

Step 1: Identity and address of the business operator which manufactures or imports the plastic materials or articles or the substances intended for the manufacturing

Scanfill AB
Bronsgatan 8
271 39 Ystad
VAT-No./USt-Nr.SE556765044801

Step 2: Identity and address of the business operator which manufactures or imports the materials or articles of plastic or products in a phase intermediate manufacturing, as well as substances intended for the manufacturing of those materials and items:

Scanfill AB
Bronsgatan 8
271 39 Ystad
VAT-No./USt-Nr.SE556765044801

Step 3: Identity of the materials, articles, products from intermediate stages of manufacture or the substances intended for the manufacturing of those materials and items:

Co-extruded sheet in SCANFILL Foil grade material and polypropylene.

Step 4: Date of declaration:

27 March 2018

Step 5:

Scanfill AB declares and confirms that the sheet of plastic material mentioned above meet relevant requirements in the following Regulations:

- Regulation n. EU 10/2011 and subsequent amendments and modifications (on materials and articles made of plastics intended to come into contact with food products)
- Regulation n. 1935/2004/EC (on materials and articles intended to come into contact with food products)
- Regulation n. 2023/2006/EC (on good manufacturing practice for materials and articles intended to come into contact with food products)
- Regulation n. 1895/2005/EC (on the restriction of use of certain epoxy derivatives in materials and articles intended to come into contact with food products)

Step 6:

Scanfill AB does not use, or enter directly, substances subject to restrictions or specifications. During the whole production process the material (see point 2) does not come into contact with any harmful substance or subject to the restrictions and specifications.

It is our duty, however, indicate that the raw material contains departing restricted substances for which we did conduct analysis of specific migration. We will list below the first liquid simulants, followed by a table that contains all the substances for which we did conduct analyses of specific migration:

Liquid food simulants	Contact conditions
Isooctane	1.5 hours at 60°C + 2 days at 30°C
Acetic acid 3%	2h at 100°C + 10 days at 60°C
Olive oil	2h at 100°C + 10 days at 60°C

For all the simulants the specific migration limits are listed below:

Sample ID: Specific compound	CAS Number	Food simulant	Reference Limit value (mg/kg) (Reg. EU 10/2011)	Average value determined (mg/kg)
Irganox 1076	2082-79-3	Olive oil	6	< 6
1-hexene	592-41-6	Olive oil	3	< 0.1
BBOT	7128-64-5	Isooctane	0.6	< 0.2
Dibutylphthalate	84-74-2	Isooctane	0.3	< 0.3
Barium	7440-39-3	3% acetic acid	1	0.007
Aluminium	7429-50-5	3% acetic acid	1	<0.03
Manganese	7439-96-5	3% acetic acid	0.6	0.03
Zinc	7440-66-6	3% acetic acid	5	0.1
Cobalt	7440-48-4	3% acetic acid	0.05	< 0.0005
Copper	7440-50-8	3% acetic acid	5	0.03
Iron	7439-89-6	3% acetic acid	48	0.2
Lithium	7439-93-2	3% acetic acid	0.6	0.01

Under the below stated conditions of temperature and contact time, below global migration tests were tested on sheet form:

Acetic acid 3%:

2 hours at 100°C

Limit value (according to Reg.10/2011): 10 mg/dm²

Average value determined: 1.6 mg/dm²

Ethyl alcohol 10%:

2 hours at 80°C

Limit value (according to Reg.10/2011): 10 mg/dm²

Average value determined: < 1 mg/dm²

Olive oil:

2 hours at 100°C

Limit value (according to Reg.10/2011): 10 mg/dm²

Average value determined: < 2 mg/dm²

Step 7:

According to the regulations in 1333 and 1334/2008 CE there are no Dual Use additives. We have no reason to suspect any NIAS entering our product. The product does not contain heavy metals according to directive EC/94/62, article 11:§1.

Step 8: specifications for use

High temperature applications up to 121°C for all food stuffs, according to 10/2011/EC – OM5. Materials approved for OM5 are also approved for OM1, OM2, OM3 and OM4.

The ratio of surface area in contact with the food product and the volume used to determine the suitability of the material or object is in contact with 1 dm³ - 1:1 ratio.

Step 9: The surface layer complies with Article 13 (2), (3) and (4) of Regulation 10/2011.

This statement is prepared in accordance with **Annex IV of Regulation (EU) 10/2011 of 14 January 2011** relating to materials and articles made of plastics intended to come into contact with foodstuffs, as amended. To facilitate the reading of this statement we have incorporated in this Annex IV.

All information contained herein and provided by Scanfill AB to the undersigned recipient, remain property of Scanfill AB and will be considered a loan for the above specified, and the undersigned recipient may not be able to use it, use, transfer, communicate, hand, indicate, reproduce, copy or duplicate, any part of such confidential information without the specific written consent of Scanfill AB. The undersigned recipient is also invited to take all the necessary measures in order to ensure that its employees, contractors, or others, who will not necessarily have access to, or get revelations in all or part of, the said confidential information, the take in the most absolute confidentiality. The consignee, hereby acknowledges that the violation of the confidentiality obligations is entitled to Scanfill AB obtain compensation for any direct, indirect or consequential damages resulting from the breach and legitimate Scanfill AB to act with the urgency of protective measures without any prejudice to further action for damages.

This Food compliance is addressed to:

Treform Packaging AB
Axeltoftavägen 170
261 35 Landskrona
Sweden
VAT-no: SE556926243801

Date : 27 March 2018
Name: Karl Banke
Position: Development manager
Signed:

15.1.2011 EN Official Journal of the European Union L 12/81

ANNEX IV

Declaration of Conformity

The written declaration referred to in Article 15 shall contain the following information:

- 1) the identity and address of the business operator issuing the declaration of conformity;
- 2) the identity and address of the business operator which manufactures or imports the materials or articles of plastic material or products from intermediate stages of manufacture or the substances intended for the manufacturing of those materials and articles;
- 3) the identity of the materials, articles, products from intermediate stages of manufacture or the substances intended for the manufacturing of those materials and articles;
- 4) the date of the declaration;
- 5) confirmation that the materials or articles of plastic material or products from intermediate stages of manufacture or the substances meet relevant requirements laid down in this Regulation and Regulation (EC) n. 1935/2004;
- 6) adequate information relative to the substances used or products of degradation to which Annexes I and II to this Regulation, determine restrictions and / or specifications, so as to allow the downstream business operators to comply with these restrictions;
- 7) adequate information about the restricted substances in food, obtained by experimental data or theoretical calculation about the level of their specific migration and, where appropriate, purity criteria in accordance with Directives 2008/60 / EC 95/45 / EC and 2008/84 / EC, as well as to allow users of these materials or articles to comply with the relevant provisions of the EU or, in the absence of EU rules, national provisions applicable to food;
- 8) specifications on the use of the material or object, such as:
types of food with which it is intended to come into contact;
the duration and temperature of treatment and storage in contact with the food product;
the relationship between the contact surface of the food product and the volume used to determine the compliance of the material or article;
- 9) in the case of using a functional barrier in a material or a multilayer object, the confirmation that the material or article complies with the requirements referred to in Article 13, paragraphs 2, 3 and 4 or Article 14, paragraphs 2 and 3 of this Regulation.