



LIMITED LIABILITY COMPANY  
**TOBOLSK-POLYMER**  
(Tobolsk-Polymer LLC)

To whom it may concern

19.05.2014 № 07/0X-1215

### **Declaration of Compliance for Polypropylene (PP) Grades**

PP H030 GP/3, PP H040 GP/3, PP H060 GP/3, PP H080 GP/3, PP H120 GP/3,  
PP H032 TF/3, PP H033 FF/3, PP H031 BF/3

Dear Customer,

We hereby certify that the following polypropylene grades PP H030 GP/3, PP H040 GP/3, PP H060 GP/3, PP H080 GP/3, PP H120 GP/3, PP H032 TF/3, PP H033 FF/3, PP H031 BF/3 that we supply comply with the relevant requirements laid down in the following EU Regulations as amended to date:

- Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food, as amended to date;
- Regulation (EC) No 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food<sup>1</sup>;
- Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food<sup>2</sup> as amended by Regulation (EU) No 1183/2012<sup>3</sup> and Regulation (EU) No 202/2014<sup>4</sup>.

These grades have been manufactured only with monomers and additives that are authorized pursuant to Annex I to Regulation (EU) No 10/2011. The relevant restrictions and specifications set therein, including the generic specific migration limit ('SML') of 60 mg/kg, as applicable, are met for all the monomers and additives. For the assessment of some of the substances used in the composition of our PP grades we have relied upon the DoC provided to us by our suppliers.

### **Nanomaterials**

No nanomaterial as defined by the European Commission's Recommendation 2011/696/EU<sup>5</sup> is intentionally used in the production of the above mentioned PP grades.

<sup>1</sup> Commission Regulation (EC) No 2023/2006 of December 22, 2006 on good manufacturing practice for materials and articles intended to come into contact with food.

<sup>2</sup> Commission Regulation (EU) No 10/2011 of January, 14, 2011 on plastic materials and articles intended to come into contact with food.

<sup>3</sup> Commission Regulation (EU) No 1183/2012 of November 30, 2012 amending and correcting Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food.

<sup>4</sup> Commission Regulation (EU) No 202/2014 of March 3, 2014 amending and correcting Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food.

<sup>5</sup> Commission Recommendation of October, 18, 2011 on the definition of nanomaterial (2011/696/EU).

## Catalysts and known NIAS

Catalysts and known non-intentionally added substances ('NIAS') have been assessed in accordance with Article 19 of Regulation (EU) No 10/2011 and comply with Article 3.1 a) of Regulation (EC) No 1935/2004.

## Dual use additives

The following substance used in the PP grades referred to above is a dual use additive (only for PP H030 GP/3, PP H040 GP/3, PP H060 GP/3, PP H080 GP/3, PP H120 GP/3, PP H032 TF/3):

- Calcium distearate (CAS Reg. No 1592-23-0): FCM Substance No 106 and E 470a. The residual amount of calcium distearate in end-products of PP is  $\leq 0.05\%$ .

## Specifications on the use of the material

To verify compliance with the SMLs, the worst-case migration calculations, supporting the above compliance statement, have been conducted taking into account the following standard assumptions<sup>6</sup>:

- 6 dm<sup>2</sup> is in contact with 1 kg food;
- Migration occurs from a thickness of 0.025 cm of the polymer that is in contact with the food.

Taking into consideration the information received from our suppliers and the above assumptions, the PP Grades subject to this declaration of compliance may be used in materials and articles intended to come into contact with all types of foodstuffs under all time and temperature conditions.

## Further verifications in the final article

As Tobolsk-Polymer LLC (SIBUR Holding OJSC) is a producer of intermediate plastic materials, Tobolsk-Polymer LLC (SIBUR Holding OJSC) wishes to stress that it is the responsibility of manufacturer of the final article to ascertain (i) compliance with the overall migration limit of 10 mg/dm<sup>2</sup> or 60 mg/kg, as applicable<sup>7</sup>, and (ii) compliance with Article 3.1 c) of Regulation (EC) No 1935/2004 prohibiting the alteration of the organoleptic characteristics of the food.

**May 15, 2014**

Chief Engineer



A. Tretyakov

<sup>6</sup> See Note for guidance for petitioners presenting an application for the safety assessment of a substance to be used in food contact materials prior to its authorization, page 91.

<sup>7</sup> See Article 12 of Regulation (EU) No 10/2011.