



**NatureFlex™ NK**  
**Declaration of Compliance**  
 for materials and articles intended to come into contact with food

**I Legal Basis**

This declaration is issued in accordance with:

- Article 16(1) of Regulation (EC) No 1935/2004 (“Framework Regulation”)
- Article 6 of Directive 2007/42/EC (“RCF Directive”)

**II Assurances**
**1 Identity and address of the business operator issuing the declaration of compliance:**

Applicable entity from among the following:

<b>Legal Entity Company Registration Number</b>	<b>Registered Office Address</b>
Futamura Australia Pty Limited A.B.N. 11 612 603 193 A.C.N. 612 603 193	19 Potter Street Craigieburn 3064 Victoria Australia.
Futamura Chemical UK Limited 10042418 Registered in England and Wales.	Station Road Wigton Cumbria · CA7 9BG United Kingdom.
Futamura Mexico, SA de CV FME 160524N31	Ave. D 1111 Col. Hacienda Los Morales San Nicolas de Los Garza, NL · C.P. 66495 · Mexico.
Futamura USA Inc E.I.N. 81-2619127	290 Interstate North Cir SE · Suite 100 Atlanta, GA 30339-2401 · United States of America.

**2 Identity and address of the business operator which manufactures the material:**

Futamura Chemical UK Limited  
 Station Road · Wigton · Cumbria · CA7 9BG · United Kingdom.

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## II Assurances continued

### 3 Identity of the material:

This declaration applies to the following products supplied by Futamura from its site in Wigton, England:

- **NatureFlex™ 19NK**
- **NatureFlex™ 23NK**
- **NatureFlex™ 30NK**
- **NatureFlex™ 45NK**

subsequently referred to as "**NatureFlex™ NK**".

**NatureFlex™ NK** is a multi-material multi-layer (MMML) material. It is composed of a non-plastic layer (of regenerated cellulose film) and two coating layers consisting of plastics.

Only the plastics coating layers fall within the scope of the EU Plastics Regulation (EU) No 10/2011 (Article 2(1)(e)). The regenerated cellulose film layer is outside the scope of the EU Plastics Regulation.

#### NOTE:

This and all subsequent references to Regulation (EU) No 10/2011 mean that Regulation as amended by Regulations (EU) Nos 321/2011, 1282/2011, 1183/2012 (including Corrigendum of 19.12.2012), 202/2014, 2015/174 & 2016/1416 and as corrected by Regulation (EU) No 865/2014.

### 4 Period of supply for which this declaration is valid:

This declaration applies to **NatureFlex™ NK** supplied in the period:

**01 July 2016 to 30 June 2018**

### 5 Confirmation that the material meets relevant requirements laid down in EU legislation for food contact materials and articles:

**NatureFlex™ NK** complies with the following:

- Regulation (EC) No 1935/2004 as amended by Regulation (EC) No 596/2009**  
*("Framework Regulation" for food contact materials and articles)*
  - Article 3 ("General requirements")
  - Article 11(5) ("Community Authorisation": notification of new scientific or technical information for an authorised substance)
  - Article 15 ("Labelling")
  - Article 17 ("Traceability")
- Regulation (EC) No 2023/2006 as amended by Regulation (EC) No 282/2008**  
*("GMP Regulation" for food contact materials and articles)*
  - Article 4 ("Conformity with good manufacturing practice")
  - Article 5 ("Quality assurance system")
  - Article 6 ("Quality control system")
  - Article 7 ("Documentation")
- Directive 2007/42/EC (unamended at current date)**  
*("Regenerated Cellulose Films Directive" / "RCF Directive")*
  - Article 4

#### NOTE:

Article 4(2) of Directive 2007/42/EC foresees that plastic coatings for food contact RCFs should be formulated using substances authorised at EU level for food contact plastic materials and articles. It also foresees that the film should comply with restrictions set out for those substances in the relevant legislation.

Directive 2007/42/EC has not yet been amended to update the references to EU plastics legislation. This declaration takes account of the repeal of Directive 2002/72/EC on 1 May 2011. Futamura has assumed that the obsolete references to that directive in Directive 2007/42/EC should be read as references to Regulation (EU) No 10/2011.

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## II Assurances continued

### 5 Confirmation that the material meets relevant requirements laid down in EU legislation for food contact materials and articles continued

#### d Regulation (EU) No 10/2011

as amended by Regulations (EU) Nos 321/2011, 1282/2011, 1183/2012 (including Corrigendum of 19.12.2012), 202/2014, 2015/174 & 2016/1416 and as corrected by Regulation (EU) No 865/2014

(*“Plastics Regulation”/“Plastics Implementing Measure”/“PIM”*)

- Article 14 (“Multi-material multilayer materials and articles”) (in respect of the plastics coating layers)

#### e Directive 78/142/EEC including Corrigendum of 20.6.1978

(*“Vinyl Chloride Monomer Directive”/“VCM Directive”*)

- Article 2(1)

#### f NOT APPLICABLE

Regulation (EC) No 1895/2005 (unamended at current date)

(*“Epoxy Derivatives Regulation”/“Epoxy Regulation”*)

Futamura does NOT introduce (i) BADGE or BADGE derivatives; (ii) BFDGE; or (iii) NOGE, in the manufacture of **NatureFlex™ NK**.

**NatureFlex™ NK** is outside the scope of the Regulation.

#### g NOT APPLICABLE

Regulation (EC) No 282/2008 as amended by Regulation (EU) 2015/1906

(*“Recycled Plastics Materials and Articles Regulation”*)

Futamura does NOT introduce (i) “post-consumer recycled materials”; (ii) “post-consumer recovered materials”; (iii) “post-consumer plastic materials”; (iv) “post-consumer materials”; (v) “post-use plastic materials”; (vi) “post-use plastic articles”; or (vii) “post-consumer waste” in the manufacture of **NatureFlex™ NK**.

**NatureFlex™ NK** does NOT contain “recycled plastic.”

**NatureFlex™ NK** is NOT a “recycled plastic material” or a “recycled plastic article.”

**NatureFlex™ NK** is outside the scope of the Regulation (see Article 1 of the Regulation).

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## II Assurances continued

**6 Adequate information relative to the substances used or products of degradation thereof for which restrictions and/or specifications are set out in Annexes I and II to Regulation (EU) No 10/2011 to allow downstream business operators to ensure compliance with those restrictions:**

Based on information received from component material suppliers, certain substances having specific migration restrictions listed in Annexes I & II of Regulation (EU) No 10/2011 are or could be present in the plastics coating layers of **NatureFlex™ NK**.

Futamura confirms that when **NatureFlex™ NK** is used in accordance with the conditions explicitly specified in Section 8 ("Specifications on use of the material"):-

- for each of the following substances, migration complies with the Specific Migration Limit assigned to the substance:

FCM Substance No.	Substance Name	Specific Migration Limit (mg/kg food)
127	vinyl chloride	ND (LoQ = 0.01 mg/kg food)
130	vinylidene chloride	ND (LoQ = 0.01 mg/kg food)
225	acrylonitrile	ND (LoQ = 0.01 mg/kg food)
239	2,4,6-triamino-1,3,5-triazine (= melamine)	2.5
246	tetrahydrofuran	0.6
312	methacrylonitrile	ND (LoQ = 0.01 mg/kg food)

- for other substances subject to Specific Migration Limits<sup>(†)</sup>: migration cannot exceed one tenth of the respective limit values, based on worst-case calculation or mathematical modelling or experimental test data.

<sup>(†)</sup> Futamura is not required to disclose the identities of these substances in this Declaration of Compliance. For further information, please refer to the "Union Guidance on Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food as regards information in the supply chain":

[http://ec.europa.eu/food/food/chemicalsafety/foodcontact/docs/guidance\\_reg-10-2011\\_en.pdf](http://ec.europa.eu/food/food/chemicalsafety/foodcontact/docs/guidance_reg-10-2011_en.pdf)

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## II Assurances continued

### 7 “Dual Use Substances”

Adequate information relative to the substances which are subject to a restriction in food, obtained by experimental data or theoretical calculation about the level of their specific migration and, where appropriate, purity criteria to enable the user of the material to comply with relevant EU provisions or, in their absence, with national provisions applicable to food:

Based on information received from component material suppliers, one substance authorised as a food additive by Regulation (EC) No 1333/2008 and which is subject to a restriction in food is present in the plastics coating layers of **NatureFlex™ NK**. It is:

E Number	Additive Name	Limit in Food (mg/kg food)	Maximum Migration <sup>(††)</sup> (% of limit in food)
E 321	butylated hydroxytoluene	100	< 1

<sup>(††)</sup> assuming complete migration from one surface and a surface area : food mass ratio of 6.00 dm<sup>2</sup> per kg food

Based on information provided by suppliers, the components that Futamura uses to make the plastics coating layers of **NatureFlex™ NK** are not formulated to contain any substances authorised as flavourings by Regulation (EC) No 1334/2008.

NOTE:

Regulation (EC) No 1333/2008 means that Regulation as amended up to and including Regulation (EU) 2016/1776 of 6 October 2016.

Regulation (EC) No 1334/2008 means that Regulation as amended up to and including Regulation (EU) 2016/1244 of 28 July 2016.

### 8 Specifications on use of the material:

#### a Types of food with which it is intended to be put in contact.

**NatureFlex™ NK** meets the applicable legal requirements for contact with those food categories for which the following food simulants are assigned in Table 2 of Annex III of Regulation (EU) No 10/2011:

- Food simulant A (ethanol 10% v/v)
- Food simulant B (acetic acid 3% w/v)
- Food simulant C (ethanol 20% v/v)
- Food simulant D1 (ethanol 50% v/v)
- Food simulant D2 (vegetable oil containing less than 1% unsaponifiable matter)
- Food simulant E (poly(2,6-diphenyl-*p*-phenylene oxide) of defined particle size and pore size)

Futamura does not recommend **NatureFlex™ NK** for applications that would involve direct contact with alcoholic foods or beverages. This is due to a restriction under US FDA legislation.

On the basis of the film's physical properties, Futamura does not recommend **NatureFlex™ NK** for use as a monoweb material for the holding of liquid foods.

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**8 Specifications on use of the material** continued

**b Time and temperature of treatment and storage in contact with the food.**

**NatureFlex™ NK** meets the applicable legal requirements for contact with food under the following conditions:

- at temperatures up to 40°C without restriction on contact time, including refrigerated and frozen storage conditions
- at temperatures between 40°C and 70°C for periods up to 2 hours
- at temperatures between 70°C and 100°C for periods up to 15 minutes
- “hot fill” as defined in Article 3, point 19 of Regulation (EU) No 10/2011

**NatureFlex™ NK** is intended for contact with food under temperate or chilled conditions (temperature range: 0 to +40°C).

**Low Temperature Applications:**

Futamura has not evaluated the performance of **NatureFlex™ NK** at very low temperatures.

On the basis of its physical properties, Futamura recommends that **NatureFlex™ NK** should not be used in applications that would involve processing or storage at temperatures below -30°C (for example, blast freezing).

**Elevated Temperature Applications:**

**NatureFlex™ NK** is suitable for short-term contact with many warm foods (food temperature: up to 100°C) in ordinary “hot fill” food packing operations.

Futamura has not evaluated the performance of **NatureFlex™ NK** at high temperatures.

Futamura recommends that the film should not be used to hold or store food for prolonged periods (> 15 minutes) at temperatures above +70°C.

**c Ratio of food contact surface area to volume used for establishing compliance of the material.**

6.00 dm<sup>2</sup> of contact surface per kg of food

**NOTE:**

For containers and other articles intended to contain less than 500 mL or 500 g of food – including small packs – relevant legislation states that it is permissible to apply a ratio of 6 dm<sup>2</sup> per 1 kg of food irrespective of the actual ratio in real life.

This is also permissible for sheets and films not yet in contact with food.

**d Contact geometry.**

**NatureFlex™ NK** has been developed for applications in which only one surface of the film makes contact with food.

There is no restriction on which of the two surfaces is placed in contact with food.

For advice on using **NatureFlex™ NK** in applications in which both surfaces of the film would make direct contact with food, please contact your Futamura representative.

**9 Functional barrier:**

Futamura has not evaluated **NatureFlex™ NK** to verify whether it would perform as a functional barrier in any specific food contact application.

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### III Cooperation with Competent Authorities/Enforcement Authorities

Addressed to downstream business operators in EEA States (EU-28 + NO/IS/LI) and stated in respect of Article 16(1) of the Framework Regulation (EC) No 1935/2004.

Futamura undertakes to make available to the food control authorities any supporting documentation that they may reasonably require, to demonstrate that **NatureFlex™ NK** complies with the applicable legal requirements.

NOTE:

Croatia completed negotiations for its accession to the EEA in November 2013.

Since 12 April 2014 Croatia is provisionally applying the EEA Agreement pending the ratification of its accession by all EEA contracting states.

### IV Other Provisions

This declaration applies to **NatureFlex™ NK** as placed on the market by Futamura.

It remains the responsibility of the food packer to verify the suitability of the final material or article for the intended food contact application, including:

- checking that the physical properties of the final material or article make it suitable for the intended application
- verifying compliance of the final material or article with any applicable migration limits
- checking for the possible influence of the final material or article on the composition and organoleptic properties of the contacted food

As a precautionary measure to ensure food safety, Futamura recommends that customers should discard the outermost and innermost circumferential turns of film on each slit reel during its subsequent conversion or use.

The content of this declaration is subject to the FUTAMURA TERMS AND CONDITIONS OF SALE governing the applicable sales contract which are incorporated by reference.

NatureFlex™ is a registered trademark of the Futamura Group in many countries.

### V Author, Place, Date & Reference

This declaration was prepared by:  <b>Richard J Armstrong</b> <i>Regulatory Affairs Manager</i> <i>EMEA &amp; Americas Operations</i>	Signature:  
Place of issue: Date of issue:	<b>Wigton, England</b> <b>31 October 2016</b>

**Full Document Reference – for Futamura use only:**

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