

DECLARATION OF COMPLIANCE



Product reference: **SKINTITE HB**
as supplied by: AMCOR FLEXIBLES Valkeakoski Oy
Teollisuustie 1, FI-37601 Valkeakoski, Finland

to customer: Protectpack Ltd
12390 Moscow
RU

This product is composed of the following components:

table 1 – product composition (from the external layer to the internal layer).

75 - 150 μ	PE with High Barrier EVOH
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The exact nature of the components used is Amcor Flexibles Valkeakoski proprietary information. Details of the formulation could be supplied to an independent third party under secrecy agreement.

1. Compliance with food contact legislation.

This product complies with Regulation (EC) No 1935/2004. In particular, it is manufactured under good manufacturing practices, from components and ingredients which are declared suitable for food contact use, and is therefore considered to comply with the general safety requirements (Art. 3). We also comply with Art. 11(5), the provisions on labelling (Art. 15), declaration of compliance (Art. 16) and traceability (Art. 17). See below for details on the conditions of use.

Our good manufacturing practices meet the requirements of Regulation (EC) No 2023/2006 and follow relevant sections of the "Code for Good Manufacturing Practices for Flexible and Fibre-Based Packaging for Food" issued by Flexible Packaging Europe (<http://www.flexpack-europe.org/>).

The following table lists the regulatory status of the components used in manufacturing our product:

table 2 – regulatory status of product components.

Component	Legal Reference	Status
plastics	Regulation (EU) No 10/2011 (*)	monomers & additives listed; see below for further compliance aspects.
plastic functional barrier	Regulation (EU) No 10/2011 (*), Art. 13(2) and 14(2).	monomers & additives not listed in the Union List are not used in a plastic layer of our product.
vinyl chloride monomer	Directive 78/142/EEC	VCM is not used.
recycled plastics	Regulation (EC) No 282/2008	recycled plastics are not used.
active & intelligent	Regulation (EC) No 450/2009	A&I are not used.
Bisphenol A	Regulation (EU) 2018/213	BPA is not used.
epoxy derivatives	Regulation (EC) No 1895/2005	epoxy is not used.
nanomaterials	Recommendation 2011/696/EU	nanomaterials are not used.
biocides	Regulation (EU) No 528/2012	biocides are not used.
surface lubricants		not used.

(*) Regulation (EU) No 10/2011 replaces Directive 2002/72/EC since 1 May 2011. It was amended by Regulations 321/2011, 1282/2011, 1183/2012, 202/2014, 2015/174, 2016/1416, 2017/752, 2018/79, 2018/213, 2018/831, 2019/37 and 2019/1338. Reference to Regulation 10/2011 in this document includes these amendments unless noted otherwise.

2. Further details on EU food contact compliance.

2a. Overall Migration Limit

Our product is a plastic as defined in the scope of Regulation (EU) No 10/2011, and therefore subject to an Overall Migration Limit (OML) of 10 mg/dm² as laid down in Article 12 of the Regulation.

In testing for verification of the OML we follow the methods that have been laid down in the EN 1186 series of standards by CEN.

2b. Migration test conditions and conditions of use

The overall migration, when tested on relevant samples, was found to comply with the OML in the following test conditions:

- OM2 (10 days at 40°C) + OM5 (2 hours at 100°C or at reflux) in simulants A, B, D2 (and/or alternatives).

The test results, obtained on a relevant sample (this product or one of similar composition) in the conditions listed, are as follows:

table 3 – OML test results.

simulant	test condition	result (mg/dm ³)
simulant A (10% ethanol)	OM2+ OM5	< 2
simulant B (3% acetic acid)	OM2+ OM5	< 2
simulant D2 (vegetable oil)	OM2 + OM5	< 3

Notes:

- Simulant E (Tenax) is intended for SML testing.
- According to section 4 of Annex III of the Regulation, for OML testing the combination of simulants A, B and D2 allows to conclude on compliance for all types of foods.
- According to Chapter 3 of Annex V of the Regulation, OML test condition OM5 represents the worst case test condition for materials having a polyolefin (PE, PP) food contact layer. Polyolefin-based materials passing this test are considered sufficiently inert even if the time/temperature conditions in actual use exceed the test condition.

Taking into account the relevant legal provisions as well as the formulation of our raw materials and the SML compliance information reported below, we can give clearance for the use of our product in contact with food in the following conditions of use:

- food contact side (see layer sequence in Table 1): PE (info on reel label).
- food types: all foods.
- packed food storage conditions: indefinite storage time, up to room temperature.
- in-pack processing: hot-fill as defined in Reg. 10/2011, Art. 3 (19).
- in-pack processing: heating up to a temperature T between 70 and 100 °C for maximum duration of $t = 120/2^{((T-70)/10)}$ minutes.

These conditions of use may include microwave re-heating on provision that the conditions inside the package, to be verified by the customer, do not exceed the time and temperature listed.

The conditions of use reported above take into consideration the restrictions (if any) that follow from the SML compliance assessment reported in Table 5.

2c. Specific restrictions on substances in plastics.

Our product contains one or more plastic components regulated by Regulation (EU) No 10/2011. This Regulation provides specific restrictions on monomers, starting substances and additives used in the manufacturing of plastics.

Some or all of the restricted substances listed in table 4 may be present in the finished material:

table 4 – specific restrictions on plastics under Regulation (EU) No 10/2011.

No.	PM ref.	Substance name	CAS Nr.	Restriction (**)	Status (table 5)
00231	10120	acetic acid, vinyl ester	108-05-4	SML = 12 mg/kg	6
00254	13720	1,4-butanediol	110-63-4	SML (T) = 5 mg/kg	3, 5
00282	18430	hexafluoropropylene	116-15-4	SML = ND; DL = 0.01 mg/kg	5
00356	18820	1-hexene	592-41-6	SML = 3 mg/kg	6
00234	19960	maleic anhydride	108-31-6	SML(T) = 30 mg/kg (maleic acid)	3, 6
00150	20020	methacrylic acid	79-41-4	SML (T) = 6 mg/kg	3, 6
00246	25150	tetrahydrofuran	109-99-9	SML = 0.6 mg/kg	3, 5
00132	26140	vinylidene fluoride	75-38-7	SML = 5 mg/kg	6
00584	40320	boric acid	10043-35-3	SML(T) = 6 mg/kg (Boron)	5, 6
00315	46640	2,6-di-tert-butyl-p-cresol = 3,5-di-tert-butyl-4-hydroxytoluene	128-37-0	SML = 3 mg/kg	6
00433	68320	octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl) propionate	2082-79-3	SML = 6 mg/kg	3, 7
00106	89040	stearic acid (#)	557-05-1	SML(T) = 5 mg/kg (Zinc)	3
00402	96240	zinc oxide	1314-13-2	SML(T) = 5 mg/kg (Zinc)	3
		undisclosed aluminium compound(s)		SML(T) = 1 mg/kg (Aluminium)	5
		undisclosed nickel compound(s)		SML(T) = 0.02 mg/kg (Nickel)	5
		undisclosed zinc compound(s)		SML(T) = 5 mg/kg (Zinc)	5
		proprietary substance(s)		not known	5

(**) Restrictions can be a specific migration limit (SML), a maximum concentration (QM) in the plastic, a maximum quantity per surface area (QMA), or a 'no detectable migration' (ND) requirement at a certain detection limit (DL). Suffix (T) indicates a combined restriction for 2 or more substances.

(#) The substance used is a salt of an authorised acid; the Substance No., PM Ref nr. and substance name refer to the authorised acid; the CAS nr. and restriction refer to the salt.

The above list of restricted substances is complete to the extent that accurate information was received from our raw material suppliers. The status with regard to the latest amendments of Regulation 10/2011 is as follows:

- Amendments up to 2019/1338 : fully covered by Table 4.

2d. [Compliance with specific restrictions on substances](#)

The specific restrictions on substances listed in Table 4, apply to our product and/or its plastic components. In assessing compliance with these restrictions, it has to be noted that Article 17 of Regulation (EU) No 10/2011 provides that for sheet and film not yet in contact with food, the value of migration is expressed in mg/kg by applying the conventional surface to volume ratio of 6 dm²/kg. This applies also to the finished food package if it contains less than 500 ml or more than 10 l.

The highest surface to volume ratio for which the compliance of this product has been assessed, is 6 dm²/kg. The results of this compliance assessment, summarized in table 5 here below, have been taken into account in the conditions of use reported in section 2.b.

table 5 – compliance assessment for substances listed in table 4.

Status (table 4)	compliance status
3	cannot exceed the limit even if total quantity migrates
5	compliance is confirmed by our supplier
6	GC-MS / GC-FID screening shows substance is not detected/identified at 10 ppb (***)
7	GC-MS / GC-FID screening shows substance migration is well below the limit (***)

(***) results obtained on sample(s) relevant for this specific restriction.

Contact us for more details on this compliance assessment if needed.

2e. [Dual Use Additives](#)

As required by Regulation (EU) No 10/2011 the following table identifies substances used in plastics and subject to a restriction in food through an authorisation as food additive. In absence of a Union reference list of these substances, or a marking in the Regulation, there remains some uncertainty over precisely which additives are to be considered as dual use additives. Therefore the following information received from our suppliers could be considered preliminary:

table 6 – dual use additives.

food additive	substance
E170	calcium carbonate
E284	boric acid
E321	3,5-di-tert-butyl-4-hydroxytoluene
E551	silicon dioxide
E553b	talc

3. Additional information on substances.

3a. Non-Intentionally Added Substances (NIAS).

Our suppliers have either explicitly confirmed that a risk assessment according to Article 19 of Regulation 10/2011 has been carried out, or have implicitly done so by confirming compliance with Regulation 1935/2004. Information on our assessment of NIAS is part of our supporting documentation and is available to the authorities on their request.

4. Environmental Compliance

Our product is manufactured in compliance with Directive 94/62/EC on Packaging and Packaging Waste, as amended. More specifically, the combined total amount of Lead, Cadmium, Mercury and hexavalent Chromium in above-mentioned material does not exceed 100 ppm.

In addition we can confirm that our product is made of plastics which, according to Annex B of EN standard 13431:2004 provide a positive calorific gain upon incineration.

With regard to the requirement on source reduction we point to Table 2 of EN 13427:2004 where it is explained that this assessment needs to be made at the level of the complete packaging system i.e. primary + secondary + tertiary packaging; consequently it is out of our control.

5. BSE/TSE

Throughout the plastics converting industry, certain low-level additives which are based on fatty acids, fatty acid esters or glycerol that are derived from animal fats (tallow) are in widespread use; the use of these additives is generally considered to be unavoidable in many different types of plastics. Tallow itself is not used in our products.

However, it has to be pointed out that:

- these substances are approved for food-contact use.
- Regulation (EC) No 999/2001 and its amendments assure that Specified Risk Materials (SRM) are removed prior to production of the materials of animal origin from which the above-mentioned substances are derived.
- the production of these additives is subject to very severe processing conditions that meet or exceed the recommendations for complete inactivation of TSE agents.

We therefore are certain that no danger for human health can result from the use of the above-mentioned additives and, by extension, our product.

6. Absence of chemical substances

Based on the information available to us, the following substances are not intentionally used in our raw materials nor added during manufacturing. Therefore our product is not expected to contain:

- acrylamide
- allergens listed in Annex II of Regulation (EU) No 1169/2011 as amended
- azodicarbonamide and semicarbazide
- asbestos
- brominated flame retardants

- substances intended to function as biocides and fungicides incl. dimethyl fumarate, paraben.
- Bisphenol A, Bisphenol S
- Bisphenol A Diglycidyl Ether (BADGE), Bisphenol F Diglycidyl Ether (BFDGE) or Novolac Glycidyl Ethers (NOGE)
- dioxins
- genetically modified organisms (GMO) or products containing GMO
- mineral oil solvents not listed in Reg. 10/2011, other mineral oil saturated hydrocarbons (MOSH), mineral oil aromatic hydrocarbons (MOAH)
- natural rubber or natural rubber latex
- nonylphenol or nonylphenol ethoxylate
- ozone depleting substances according to the Montreal Protocol
- perfluoro-octanoic acid (PFOA), perfluoro-octane sulfonate (PFOS), perfluoro-alkyl phosphate esters (PAPs), perfluorinated carboxylic acids (PFCAs)
- photo-initiators, including benzophenone, benzophenone derivatives, isopropyl thioxanthone (ITX), etc.
- phthalate plasticizers
- phthalates used as technical support agent in polymer catalysis
- polybrominated biphenyls (PBB) or polybrominated diphenyl ethers (PBDE)
- polychlorinated biphenyls (PCB)
- polycyclic aromatic hydrocarbons (PAH)
- post-consumer recycled waste
- PVC or PVDC
- titanium acetyl acetonate (TAA) or acetyl acetone
- triclosan
- UV-curing components

The absence of these substances has not been confirmed by testing. We cannot exclude trace impurities at insignificant levels resulting from incidental contamination or from impurities in precursors to our raw materials.

7. Disclaimer

This declaration is given in good faith and to the best of our current knowledge. It only covers the food contact compliance status of our product as it leaves our premises and does not imply any conclusions regarding technical aspects of the use of our product nor any unforeseen interactions of our product with the packaging process or the filling good.

This declaration replaces all previous declarations for the same specification/product. It remains valid until a change in the legislation or new scientific information change the legal status. At such time we will inform our customers accordingly.

Mika Kuusela
 Quality Coordinator
 Amcor Flexibles Valkeakoski Oy
 (valid without signature)