenti, di RADICIFIN S.A.P.A. di Paolo Partecipazioni S.r.l. unip. Angelo Radici Partecipazioni S.r.l. unip. Maurizio Radici Partecipazioni S.r.l. unip., con sede in Bergamo.

any case, Radici Novacips S.p.A, using all its technical knowledge and competence concerning our products, can assist our customer in checking compliance.

This declaration holds for the above mentioned grade as it leaves one of our production facilities in its original packages and cannot be considered valid in the case that additives, pigments or similar were subsequently added by the converter and nor responds it for any negative influence the final article may have on the organoleptic properties of the packaged food.

The material grade **RADILON® S HS 105 M NT** meets the requirements for food contact suitability in compliance with the relevant parts of the following directives and regulations:

Europe

Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004³;

Resolution AP (89) 1⁴;

Resolution AP (92) 2⁵;

Commission Regulation (EC) No 1895/2005 of 18 November 2005⁶;

Commission Regulation (EC) No 2023/2006 of 22 December 2006⁷;

D.P.R. 23 Agosto 1982, n. 777⁸

Commission Regulation (EU) No 10/2011 of 14 January 2011⁹, as amended by the next:

Commission Implementing Regulation (EU) No 321/2011 of 1 April 2011¹⁰;

Commission Regulation (EU) No 1282/2011 of 28 November 2011¹¹;

Commission Regulation (EU) No 1183/2012 of 30 November 2012¹²

Commission Regulation (EU) No 202/2014 of 3 March 2014¹³;

Commission Regulation (EU) No 865/2014 8 August 2014¹⁴

Commission Regulation (EU) No 2015/174 of 5 February 2015¹⁵;

Commission Regulation (EU) No 2016/1416 of 24 August 2016¹⁶

Commission Regulation (EU) No 2017/752 of 28 April 2017¹⁷;

Commission Regulation (EU) No 2018/79 of 18 January 2018¹⁸.

Commission Regulation (EU) No 2018/213 of 12 February 2018¹⁹

³ OJ L 338, 13.11.2004.

⁴ Resolution AP (89) 1, ON THE USE OF AZOCOLOURANTS IN PLASTICS MATERIALS COMING IN TO CONTACT WITH FOOD, adopted by the Committee of Ministers on the 13 September 1989,

⁵ Resolution AP (92) 2, ON CONTROL OF AIDS TO POLYMERISATION (TECHNOLOGICAL COADJUVANTS) FOR PLASTICS AND ARTICLES INTENDED TO COME IN CONTACT WITH FOODSTUFFS, adopted by the Committee of Ministers on the 19 October 1992

⁶ OJ L 302, 19.11.2005

⁷ OJ L 384, 29.12.2006

⁸ GU n. 298, 29.10.1982

⁹ OJ L12/1, 15.01.2011 that repeals directives 80/766/EEC, 81/432/EC and Directive 2002/72/EC with effect from 1st May 2011.

¹⁰ OJ L 87/1, 02.04.2011 implementing Regulation (EU) No 10/2011

¹¹ OJ L 328/22, 10.12.2011, 2nd amendment of the Reg. (EU) n. 10/2011

¹² OJ L 338/11, 12.12.2012 amending Regulation (EU) No 10/2011

¹³ OJ L 62/13, 04.03.2014, amending Regulation (EU) No 10/2011

¹⁴ OJ L 238/1, 01.08.2014, amending Regulation (EU) No 10/2011

¹⁵ OJ L 30/2, 06.02.2015, amending Regulation (EU) No 10/2011

¹⁶ OJ L 230/22, 25.8.2016, amending Regulation (EU) No 10/2011

¹⁷ OJ L 113/18, 29.4.2017, amending Regulation (EU) No 10/2011

¹⁸ OJ L 14/31, 19.1.2018, amending Regulation (EU) No 10/2011

¹⁹ OJ L 41/6, 14.1.2018, amending Regulation (EU) No 10/2011

RADICI NOVACIPS SPA

Sede Amministrativa, Legale e Unità Operativa:
Via Bedeschi, 20 IT - 24040 CHIGNOLO D'ISOLA (BG)
Ph. +39 035 4991311 Fax +39 035 994386
www.radicigroup.com
info.plastics@radicigroup.com

Unità Operativa:
Via Provinciale, 1331
IT - 24020 VILLA D'OGNA (BG)
Tel. +39 0346 22453
Fax +39 0346 23730

Cap Soc. Euro 15.000.000 int. vers.
C.F./P. IVA 00917130163
VAT IT 00917130163
R.E.A. Bergamo N°187124
Reg. Imp. Bergamo 00917130163

Società soggetta alla attività di direzione e coordinamento,
ex art. 2497 c.c. e seguenti, di RADICIFIN S.A.P.A. di Paolo
Partecipazioni S.r.l. unip. Angelo Radici Partecipazioni S.r.l.
unip. Maurizio Radici Partecipazioni S.r.l. unip., con sede in
Bergamo.

Commission Regulation (EU) No 2018/831 of 5 June 2018²⁰

Commission Regulation (EU) No 2019/37 of 10 January 2019²¹

Germany

Recommendations of the Federal Institute for Risk Assessment on plastics intended to come into contact with food (*Kunststoff Empfehlungen* by the *Bundesinstitute für Risikobewertung - BfR*): X "Polyamide" (as of 01.06.2013)²².

Italy

Decreto Ministeriale 6 aprile 2004, n. 174.²³

USA

U.S. Code of Federal Regulation, issued by Food and Drug Administration (FDA), Title 21CFR Chapter 1, part 177.1500 (4-1-18 Edition); in particular the above mentioned material grade complies with the material requirements as for point (b) 6.1 (*Nylon 6 resins*). Further additives included in the product composition, are recognized as "indirect" food additives by the U.S. Food and Drug Administration (FDA) Center for Food Safety and Applied Nutrition (CFSAN), and they are mentioned in Title 21 of the *U.S. Code of Federal Regulations* (21CFR) Parts 177 (polymers) and/or 178 (adjuvants and production aids).

Every further information regarding composition and chemical – physical properties of our products are available on the corresponding MSDS, we kindly invite you to ask to our Customer Service (info.plastics@radicigroup.com) in the case of needs.

Best regards,

Contact:

RADICIGROUP High Performance Polymers
Product Stewardship & Regulatory Affairs Leader

Anna De Sio
Tel.: +39 035 4991311
anna.desio@radicigroup.com

RADICIGROUP High Performance Polymers

Corrado Armanni 
Research & Development and
Quality Control Lab Manager

²⁰ OJ L 140/35, 6.6.2018, amending Regulation (EU) No 10/2011

²¹ OJ L 9/88, 11.1.2019, amending Regulation (EU) No 10/2011

²² https://bfr.ble.de/kse/faces/DBEmpfehlung_en.jsp?filter=clear

²³ GU n. 166 on 17.7.2004

RADICI NOVACIPS SPA

Sede Amministrativa, Legale e Unità Operativa:
Via Bedeschi, 20 IT - 24040 CHIGNOLO D'ISOLA (BG)
Ph. +39 035 4991311 Fax +39 035 994386
www.radicigroup.com
info.plastics@radicigroup.com

Unità Operativa:
Via Provinciale, 1331
IT - 24020 VILLA D'OGNA (BG)
Tel. +39 0346 22453
Fax +39 0346 23730

Cap Soc. Euro 15.000.000 int. vers.
C.F./P. IVA 00917130163
VAT IT 00917130163
R.E.A. Bergamo N°187124
Reg. Imp. Bergamo 00917130163

Società soggetta alla attività di direzione e coordinamento, ex art. 2497 c.c. e seguenti, di RADICIFIN S.A.P.A. di Paolo Partecipazioni S.r.l. unip. Angelo Radici Partecipazioni S.r.l. unip. Maurizio Radici Partecipazioni S.r.l. unip., con sede in Bergamo.