

Chignolo d'Isola, 23 January 2017

Subject: Food Contact Declaration: RADILON® S 40 TYPE NATURAL -

Dear Customer,

The material grades named as follow:

RADILON® S 40 100 NT
RADILON® S 40F 100 NT
RADILON® S 40L 100 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

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

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.



RADICI NOVACIPS SpA – Produzione, lavorazione, commercializzazione materie plastiche

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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.

This declaration holds for the above mentioned grades as they leave one of our production facilities in their 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 grades **RADILON® S 40, or S 40F, or S40L 100 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 2004²;

Resolution AP (89) 1³;

Resolution AP (92) 2⁴;

Commission Regulation (EC) No 1895/2005 of 18 November 2005⁵;

Commission Regulation (EC) No 2023/2006 (GMP) of 22 December 2006⁶;

Commission Regulation (EU) No 10/2011 of 14 January 2011⁷, as amended by the next:

Commission Implementing Regulation (EU) No 321/2011 of 1st April 2011⁸;

Commission Regulation (EU) No 1282/2011 of 28 November 2011⁹;

Commission Regulation (EU) No 1183/2012 of 30 November 2012¹⁰;

Commission Regulation (EU) No 202/2014 of 3 March 2014¹¹;

Commission Regulation (EU) No 2015/174 of 5 February 2015¹².

Germany

Recommendations of the Federal Institute for Risk Assessment on plastics intended to come into contact with food (*Kunststoff Empfehlungen* by the *Budeninstitute für Risikobewertung - BfR*): X "Polyamide" (as of 01.06.1998).

² OJ L 338, 13.11.2004.

³ Resolution AP (89) 1, ON THE USE OF AZOCOLLOURANTS IN PLASTICS MATERIALS COMING IN TO CONTACT WITH FOOD, adopted by the Committee of Ministers on the 13 September 1989,

⁴ 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

⁵ OJ L 302, 19.11.2005

⁶ OJ L 384, 29.12.2006

⁷ OJ L12, 15.01.2011. Reg. (EU) No 10/2011 repeals as of 1st May 2011 Directive 2002/72/EC, including six amendments (Dir No 2004/1/EC, Dir 2004/19/EC, Dir 2005/79/EC, Dir 2007/19/EC, Dir 2008/39/EC and Reg. (EC) No 975/2009) and Dir 2011/8/EU; furthermore it replaces as of 1st January 2013 Directive 82/711/EEC, including Dir 93/8/EEC and 97/48/EEC, and Directive 85/572/EEC.

⁸ OJ L 87, 02.04.2011

⁹ OJ L 328, 10.12.2001, 2nd amendment of the Reg. (EU) n. 10/2011

¹⁰ OJ L 338, 12.12.2012

¹¹ OJ L 62, 04.03.2014, amending Regulation (EU) No 10/2011

¹² OJ L 30/3, 06.02.2015, amending Regulation (EU) No 10/2011



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unip. Maurizio Radici Partecipazioni S.r.l. unip., con sede in
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USA

U.S. Code of Federal Regulation, issued by Food and Drug Administration (FDA), Title 21CFR Chapter 1, part 177.1500 (4-1-08 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,

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