

Chignolo d'Isola, 23 July 2018

Subject: Food and Drinkable Water Contact Declaration:
- RADILON® A RV300RKC 106 NT;

Dear Customer,

The material grades named as:

RADILON® A RV300RKC 106 NT

in accordance to the below mentioned provisions and based on their material 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
305	15274 18460	000124-09-4	Hexamethylenediamine	SML = 2,4 mg/Kg

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

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

The above mentioned product contains substances which are subject to restrictions referring to a specific migration limit (SML). 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**

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.

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.

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 preparation **RADILON® A RV300RKC 106 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, Article 3, 11(5), 15 and 17;

Resolution AP (89) 1⁴;

Resolution AP (92) 2⁵;

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

Commission Regulation (EC) No 2023/2006 (*GMP*) 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 1st 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 174/2015 of 5 February 2015¹⁴;

Commission Regulation (EU) No 2016/1416 of 24 August 2016¹⁵;

Commission Regulation (EU) No 2017/752 of 28 April 2017¹⁶.

Commission Regulation (EU) No 2018/79 of 18 January 2018¹⁷

Commission Regulation (EU) No 2018/831 of 5 June 2018¹⁸

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, 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.

¹⁰ OJ L 87, 02.04.2011

¹¹ OJ L 328, 10.12.2001, 2nd amendment of the Reg. (EU) n. 10/2011

¹² OJ L 338, 12.12.2012

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

¹⁴ OJ L 30/3, 06.02.201, amending Regulation (EU) No 10/2011

¹⁵ OJ L 230/22, 25.8.2016, amending Regulation (EU) No 10/2011

¹⁶ OJ L 113/18, 29.4.2017, amending Regulation (EU) No 10/2011

¹⁷ OJ L 14/31, 19.1.2018, amending Regulation (EU) No 10/2011

¹⁸ OJ L 140/35, 6.6.2018, amending Regulation (EU) No 10/2011

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Bergamo.

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 01.06.2013).

USA

U.S. Code of Federal Regulation, issued by Food and Drug Administration (FDA), Title 21CFR Chapter 1, part 177.1500 (4-1-17 Edition); in particular the above mentioned material grade complies with the material requirements as for point (b) 1 (*Nylon 66 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).

The material preparation **RADILON® A RV300RKC 106 NT** meets the requirements for drinking water contact suitability in compliance the following regulations:

Italy

Decreto Ministeriale 6 aprile 2004, n. 174.¹⁹

WRAS Approval (UK)

The above mentioned material grades, in compliance with the provisions of the Water Regulations Advisory Scheme, meet the requirements of the **BS 6920-1:2000** 'Suitability of non-metallic products for use in contact with water intended for human consumption with regard to their effect on the quality of the water'.

For use with water up to 85°C;
Section: 5180 Nylon
Section Subtitle: Material only
Approval Number: 1707511
Expiry date: 31/07/2022
Supplier: Radici Novacips S.p.A.

DVGW Approval (DE)

The above mentioned material grade, in compliance with the provisions of Umweltbundesamt (UBA) (Bundesgesundheitsblatt aktuelle Fassung), meets the requirements of "Guideline for the Hygienic Assessment of Organic Materials in Contact with Drinking Water (**KTW** Guideline)", for use with water at 23°C.

Hygiene-Institut K-284590-17-Bs/st

¹⁹ GU n. 166 on 17.7.2004

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APPROVAL HOLDER: RADICI NOVACIPS S.p.A.

RADILON A RV500RKC 106 NT also complies to DVGW-Standard **W270** (11/2007) "Vermehrung von Mikroorganismen auf Werkstoffen für den Trinkwasserbereich – Prüfung und Bewertung".

Hygiene-Institut W-297383e-18-SI/to

APPROVAL HOLDER: RADICI NOVACIPS S.p.A.

We furthermore confirm that the glass fiber used in manufacturing the above mentioned grade is in compliance with Article 5 of Commission Regulation (EU) N. 10/2011²⁰, that entered entirely into force on December 31st, 2015, as provided by Article 23 of the same EU Regulation.

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:

Product Stewardship & Regulatory Affairs Leader
RADICIGROUP – Performance Plastics

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

RADICIGROUP-Performance Plastics

Corrado Armanni



*Research & Development and
Quality Control Lab Manager*

Important: This information relates only to the above mentioned materials as delivered in their original packaging. It does not relate to any product made of these materials with or without the inclusion of further additives, such as processing aids or colorants.

²⁰ 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.

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