

**DECLARATION OF COMPLIANCE WITH REGULATIONS ON MATERIALS
AND ARTICLES INTENDED TO COME INTO CONTACT WITH FOOD¹**

I, the undersigned, **Ms Sonia AIT HAMMOU**:

- Company: **Flexico**
- Address: **1 route de Méru - BP 70429 Hénonville
60544 MERU CEDEX - FRANCE**

acting in her/his position of: **Hygiene & Food Safety Manager**

hereby declares that the material and/or article referenced by the customer as follows (*references of the specifications or other documents describing the material, type of packaged food and conditions of use of the material by the client*) :

Zipper Doypack Pouches with Clicky Zipper (ZG 139 A/4): references ITM080101, ITM080102, ITM080103, ITM080104, ITM080105, ITM080106, ITM080107, ITM080108.

and characterized as follows – indicate the components of the material or article covered by this declaration (in the case of multi-material multi-layers, specify the nature of the different layers from the inner to the outer layer – specify whether one of the layer is a functional barrier):

*e.g.: printed material, from the inner to the outer layer: polyethylene (PE), polyurethane adhesive (PU), a metallized polyester (PET)
- functional barrier, a nitrocellulose gravure printing and a nitrocellulose coating*

Polyethylene (PE) / Polyester (PET)

manufactured in accordance with the following regulation:

- Regulation (EC) No 1935/2004 of 27th October 2004 on material and articles intended to come into contact with food;
- Regulation (EC) No 2023/2006 of 22nd December 2006 amended on good manufacturing practices for materials and articles intended to come into contact with food;
- French regulation in force concerning materials and articles intended to come in contact with food, that is to say sanction decree No 2007-766 of 10th may 2007, amended by the decree No 2008-1469 of 30th December 2008;
- Specific regulations when they exist for each part of the material or article as described previously (quote text(s) concerned):
 - o *Regulation (EU) No 10/2011 and its amendments*
- and the following reference texts, when existing, for each part of the material or article as described previously (governmental or professional, or opinion from an official scientific body – quote text(s) concerned):
 - o *e.g.: BfR Recommendation No XXXVI relative to paper and board for food contact, FEICA guidelines on good manufacturing practices in the production of adhesives and sealants intended for food contact materials*

¹ *The present declaration concerns materials and articles intended to come into contact with food as defined in the field of application of Regulation (EC) No 1935/2004 and amended French decree No 2007-766 of 10th may 2007. This declaration also concerns materials in contact with feedstuff for livestock and pets, as well as teats and dummies / soothers, still covered by the decree No 92/631.*

won't bring about, in accordance with Regulation (EC) No 1935/2004, under normal or foreseeable conditions of use, an unacceptable change in the composition or a deterioration in the organoleptic characteristics of the food, in the following conditions of contact (tick the appropriate boxes)²:

- contact with all types of food products

- or only:

. contact with dry foods:

. contact with moist foods / aqueous foods:

. contact with fatty foods:

If the article or article is concerned by Regulation (EC) No10/2011 and corrective factors, specify them:

. contact with acidic foods:

. contact with alcoholic foods:

. contact with frozen foods or ice cream:

. other type of contact (to be specified):

- for heat treatment:

If applicable, specify the maximum temperature and the duration of cooking in a traditional oven, in a microwave, during sterilization, etc.:

E.g.: Sterilization at 128°C during 10 min

.....

- contact conditions (shelf life and temperature) with the food, as specified by the customer:

.....

In addition,

- The compliance is understood to be subject to the conformity with the conditions of storage, handling and use, taking into account the specific characteristics of the material or article, and the conditions such as prescribed by professional practices or codes.
- In the event of a change in the packaged product, its composition or its intended use, as well as in the event of a change in the conditions for using the material or the article, the person for whom this declaration is intended must ensure the compatibility packaging / content for which he/she then accepts responsibility.

This declaration of compliance has been established on the following (tick the appropriate boxes, if concerned):

▪ Declaration(s) by suppliers of raw materials

(components of the material covered by the present declaration)

▪ Overall migration testing

If applicable, please specify the simulant(s) and testing conditions

Simulants	Time	Temperature
<i>Simulant A</i>	<i>10 days</i>	<i>40°C</i>
<i>Simulant B</i>	<i>10 days</i>	<i>40°C</i>
<i>Simulant C</i>	<i>10 days</i>	<i>40°C</i>
<i>Simulant D1</i>	<i>10 days</i>	<i>40°C</i>
<i>Simulant D2</i>	<i>10 days</i>	<i>40°C</i>
<i>Simulant E</i>	<i>10 days</i>	<i>40°C</i>

According to regulation (EU) No 10/2011: “testing for 10 days at 40 °C shall cover any long term storage at room temperature or below, including heating up to 70 °C for up to 2 hours, or heating up to 100 °C for up to 15 minutes”

² Types of contact are described, for example, in Regulation (CE) No10/2011, annex III.

- Testing of substances subject to restriction or, for paper and board, substances with purity criteria (see good manufacturing practices)
If applicable, please specify the substance(s) subject to restriction and the authorized limit(s)

PM REF No	Chemical name/nature	Restriction*	Results
111-46-6	Diethylene glycol	SML(T) = 30 mg/kg	OK
1309-64-4	Antimony trioxide	SML = 0,04 mg/kg	OK
128-37-0	2,6-Di-tert.-butyl-p-cresol	SML=3 mg/kg	OK
5873-54-1	Diphenylmethane-2,4-diisocyanate	QM (T) = 1 mg/kg	OK
822-06-0	Hexamethylene-1,6-diisocyanate and its isocyanurate trimer	QM (T) = 1 mg/kg	OK
4098-71-9	1-Isocyanate-3-isocyanatomethyl-3,5,5-trimethylcyclohexane	QM (T) = 1 mg/kg	OK
77-99-6	1,1,1-Trimethylolpropane	SML = 6 mg/kg	OK
502-44-3	Caprolactone	SML (T) = 0,05 mg/kg	OK
74400	Tris(nonphenyl)phosphite	SML = 30 mg/kg	OK
111-66-0	1-Octene	SML = 15 mg/kg	OK
592-41-6	1-hexene	SML = 3 mg/kg	OK
108-05-4	Acetic acid, vinyl ester	SML = 12 mg/kg	OK
96-33-3	Acrylic acid, Methyl ester	SML (T) = 6 mg/kg	OK
75-38-7	Vinylidene fluoride	SML = 5 mg/kg	OK
116-15-4	Hexafluoropropylene	SML = ND (DL = 0,01 mg/kg)	OK

* Restrictions can be a specific migration limit (SML), a maximum concentration (QM), 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

* SML cannot be exceeded according to **worst case calculation** performed by raw material supplier.

- Presence of dual-use additives, as specified by the user (food additive E... or flavouring substance FL...)³
Please specify substances concerned

PM REF No	Chemical name/nature

³ Regulation (EC) No 1333/2008 on food additives and Regulation (EC) No 1334/2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods

128-37-0	2,6-Di-tert.-butyl-p-cresol
126-13-6	Sucrose acetate isobutyrate
25322-68-3	Polyethylene glycol
07631-86-9	Silicon dioxide*
13463-67-7	Titanium Dioxide*

* Silicon dioxide and titanium dioxide are fixed in the matrix in such a way that no migration into food is expected.

If concerned by:

- Regulation (EC) No 450/2009 on active and intelligent materials and articles, specify the substance used and the community register number:

.....

- Regulation (EC) No 282/2008 on recycled plastic materials and articles intended to come into contact with foods, specify the type of material and in case of plastic materials, the authorization number of the recycling process mentioned in the community register of recycling processes:

.....

- Regulation (EC) No 10/2011 concerning the ratio surface / volume in contact with food, specify this ratio:

1 kg of foodstuff packed in 6 dm²

- Regulation (EC) No 10/2011, concerning non intentionally added substances (NIAS) and non listed substances

Names	Identification (CAS, EINECS, etc.)

This declaration of compliance is valid as long as the material composition has not changed, its destination has not changed and in absence of regulatory changes.

This declaration is established in accordance with article 16 of Regulation (EC) No 1935/2004 for materials subject to specific European measures and the amended French decree No 2007-766 for other materials.

Signed in **Hénonville** on **07 March 2017**
 (signature and stamp of the company)

