DECLARATION OF COMPLIANCE, EUROPE

Product description

THERMAL ECO BPA FREE-FSC / RH9X
Sales Code: BZE/RH9X
Use: Paper and adhesive, a pressure-sensitive label.

Food contact regulations

Scope:
The above mentioned label material is a typically a semi-finished product intended to be used as part of food packaging.

Purpose of the Declaration of Compliance (DoC):
The DoC provides essential information to customers to support them in carrying out their risk assessment and to establish their product's compliance with applicable legislation for food packaging.

UPM Raflatac's Responsibility:
UPM Raflatac's responsibility is to provide adequate information through the DoC.

We cannot give any guarantees to the legal compliance for the final packaging regarding food contact materials. As compliance depends on various factors such as container thickness, usage conditions, temperature, and additional processes like the printing inks or varnishing. These factors are beyond our control. Only the manufacturer of the final packaging item can verify compliance based on the real or foreseeable use. As a self-adhesive label stock manufacturer, we cannot perform this verification or provide such assurances.

Customer/End-User Responsibility:
The Specification of Use (SoU) is defined for individual components such as face material and adhesive.
The component with the worst-case SoU should be taken into consideration.
Customers/ End-Users must assess other components (e.g., printing inks) to ensure specific migration limits (SMLs) are not exceeded for the entire packaging as every part of the multi-layer counts. It is the end users responsibility to assess the final package. Even if there is a suitable functional barrier the packaging must not contain substances that are mutagenic, carcinogenic or toxic to reproduction or nanomaterials as these are not covered by the functional barrier concept.

EU Measures:
The framework REGULATION (EC) No 1935/2004 covers all food contact materials.
Currently, there are no specific EU measures for adhesives or papers; regulations mainly apply to plastics.

UPM Raflatac

Tesomankatu 31
PO Box 53
FI-33101 Tampere
Finland

E-mail Productsafety.emeia@upmraflatac.com

www.upmraflatac.com

DECLARATION OF COMPLIANCE, EUROPE

Product description

THERMAL ECO BPA FREE-FSC / RH9X
Sales Code: BZE/RH9X
Use: Paper and adhesive, a pressure-sensitive label.

Specific Migration Limits (SMLs)

SMLs from plastic Regulation (EU) No 10/2011 are applicable to adhesives.
Adhesives cannot be tested like plastics due to material differences.
Our adhesive has only been assessed for use for long term storage at room temperature, typically for contact with dry moist and non-fatty food with a maximum contact area of 2 dm²/1 kg food. (See under section on “Determination of the migration")
Modified test methods based on plastic Regulation (EU) No 10/2011 are used to simulate real-world application conditions by an accredited lab.
The entire packaging must be evaluated for SMLs and substances (also present in inks, varnishes, or plastic components).

SML List:

The SML list provides the maximum permissible values from Annex I of the EU Regulation 10/2011 of their constituents which should not be exceeded and transferred to food by plastic and articles. These are expressed in mg of substance per kg of food (mg/kg).
Please note that it is not a list of ingredients of the self-adhesive label or concentrations.

Specifications on the use of the material

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. The SoU is listed separately for each layer and if they are different, then the layer with the worst-case specification of use must be taken into consideration.

Face material
According to our supplier, the face paper is suitable for direct contact with such kind of foodstuffs which are peeled, shelled or washed before consumption.

Adhesive
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) 2023/1627 of 10 August 2023. The maximum contact area in direct labelling of foodstuffs is 2 dm²/1 kg food.

DECLARATION OF COMPLIANCE, EUROPE

Product description

THERMAL ECO BPA FREE-FSC / RH9X
Sales Code: BZE/RH9X
Use: Paper and adhesive, a pressure-sensitive label.

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.

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.

Compliance

We hereby confirm that the above mentioned semi-finished product is in compliance with the applicable sections of 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 have a food safety management system.

UPM

DECLARATION OF COMPLIANCE, EUROPE

Product description

THERMAL ECO BPA FREE-FSC / RH9X
Sales Code: BZE/RH9X
Use: Paper and adhesive, a pressure-sensitive label.

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

Please note that it is not a list of ingredients of the self-adhesive label or concentrations.

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

Substance name	Substance identification	Restrictions
waxes, refined, derived from petroleum based or synthetic hydrocarbon feedstocks, high viscosity	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 m2/s). Content of mineral hydrocarbons with Carbon number less than 25, not more than 5 % (w/w).
white mineral oils, paraffinic, derived from petroleum based hydrocarbon feedstocks	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 m2/s). Content of mineral hydrocarbons with Carbon number less than 25, not more than 5 % (w/w).
petroleum hydrocarbon resins (hydrogenated)	FCM: 97 CAS: —	No **Other Specifications:** Petroleum hydrocarbon resins, hydrogenated are produced by the catalytic or thermalpolymerisation 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,

DECLARATION OF COMPLIANCE, EUROPE

Product description

THERMAL ECO BPA FREE-FSC / RH9X
Sales Code: BZE/RH9X
Use: Paper and adhesive, a pressure-sensitive label.

2-methyl-1,3-butadiene	FCM: 144 CAS: 0000078-79-5	**SML:** 0,01 mg/kg **QM:** 0,0001 % **SML(T) Remark:** 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 mg/kg in final product **Other Specifications:** 1 mg/kg in final product
4,4'-dihydroxydiphenyl sulphone	FCM: 154 * CAS: 0000080-09-1	**SML:** 0,05 mg/kg
butadiene	FCM: 223 CAS: 0000106-99-0	**SML:** 0,01 mg/kg **QM:** 0,0001 % **SML(T) Remark:** 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 mg/kg in final product **Other Specifications:** 1 mg/kg in final product
thiodipropionic acid, didodecyl ester	FCM: 294 * CAS: 0000123-28-4	**SML:** 5 mg/kg **SML(T) Remark:** Group 14: Expressed as the sum of the substances and their oxidation products (294, 368, 894)
2,4-bis(octylmercapto)-6-(4-hydroxy-3,5-di-tert-butylanilino)-1,3,5-triazine	FCM: 384 * CAS: 0000991-84-4	**SML:** 30 mg/kg
octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate	FCM: 433 CAS: 0002082-79-3	**SML:** 6 mg/kg
silicon dioxide	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.

UPM Raflatac

Tesomankatu 31
PO Box 53
FI-33101 Tampere
Finland

E-mail Productsafety.emeia@upmraflatac.com

www.upmraflatac.com

DECLARATION OF COMPLIANCE, EUROPE

Product description

THERMAL ECO BPA FREE-FSC / RH9X
Sales Code: BZE/RH9X
Use: Paper and adhesive, a pressure-sensitive label.

4,4'-butylidene-bis(6-tert-butyl-3-methylphenyl-ditridecyl phosphite)	FCM: 608 CAS: 0013003-12-8	**SML:** 6 mg/kg
2,4-bis(octylthiomethyl)-6-methylphenol	FCM: 756 CAS: 0110553-27-0	**SML:** 5 mg/kg **SML(T) Remark:** 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.

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

Name / Element	Restriction
Lithium	SML: 0,6 mg/kg

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)
Talc	E 553b
Silicon dioxide	E 551
Calcium carbonate	E 170
Octadecanoic acid	FL 8.015
Oleic acid	FL 8.013
Hexadecanoic acid	FL 8.014
Isopropyl dodecanoate	FL 9.605

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.

DECLARATION OF COMPLIANCE, EUROPE

Product description

THERMAL ECO BPA FREE-FSC / RH9X
Sales Code: BZE/RH9X
Use: Paper and adhesive, a pressure-sensitive label.

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	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. 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: (i) In dry foods. The quantity of adhesive that contacts packaged dry food shall not exceed the limits of good manufacturing practice. (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. 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). Specifications of use n/a

DECLARATION OF COMPLIANCE, EUROPE

Product description

THERMAL ECO BPA FREE-FSC / RH9X
Sales Code: BZE/RH9X
Use: Paper and adhesive, a pressure-sensitive label.

Determination of the migration

Please note that face material, top coating 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/dm²

Test conditions	Additional simulants/conditions
See exception note¹ 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.

Organoleptic properties

We have not determined whether a material or final article that is produced with this Product will induce an

DECLARATION OF COMPLIANCE, EUROPE

Product description

THERMAL ECO BPA FREE-FSC / RH9X
Sales Code: BZE/RH9X
Use: Paper and adhesive, a pressure-sensitive label.

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.

UPM Raflatac

Tesomankatu 31
PO Box 53
FI-33101 Tampere
Finland

E-mail Productsafety.emeia@upmraflatac.com

www.upmraflatac.com

DECLARATION OF COMPLIANCE, EUROPE

Product description

THERMAL ECO BPA FREE-FSC / RH9X
Sales Code: BZE/RH9X
Use: Paper and adhesive, a pressure-sensitive label.

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.

Abbreviations
*DL = Detection limit of the method of analysis
ND = Not detectable
OML= Maximum permitted amount of non-volatile substances released from a material or article into food simulants
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.

UPM Raflatac

Tesomankatu 31
PO Box 53
FI-33101 Tampere
Finland

E-mail Productsafety.emeia@upmraflatac.com

www.upmraflatac.com