Natur-Drogeriet A/S
Nydamsvej 13-15
8362 Hørning
DK - Denmark

Declaration of Compliance

This declaration is valid for the following item:

Item no	Description
199	Klar pose: Sidefals-pose med fladforsegling

This product is composed of the following components:

Table 1 - Product composition.

15 µ	Oriented polyamide film.
± 3 µ	Adhesive (polyurethane based).
70 µ	Polyethylene film.

The exact nature of the components used is our supplier's proprietary information. Details of the formulation could be supplied to an independent third party under secrecy agreement.

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 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.
Plastics	FDA 21 CFR 177.1500 and 177.1520	Compositional compliance.
Adhesives	Regulation (EU) No 10/2011 (*) BfR XXVIII FDA 21 CFR 175.105	Compositional compliance with at least one of these legal references.

(*) Regulation (EU) No 10/2011 replaces Directive 2002/72/EC from 1 May 2011. It was amended by Regulations 321/2011 and 1282/2011. Reference to Regulation 10/2011 in this document includes these amendments unless noted otherwise.

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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, or it is a multimaterial-multilayer as defined in the Regulation for which we nonetheless consider the OML relevant.

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.

Migration test conditions and conditions of use

According to Articles 22 and 23 of Regulation (EU) No 10/2011 the currently valid (until 31/12/2012) test conditions and simulants – which we refer to in this section – are those of Directives 82/711/EEC and 85/572/EEC as amended. Article 20 of the Regulation amends the simulants in Directive 85/572/EEC as from 31/12/2012. During a transition period from 1/1/2013 until 31/12/2015 the test conditions of Directive 82/711/EEC remain valid in parallel with Annex V of Regulation 10/2011.

The overall migration, when tested on relevant samples, was found to comply with the OML in the following test conditions:
- 10 days at 40°C in simulants B, C and D

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/dm²)
simulant B (3% acetic acid)	10 days at 40 °C	< 2
simulant C (10% ethanol)	10 days at 40 °C	< 2
simulant D (olive oil)	10 days at 40 °C	< 3

According to Directive 97/48/EC, compliance in the above testing conditions allows the conclusion that the product is suitable for contact with food in the following conditions of use:
- All food types and indefinite storage time at room temperature, including heating up to 70 °C for up to 2 hours, or up to 100 °C for up to 15 minutes.

Note that also the compliance with specific restrictions on substances needs to be taken into account.

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:

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Table 4 - Specific restrictions on plastics under Regulation (EU) No 10/2011.

No.	PM ref.	Substance name	CAS Nr.	Restriction (**)	Status (table 5)
00212	14200	Caprolactam	105-60-2	SML(T) = 15 mg/kg	5
00264	22660	1-octene	111-66-0	SML = 15 mg/kg	5
00433	68320	Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl) propionate	2082-79-3	SML = 6 mg/kg	5
00106	89040	Zinc stearate	-	SML(T) = 25 mg/kg (Zinc)	5
00402	96240	Zinc oxide	1314-13-2	SML(T) = 25 mg/kg (Zinc)	5
		Isocyanate		QM(T) = 1 mg/kg (free NCO)	10
		Primary aromatic amines		SML = ND; DL = 0.01 mg/kg	10

(**) 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 above list of restricted substances is complete to the extent that accurate information was received from our raw material suppliers.

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 migration limits expressed in mg/kg are expressed in mg/dm² units after division by the conventional conversion factor of 6 dm²/kg. This applies also to the finished food package if it contains less than 500 ml or more than 10 l.

Table 5 here below summarizes our compliance assessment for the restricted substances listed in table 4 above:

Table 5 - Compliance assessment.

Status (table 4)	Compliance information
5	Compliance is confirmed by our supplier.
10	Finished product complies when the curing is complete.

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 Community reference list of these substances, or a marking in the Regulation, the following information received from our suppliers, can only be considered preliminary:

Table 6 - Dual use additives.

Food additive	Substance
	None.

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Disclaimer

This declaration is given in good faith and to the best of our current knowledge. It covers the composition of the above-mentioned material and does not imply technical suitability of our product in its intended use. Appropriate filling and storage tests remain necessary. This declaration may become invalid when our product is not properly processed or when it is altered by thermal or other degradation processes.

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.

The food packer is responsible for ensuring that the finished food package complies with applicable restrictions in the food itself under actual conditions of use. Possible interactions of the film and its components with the foodstuff (i.e. modification of odour, taste, consistency, migration, etc.) are to be checked prior to use and in function of the end-uses.

The information above was provided by our supplier.

On behalf of **Natur-Drogeriet A/S**
21.07.2023
Rikke F. Knudsen
Rikke Fastrup Knudsen
QA assistant