

## Regulatory Affairs Compliance Information (RACI)

NatureWorks LLC has a fundamental duty to all those that use our products, and for the environment in which we live today and in the future. This duty is the basis for our Product Stewardship philosophy, by which we assess the health and environmental information on our products and their intended use. Our job is to maintain an effective product stewardship program to ensure that customers involved with our product receive sufficient information and training to store, use, and dispose of our product with no harm to human health or the environment. If you need further information regarding the toxicology or safe handling of our material please feel free to contact us.

### **FOOD PACKAGING MATERIALS COMPLIANCE**

Ingeo™ packaging grades suitable for food contact have compliance with a number of food contact packaging regulations around the globe. Below is a sample of the data from the US and Europe, if you need data on Australia, Argentina, Brazil, Canada, Israel, Japan, Korea, Mexico, New Zealand, Paraguay, Uruguay, South Africa, Switzerland, Taiwan, or another geographic region please contact us.

As supplied from our factory, the following grades comply with the following requirements:

Ingeo Packaging Resin Grades			
2002D	2003D	2100D	3001D
3051D	3052D	3251D	4032D
4042D	4043D	6202D	6302D
6252D	7000D	7001D	8051D
8052D	8251D		

In the US under FCN 178 (Food Contact Notification) which is inclusive of all food types with the limitation of condition of use B-H.

In Europe as a raw material with 1935/2004/EEC and Regulation 10/2011, this applies to all EU Member States. Regulation 10/2011 specifies overall migration less than 10 mg/dm<sup>2</sup>, there are no SML's for the above referenced grade in Regulation 10/2011.

As supplied from our factory, the following grades comply with the following requirements:

Ingeo Packaging Resin Grades			
4060D	8300D	8301D	8302D
6060D			

In the US under FCN 475 (Food Contact Notification) which is inclusive of all food types with the limitation of condition of use C-G.

In Europe as a raw material with 1935/2004/EEC and Regulation 10/2011, this applies to all EU Member States. Regulation 10/2011 specifies overall migration less than 10 mg/dm<sup>2</sup>, there are no SML's for the above referenced grade in Regulation 10/2011.

More information about the FCN process or current list of materials can be found on FDA's website at <http://www.cfsan.fda.gov/~dms/opa-fcn.html>.

We urge all of our customers to perform GMP (Good Manufacturing Procedures) when constructing a package so that it is suitable for the end use. Please note that it is the responsibility of both the manufacturers of finished food contact articles as well as the industrial food packers to make sure that these articles in their actual use are in compliance with the imposed specific and overall migration requirements.

### **BIOBASED CONTENT**

NatureWorks LLC carries the “OK biobased” certification from Vinçotte. This certification is based on the biobased content of Ingeo which can be determined through radiocarbon dating according to ASTM D6866-5 (Standard Test Method for Determining the Biobased Content of Natural range Materials Using Radiocarbon and Isotope Ratio mass Spectrometry Analysis).

The application of radiocarbon dating to derive "biobased content" is built upon the same concepts as determining a radiocarbon age, but without use of the age equations. It is done by deriving a ratio of the amount of radiocarbon (C) in an unknown sample to that of a modern reference standard. If the material being analyzed is a mixture of present day radiocarbon and fossil carbon (containing no radiocarbon), then the values obtained correlates directly to the amount of biobased material present in the sample. Below is a sample of the grades that carry the OK Biobased certification from Vinçotte:

<b>Ingeo Grades Covered</b>					
2002D	2003D	3001D	3051D	3052D	3251D
4032D	4042D	4043D	4060D		
6201D	6202D	6204D	6252D	6302D	6400D
6752D	7000D	7001D	8052D	8251D	

This information is not intended to relieve you from the requirement to test your biobased packaging. Under the OK biobased certification program, a customer of NatureWorks LLC cannot use the OK biobased logo on their products without gaining this certification on their end products from Vinçotte.

### **CHEMICAL CONTROL LAW COMPLIANCE**

Across the globe regulations exist for local environmental authorities to evaluate materials to assure the protection of human health and the environment from any unreasonable risks associated with chemical substances. Ingeo as supplied from the factory gate complies with the below global chemical inventories:

<b>Ingeo Grades Covered</b>					
2002D	2003D	2100D	3001D		
3051D	3052D	3251D			
4032D	4042D	4043D	4060D		
6201D	6202D	6204D	6251D	6252D	6300D
6302D	6350D	6360D	6400D	6702D	6751D
6752D	6800D	7000D	7001D	7032X	8051D
8052D	8251D	8301D	8302D		

United States (TSCA)  
Prop 65

Listed  
Not Listed

European Union (EINECS)/REACH	Compliant
Japan (ENCS)	Listed
Australia (AICS)	Listed
Korea (KCL)	Listed
Philippines (PICCS)	Not Listed
China (IECSC)	Listed

If you need further data on chemical control law status in other regions of the world, please contact us.

### **ORGANIC RECYCLING – INDUSTRIAL COMPOSTING**

Composting is a method of waste disposal that allows organic materials to be recycled into a product that can be used as a valuable soil amendment. Ingeo is a compostable material in municipal and industrial composting facilities where available. Ingeo breaks down, like other carbon based organic matter under industrial composting conditions.

Ingeo is intended for industrial-based composting systems which regulate temperature, moisture, and aeration.

Below is a sample data set of our certifications in the US and in Europe. If you need further data on composting or the certification systems in other regions of the world, please contact us.

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#### **In the United States:**

NatureWorks LLC has carried out compost testing in accordance to ASTM D-6400 guidelines at an independent testing laboratory and found Ingeo to pass all required tests. Ingeo as supplied from our factory is covered under our BPI (Biodegradable Products Institute) certificate with the limitation of:

<b>Ingeo Grades Covered</b>	<b>Limitation</b>
Ingeo 2002D, 2100D, 3001D, 3051D, 4032D, 4042D, 4043D, 4060D, 7000D, 7001D, 8300D, 8251D, 8301D, 8300D	2.0 mm layer thickness
Ingeo 2003D, 3052D, and 3251D	3.2 mm layer thickness

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#### **In Europe:**

NatureWorks LLC has carried out compost testing in accordance to EU guidelines at an independent testing laboratory and found Ingeo to pass all required tests Ingeo as supplied from our factory is covered under our DIN CERTCO certificate according to EN-13432 with the limitation of:

<b>Ingeo Grades Covered</b>	<b>Limitation</b>
Ingeo 2002D, 2003D, 2100D, 3001D, 3051D, 3052D, 4032D, 4042D, 4043D, 4060D, 7000D, 7001D, 8300D, 8251D, 8301D,	2.0 mm layer thickness

This data is not intended to relieve you from the requirement to test your compostable packaging. We recommend you examine the regulation to determine your responsibilities as a manufacturer for ensuring

your product is compliant. Any post addition of additives or colorants to NatureWorks LLC resin will have to pass all required testing to meet compostability standards.

### **KOSHER**

NatureWorks LLC has obtained certification for Ingeo (neat) biopolymer resin through the Kashruth Division of the Union of Orthodox Jewish Congregations of America and such grades are accordingly kosher and pareve.

### **ALLERGIES**

There are no concerns with Ingeo biopolymer regarding corn allergies. Triggers of allergic responses are antigens, often proteins, which can be found in air, food and water. In the case of corn allergens, profilin has been identified in corn and in many other plant (food) extracts. When food is heated past the heat-labile point, its chemical configuration changes. Due to the extreme heat and numerous processing steps to convert corn into our feedstock and then to Ingeo, it would not contain immunologically reactive profilin.

Ingeo biopolymer does not contain any known amounts of components derived from the ingredients listed in Directive 2003/89/EC and its amendments regarding allergens.

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The information herein is presented in good faith and believed to be accurate as of the effective date of this document. However, no warranty, express or implied is given. Regulatory requirements are subject to change and may differ from one location to another; it is the buyer's responsibility to ensure that its activities comply with federal, state or provincial, and local laws. The following specific information is made for the purpose of complying with numerous federal, state or provincial, and local laws and regulations.

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Document Control – RACI062811  
Authorized Individual – Regulatory Affairs Manager