


# environmentally innovative packaging™



Perspective of a rigid packaging  
producer on product safety and  
compliance

*Plastipak*

# Safety & Compliance - Agenda

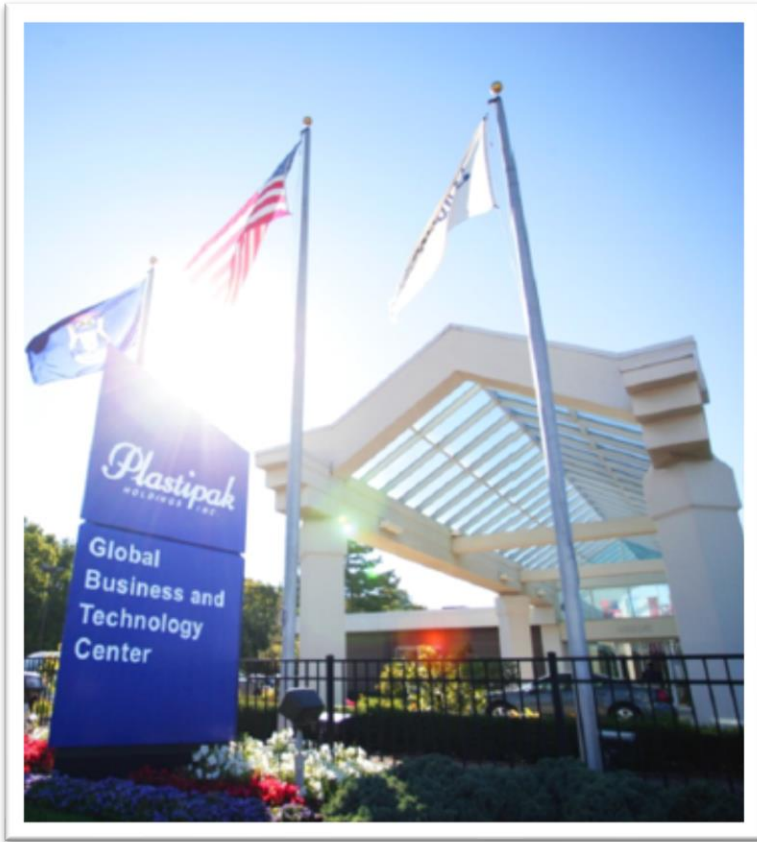
Plastipak - Introduction

Raw materials

Preforms - Containers

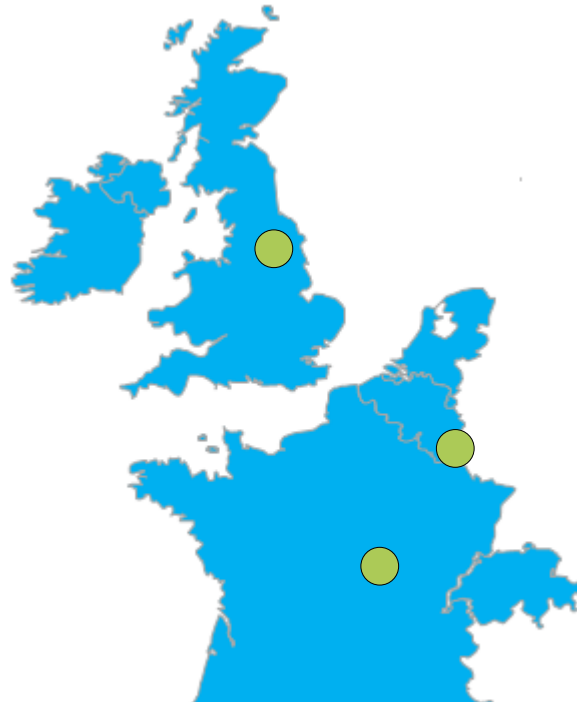
Declarations of Compliance (DoC)

# Our Company



- Family owned, founded in 1967
- \$2.8b turnover
- 40 production plants in North America, South America, Europe & Asia
- 6600 employees
- **Major recycler**
- Hold 1500+patents

# Plastipak's European recycling capability



Hemswell Cliff, UK  
25k tonnes rPET flakes  
40k tonnes rPET pellets

Bascharage, Luxembourg  
Processes rPET flakes  
in to 25k tonnes of rPET  
pellets

**Europe's largest rPET food grade pellet supplier**

Beaune, France  
40k tonnes of flakes  
50k tonnes rPET pellets



# Our Purpose

Creating products which inspire choice, provide value and are sustainably balanced for our customers

**Inspire  
Choice**



**Provide  
Value**



**Sustainably  
Balanced**



## 15 Operational Sites (exc TTW)

Anagni, Italy

Bascharage, Luxembourg

Bierne, France

Beaune, France

Brecht, Belgium

El Jadida, Morocco

Gresford, UK

Hemswell, UK

Inegol, Turkey

Mendig, Germany

Rudna, Czech

Toledo, Spain

Tychy, Poland

Urlati, Romania

Verbania, Italy



European Head Office - Wrexham

# Our European Customers



Coca-Cola Iberian Partners



DANONE



THE BODY SHOP.



Plastipak

# Products

Injection Moulding  
- Preforms



Blow Moulding -  
Containers





Consumers First  
*Always!*<sup>TM</sup>



# Safety & Compliance - Agenda

Plastipak - Introduction

Raw materials

Preforms - Containers

Declarations of Compliance (DoC)

# Scope of Compliance



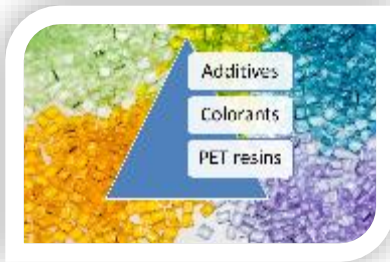
Raw materials  
DoC and NIAS



Manufacturing –  
preforms and  
containers



Declaration of  
Compliance (DoC)



EU Food Contact Legislation  
Preform – Plastic Intermediate Materials

1. Issued by:  
Plastipak Europe – Corporate Quality  
Ringlaan 7  
2900 Herent, Belgium
2. Preforms are manufactured by:  
Plastipak UK  
Cresford Industrial Park  
Cresford, Wrexham  
LL12 8XL  
UK
3. Identity of the preforms: PET  
[SAP code and description of the preforms –  
make sure there is a line with the description of  
the goods on the delivery note]
4. Date of DoC: .....  
[fill in the date of issuing the DoC]
5. Compliance with the relevant legisla-  
tion:  
The preforms listed above are in compliance  
with the following Regulations and require-  
ments, as amended up to the date of issuance  
of this Declaration of Compliance (DoC).

Communication in the supply chain → safety and compliance

# Raw Materials

A large pile of multi-colored PET resin granules in shades of green, yellow, orange, blue, and purple. A blue triangle is overlaid on the right side, containing three white rounded rectangular boxes with text labels: 'Additives', 'Colorants', and 'PET resins'.

Additives

Colorants

PET resins

# Variation in DOCs

**Confidentiality**

## Applicable Restrictions (if any)

Additive 1 is listed in European Commission regulation 10/2011 (as amended) with a SML of 60.00 mg/kg  
Additive 2 is listed in European Commission regulation 10/2011 (as amended) with a SML of 5.00 mg/kg

This product contains a substance that is also permitted as food additive, listed in EU regulation 1333/2008, as follows:

Components with SML

Substance	Specific Migration Limit (SML)
phosphoric acid (E 338)	5 mg/kg
tetrahydrofuran	0.6 mg/kg
terephthalic acid	7.5 mg/kg
isophthalic acid	5 mg/kg
ethylene glycol + diethylene glycol	30 mg/kg combined
Antimony Oxide	0.04 mg/kg

**All information there**

Specific Migration Limit (SML) - 1,4-Butanediol = 5 mg/kg  
Specific Migration Limit (SML) - tetrahydrofuran = 0.6 mg/kg  
Specific Migration Limit (SML) - terephthalic acid = 7.5 mg/kg  
Specific Migration Limit (SML) - isophthalic acid = 5 mg/kg  
Specific Migration Limit (SML) - ethylene glycol + diethylene glycol = 30 mg/kg combined  
Specific Migration Limit (SML) - Antimony Oxide = 0.04 mg/kg

**Clearly defined**

*Differences in information on DoCs makes compliance work more time consuming...*

# Actions Taken

Included a strong regulatory section in supplier quality audit questionnaires

- Results influence the scores of the supplier!

Established direct connection with regulatory specialists at suppliers

- Communication of regulatory requirements

Regulatory approval of each new supplier and raw material

- Continuous review

Improvement of communication in the supply chain

# NIAS in raw materials



IAS

Intentionally Added  
Substances

- Monomers
- Catalysts
- Additive substances

NIAS

Non Intentionally Added  
Substances

- Degradation products
- Reaction intermediates
- Impurities
- Contaminants

# Actions taken

NIAS screening included in approval process of raw materials

- Results can lead to rejection of raw material

GC-FID or MS with headspace extraction  
1h@200°C (=Fraunhofer method for volatiles)

- Results confirmed by Fraunhofer

Risk assessments by specialised labs

NIAS investigation is part of our process for compliance



# Example

*A screening test on a raw material (before use) was performed and we found an undesired substance at a significant concentration*

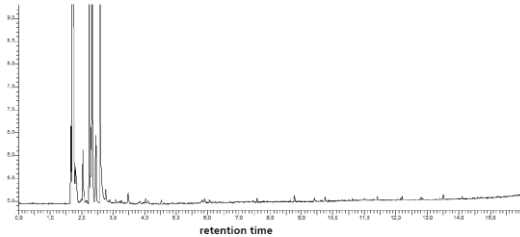


Figure 1: Headspace gas chromatogram of sample 1



- Result confirmed by Fraunhofer Dr. Frank Welle
- We informed our supplier about the substance
- Supplier found root cause and corrected its composition

# NIAS

- Important for us to follow up the NIAS from raw materials up to the final product and incorporate this in our procedures
- We only use widely accepted established test methods in our lab
- Communication and collaboration with suppliers is key as we are 'converting' raw materials into shapes with known process parameters
- It is only possible to identify relevant NIASes through familiarity of own products, supported with knowledge of chemistry in addition to specialized GC-MS trained personnel

# Scope of Compliance



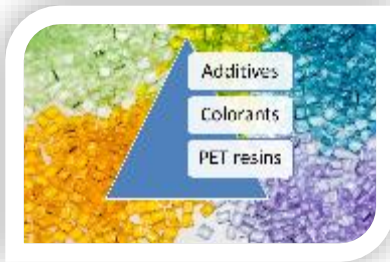
Raw materials  
DoC and NIAS



Manufacturing –  
preforms and  
containers



Declaration of  
Compliance (DoC)



EU Food Contact Legislation  
Preform – Plastic Intermediate Materials

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Cresford, Worsbarn  
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Communication in the supply chain → safety and compliance

# Verification of Compliance

*Creating our « supporting documents »*

- Repository of all Plastipak food contact approved raw materials with supporting documents attached and accessible for all QA managers
- Worst case calculations
- Migration modelling of substances with known or worst case concentrations



# Verification of Compliance

*Creating our « supporting documents »*

- Migration testing on 100% PET bottles
- Migration testing on bottles with barrier materials
- Migration testing on bottles with specific additives
- NIAS Screening reports

# Verification of Compliance

*There is a difference between the 'legal' requirements and the 'customer' requirements...*

*Objective is consumer health and a satisfied customer.*

# Verification of Compliance

A glance at our partners



# Scope of Compliance

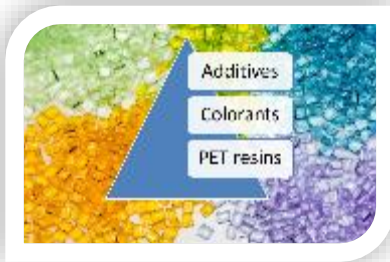
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Communication in the supply chain → safety and compliance



# Declaration of Compliance



## Preform = Plastic Intermediate Material

These will undergo a blowing process to shape the bottle

Union Guidance on Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food as regards information in the supply chain **4.3**

# Declaration of Compliance



Container =  
Plastic Final Article

Union Guidance on Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food as regards information in the supply chain **4.4**

# Declarations of Compliance

### EU Food Contact Legislation

#### Preforms – Plastic Intermediate Materials

- Issued by:**  
Plastipak Europe – Corporate Quality  
Ringlaan 7  
2960 Brecht, Belgium
- Preforms are manufactured by:**  
Plastipak UK  
Gresford Industrial Park  
Gresford, Wrexham  
LL12 8XL  
UK
- Identity of the preforms: PET**  
*(SAP code and description of the preforms – make sure there is a link with the description of the goods on the delivery note)*
- Date of DoC:** .....  
*(fill in the date of issuing the DoC)*
- Compliance with the relevant legislation:**  
The preforms listed above are in compliance with the following Regulations and requirements, as amended up to the date of issuance of this Declaration of Compliance (DoC):
  - Regulation (EC) No 1935/2004** on materials and articles intended to come into contact with food, as amended up to the date of issuance of this Declaration of Compliance (the Framework Regulation): more specifically, the preforms are compliant with the safety requirement set out in Article 3.1(a) of this Regulation. Given that preforms are subject to further processing (i.e. blowing of the preforms into bottles), it is for the final food contact article manufacturer to ensure that the final article is still in compliance with Article 3.1(a). It is also the responsibility of the final article manufacturer to ensure that it does not alter the composition of the packaged

foods (Article 3.1.b) and/or downstream users putting the final article in contact with foods, (e.g., the filler – if he is not the manufacturer of the finished bottle), to ensure that the organoleptic characteristics of the packaged food are not altered (Article 3.1 (c));

- Regulation (EC) No 2023/2006** on good manufacturing practice for materials intended to come into contact with food
- Regulation (EU) No 10/2011** (as amended up to 2018/213) on plastic materials intended to come into contact with food
- 94/62/EC (as amended)** on packaging & Packaging Waste Directive
- in the case Recycled Material used in the manufacturing of the preforms, the customer requirements, with the Regulation (EC) on recycling process used to produce plastics used in the preforms, as evaluated by EFSA. Information about the safety assessment processes used in recycled plastic materials, please contact us.

**Polyethylene terephthalate**

- Based on the DoC(s) of monomers and the additives used are listed in the Regulation (EU) No 10/2011 up to 2018/213.

**Colorant(s) and/or other additives**

- Our suppliers have confirmed to Plastipak articles and the specifications below.

Material group	Country
Colorants	Europe – ODA
Colorants	France – ODA

Colorants	Country
Colorants	France
Colorants	France

### EU Food Contact Legislation

#### Containers – Plastic final article

- Issued by:**  
Plastipak Europe – Corporate Quality  
Ringlaan 7  
2960 Brecht, Belgium
- Containers are manufactured by:**  
Plastipak UK  
Gresford Industrial Park  
Gresford, Wrexham  
LL12 8XL  
UK
- Identity of the containers: PET**  
*(SAP code and description of the containers)*
- Date of DoC:** .....  
*(fill in the date of issuing the DoC)*
- Compliance with the relevant legislation:**  
The containers listed above are in compliance with the following Regulations and requirements, as amended up to the date of issuance of this Declaration of Compliance (DoC):
  - Regulation (EC) No 1935/2004** on materials and articles intended to come into contact with food, as amended up to the date of issuance of this Declaration of Compliance (the Framework Regulation): more specifically, the containers are compliant with the safety requirement set out in Article 3.1(a) of this Regulation. It is the responsibility of downstream users putting the final article in contact with foods, (e.g., the filler), to ensure that the organoleptic characteristics of the packaged food are not altered (Article 3.1 (c)).
  - Regulation (EC) No 2023/2006** on good manufacturing practice for materials and articles intended to come into contact with food;

- Regulation (EU) No 10/2011 (as amended up to 2018/213)** on plastic materials and articles intended to come into contact with food;
- 94/62/EC (as amended up to 2015/720/EC)** - Packaging & Packaging Waste Directive;
- In the case Recycled Material has been used for the manufacturing of the containers conforming to the customer requirements, the containers are compliant with the **Regulation (EC) No 282/2008**; the recycling process used to manufacture the recycled plastics used in the containers has been favorably evaluated by EFSA. Should you need more information about the safety assessment of the recycling processes used in the manufacture of recycled plastic materials, please do not hesitate to contact us.  
*Applicable to this containers: Yes or No*

**Polyethylene terephthalate material used:**

- Based on the DoC(s) of our PET supplier(s), the monomers and the additives used in PET resin used are listed in the Plastics Regulation or **Regulation (EU) No 10/2011 up to amendment 2018/213 of 12<sup>th</sup> of February 2018**.

**Colorant(s) and/or other additive used:**

- Our suppliers have confirmed that the colorants supplied to Plastipak are compliant with the requirements and the specifications as laid down in the table below.

Material group	Country	Legislation
Colorants	France – ODA	Council of Europe Resolution AP(2004) on the use of colorants or plastic materials coming into contact with food
Colorants	France – ODA	Directive 76/769/EEC 2007
Colorants	France	Commission Recommendation on quality of colorants for plastics used in food contact
Colorants	France	The Community Act on Packaging and Food Materials Regulation of The Netherlands and its members
Colorants	France	Various list of food additives on the part of your supplier

**Potential knowledges (NIAS)**

- Non-Intentional Additives (NIAs) present in the production process of the containers
  - Input materials
  - Production process
  - Recycling process
- Referring to the information confirmed that the containers used in the production of the containers are in compliance with the requirements and the specifications as laid down in the table below.

Substance	Country
Colorants	France

**Overall Migration**

- The containers are compliant with the requirements and the specifications as laid down in the table below.
- Simulants:
  - Simulant 1
  - Simulant 2
  - Simulant 3
- Test conditions

1 Group restriction 211.

