

Declaration of compliance

According to our supplier of packaging materials:

With the legislation(s) for articles intended to come into contact with foodstuff.

Identity of the product or representative sample:

Article no: 100057197RO 76 SL 120 CC/40MM PP/ EVOH/PP 800 CLRMaterial: PP EVOH PP Clear

Date of declaration:

13-03-17

EU regulatory status of the product

- Commission regulation EC No. 2023/2006 (GMP) Product has been manufactured in accordance with relevant requirements of Commission Regulation EC No. 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food.
- Regulation (EC) No. 1935/2004 (Traceability)
 Manufacturer/ importer has system in place fulfilling the relevant aspects on traceability as required in article 17.1 of Regulation (EC) No. 1935/2004
- Regulation (EC) 282/2008 (Recycling)
 - *The product does not contain recycled materials that falls under this regulation (EC) 282/2008*
- Regulation (EC) 450/2009 (Active and intelligent packaging materials)
 The product does not fall under the regulation for Active and Intelligent packaging materials.

Used monomers and additives

- Plastic Regulation 10/2011/EC
 - Product has been manufactured only with monomers, other starting substances and additives that are authorised under the Plastic Regulation 10/2011/EC (up to and including the amendment EU 2016/1416)

Other substances used in the formulation of this product

The other substances used in the manufacturing of this article are listed in:

- Dutch Regeling Verpakkingen- en Gebruiksartikelen (Warenwet), chapter 1-Kunststoffen
- German Empfehlung of Kunststoffe im Lebensmittelverkehr: Empfelungen des Bundesinstitus für risikobewurtungen (BfR)

Pigments, Colorants and Adhesives (in case of a coloured/ printed or labeled article):

Other colorants and/or pigments used in the formulation of this product, that are not regulated by 10/2011/EC (up to and including the amendment 202/2014/EC), are incompliance with:

Dutch Regeling Verpakkingen- en Gebruiksartikelen (Warenwet). Chapter XI – Colorants and pigments.

And/or

Resolution AP (89) 1 of the Council of Europe "On the use of colorants in plastic materials coming into contact with food", II, 2 (purity).

And/or

The swiss regulation 817.023.21 "on the use of inks for materials or objects coming into contact with food"

And/or

The French positive list on pigments and colorants, published in the Circulaire no 176 consolidée du décembre 1959 modifée relative aux pigments et colorants des matières plastiques et emballages, as emanded

<u>All intentionally added substances</u> not subject to listing in Annex 1 comply with the relevant requirements of the framework Regulation 1935/2004 and a risk assessment in accordance with Article 19 of Plastic Regulation 10/2011 has been performed.

Overall Migration

Overall migration experiments with a representative sample made of a comparable grade have been performed and comply with the overall migration limits of **10mg/dm²**. Migration tests have been performed with the following test conditions;

Tests are based on 10/2011/EC

Surface – volume ratio of representative sample: 9,9

Overall migration test

Food simulant:		Test time and test temperature		Aver. Result (mg/dm²)
Α	10% ETHANOL	4 hours – 80 °C	- 10 days – 40 °C	<1
В	3% ACETIC ACID	4 hours – 100 °C	- 10 days – 60 °C	<1
D2	OLIVE OIL	1 hour – 130 °C	- 10 days – 60 °C	<2

It should be noted that the representative samples have been tested for the above mentioned conditions only. It is the responsibility of the legal entity responsible for placing the article on the market to ensure the usage of the article is safe, lawful and technically suitable and can determined through mutual consultation and agreement.

The product is not yet in contact with food and/ or intended for direct use by consumers.

It has therefore not been determined if the product induces an unacceptable change in the composition of the food or organoleptic changes of the food.

Regulatory status of used substances

We declare that:

Used substances subject to restriction in national legislation

Substances (colorants, polymer production aids, substances on the provisional list) used in the formulation of the product are subjected to restrictions in national legislation.

Presence of substances subject to SML or QM restrictions (national legislation)

Substance:	CAS number	Country	Restriction (mg/kg)
NA	NA	NA	NA
NA	NA	NA	NA

Substances, monomers and additives, subject to SML or QM restrictions

Substances, monomers, and additives, subject to SML or QM restrictions used in the formulation of the product are listed in EU regulation 10/2011/EC (up to and including the amendment 202/2014/EC).

Presence of substances subject to SML or QM restrictions (Annex I)

Substance:	EC reference number:	e Restriction (mg/kg)	Aver. Result (mg/kg)
Vinylacetate	231	12	0
Maileic Anhydride	234	30 (group restriction)	<1
Octadecyl3-(3,5-di-tert.butyl-4- hydroxyphenyl) propionate	433	6	<6
Ethylidenebicyclo [2.2.1] hept-2-ene	621	0.05	<0.05
Vinyl Tri-methoxy silane 2	453	0.05	<0.05
Zinc stearate	0	5 (as zinc)	<0.023
X	X	X	x
X	X	X	x
X	X	X	X
X	X	X	X

Substances listed in Annex II (1), metals

When the product contains substances listed in Annex II (1), to the Plastic Regulation, these substances cannot be released above the limit specified.

This product has been tested on containing substances of Annex II, these results are listed below.

Substance:	Restriction (mg/kg)	Aver. Result (mg/kg)
Barium	1	0.0021
Cobalt	0.05	<0.0005
Copper	5	0.001
Iron	48	<0.05
Lithium	0.6	<0.005
Manganese	0.6	<0.01
Zinc	5	0.023

X X 0

PAAs (Primary Aromatic Amines) covered by Annex II (2) to the Plastic Regulation

The product does not contain intentionally added PAAs. PAAs cannot be released above the detection limit.

Restrictions of substances in product mentioned in point b)/c) and d) are complied with, based on worst case calculations, migration modeling or migration testing.

Food simulant		Test time and test temperature		
Α	10% ETHANOL	4 hours – 80 °C -	10 days- 40 °C	
В	3% ACETIC ACID	4 hours – 100 °C -	10 days – 60 °C	
D2	OLIVE OIL	1 hour – 130 °C -	10 days- 60 °C	
D2 subst.	ISOOCTANE	2,5 hours – 60 °C -	2 days- 30 °C	
X	X	X	x	

Specific migration is tested under the following conditions: SM test conditions

Compliance of substances used in inks, coatings or adhesives

- That are also listed with a restriction in Annex I or II of the Plastic Regulation and Swiss ordinance – has been assessed. See Other substances used in the formulation of the product.

Presence of dual use additives. Identity of substance as listed in the European legislation on additives or flavourings, (Regulation (EC) NO 1333/2008, Regulation (EC) No 1334/2008) (Substance name and E-number or FL-number)

Substance:	E/FL-no:	Substance	E/FL-no:
Magnesium oxyd	E530	X	X
Sodium, Potassium and calcium salt	E470a	X	X
Silicium Dioxyd	E551	X	X
Calcium stearate	E470	X	X
Glycerol monostearate	E471	X	X
X	X	X	X
X	Х	X	Х

Final use of the product

The product is allowed to be in contact with the	All
following kinds of food:	
Specification of time and temperature of treatment	Any time at room temperature or
and storage with food:	below including pasteurization and
	sterilization processes
Ratio of the area of the food contact material to the	9.9
volume used to determine the compliance of the	
plastic food contact material or article	

Functional barrier

The product does not contain plastic layers behind a functional barrier

The information provided in this document is restricted to **this product** as it leaves its production facilities.

The information included in this document is valid from the stated version date until this document is superseded. Because of possible changes in the underlying legislation and regulations, as well as possible changes in our products, we cannot guarantee that the status of this document will remain unchanged. We, therefore recommend our customers to verify the regulatory status periodically. It will renewed in all cases where the previous conformity is no longer ensured.

Signature:

Date: 18-11-19

Femke van de Merwe Quality assistant