Plastirol
part of PAG

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Declaration of Compliance

1. Issued by
Plastirol B.V.
Ringersstraat 1-3
3364 BA
Sliedrecht
Nederland

Production: Plastirol Belgium

2. Identity of the product
PPH clear

3. Issue date
September 2025
This Declaration of Compliance supersedes previous versions where applicable.

4. Applicable legislation and purity confirmation
European Commission Regulation definition:
- 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 and repealing Directives 80/590/EEC and 89/109/EEC, (hereinafter referred to as "Regulation (EC) No 1935/2004").
- 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, amended up to COMMISSION REGULATION (EC) No 2022/1616 of 15 September 2022, (hereinafter referred to as "Regulation (EC) No 2023/2006").
- COMMISSION REGULATION (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food, amended up to 2025/351 COMMISSION REGULATION (EU) 2023/1627, (hereinafter referred to as "Regulation (EU) No 10/2011")
Amended up to and including Commission Regulation (EU) 2025/351
- COMMISSION REGULATION (EC) No 2022/1616 of 15 September 2022 on recycled plastic materials and articles intended to come into contact with foods and amending Regulation (EC) No 2023/2006, amended up to COMMISSION REGULATION (EU) 2015/1906 of 22 October 2015, (hereinafter referred to as "Regulation (EC) No 282/2008").

A. Europe

i. Compliance with the requirements of the Framework Regulation
- Regulation (EC) No 2023/2006; Good Manufacturing Practice (GMP): YES
- Article 3 of Regulation (EC) No 1935/2004; General safety aspects: YES

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- Article 17 of Regulation (EC) No 1935/2004; Traceability: YES

ii. Compliance with the requirements of the Plastics Regulation

- Regulation (EU) No 10/2011: YES

Plastics used to produce this Product and not separated from the food by a functional barrier are manufactured from only monomers, other starting substances and additives authorized under Regulation (EU) No 10/2011.

iii. Compliance with the requirements of the Recycled Plastics Regulation

- Regulation (EC) 2022/1616

Iv – High degree of purity

All substances intentionally used in the manufacture of this Product meet the Requirement of a high degree of purity as introduced by Regulation(EU) 2025/351.

B. Member State legislation and non-European legislation

Intentionally added substances not subject to listing in Annex I according to Article 6 of Regulation (EU) No 10/2011, and other components made from non-plastic materials, are either risk assessed in accordance with Article 3 of Regulation (EC) No 1935/2004 or comply with the requirements of the legislation listed below.

C. Non-intentionally added substances

The majority of the NIAS consists of oligomers (linear and branched alkanes, alkenes), components expected from polymerization and degradation/decomposition products expected from the additives. These substances are expected to be of low toxicological concern.

However we want to pay your attention to the fact that a NIAS assessment has to be performed on the final food contact article. The conversion process (thermal and mechanical treatment, addition of other chemical substances) and the applied test conditions can affect the amount and the nature of the NIAS. A raw material screening can never be representative for all potential usage conditions of the final article.

D. Overall migration limit

This product complies with the overall migration limit tested under the following conditions:

Simulants

- D1: Ethanol 50% (v/v)
- D2: Vegetable oil. This may be any vegetable oil with a fatty acid distribution as described in EC 10/2011.
- B: Acetic acid 3% (w/v)

Test conditions

OM2 10 d at 40 °C
OM5 2h at 100 °C

E. Organoleptic properties

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We have not determined whether a material or final article that is produced with this Product will induce an unacceptable change in the composition of the food or will cause deterioration of the organoleptic properties of the food. It is the responsibility of the downstream user to perform these tests.

6. Limits, restrictions and compositional specifications
A. Limits and restrictions of non-listed substances
This Product does not contain non-listed substances with restrictions.

B.Substances with limits and restrictions as listed in Regulation (EU) No 10/2011, Annex I

SML's

9,9-bis(methoxymethyl)fluorene	CAS No 182121-12-6	SML 0,05 mg/kg.
Cyclohexanadicarboxylic acid, calcium salt	Ref 45704	SML 5 mg/kg
Zinc Stearate	Ref 89040	SML 5 mg/kg
Aluminium		SML 1 mg/kg

Dual Use Additive(s)

Calcium stearate	Ref. No: 89040; E470a
Glycerol monostearate	Ref. No: 56585; E471

7. Specifications for use
Specifications of use as regards of type or types of food
All aqueous, acidic and alcoholic foods, foods which contain free fats at the surface and milk products
Specifications for use as regards of time and temperature of treatment and storage of food
For long term storage above 6 months at room temperature and below including heating up to 70 °C for up to 2 hours, or heating up to 100 °C for up to 15 minutes.
Any other limitations of use
Compliant with the provisions within Regulation (EU) No 10/2011 for infants and young children: YES
Compliant with the provisions within Regulation (EU) No 10/2011 for repeated-use articles: NO
A surface/volume ratio expressed in dm² FCM/kg food of: 6 dm² FCM / kg food

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Disclaimer
The information included in this document is based on the present state of our knowledge and is valid from the stated issue date until this document is superseded. Because of possible changes in the underlying legislation and regulations, as well as possible changes in this Product, we cannot guarantee that the status of this document will remain unchanged. This document is valid 2 years after the issue date.

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