Declaration of Compliance

Alpha Packaging International
Bijsterhuizen 2401
6604 LK Wijchen
Netherlands

Customer article code:

Version: 1.0

Print date: 2018-07-25

Remarks on update: NOT SPECIFIED

1. Issued by
Alpha Packaging International (Hereinafter referred to as "We", "Us", or "Our").
Bijsterhuizen 2401
6604 LK
Wijchen
Netherlands

2. Manufactured/imported by
Alpha Packaging BV
Vaartveld 4b
4704 SE
Roosendaal
Netherlands

3. Identity of the product
PET Clear (Hereinafter referred to as "Product").

Product type: Final material or article
Product description: NOT SPECIFIED

4. Issue date
2018-07-25

5. Applicable legislation and purity confirmation

European Commission Regulation definition:
- REGULATION (EC) No 1935/2004 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC, (hereinafter referred to as "Regulation (EC) No 1935/2004").
- COMMISSION REGULATION (EC) No 2023/2006 of 22 December 2006 on good manufacturing practice for materials and articles intended to come into contact with food, amended up to COMMISSION REGULATION (EC) No 282/2008 of 27 March 2008, (hereinafter referred to as "Regulation (EC) No 2023/2006").
- COMMISSION REGULATION (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food, amended up to Commission Regulation (EU) 2018/831 of 5 June 2018., (hereinafter referred to as "Regulation (EU) No 10/2011").
- COMMISSION REGULATION (EC) No 282/2008 of 27 March 2008 on recycled plastic materials and articles intended to come into contact with foods and amending Regulation (EC) No 2023/2006, amended up to COMMISSION REGULATION (EU) 2015/1906 of 22 October 2015, (hereinafter referred

to as "Regulation (EC) No 282/2008").

A. Europe

i. Compliance with the requirements of the Framework Regulation
- Regulation (EC) No 2023/2006; Good Manufacturing Practice (GMP): YES
- Article 3 of Regulation (EC) No 1935/2004; General safety aspects: YES
- Article 17 of Regulation (EC) No 1935/2004; Traceability: YES

ii. Compliance with the requirements of the Plastics Regulation
- Regulation (EU) No 10/2011: YES

Plastics used to produce this Product and not separated from the food by a functional barrier are manufactured from only monomers, other starting substances and additives authorized under Regulation (EU) No 10/2011.

iii. Compliance with the requirements of the Recycled Plastics Regulation
- Regulation (EC) 282/2008: NOT APPLICABLE

iv. Other EU legislation

Material group	Country	Legislation
GENERAL	Europe - 94/62/EC	Packaging Waste Directive Specifications of use n/a

B. Member State legislation and non-European legislation
Intentionally added substances not subject to listing in Annex I according to Article 6 of Regulation (EU) No 10/2011, and other components made from non-plastic materials, are either risk assessed in accordance with Article 3 of Regulation (EC) No 1935/2004 or comply with the requirements of the legislation listed below.

National legislation in EU Member States and legislation for countries outside the EU: NOT SPECIFIED

C. Non-intentionally added substances
Non-intentionally added substances in plastics, according to Article 6(4a) of Regulation (EU) No 10/2011, and in non-plastic materials, are risk assessed in accordance with Article 3 of Regulation (EC) No 1935/2004. Adequate information on non-intentionally added substances can be found in section 6A of this document.

D. Overall migration limit
This product complies with the overall migration limit tested under the following conditions:

Simulants
- A: Ethanol 10% (v/v) - B: Acetic acid 3% (w/v) - D2: Vegetable oil. This may be any vegetable oil with a fatty acid distribution as described in EC 10/2011.

Test conditions			
Test Number	**Test conditions**	**Intended food contact conditions**	**Covers also food contact conditions described for**

OM2	10 d at 40 °C	Any long term storage at room temperature or below, including when packaged under hot-fill conditions, and/or heating up to a temperature T where 70 °C ≤ T ≤ 100 °C for a maximum of t = 120/2^((T-70)/10) minutes.	Test OM2 covers also food contact conditions described for OM1 and OM3.

E. Organoleptic properties

We have not determined whether a material or final article that is produced with this Product will induce an unacceptable change in the composition of the food or will cause deterioration of the organoleptic properties of the food. It is the responsibility of the downstream user to perform these tests.

6. Limits, restrictions and compositional specifications

A. Limits and restrictions of non-listed substances

This Product does not contain non-listed substances with restrictions.

B. Substances with limits and restrictions as listed in Regulation (EU) No 10/2011, Annex I

FCM number	EEC reference number	CAS number	Substance name
246	25150	0000109-99-9	tetrahydrofuran
785	24910	0000100-21-0	terephthalic acid
398	35760	0001309-64-4	antimony trioxide
263	13326; 15760; 47680	0000111-46-6	diethyleneglycol
254	13720; 40580	0000110-63-4	1,4-butanediol
227	16990; 53650	0000107-21-1	ethyleneglycol
291	19150	0000121-91-5	isophthalic acid

C. Limits and restrictions as listed in Regulation (EU) No 10/2011, Annex I

i. Restrictions; Annex I – table 1

FCM number	Fat-reduction factor	Restriction(s)	Restrictions and specifications	Notes
246	no	SML: 0,6 mg/kg	-	
785	no	Group: (28)	-	
398	no	SML: 0,04 mg/kg	SML expressed as antimony	(6)
263	no	Group: (2)	-	
254	no	Group: (30)	-	
227	no	Group: (2)	-	
291	no	Group: (27)	-	

ii. Group restrictions; Annex I – table 2

Number	Restriction(s)	Other substances in this group
Group (28)	SML(T) 7,5 mg/kg; expressed as terephthalic acid.	191, 192, 785
Group (2)	SML(T) 30 mg/kg; expressed as ethyleneglycol.	89, 227, 263, 1048
Group (30)	SML(T) 5 mg/kg; expressed as 1,4-butanediol.	254, 344, 672
Group (27)	SML(T) 5 mg/kg; expressed as isophthalic acid.	188, 291

iii. Notes on verification of compliance; Annex I – table 3

Number	Note
Note (6)	Migration limit might be exceeded at very high temperature.

D. Limits and restrictions as listed in Regulation (EU) No 10/2011, Annex II, Metals

This Product does not contain metals with restrictions listed in Annex II.

E. Limits and restrictions as listed in Regulation (EC) No 10/2011, Annex II, Primary Aromatic Amines

This Product may contain Primary Aromatic Amines according to Annex II: YES

F. Compliance confirmation
This Product complies with the limits and restrictions in points 6A, 6C, 6D and 6E within this document, based on worst-case calculations, migration modeling or migration testing.

Specific migration is tested under the following conditions:

Test conditions			
Contact time:	Above 6 months at room temperature and below	Contact temperature:	10 days at 60 °C
Test time:	10 days at 60 °C	Test temperature:	60°C

The following substances with limitations in this Product have not yet been risk assessed by Us and therefore need to be evaluated by the downstream user based on the information listed below:

i. Non-listed substances

All substances comply with the applicable limitations.

ii. Substances listed in Regulation (EU) No 10/2011, Annex I

All substances comply with the applicable limitations.

iii. Substances listed in Regulation (EU) No 10/2011, Annex II, Metals

All metals comply with the applicable limitations.

iv. Substances listed in Regulation (EU) No 10/2011, Annex II, Primary Aromatic Amines

It is up to the downstream user to determine compliance with the applicable limitations.

G. Inks, coatings or adhesives
In case this Product is printed on, covered by a coating, or if different layers are held together by adhesives, We confirm that substances listed in Annex I, coming from inks, adhesives or coatings used in this Product, comply with the relevant restrictions.

This Product may contain substances with limitations listed in the tables under 6A or 6B within this document coming from inks, adhesives or coatings but may not be identified as such by Our suppliers.

7. Dual Use Additive(s)
A substance is defined as a "Dual Use Additive" if the chemical identity of the plastic additive matches that of an authorized food additive or flavoring, regardless of its purity or whether or not the substance is subject to a restriction in food and/or in the plastic. In the case of salts it is the salt that matters, not the authorized acid, phenol or alcohol.

Number (E or FL)	Name	Maximum concentration
E 338	Phosphoric acid	-

The purity of the Dual Use Additives used in this Product respect the purity criteria set out in Annex I of Regulation (EU) No 10/2011.

8. Specifications for use

Specifications of use as regards of type or types of food

All type of foods

Specifications for use as regards of time and temperature of treatment and storage of food

Testing for 10 days at 60 °C shall cover storage above 6 months at room temperature and below, including hot-fill conditions and/or heating up to 70 °C ≤ T ≤ 100 °C for maximum t = 120/2^((T-70)/10) minutes.

Any other limitations of use
Any other limitations of use

Compliant with the provisions within Regulation (EU) No 10/2011 for infants: NO
Compliant with the provisions within Regulation (EU) No 10/2011 for repeated-use articles: NO
A surface/volume ratio expressed in dm² FCM/kg food of: 6 dm² FCM / kg food

9. Functional barrier

This Product contains a functional barrier: NO

Legend
If the compliance assessment is based on a worst-case family strategy, the identity of the product on which the compliance assessment is based will be indicated here.

* Substances marked with a single asterisk in this document are reportable substances with variable

concentrations due to variations in supply source.

** Substances marked with a double asterisk in this document are not present in this Product. However, they are included in this document due to compliance assessment of a worst-case product.

*** Substances marked with a triple asterisk in this document are substances to which both remarks * and ** apply.

For all substances with a single asterisk, *, you are advised to contact your supplier before carrying out any specific migration tests to verify the concentration of the substance within this Product.

EXCP[1]: If it is found that carrying out the tests under the contact conditions specified in Table 3 causes physical or other changes in the test specimen which do not occur under worst foreseeable conditions of use of the material or article under examination, the migration tests shall be carried out under the worst foreseeable conditions of use in which these physical or other changes do not take place.

EXCP[2]: If it is found that carrying out the tests under the combination of contact conditions specified in Tables 1 and 2 causes physical or other changes in the test specimen which do not occur under worst foreseeable conditions of use of the material or article under examination, the migration tests shall be carried out under the worst foreseeable conditions of use in which these physical or other changes do not take place.

Karin Vermaat

Alpha Packaging International
Bijsterhuizen 2401
6604 LK
Wijchen
Netherlands

Disclaimer
The information included in this document is based on the present state of our knowledge and is valid from the stated issue date until this document is superseded. Because of possible changes in the underlying legislation and regulations, as well as possible changes in this Product, we cannot guarantee that the status of this document will remain unchanged. It will be renewed in all cases where the previous conformity is no longer ensured.