Page 1 of 3 Rev: 2020-10-29

**RKW Sweden AB**Bunkagårdsgatan 2 | S-25368 Helsingborg



# Statement of compliance

Product name: FPO®PP Compound 419

All individual components included in the above mentioned product manufactured by RKW Sweden AB, as supplied in original packaging, according to our production methods and our suppliers' confirmations complies with the following legislations:

## 1. Framework Regulation 1935/2004/EC

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 is a framework regulation. So far it is applicable to the components in the product. The organoleptic characteristics of food contact materials are influenced by converting conditions, time and temperature of storage and type of food, therefore compliance with article 3 must be verified and tested by the producer of the final packaging material.

We hereby certify that the product and all of the individual components complies with the relevant requirements of 1935/2004/EC.

## 2. Good Manufacturing Practice (GMP) 2023/2006/EC

The European Commission\* issued a Regulation on Good Manufacturing Practice (GMP) and published it in December 2006 as Regulation 2023/2006/EC. The new regulation applies from August 2008. (\*The Commission of the European Communities has responsibility for regulating business operator selling to EU Countries).

Application of GMP means implementation of "those <u>aspects of quality assurance</u> which ensure that materials and articles are consistently produced and controlled to ensure conformity with the rules applicable to them and with the quality standards appropriate to their intended use by not endanger human health or causing an unacceptable change in the composition of the food or causing a deterioration in the organoleptic characteristics thereof".

We hereby certify that this material is manufactured in accordance with GMP Regulation 2023/2006/EC.

# 3. Food Allergen Labeling 2000/13/EC

According to our suppliers confirmations the raw material used for the manufacture of this product does not contain the following allergens (as defined in Regulation (EU) No 1169/2011):

- 1. Cereals containing gluten and products thereof
- 2. Crustaceans and products thereof
- 3. Eggs and products thereof
- 4. Fish and products thereof
- 5. Peanuts and products thereof
- 6. Soybeans and products thereof
- 7. Milk and products thereof (incl. Lactose)
- 8. Nuts and products thereof
- 9. Celery and products thereof
- 10. Mustard and products thereof
- 11. Sesame seeds and products thereof
- 12. Sulphur dioxide and sulphites at concentrations of more than 10 mg/kg expressed as SO<sub>2</sub>

**RKW Sweden AB**Bunkagårdsgatan 2 | S-25368 Helsingborg



- 13. Lupin and products thereof
- 14. Molluscs and products thereof

Consequently our product may reasonably be expected not to contain allergenic proteins. Our company has also taken serious precautions in accordance with Good Manufacturing Practice to prevent unintentional contamination of our products with food allergens.

#### 4. Plastics directive 10/2011/EC

From 1th of May 2011, directive 2002/72/EC with amendments, was replaced by Commission Regulation 10/2011/EC. This Regulation establishes the specific rules for plastic materials and articles to be applied for their safe use and repeal Commission Directive 2002/72/EC of 6 August 2002 on plastic materials and articles intended to come into contact with foodstuffs. According to our suppliers' confirmations', we declare that the components within our product fulfill the requirements of 2011/10/EC and all its amendments.

According to the provisions of the Regulation 1935/2004 and Directive 10/2011/EC, the overall migration limit, for which a maximum value of 10 mg/dm² is fixed, has to be controlled on the finished articles intended to come into contact with foodstuffs. Please note that it is the responsibility of the producer of the final package to insure that the article does not transfer taste or odor to the packed food stuff in the final package and that the migration limits are not exceeded.

#### **Specific Migration Limit substances (SMLs)**

According to our suppliers confirmations the raw material used for the manufacture of this product contains the following monomers and/or additives that can be found in Annex I of 10/2011/EC.

PM Ref/CAS	Chemical name / nature	SML limit mg/kg
182121-12-6	9,9-bis(methoxymethyl)fluorine	0,05
7429-90-5	Aluminium	1mg/kg
7440-39-3	Barium	1 mg/kg
7440-48-4	Cobalt	0.05 mg/kg
7440-50-8	Copper	5 mg/kg
7439-89-6	Iron	48 mg/kg
7439-96-5	Manganese	0.6mg/kg
7440-02-0	Nickel	0.02 mg/kg
7440-66-6	Zinc	5mg/kg
7 770 00-0	LITIO	

For substances for which no specific migration limit or other restrictions are provided in Annex I, a generic specific migration limit of 60 mg/kg shall apply

#### **Dual Use Additives (DUAs)**

"Dual use additives" are additives that may be used both in certain kinds of food and in its packaging at the same time. When some of this additive migrates from the packaging to the food, the additive content in the food increases of course. In the food these additives are subject to maximum permitted levels. In plastic packaging materials they are subject to migration limits. In some cases they have a specific migration limit, in other cases only the overall migration limit applies, according to Annex II of 1129/2011/EC.

Page **3** of **3** Rev: 2020-10-29

**RKW Sweden AB**Bunkagårdsgatan 2 | S-25368 Helsingborg



According to our suppliers confirmations the raw material used for the manufacture of this product contains the following Dual-Use-Additives

<u>Chemical name / nature</u> Calcium salts of fatty acids (E470a) Talc (E553b)

# 5. Waste directive 94/62/EC Requirements

Our suppliers declare that they fulfill packaging and packaging waste directive 94/62/EC requirements (PPWD) and declare that the sum of Pb, Cd, Hg and Cr (VI) is < 100 ppm according to the requirements on packaging or its components in Article 11 in the Directive 94/62/EC.

### 6. REACH Compliance and absence of SVHC's 1907/2006/EC

Regulation (EC) No 1907/2006 of the European parliament and of the council of 18 December 2006 concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH).

As RKW Sweden is a compounding / film blowing company we do not manufacture any raw materials and we are exempted from the rules to register our products. We need to register to ECHA if we import raw materials from outside of Europe and make sure that the raw materials are registered.

REACH establishes different obligations and requirements for EU legal entities that manufacture, import, place on the market and use chemical substances on their own, in preparations or in articles. Our suppliers ensure pre-registration and registration of all substances that are manufactured in or imported into the EU, and that are contained in or used for manufacturing of our product and to comply with all other obligations concerning these substances. According to our suppliers, we declare that the product fulfill the REACH compliance and agree with its content.

According to our suppliers' confirmations we also declare that the components within our product does <u>not</u> contain any of the Substances of Very High Concern (SVHC) in Annex XIV of REACH, nor any in the candidate list at <a href="http://echa.europa.eu/web/guest/candidate-list-table">http://echa.europa.eu/web/guest/candidate-list-table</a> in concentrations above 0,1% (w/w) since the update of **2020-06-25** in accordance to the criteria and properties mentioned in Article 57 in REACH. Additionally we declare that we don't intentionally add any SVHC to our product.

The product is recommended to be stored in a dry area with ambient temperatures, protected from ozone and sunlight. Stored properly, recommended storage time no more than 1 year.

This confirmation is an electronic document, therefore without signature

Revision: 2020-10-29

Prepared by: Stefan Jansson