



A tradition of
personal service

DECLARATION OF COMPLIANCE

Products: **442382 RaniBag EK 3 L** **230 X 400 X 0,025 MM 350 KPL/RLL**
 442383 RaniBag EK 5 L **300 X 450 X 0,025 MM 150 KPL/RLL**

Material: Polyethylene

1. Compliance with food contact regulations

We confirm that the above mentioned products complies with the requirements on materials used for articles intended to come into contact with food as described in:

Commission Regulation (EC) No 1935/2004
Commission Regulation (EU) No 10/ 2011 as amended

We like to draw your attention to the fact that Commission Regulation (EU) No 10/2011, which applies to all EU-Member States, includes a limit of 10 mg/dm² on the overall migration from finished plastic articles into food.

In accordance with Commission Regulation (EU) No 10/2011 the migration should be measured on finished articles placed into contact with the foodstuff or appropriate food simulants in accordance with Annex III of Commission Regulation (EU) No 10/2011 for a period and at a temperature which are chosen by reference to the contact conditions in actual use, according to the provisions in Article 22 of Commission Regulation (EU) No 10/2011.

Concerning Non-Intentionally Added Substances (NIAS), Commission Regulation (EU) 2011/10 notes that not all contaminants and reaction products of authorised monomers and additives can be listed in its Annex I. The identification of non-listed migrants may therefore not be an exclusion criterion in itself.

The major fractions of NIAS in Polyolefins are oligomers, which are chemically related to the aliphatic ingredients in mineral oils. These oligomers are unavoidably formed during polymerisation and cannot be removed. A recent study ("Determination of the Migration of Oligomers from Polyolefins"), concluded that the migration of oligomers in all types of polyolefins only consists of linear and branched alkanes (POSH) and alkenes (POMH). The study also concluded that oligomers from the polyolefin plastics food packaging, under typical conditions of use, are not a safety concern to human health. (Plastics Europe; Polyolefin Oligomers, Research Project for Risk Assessment)

However, any modification of the product, such as thermal modification, is beyond the control of Rani Plast. Therefore, any product screening can never monitor all potential criteria, so we cannot provide a final answer in this regard.



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Specific Migration Limitations

Specific migration limitations (SML) for certain substances are imposed by the EU/EFTA-member countries as follows:

Monomers:

Monomers are not used for the manufacturing of these products

Additives:

Area / volume ratio used in migration estimation of additives = 6 dm² / l. Theoretical calculations has been made. No additives exceeded the SML-limit.

Food additives:

EU Ref. No. 76960, Polyethylene glycol

EU Ref. No. 93520, alpha-tocopherol

The information herein is based on our knowledge and on information from our suppliers.

2. Good manufacture practice (GMP)

These products are manufactured in accordance with good manufacturing practice as outlined in Commission Regulation (EC) No 2023/2006 of 22 December 2006.

3. Handling and storing

Indoor storing at a temperature of maximum 30 °C is recommended. Products have to be protected from direct UV-light. Improper storage can initiate degradation, which results in odour generation and colour changes and can have negative effects on the physical properties of the products.

Recommended operation time for products is one year from manufacturing in food applications. It is the responsibility of the converter or food packer to control that the products are used during this time period. After operation time period user of the products is liable to take any necessary tests to prove that products are still feasible in food applications.

This certificate is valid 1 year from the date mentioned below.



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Teerijärvi 6.6.2025

A handwritten signature in blue ink, appearing to read "Anneli Timmerbacka".

Anneli Timmerbacka
Product Development
Ab Rani Plast Oy