Nette
PARTNER IN HANDEL & INDUSTRIE

nette-deutschland.de

Lebensmittelrechtliche Konformitätserklärung

Für unseren Artikel:

OPP-Zuschnitte 9x12cm 20my im Spenderkarton a 16000 Blatt

mit der folgenden Artikel-Nummer:

1264

Hiermit bestätigen wir auf der Grundlage der uns vorliegenden Lebensmittelunbedenklichkeits-erklärung des Produzenten, dass die von uns oben genannten Artikel für den Kontakt mit Lebensmitteln geeignet sind und den dafür vorgesehenen Gesetzen sowie Richtlinien entsprechen.

Zum eigenen Schutz unserer Lieferquellen sind Vorlieferant und Untersuchungslabor sowie dritte beteiligte Personen unkenntlich gemacht. Die uns vorliegende Originalerklärung kann den zuständigen Behörden auf Verlangen zur Verfügung gestellt werden.

Unsere Bestätigung setzt voraus, dass der Packstoff sachgemäß weiterverarbeitet wird. Die spezielle Eignung dieses Packstoffes kann nur vom sachkundigen Füllguterzeuger oder Abpacker beurteilt werden.

Diese Konformitätserklärung ersetzt zuvor ausgestellte Konformitätserklärungen und besitzt eine allgemeine Gültigkeit ab Ausstellungsdatum bzw. bis zur Änderung der Gesetzeslage.

Göttingen, den 08.09.2023

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Göttingen

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Lebensmittelunbedenklichkeitserklärung des Lieferanten:

ANFANG LEBENSMITTELUNBEDENKLICHKEITSERKLÄRUNG DES LIEFERANTEN

BS 20 – 25 - 30

PRODUCT MANUFACTURER

The product BS 20 – BS 25 – BS 30 are manufactured by [redacted] BOPP Division.

GOOD MANUFACTURING PRACTICES (GMP)

The manufacturing of these products has been done in regards to requirements on Good Manufacturing Practices as defined by the framework Regulation 1935/2004/EC and "GMP" Regulation 2023/2006/EC as amended.

STATEMENT OF COMPLIANCE WITH FOOD CONTACT REGULATIONS

We confirm that the composition of these products complies with the following Legislations, Recommendations or Communications for the production of food packaging:

Italy

"Decreto Ministeriale del 21/03/1973 and amendments.

European Union

"Regulation 1935/2004" of the European Parliament and Council of 27 October 2004.

"Regulation 10/2011" of the European Commission of 14 January 2011 as amended.

The 15th amendment of Reg.EU 10/2011 lays down new requirements for plastic materials and articles intended to come into contact with food, at every stage of the manufacturing chain.

The compliance with the last amendment concerns the following evaluation:

Identification and amount of substances, in the intermediate material, that are subject to restrictions in Annex II, or for which genotoxicity has not been ruled out, and which originate from an intentional use during a manufacturing stage of that intermediate material and which could be present in an amount that foreseeably gives rise to a migration from the final material exceeding 0,00015 mg/kg food or food simulant;
Disclosure of identity and concentration of substances in the intermediate material which are listed in Annex II of the regulation with a restriction, including also non-intentionally added substances (NIAS), like for example impurities.

According to the recipe, the Safety Data Sheets and the information shared by our suppliers of raw materials, we can declare that:

- There are no potentially genotoxic substances derived from an intentional use during a manufacturing stage.

All the monomers and additives used to produce the components of our products are listed in Annex I of the Regulation 10/2011 as amended.
The overall migration measured on these products is under the limit of 10 mg/dm^2 (Surface/Volume Ratio = 8 dm^2/ml) specified by Regulation 10/2011/EC and subsequent amendments.
The level of migration has been measured according to the rules specified in Regulation 10/2011/EC, Annex III and Annex V, using the following simulants/test conditions:

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Food Simulant	Testing Conditions
A, Ethanol 10% (v/v)	10 days, 60°C
B, Acetic acid 3% (p/v)	10 days, 60°C
D2, Oil	10 days, 60°C

For the following additives a SML is established in Regulation 10/2011/EC:

Ref. No	Restrictions
39090	SML (T) = 1,2 mg/Kg (expressed as tertiary amine)

The level of migration has been measured according to the rules specified In Regulation 10/2011/EC, Annex III and Annex V, using the following simulants/test conditions:

Food Simulant	Testing Conditions
Isooctane	10 days, 60°C

Ref. No	Restrictions
20440	SML = 0,05 mg/Kg

The level of migration has been measured according to the rules specified In Regulation 10/2011/EC, Annex III and Annex V, using the following simulants/test conditions:

Food Simulant	Testing Conditions
Ethanol 95%	10 days, 60°C

Ref. No	Restrictions
21130	SML = 6 mg/Kg

The level of migration has been measured according to the rules specified In Regulation 10/2011/EC, Annex III and Annex V, using the following simulants/test conditions:

Food Simulant	Testing Conditions
H_2O	10 days, 60°C

The specific migration measured on this product for the aforementioned additives is under their limits (surface volume ratio 8 dm^2/l) specified by Regulation 10/2011/EC.

Additives with Specific Migration Limits Annex I Table 1

List of additives in the product with specific migration limit, for which it is not necessary to perform migration tests (based on "worst case" calculation, assuming a surface ratio of 6 dm^2 of film per 1 Kg of food):

Ref. No	Restrictions
83595	SML = 18 mg/Kg
39120	SML (T) = 1.2 mg/Kg expressed as tertiary amine excluding HCl
68320	SML = 6 mg/Kg
38820	SML = 0.6 mg/Kg
92560	SML = 18 mg/Kg
95360	SML = 5 mg/Kg
39815	SML = 0.05 mg/kg

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19960	SML (T) = 30 mg/kg expressed as maleic acid
55910	SML (T) =60 mg/kg
94560	SML = 5 mg/kg
34690	No SML

List of additives which are also authorised as food additives, sweeteners, colours and flavourings (dual use additives; ref. Regulation 1333/2008 and amendments):

E-nr / Ref. nr	***Restrictions***
E471	No SML
E 475	No SML
E330	No SML
E470b	No SML
E551	No SML
E570	No SML
E173	SML= 1 mg/Kg
E470a	No SML

List of salts allowed in accordance with Article 6(3)(a) and that are listed in Annex II Table 1:

E-nr / Ref. nr	***Restrictions***
Calcium	No SML
Magnesium	No SML

However, the amount of these substances in the films is too low so even in the worst case of a 100% migration, this limit can't be exceeded. No further analysis is required for these films according to art. 18 par. 3 of the Regulation 10/2011/EC.

Restrictions on plastic materials and articles Annex II Table 1

The specific migration measured on these products for the below mentioned substances is under theirlimits (surface volume ratio 8 dm^2/l) specified by Regulation 10/2011/EC:

Substance	***Restrictions***
Aluminium	SML = 1 mg/Kg
Antimony	SML = 0.04 mg/Kg
Arsenic	ND
Barium	SML = 1 mg/Kg
Cadmium	ND
Chromium	ND
Cobalt	SML = 0.05 mg/Kg
Copper	SML = 5 mg/Kg
Iron	SML = 48 mg/Kg
Lead	ND
Lithium	SML = 0.6 mg/Kg
Manganese	SML = 0.6 mg/Kg
Mercury	ND
Nickel	SML = 0.02 mg/Kg
Zinc	SML = 5 mg/kg

The level of migration has been measured according to the rules specified In Regulation 10/2011/EC, Annex III and Annex V, using the following simulants/test conditions:

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Food Simulant	Testing Conditions
B, Acetic acid 3% (p/v)	10 days, 60°C

According to these results the products are suitable for contact with all food types at room temperature or below including hot-fill conditions and/or heating up to 70 °C ≤ T ≤ 100 °C for maximum t = 120/2^((T-70)/10) minutes, where use of food simulants A, B and D2 is expected.

We remind You that the overall/specific migration shall be measured on the finished articles using the actual foodstuff or the appropriate food simulant at the real food/temperature conditions of use, according to te rules specified in Regulation 10/2011/EC as amended.

NIAS STATEMENT

We have carried out semi-quantitative analysis in order to identify and evaluate the risk associated to the presence of "non intentionally added substances" present in the formulation of sample of the above-mentioned products, which are representative of the industrial campaign.

The aforementioned screening has concerned:

- Evaluation of volatile substances (through GC-MS analysis, and the sample previously conditioned 30 minutes at 125°C); detectable limit used 0,10 mg/m2.
- Evaluation of non-volatile substances (after solvent extraction and sonication, the sample has been analyzed through the GC-MS technique). detectable limit used 1,0 mg/Kg.

The NIAS screening has identified the presence of the following non-volatile substances:

Substance	CAS Number	Notes
Isopropyl Myristate	110-27-0	
(Z)-docos-13-enamide (Erucamide)	112-84-5	This substance is included in the Union List taken from Annex I of the Commission Regulation (EU) No10/2011, identified by Reference Number 52720
9-octadecenenitrile, (Z)-	112-91-4	
7,9-di-tert-butyl-1-oxaspiro(4,5) deca-6,9-diene-2,8-dione	82304-66-3	
Oleamide (9-Octadecenamide)	301-02-0	Some data submitters indicate they consider this substance as Skin sensitizing. This substance is included in the Union List taken from Annex I of the Commission Regulation (EU) No10/2011, identified by Reference Number 68960
Phenol, 2,4-bis(1,1-dimethylethyl)-phosphite (3:1)	31570-04-4	Under assessment as Persistent, Bioaccumulative and Toxic (PBT). However, this substance is included in the Union List taken from Annex I of the Commission Regulation (EU) No10/2011, identified by Reference Number 74240
Tris (2,4-di-tertbutylphenyl) phosphate	95906-11-9	

The NIAS screening of volatile substances, on the other hand, has not identified any other substance in amount greater than the detectable limit.

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This information applies to the material as it leaves [redacted] production facilities.
The information in this document is, to our knowledge, true and accurate at the time and date of issue.
Due to possible changes in the laws and regulations, or other reasons, we cannot guarantee that the status of this product will remain unchanged.

Our certificate does not cover:

- Any modification of the warranted product by any addition of any other product to it;
- Any prejudicial modification of the warranted product resulting from a processing of the product;
- An inadequate use and/or storage of the material and of the finished articles;

The data and information presented herein are to the best of our knowledge accurate and reliable. The company assumes no responsibility, express or implied, for use of said data and information.

[redacted]

[redacted]

08.09.2023

ENDE LEBENSMITTELUNBEDENKLICHKEITSERKLÄRUNG DES LIEFERANTEN

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