12/2014

# Mod: C25-1530

**Production code: C15x30/90** 





#### CONFORMITY DECLARATION OF SMOOTH AND EMBOSSED VACUUM BAGS

Herewith it is affirmed that:

The item supplied is suitable to all food packaging is standard:

To all legislative orders concerning it, with particular reference to the following European community legislation:

Regulation (EU) 1935/04

Regulation (EU) 2023/06

Regulation (EU) 10/2011 and following updates and modifications

Regulation (EU) 1895/05

And to the following Italian legislation:

Ministerial Decree 21/3/73 and following updates and modifications DPR 777/82 and following updates and modifications Decree 24 September 2008 n°174

The plastic material is manufactured with the following materials and substances:

- PA
- PE (side in contact with food)

It is affirmed that:

 The material contains substances which are subjects to restrictions and keeps the global migration limits and the specific restrictions:

**Specific migration limit (SML)** 

| FCM substance | substance:   | SML:                        | Comment:                    |
|---------------|--|-----------------------------|-----------------------------|
| No.:          |  |                             |                             |
| 212           | caprolactam  | SML(T): 15<br>mg/kg         | expressed as<br>caprolactam |
| 231           | acetic acid, vinyl ester   | 12 mg/kg                    | -                           |
| 433           | octadecyl 3-(3,5-di-tert-butyl-4-<br>hydroxyphenyl)propionate  | 6 mg/kg                     | -                           |
| 305           | hexamethylenediamine   | 2,4 mg/kg                   | -                           |
| 69            | phosphorous acid, tris(nonyl-and/or dinonylphenyl)<br>ester  | 30 mg/kg                    | -                           |
| 402           | zinc oxide   | 25mg/kg <x>60m<br/>g/kg</x> | -                           |
| 799           | polyethyleneglycol (EO = 1-50) ethers of linear and<br>branched primary (C8-C22) alcohols  | 1,8 mg/kg                   | -                           |
| 334           | ethyleneimine in trace level; it is expected that the residual monomer content volatilizes during the drying process of the primer | ND                          | -                           |

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In the following test conditions:

| Performing **                               | Test time* and Temperarure** |  |
|---|------------------------------|--|
|   | 10 DD- 40°C                  |  |
| B (acetic acid at 3% in distilled water)    | 2h - <70°C                   |  |
|   | 15' - < 100°C                |  |
|   | 10 DD- 40°C                  |  |
| C (ethyl alcohol at 10% in distilled water) | 2h - <70°C                   |  |
|   | 15' - < 100°C                |  |
|   | 10 DD- 40°C                  |  |
| D (rectified olive oil)                     | 2h - <70°C                   |  |
|   | 15' - < 100°C                |  |

The global migration limits, jointly to the other specific restrictions to which the monomers and/or the additives present in the material can be submitted, are respected in the above mentioned using conditions. The statement is supported by analytical tests carried out in accordance with the DM 21/3/73 or on the strength of calculations made considering the contents of the substances submitted to migration limits.

#### **Migrational requirements**

It can be expected from previous experience and data (see below) that the above film will pass the overall migration tests for many food types and normal applications. Tests carried out on overall migration using food simulants indicate migration will be within the limit of 10 mg/dm² under normal conditions of use.

We regularly have migration tests carried out over our complete product range at accredited laboratories, but because the migration is also depending on the real conditions of use and storage, the packer has to prove the adequacy of the packaging material under practical conditions for the compliance with the migration limits.

Also the user is responsible for verifying, if the film is applicable for special fillings and pack processes. We therefore recommend application technical trials with the fillings.

Type or types of food with which it is intended to be but in contact:

The films are suitable for dry, aqueous, acidic and fatty food.

Ratio of food contact surface area to volume used to establish the compliance of the material or article:

EU-Cube: 1kg Food in 6dm<sup>2</sup> film

## List of Additives with limits in foodstuff ("Dual Use Additives")

| substance           | E-No: | amount in film |
|---------------------|-------|----------------|
| talc                | E553b |                |
| siliciumdioxide     | E551  | -              |
| polyethylene glycol | E1521 | -              |

The information concerning additives, which are also foodstuff-additives and flavour-additives ("Dual Use Additives") is based on our current knowledge. As there is no official list concerning "Dual Use Additives", we refer to the "EUPC study on Dual Use Additives", PACK Co. srl, Milano 2006, which is incomplete. The absence of information about this group of additives from certain suppliers, which face the same difficulties, does not allow us to secure the completeness of our information

Besser Vacuum S.r.l.

Via Casarsa, 57 33030 Dignano Udine – Italia P. IVA 02017480415 Tel. +39.0432.953097 Fax +39.0432.953591 info@besservacuum.com www.besservacuum.com



## **Functional barrier**

If a functional barrier is used in our multilayer materials we declare, that the material complies with the regulation (EU) 10/2011 Art. 13 section 2, 3 and 4 or Art. 14 section 2 and 3.

#### **General Information**

This declaration is valid for the product delivered by us as specified above. The Directives 82/711/EEC and 85/572/EEC provide a guideline for the selection of test conditions to be used for various food products. According to that and under consideration of the food contact conditions stated, the product complies with the stipulations of these Directive regarding the packaging of food products to be packed. The user shall verify himself that the product is suitable for the intended food to be packed beyond the stipulations of the Directives.

In particular it is emphasized that in case of printed material, no contact is allowed between the printing ink and the food product.

In order to support what is above-written, the company affirms to have to the competent Authority disposal:

- test reports carried out on the finished product
- other documents in support provided for the Reg.(CE) N.1935/2004, art.16, comma 1

This declaration has validity from the date written on the basis of the page and it must be substituted in case of important modifications in the production of the material able to change some essential requirements for the conformity or when the mentioned legislative references are modified and updated so as to need a new test to verify the material conformity

Dignano, 2014

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