

DECLARATION OF CONFORMITY, EUROPE

Product description

THERMAL ECO BPA FREE-FSC / RH9X

Sales Code: BZE/RH9X

Use: Paper and adhesive, a pressure-sensitive label.

Food contact regulations

We hereby confirm that the above mentioned product is in compliance with the EC regulations

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 282/2008 of 27 March 2008, (hereinafter referred to as "Regulation (EC) No 2023/2006").

All UPM Raflatac manufacturing sites in Europe have food safety system according to ISO 22000.

Substances with limits and restrictions as listed in Regulation (EU) No 10/2011

Limits and restrictions as listed in Regulation (EU) No 10/2011, Annex I

Substance name	Substance identification	Restrictions
<i>Proprietary substance</i>	FCM: - * CAS: -	SML:(1) 30 mg/kg
<i>Proprietary additive</i>	FCM: - * CAS: -	SML:(1) 5 mg/kg
<i>waxes, refined, derived from petroleum based or synthetic hydrocarbon feedstocks, high viscosity</i>	FCM: 94 CAS: —	No Other Specifications: Average molecular weight not less than 500 Da. Viscosity at 100 °C not less than 11 cSt (11 × 10 ⁻⁶ m ² /s). Content of mineral hydrocarbons with Carbon number less than 25, not more than 5 % (w/w).
<i>white mineral oils, paraffinic, derived from petroleum based hydrocarbon feedstocks</i>	FCM: 95 CAS: —	No Other Specifications: Average molecular weight not less than 480 Da. Viscosity at 100 °C not less than 8,5 cSt (8,5 × 10 ⁻⁶ m ² /s). Content of mineral hydrocarbons with Carbon number less than 25, not more than 5 % (w/w).

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<i>petroleum hydrocarbon resins (hydrogenated)</i>	FCM: 97 CAS: —	No Other Specifications: Petroleum hydrocarbon resins, hydrogenated are produced by the catalytic or thermal polymerisation of dienes and olefins of the aliphatic, alicyclic and/or monobenzenoidarylalkene types from distillates of cracked petroleum stocks with a boiling range not greater than 220 °C, as well as the pure monomers found in these distillation streams, subsequently followed by distillation, hydrogenation and additional processing. Properties: Viscosity at 120 °C: > 3 Pa.s, Softening point: > 95 °C as determined by ASTM Method E 28-67, Bromine number: < 40 (ASTM D1159), The colour of a 50 % solution in toluene < 11 on the Gardner scale, Residual aromatic monomer = 50 ppm,
<i>2-methyl-1,3-butadiene</i>	FCM: 144 CAS: 0000078-79-5	SML:(1) 0,01 mg/kg QM:(1) 0.0001 % SML(T) Remark:(1) Annex I. SML= ND. Unless specific detection limits have been set for particular substances or groups of substances, a detection limit of 0,01 mg/kg shall apply QM(T) Remark:(1) 1 mg/kg in final product Other Specifications: 1 mg/kg in final product
<i>4,4'-dihydroxydiphenyl sulphone</i>	FCM: 154 CAS: 0000080-09-1	SML:(1) 0,05 mg/kg
<i>butadiene</i>	FCM: 223 CAS: 0000106-99-0	SML:(1) 0,01 mg/kg QM:(1) 0.0001 % SML(T) Remark:(1) Annex I. SML= ND. Unless specific detection limits have been set for particular substances or groups of substances, a detection limit of 0,01 mg/kg shall apply QM(T) Remark:(1) 1 mg/kg in final product Other Specifications: 1 mg/kg in final product
<i>octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate</i>	FCM: 433 CAS: 0002082-79-3	SML:(1) 6 mg/kg
<i>silicon dioxide</i>	FCM: 504 CAS: 0007631-86-9	No Other Specifications: For synthetic amorphous silicon dioxide: primary particles of 1 – 100 nm which are aggregated to a size of 0,1 – 1 µm which may form agglomerates within the size distribution of 0,3 µm to the mm size.

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<i>4,4'-butylidene-bis(6-tert-butyl-3-methylphenyl-ditridecyl phosphite)</i>	FCM: 608 CAS: 0013003-12-8	SML:(1) 6 mg/kg
<i>2,4-bis(octylthiomethyl)-6-methylphenol</i>	FCM: 756 CAS: 0110553-27-0	SML:(1) 5 mg/kg SML(T) Remark:(1) Group 24: expressed as the sum of the substances (756, 758)

* Substances marked with a single asterisk in this document are reportable substances with variable concentrations due to variations in supply source.

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Limits and restrictions as listed in Regulation (EU) No 10/2011, Annex II, Metals

This Product does not contain metals with restrictions listed in Annex II.

Dual use additives

A substance is defined as a "Dual Use Additive" if the chemical identity of the plastic additive matches that of an authorized food additive or flavoring, regardless of its purity or whether or not the substance is subject to a restriction in food and/or in the plastic. In the case of salts it is the salt that matters, not the authorized acid, phenol or alcohol.

The following dual use substances may be present:

Name	Number (E or FL)
Silicon dioxide	E 551
Talc	E 553b
Calcium carbonate	E 170
Isopropyl dodecanoate	FL 9.605
Hexadecanoic acid	FL 8.014
Octadecanoic acid	FL 8.015
Oleic acid	FL 8.013
Vinylbenzene	FL 1.015

The purity of the Dual Use Additives used in this Product respect the purity criteria set out in Annex I of Regulation (EU) No 10/2011.

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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.

Legislation for countries outside the EU

Material group	Country	Legislation
ADHESIVES	United States - FDA § 21 CFR 175.105 – Adhesives	<p>UPM Raflatac has surveyed suppliers of components used to formulate the adhesive used to manufacture this product and verified with the requirements of § 21 CFR 175.105 (a)(2) – Adhesives.</p> <p>Note that § 21 CFR 175.105 (a)(2) states that for a complying adhesive: The adhesive is either separated from the food by a functional barrier or used subject to the following additional limitations:</p> <p>(i) In dry foods. The quantity of adhesive that contacts packaged dry food shall not exceed the limits of good manufacturing practice.</p> <p>(ii) In fatty and aqueous foods. (a) The quantity of adhesive that contacts packaged fatty and aqueous foods shall not exceed the trace amount at seams and at the edge exposure between packaging laminates that may occur within the limits of good manufacturing practice.</p> <p>It is the label end user’s responsibility to determine if its intended end use of UPM Raflatac’s products complies with 21 CFR 175.105 (a)(2).</p> <p><u>Specifications of use</u> n/a</p>

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Determination of the migration

Please note that face and adhesive have been assessed individually. Some of the substances with SMLs listed above are declared by our suppliers and not included in migration testing.

Determination of the migration for the adhesive

Testing conditions and simulants are chosen by the testing laboratory. The determination was carried out according to the methods for the "Examination of consumer goods" corresponding to the directives B 80.30, 1 to 3 (EG) of the Official Collection of Analytical Methods according to § 64 LFGB and according to the rules of the series of standards EN 1186, EN 13130 and CEN/TS 14234 as well as 14235 "Materials and articles in contact with foodstuffs – Plastics or polymer coatings, respectively".

Simulants and overall migration results (correction factors may apply)
- D1 - Ethanol 50% (v/v) : < 2,0 mg/dm ²

Test conditions	Additional simulants/conditions
See exception note Test time: 24 hours Test temperature: 40°C	Exception - see exception note

EXCP¹: If it is found that carrying out the tests under the contact conditions specified in Table 3 causes physical or other changes in the test specimen which do not occur under worst foreseeable conditions of use of the material or article under examination, the migration tests shall be carried out under the worst foreseeable conditions of use in which these physical or other changes do not take place.

EXCP²: If it is found that carrying out the tests under the combination of contact conditions specified in Tables 1 and 2 causes physical or other changes in the test specimen which do not occur under worst foreseeable conditions of use of the material or article under examination, the migration tests shall be carried out under the worst foreseeable conditions of use in which these physical or other changes do not take place.

Determination of the overall migration for the paper

Simulants and test conditions
Test conditions and simulants for overall migration of the face paper were not allocated by our supplier. Therefore it remains the responsibility of the converter to verify that the finished article meets the technical and regulatory requirements of the intended application.

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Specifications on the use of the material

According to the migration tests performed by an accredited laboratory (EN ISO 17025), the face paper may be used safely in thermal printers and scales for labelling of goods. It is suitable for direct contact with such kind of foodstuffs which are washed, shelled and/or peeled before consumption.

According to the migration tests performed by an accredited laboratory (EN ISO 17025), the adhesive may be used safely for the reverse coating of the labels for storage at room temperature. The adhesive layer may stand in direct contact with dry, moist and such kind of fatty foodstuffs to which the food simulant D1 is assigned (e.g. dairy products) according to the regulation (EU) No 10/2011 up to the amendment Regulation (EU) 2020/1245 of 3 September 2020. The maximum contact area in direct labelling of foodstuffs is 2 dm²/1 kg food.

Furthermore, the product may be used in labelling food packaging materials for storage at room temperature or below. The maximum contact area in laminating application is 6 dm²/1 kg food. The relevant migration limits have to be ensured individually.

Please note the specification of use (SoU) in this statement is only for the semi-finished product. This is typically used as a component of a multi layered packaging system and that further processing and converting of this material is carried out. If the SoU is listed separately for each layer and they are different, then the layer with the worst-case specification of use must be taken into consideration. The downstream users must make their own assessment so that they can produce their own food contact statements taking into account the inks and the printing process and other layers to ensure that the relevant migration limits are met for the packaging system as a whole and that through all stages of the manufacturing process the requirements of Good Manufacturing Practice (GMP) according to Regulation (EC) No 2023/2006 are met.

Organoleptic properties

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.

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In view of many factors that may affect processing and application of our product, this does not relieve processors from carrying out their own investigations and tests. This declaration is valid for the production from our sites after the date above for 3 years or when new scientific evidence is available, or when substantial changes in production occur and/or until the next relevant legislative or regulatory change comes into force, whichever is sooner.

*DL = Detection limit of the method of analysis

ND = Not detectable

QM = Maximum permitted quantity of the residual substance in the material or article

QM(T) = Maximum permitted quantity of the residual substance in the material or article expressed as mg of total of moiety or substance(s) based on 6 dm² of the surface in contact with foodstuffs

QMA = Maximum permitted quantity of the 'residual' substance in the finished material or article based on 6 dm² of the surface in contact with foodstuffs

QMA(T) = Maximum permitted quantity of the residual substance in the finished material or article expressed as mg of total of moiety or substance(s) based on 6 dm² of the surface in contact with foodstuffs.

SML = Specific migration limit in food or in food simulant

SML(T) = Specific migration limit in food or in food simulant expressed as total of moiety or substance(s) indicated

Disclaimer

This information is based on our most up-to-date knowledge and experience, but this statement does not constitute any warranty, expressed or implied. Information is only intended for the Raflatac customer and cannot therefore be transferred to any third party. We cannot assume any liability for using our products in conjunction with other materials and the customer must make their own qualification and suitability testing before using Raflatac material as part of the customer products. The suitability of Raflatac material in customer products is solely the customer's responsibility.

All our products are sold subject to UPM Raflatac's general conditions, available at www.upmraflatac.com and upon request where our liability towards customer is exclusively defined therein.

In case of any discrepancies, the English version of this document shall prevail.