INEOS Olefins & Polymers Europe

100-GA12

Dear Madam, Sir,

In response to your request, we are pleased to provide you with the attached Regulatory Certificate issued by INEOS Olefins & Polymers Product Stewardship. It's regularly updated and freely available on line from our website.

Our policy regarding customer's questionnaire is to ask our customers to look for the information available in the on-line Regulatory Certificate. It indeed contains most of the relevant regulatory information related to our products.

Concerning the absence of specific substances in our grades, we understand your concerns that hazardous chemicals could be present in the products you buy from INEOS. We have therefore already listed at the end of the Regulatory Certificate the most current chemicals whose presence in PP or PE is restricted by an EU Regulation / Directive or any other legislation or even related to health or environment concerns linked to a recent or particular issue.
We take the opportunity to remind you that it is the responsibility of the converter to check the compliance of the final articles with the relevant legislation and applicable regulatory requirements.

Should there however be any specific topic or question unanswered for which you have a particular reason to request a declaration, justified by a legislation, the application or a specific market concern, you can of course contact us and we will then dedicate all our attention to answer you.

Best regards,

Jacques Breulet
Regulatory and External Affairs Manager
INEOS Olefins & Polymers Europe

100-GA12

Regulatory & Product Stewardship Certificate

Polypropylene grade

Pharmaceutical and medical use

In regards to the testing sets described in the US Pharmacopoeia 29, <88> Biological Reactivity Tests for Class VI Plastics, covering systemic injection test, intracutaneous test and implantation test, a production lot of the above mentioned grade has been analysed by an accredited laboratory. The analysed sample meets the requirements for USP Class VI.

Food contact EU: Declaration of Compliance (DoC)

EU Declaration of Compliance, Annex IV, Regulation (EU) 10/2011

1. **Identity and address of the operator issuing the DoC:**
   INEOS Services Belgium SA
   Product Stewardship Department
   Rue de Ransbeek 310
   B 1120 Bruxelles Belgium

2. **Identiy of the business operator which manufactures or imports the plastic:**
   INEOS O&P Europe
   3, avenue des Uttins
   CH 1180 Rolle Switzerland

3. **Identity of the material**: see header of the page

4. **Date of the declaration**: see footer of the page

5. **Confirmation that the plastic material meets the legal requirements**
   This grade complies with the relevant requirements of:
   - Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food
   - Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food, 321/2011 (1/4/2011), 1282/2011 (28/11/2011), 1183/2012 (30/11/2012), 202/2014 (3/3/2014), 2015/174 (5/2/2015), 2016/1416 (24/8/2016), 2017/752 (28/4/2017)
   - Commission Regulation (EC) No 2023/2006 of 22 December 2006 on good manufacturing practice for materials and articles intended to come into contact with food (GMP) as amended.

   The NIAS (Non Intentionally Added Substances) and the identified IAS (Intentionally Added Substances) present in this grade have been risk assessed in accordance with Art 19 of the Plastics Regulation (10/2011) and comply with the relevant requirements of the Framework Regulation (1935/2004).
   More relevant information necessary for a risk assessment of the NIAS by the downstream operator will be communicated upon request. The conversion process can indeed affect the type and quantity of NIAS present in the articles and the converter must reassess them to guarantee their compliance.

The compliance of the IAS present in this product will remain valid as no new IAS will be formed during the processing steps.

6. Adequate information on the substances used for which restrictions are set out
No monomers subject to Specific Migration Limit (SML) are used.

No additives subject to restriction (Specific Migration Limit or Quantitative Maximum) are used.

Indicative overall migration tests carried on this type of polymer on film or thin plaque, under the conditions 10 days / 40°C, in the food simulants A, B and D2 show that the Overall Migration Limit of 10 mg/dm² is not exceeded for this grade.
As the conversion process can affect migration, only the converter can guarantee the compliance of his own articles to the OML.

7. Adequate information relative to the substances which are subject to a restriction in food.
Calcium Stearate (E470) (CAS nb 1592-23-0) is approved as food additive (dual-use additive). It is present, as additive, in the above grade.

8. Specifications on the use of the material or article.
No other limitation or restriction than those listed in points 6 and 7 of this DoC applies to this grade.

9. When a functional barrier is used, confirmation that the article complies with this legislation.
This information does not apply to the plastic manufacturer.

Whereas Ineos Olefins & Polymers Europe supplies to its customers the adequate information to allow them to fulfil their own responsibilities, the converters do have to check and confirm that the final article meets both the technical and regulatory requirements of the application.

Switzerland

This product meets the requirements of the Swiss Ordinance 817.023.21 "Ordinance on Materials and Articles in Contact with Food" of 23/11/2005 in the frame of the Ordinance 817.02 "Foodstuffs and Utility Articles Ordinance" of 23/11/2005.

Food contact US

Under 21 CFR 177.1520(c)1.1a, this resin may be safely used in articles used for packing or holding food during cooking.
All adjuvants used in the manufacture of this resin are cleared for use in 21 CFR 170-189 by specific citation, generally recognized as safe (GRAS), prior sanctioned or under a specific Food Contact Notification (FCN).
No further restrictions apply to the finished polymer.

South America

This product meets the requirements of following regulations :

Mercosur (Argentina, Brazil, Paraguay, Uruguay and Venezuela):

- GMC Resolution No. 03/1992 of April 1st 1992, which "establishes the general criteria and classification of materials for packaging and equipment in contact with food"
- GMC Resolution No. 02/2012 of April 19th 2012 which provides a "positive list of monomers, other starting substances and polymers authorized for the manufacture of plastic packaging and equipment that come into contact with food"
- GMC Resolution No. 32/2007 of December 11th 2007 which provides a "positive list of additives for plastic materials intended for packaging and equipment manufacturing for contact with foods"

In order to guarantee the compliance with the Resolution, the end plastic product must be analyzed by the manufacturer concerning total migration limit and such limit must be less than 50 mg/kg or 8 mg/dm².

Brazil

- RDC Resolution No. 91/2002 of Anvisa of May 11, 2001,which "establishes the general criteria and classification of materials for packaging and equipment in contact with food"
- RDC Resolution No. 56/2012 of Anvisa of November 16, 2012 that "provides for the Positive List of monomers and other starting substances authorized polymers for the production of plastic packaging and equipment in contact with food"
- RDC Resolution No. 17/2008 of Anvisa of March 17, 2008 that "provides for Technical Regulation on the Positive List of Additives for Plastic Materials for the purpose of packaging and equipment manufacturing in contact with food"

In order to guarantee the compliance with the Resolution, the end plastic product must be analyzed by the manufacturer concerning total migration limit and such limit must be less than 50 mg/kg or 8 mg/dm².

China

Standard GB 31603-2015
This grade has been manufactured according to the requirements laid down by the General Hygiene Norm GB 31603-2015.

Standards GB 4806.1-2016 and GB 9685-2016
This grade is in compliance with the Standards GB 4806.1-2016 (General Safety Requirements for Food Contact Materials & Articles) and GB 9685-2016 (National Food Safety Standard: Standard for Uses of Additives in Food Contact Materials and Their Products).
For more details about eventual restrictions related to the use of particular monomers or additives, please refer to the § 6 and 7 of the EU DoC of the present Certificate. The restrictions listed in the new Chinese Standards are indeed fully aligned with those of the Annex 1 of the Regulation (EU) 10/2011.

Standard GB 4806.6-2016
This grade also fulfils the requirements of the Standard GB 4806.6-2016 (Plastic Resin Standard).
For more details about eventual restrictions related to SML, SML(T) and QM, please refer to the § 6 and 7 of the EU DoC of the present certificate. The restrictions applying to Plastics Resins are indeed fully aligned to those set by the Regulation (EU) 10/2011.

Standard GB 4806.7-2016
Indicative results performed on resins similar to this one show that if used under normal conditions, the articles produced should meet the requirements of Standard 4806.7-2016 (Plastic Articles Standard). It remains however the responsibility of the converter to assess the compliance of his articles with this standard.

Toys

The above grade meets the relevant requirements of Directive 2009/48/EC as amended and referred Community legal acts, and of the European Standard EN 71-3:2013+A1:2014.

Phthalates

It is well known that phthalates are used as minor component of the catalytic systems used for the production of polypropylene resins. INEOS Olefins & Polymers Europe also uses pre-catalysts containing phthalates for the production of most of its polypropylene grades.
These phthalates have been introduced in the REACH Authorisation process in 2009/2010 and have now passed their sunset date (21 February 2015).
This situation has retained our attention since the beginning. We have thus engaged discussions with all our catalytic systems suppliers and got the assurance that the use of the catalysts containing phthalates will not be negatively impacted and that we will be able to continue to use them for the production of our current polypropylene products, without any disruption and any change in their composition.

We have also gathered analytical evidence that the phthalate used in the catalytic system undergoes a complete chemical transformation during the polymerisation stage and is no longer present nor detectable as such in the final polypropylene with a detection limit well below 1 ppm.

We also confirm that all INEOS polypropylene grades manufactured from catalytic systems containing phthalate meet the relevant requirements of Commission Regulations EC 1907/2006, EU 10/2011 and those of Article 3 of Regulation EC 1935/2004.

Bovine Spongiform Encephalopathy (BSE)
Transmissible Spongiform Encephalopathy (TSE)

This grade contains stearate(s) as additive(s).

We received from our own suppliers the following guarantees:

1. The raw materials used in the production of animal-derived additives are categorized in cat 3 according to the Regulation (EC) 1069/2009, repealing the Regulation (EC) 1774/2002, and its implementing Regulation 142/2011, or originate from countries considered as BSE-free.
2. The production sites of these animal-derived additives are approved as cat 3 Oleochemical plants by local Authorities and have obtained the related certification with a registration number. The processing of beef tallow includes high temperatures (under pressure or not) for a defined duration, as prescribed by the Regulation 142/2011, in order to eliminate the risk of BSE contamination.
3. It is also claimed that BSE has never been found in beef tallow and the World Health Organisation (WHO) said that tallow does not represent a risk for both human and animal health (OMS/CDS/VPH/95.145).

Furthermore, during pelletization then conversion, the polyolefin plastics are exposed to shearing stress and to temperatures ranging from 160°C to 300°C during 20 seconds to a few minutes. These successive steps help to ensure the complete protection of people's health in respect of TSE for plastic materials used for food-contact, or similar, applications.

Genetically Modified Organisms (GMO)

Among the large variety of polymer additives and starting substances used, only a few of them may be issued of genetically modified organisms. We would like to comment on the relevance of gene modification techniques to plastic materials. The most significant fact is that the starting substances or additives (in the sense of Regulation 10/2011) deriving from raw materials issued from genetically modified organisms are manufactured through a multi-step conversion and/or purification process, involving aggressive conditions like high temperature and pressure as well as action of chemically reactive substances. The final plastic materials themselves are produced under high temperature conditions and are further submitted during conversion processes (extrusion, moulding) to high temperature for a significant period of time.

On the basis of current scientific knowledge, it can be stated that no DNA and no proteins from a given organism (genetically modified or not) can resist to and go through such a series of treatments. Therefore, their presence in our polymers and in plastic articles manufactured from them is highly unexpected.

In conclusion, we confirm that the above grade is safe to be manufactured, processed and used, even if it is manufactured from starting substances or contain additives which may be of genetically modified organisms origin.

Regulations: Hazardous Substances, RoHS, WEEE, EoL Vehicles, Packaging Waste, CONEG (Heavy Metals), Environment (France)

This grade meets the relevant requirements of the following Directives or Regulations:

- **Restriction of Hazardous Substances**: Directive 2003/11/EC of the European Parliament and of the Council of 6 February 2003 amending for the 24th time Council Directive 76/769/EEC relating to restrictions on the marketing and use of certain dangerous substances and preparations (pentabromodiphenyl ether, octabromodiphenyl ether), as amended
- **RoHS**: Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic Equipment, as amended
- **WEEE**: Directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on waste electrical and electronic equipment, as amended
- **EoL Vehicles**: Directive 2000/53/EC of the European Parliament and of the Council of 18 September 2000 on end-of life vehicles, as amended
- **Packaging Waste**: European Parliament and Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste, as amended
- **Coalition of Northeastern Governors (CONEG)**: USA CONEG Regulation, as amended
- **Environment Code (France)**: Décret n°2007-1467 du 12 octobre 2007 and Code de l'environnement, section 5-Emballages, sub-section 1, Articles R 543-42 to R 543-52, as amended

Cosmetic

This grade meets the relevant requirements of the Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products, as amended. In particular, none of substances listed in Annex II of the Regulation (EU) No 1223/2009 is used as additive or raw material.

Swiss VOC legislation

This product is in compliance with Swiss SR 814.018 "Ordinance on the Incentive Tax on Volatile Organic Compounds (OCOV) of 12 November 1997" as amended, about Volatile Organic Content (VOC).

Ozone layer-depleting agents

Chlorofluorocarbons (CFC's) and substances related to ozone depleting substances (as defined by the MONTREAL PROTOCOL and listed as class I & II substances by the US Clean Air Act) are not used as additives or raw materials in the manufacture of this grade.

None of the prohibited substances listed in Regulation (EC) 1005/2009 on substances that deplete the ozone layer (as amended), which repeals and replaces Regulation (EC) 2037/2000, is used as an additive or raw material in the manufacture of the above grade.

Nanomaterials and nanotechnology

Further to the publication of the EU Recommendation 2011/696/EU on the definition of nanomaterials, some substances used for decades as additives in the plastics industry suddenly became nanomaterials. The list includes among others, silica, carbon black and many organic pigments.
When these substances are used as additives in polyethylene or polypropylene, they end up encapsulated into a polymeric matrix and are not intended to be released under normal and foreseeable conditions.
Based on these arguments, the PP or PE products containing such additive(s) are exempt from notification under the French Decree 2012-232 (cfr Q&A n° 20bis on the website of the Ministère de l'Ecologie, du Développement Durable et de l'Energie).

REACH / SVHC

All Polyolefins materials are compliant with **REACH Regulation No. 1907/2006**.
For further details http://www.ineos.com/businesses/INEOS-Olefins-Polymers-Europe/SHE/#REACH .

- **REACH**: Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, as amended
- **CLP**: Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006, as amended

Inventories

The above product is in compliance with following inventories:

- Australian Inventory of Chemical Substances: AICS
- Canadian Chemical Registration Regulations: NDSL/DSL
- Chinese List on New Chemical Substances: IECS (Inventory of Existing Chemical Substances in China)
- European Inventory of Existing Chemical Substances: EINECS/ELINCS
- Japanese Chemical Substances Control Law under METI: CSCL
- Korean Existing Chemicals List: (K)ECL
- Philippine Inventory of Chemicals and Chemical Substances: PICCS
- US EPA Toxic Substance Control Act: TSCA
- New Zealand HSNO - Hazardous Substances and New Organisms

Absence of substances and chemicals

None of the following substances are used as additives or raw materials in the manufacture of this grade: However, since we do not systematically perform specific tests to verify the absence of these substances, we cannot guarantee that there is no trace amount of these substances, as impurity or otherwise, in this grade.

- Acrylamide
- Alkylphenol Ethoxylates (APEOs)
- Allergens (as defined in Regulation (EU) No 1169/2011, as amended)
- Aromatic amines
- Asbestos
- Azodicarbonamide or semi-carbazide compounds
- Benzophenone, hydroxybenzophenone and 4-methyl benzophenone
- Biocides
- Bisphenol-A (BPA), Bisphenol-F (BPF) and Bisphenol-S (BPS)
- Brominated flame retardants
- Chlorofluorocarbons (CFC), hydrochlorofluorocarbons (HCFC), hydrofluorocarbons (HFC)
- Chlorinated Paraffins
- Conflict minerals:
  - Columbite-tantalite (Coltan, Niobium, Tantalum)
  - Cassiterite (Tin)
  - Wolframite (Tungsten)
  - Gold
- Decabromodiphenylether (decaBDE)
- 2-Ethylhexanoic Acid (2-EHA)
- Di(ethylhexyl) adipate (DEHA) and di(ethylhexyl) maleate (DEHM)
- Dimethyl Fumarate (DMF)
- Dioxins and furans
- Endocrine Disruptors listed in the Japanese authority list "Strategic Programs on Environmental Endocrine Disruptors '98 (SPEED '98) - Table-3: Chemicals Suspected of Having Endocrine Disrupting Effects"
- Epoxy derivatives:
  - BADGE [2,2-bis(4-hydroxyphenyl)propane bis(2,3-epoxypropyl) ether],
  - BFDGE [bis(hydroxyphenyl)methane bis(2,3-epoxypropyl) ether],
  - NOGE [novolac glycidyl ether]

as defined in Directive 2002/16/EC amended by 2004/13/EC, repealed by the Regulation 1895/2005/EC
- Epoxidised Soya Bean Oil (ESBO)
- Formaldehyde (formol)
- (Heavy) metals: Antimony, Arsenic, Beryllium, Cadmium, Cobalt, Copper, Hexavalent Chromium, Lead, Mercury, Nickel, Selenium, Titanium
- Isopropylthioxanthone (ITX)
- Latexes and elastomers
- Melamine and cyanuric acid
- Mercapto mix
- N-ethyl-o,p-toluolsulfonamide (NETSA) (CAS nb 1077-66-1)
- N-ethyl-p-toluenesulphonamide (NE-PTSA) (CAS nb 80-39-7)
- Nonylphenol and its derivatives including Tris(nonylphenyl) Phosphite (TNPP)
- Organo-tin compounds
- Pentabromodiphenyl ether, octabromodiphenyl ether
- Perfluorinated compounds (PFC), Perfluorinated tenside (PFT), Perfluorooctanoic acid (PFOA) & Perfluorooctane sulfonate (PFOS) listed in Directive 2006/122/EC
- Poly(aromatic hydrocarbons) according to US Environmental Protection Agency Method 610 (EPA 610)
- Polybrominated biphenyls (PBBs), polybrominated diphenyl ethers (PBDEs), polybrominated terphenyls (PBTs)
- Polychlorinated biphenyls (PCBs), polychlorinated terphenyls (PCTs), polychlorinated naphthalenes (PCNs)
- Polycyclic Aromatic Hydrocarbons (PAH)
- Recycled products as defined by Regulation (EC) 282/2008
- Short-chain chlorinated paraffins
- Silicone
- Tert-butyl-4-hydroxyanisole (BHA) and 2,6-di-tert-butyl-p-cresol (BHT)
- Thiuram mix
- Titanium Acetyl Acetone (TAA)
- Triclosan (2,4,4'-trichloro-2'-hydroxydiphenyl ether) (CAS nb 3380-34-5)
- Vinyl chloride monomer (VCM) and its polymers or copolymers (PVC, PVDC, ...)
- Substances listed in:
  - California Proposition 65 State regulation as amended
  - GADSL, "Global Automotive Declarable Substance List", as amended
  - IKEA Specification, IOS-MAT-0010 ("General Requirements" & "Plastics"), as amended
  - IKEA Specification, IOS-MAT-0054, as amended

This certificate will be updated when appropriate. Therefore, it is recommended to visit our website at least once a year.

It is the responsibility of the customer to check the suitability of the finished article for the intended application and its compliance with the relevant legislation and applicable requirements including their restrictions.

Notice

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