

Regulatory Affairs Compliance Information (RACI)

NatureWorks 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™ biopolymer is suitable for food contact applications and has compliance with a number of food contact regulations around the globe. Information on the US and Europe can be found below, if you need information on another geographic region please contact us.

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

Ingeo Packaging Resin Grades			
2003D	2500HP		
3001D	3052D	3100HP	3251D
3260HP			
4032D	4043D	4044D	
6100D	6201D	6202D	6252D
6260D	6302D	6400D	6752D
7001D	7032D		
8052D			

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/dm², 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	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.

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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/dm², there are no SML's for the above referenced grade in Regulation 10/2011.

More information about the FCN process or current list of FCN substances can be found on FDA's website at <http://www.fda.gov/Food/IngredientsPackagingLabeling/PackagingFCS/default.htm>
 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 legislation.

CHEMICAL CONTROL LAW COMPLIANCE

Globe regulations exist 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:

United States (TSCA)	Listed
European Union (REACH)	Compliant
Japan (ENCS)	Listed
Australia (AICS)	Listed
Korea (KECL)	Listed
Philippines (PICCS)	In Process
China (IECSC)	Listed
Taiwan (TCSI)	Listed

If you need further information on chemical control law status, please contact us.

RoHs AND CONEG

Ingeo biopolymer is compliant with RoHs (2011/65/EC) and CONEG. During the manufacturing of Ingeo none of the restricted substances are intentionally added nor thought to be present.

BIOBASED CONTENT

NatureWorks carries the Vinçotte OK biobased and USDA BioPreferred certifications. These certifications are based on the biobased content of Ingeo biopolymer which can be determined through radiocarbon dating according to ASTM D6866 (Standard Test Method for Determining the Biobased Content of Natural range Materials Using Radiocarbon and Isotope Ration mass Spectrometry Analysis).

Below is a sample of the grades that carry the Vinçotte OK Biobased and USDA BioPreferred certifications:

Ingeo Packaging Resin Grades			
2003D	2500HP	3001D	3052D
3100HP	3251D	3260HP	4032D
4043D	4044D	4060D	6060D
6100D	6201D	6202D	6252D
6260D	6302D	6361D	6400D
6752D	7001D	7032D	8052D
10361D			

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

KOSHER AND HALAL

NatureWorks has obtained certification for Ingeo biopolymer resin through the Kashruth Division of the Union of Orthodox Jewish Congregations of America and such grades are accordingly kosher and pareve. Ingeo biopolymer is not currently certified according to Halal.

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, a protein, 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 and therefore no concerns regarding allergic reactions from Ingeo.

Ingeo biopolymer does not contain any known amounts of components derived from the ingredients listed in Directive 2003/89/EC and its amendments, 2000/13/EC as amended by 2007/68/EC regarding allergens or identified as “major food allergen” according to the definition under 21USC 321.201 of the FD&C Act.

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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