



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:

Legal Entity Company Registration Number	Registered Office Address
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	280 Interstate North Cir SE · Suite 530 Atlanta, GA 30339-2409 · United States of America.

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II Assurances continued

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

Wigton manufacture:

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

Tecumseh manufacture:

Futamura USA Inc
6000 SE 2nd St · Tecumseh, KS 66542-9609 · USA.

3 Identity of the material:

This declaration applies to the following products supplied by Futamura from its sites in Wigton, UK and Tecumseh, KS, USA:

- **NatureFlex™ 19NK** (marketed in Canada & the USA as **NatureFlex™ 75NK**)
- **NatureFlex™ 23NK** (marketed in Canada & the USA as **NatureFlex™ 90NK**)
- **NatureFlex™ 30NK** (marketed in Canada & the USA as **NatureFlex™ 120NK**)
- **NatureFlex™ 45NK** (marketed in Canada & the USA as **NatureFlex™ 180NK**)

subsequently referred to as “**NatureFlex™ NK**” films.

Each **NatureFlex™ NK** film is composed of a base sheet of regenerated cellulose film and two surface coating layers.

The films are within the scope of Article 2(c) of Directive 2007/42/EC.

The base sheet of regenerated cellulose film is regulated exclusively by the rules laid down in Directive 2007/42/EC.

The surface coating layers fall within the scope of Regulation (EU) No 10/2011 (Article 2(1)(e)).

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, 865/2014, 2015/174, 2016/1416, 2017/752, 2018/79, 2018/213, 2018/831 & 2019/37.

4 Date of the declaration:

This declaration was prepared on: **04 February 2019**

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

This declaration applies to consignments of **NatureFlex™ NK** directly supplied by Futamura in the period:

01 January 2019 to 30 June 2021

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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:

NatureFlex™ NK complies with the following:

- a 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”)
- b 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”)
- c 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 for food contact RCFs coming within the scope of Article 2(c), the coating layers should be formulated using substances that have been authorised at EU level according to the rules laid down in the detailed legislation applying to food contact plastics materials and articles. It also foresees that such films should comply with restrictions set out for those substances in that legislation.

Directive 2007/42/EC has not yet been amended to update the cross-references to other EU 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.

- 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, 865/2014, 2015/174, 2016/1416, 2017/752, 2018/79, 2018/213, 2018/831 & 2019/37
(“Plastics Regulation”/“Plastics Implementing Measure”/“PIM”)
- Article 14 (“Multi-material multilayer materials and articles”)
(in respect of the 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

Directive 93/11/EEC (unamended at current date)
(“N-Nitrosamines- and N-Nitrosatable Substances Directive”)

Futamura does NOT introduce (i) N-nitrosamines; or (ii) substances capable of being converted into N-nitrosamines (“N-nitrosatable substances”), in the manufacture of NatureFlex™ NK.

NatureFlex™ NK is outside the scope of the Directive.

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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

g 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.

h NOT APPLICABLE

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

("Recycled Plastics Materials and Articles Regulation")

Futamura does NOT introduce any of the following categories of materials in the manufacture of **NatureFlex™ NK**:

- "post-consumer materials"
including "post-consumer recycled materials," "post-consumer recovered materials" and "post-consumer plastic materials"
- "post-use materials"
including "post-use plastic materials" and "post-use plastic articles"
- "recycled plastic"
including "recycled plastic materials" and "recycled plastic articles"
- "post-consumer waste."

NatureFlex™ NK films are outside the scope of the Regulation (see Article 1 of the Regulation).

i NOT APPLICABLE

Regulation (EU) 2018/213 (unamended at current date)

("Regulation on the use of bisphenol A in varnishes and coatings")

Futamura does NOT introduce (i) bisphenol A (BPA); or (ii) epoxy resins based on bisphenol A (BPA), in the manufacture of **NatureFlex™ NK**.

The two coating layers in **NatureFlex™ NK** are not manufactured using BPA. As such they are outside the scope of the definition for 'varnishes' or 'coatings' given in Article 1(3) 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 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^(†): migration cannot exceed one tenth of the respective limit values, based on worst-case calculation or mathematical modelling or experimental test data.

^(†) 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 document available at the following location:

http://ec.europa.eu/food/safety/chemical_safety/food_contact_materials/related-docs_en

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II Assurances continued

7 “Dual Use Substances” · “Dual Use Additives” · “Multiple Function Additives”

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 coating layers of **NatureFlex™ NK**. It is:

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

^(††) assuming complete migration from one surface and a surface area:food mass ratio of 6.00 dm² per kg food

Based on information provided by suppliers, the components that Futamura uses to make the 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) 2018/1497 of 8 October 2018.

Regulation (EC) No 1334/2008 means that Regulation as amended up to and including Regulation (EU) 2019/36 of 10 January 2019.

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8 Specifications on use of the material:

NOTE 1:

The client should perform their own evaluation to verify the suitability of the film for their own proposed application. This includes verification of the technological suitability of the film, taking into account foreseeable conditions of use; and confirmation that the characteristics of the food product are acceptably maintained throughout. It is the sole responsibility of the client to determine whether the subject film is suitable for their own intended use. It is the responsibility of the food packer to determine the shelf life of their own processed or packed food product.

NOTE 2:

The information included in this section is based on the foreseen use of the subject films as monoweb materials in applications that would involve direct contact between the film and the food.

The content of this section does not take into account subsequent processing or treatments, or the possible presence of other components (e.g. other substrates, adhesives, printing inks, varnishes) that could influence the food contact status of the final article.

It is the responsibility of the producer of the final material or article to cooperate with the food packer in order to identify the legislation applying to the proposed application and to ensure the compliance of the final material or article with the applicable requirements.

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 recommends that **NatureFlex™ NK** films should not be used in monoweb form for the fabrication of packaging articles (e.g. bags or pouches) intended to hold liquid foods.

NOTE:

This recommendation is not related to food safety: it is based solely on the physical properties of the subject films.

Firstly: the thin surface coatings of the films result in heat seals of relatively low mechanical strength that may not be sufficient to withstand the internal pack pressure exerted by liquid foods upon storage.

Secondly: the use of standard packaging adhesives can result in the formation of seals having only modest bond strengths that may not be sufficient to withstand the internal pack pressure exerted by liquid foods upon storage.

These factors could cause bags or pouches formed from the subject films to burst once they have been filled, leading to the possibility of leakage or spillage of the liquid food product. For this reason the films are likely to be technologically unsuitable for use in monoweb form in such applications.



For Awareness: Limitation under US Legislation

Please be advised that under US FDA legislation **NatureFlex™ NK** films are not cleared (= authorised) for use in applications that would involve direct contact with alcoholic foods or beverages. Futamura advises its clients and food packers to have regard to this restriction if the processed or packed food product is to be placed on the market in countries that observe the requirements of this legislation.

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II Assurances continued

8 Specifications on use of the material continued

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

Frozen/Chilled/Temperate/Warm Fill/Hot Fill Applications:

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

- contact at room temperature or below for 6 months or more, i.e. without restriction on contact time
- “warm fill” or “hot fill” at temperatures up to +70°C for periods up to 120 minutes
- “hot fill” at temperatures up to +80°C for periods up to 60 minutes
- “hot fill” at temperatures up to +90°C for periods up to 30 minutes
- “hot fill” at temperatures up to +100°C for periods up to 15 minutes

It is the responsibility of the client to verify the suitability of the film for their own proposed application, including the confirmation that the film is technologically suitable for use under the intended conditions.

NOTE 1:

Futamura has not evaluated the performance of **NatureFlex™ NK** at low temperatures ($\leq 0^{\circ}\text{C}$).

Futamura advises that **NatureFlex™ NK** may be technologically unsuitable for use in applications that would involve processing, treatment or storage at temperatures below -30°C . This is because at very low temperatures the physical properties of the subject films can differ substantially from those exhibited under temperate conditions.

Exposure to temperatures below -30°C could result in embrittlement of the films, leading to the formation of shards or fragments which could detrimentally affect the functionality of the packaging unit and cause spoilage of the food product due to physical contamination. These outcomes could also arise if the films are subjected to rapid cooling (for instance, during commercially-operated food preservation processes such as blast freezing, snap freezing or flash freezing).

NOTE 2:

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

Futamura recommends that the films should not be used in monoweb form for the fabrication of packaging articles intended to hold or store food for prolonged periods (> 15 minutes) at temperatures above $+70^{\circ}\text{C}$.

c The highest food contact surface area to volume ratio for which compliance has been verified.

6.00 dm² of contact surface per kg of food

This is the highest surface area to volume (S/V) ratio for which Futamura offers a general assurance of compliance for the full range of food types and time-temperature conditions described in sections 8a & 8b.

Please notify your Futamura representative if you intend to use **NatureFlex™ NK** in applications in which the food contact S/V ratio would exceed the value stated above.

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 dm² 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.

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

There is no restriction on which surface is placed in contact with food as the two surfaces are nominally identical.

Please notify your Futamura representative if you intend to use **NatureFlex™ NK** in an application in which both surfaces of the film would make direct contact with food.

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II Assurances continued

9 Functional barrier:

Futamura does not offer an assurance that **NatureFlex™ NK** would perform as a functional barrier to the migration of individual substances in any specific packaging structure or for any specific food contact application.

The verification of functional barrier characteristics is not presently included as part of the Futamura quality assurance test schedules for the subject films.

For producers of multi-component packaging articles, it is the responsibility of the producer of the final article to determine whether a suitable functional barrier exists, taking into account:

- the identities of the potentially migrating substances for which the existence of a functional barrier is to be demonstrated;
- the physical and chemical characteristics of the various components from which the article is formed, and the spatial relationship of those components;
- the nature of the food with which the packaging article is to be placed in contact;
- the time and temperature of treatment and storage applying to the contact of the packaging article with the food.

Futamura may be able to offer advice on the anticipated barrier characteristics of the subject films towards certain categories of substances (e.g. mineral oil hydrocarbons). For further information please contact your Futamura representative.

III Business Operator Commitment to Cooperate with Food Control Authorities (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.

As of June 2017 the 'Agreement on the participation of the Republic of Croatia in the European Economic Area' had been ratified by 17 out of 32 parties.

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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 proposed food contact application, including:

- checking that the physical properties of the final material or article make it suitable for the proposed 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.

Advice for customers purchasing slit reels or trimmed mill rolls:

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/trimmed mill roll during their subsequent conversion or use.

Advice for customers purchasing sheets:

As a precautionary measure to ensure food safety, Futamura recommends that customers should discard the uppermost and lowermost sheets of film in each stack of packed sheets prior to their subsequent conversion or use.

Advice for customers purchasing discs:

As a precautionary measure to ensure food safety, Futamura recommends that customers should discard the uppermost and lowermost discs of film in each stack of packed discs prior to their subsequent use.

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

This declaration is issued subject to the FUTAMURA TERMS AND CONDITIONS OF SALE governing the applicable sales contract which are incorporated by reference.

No guarantee or warranty is provided that any of the subject films is adapted to the client's specific use.

It is the client's responsibility to perform their own evaluations to determine suitability for their own contemplated application.

The final decision on use of a film product remains the sole responsibility of the client.

V Author, Place, Date & Reference

This declaration was prepared by: Richard J Armstrong Global Regulatory Affairs Manager	Signature: 
Place of issue: Date of issue:	Wigton, England 04 February 2019

Full Document Reference – for Futamura use only:

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