

Version: 6
Print date: 2023-02-06

Remarks on update: NOT SPECIFIED

1. Issued by

PIT Plastics (Hereinafter referred to as "We", "Us", or "Our").
Bornsestraat 358
7601 PE
Almelo
Netherlands

2. Manufactured/imported by

Identical to the details listed under point 1 within this document.

3. Identity of the product

FAM 1: HDPE Barrels all colours (Hereinafter referred to as "Product").

Product type: final product
Product description: NOT SPECIFIED

4. Issue date

2023-02-01

5. Applicable legislation and purity confirmation

Based on information provided by our suppliers in their compliance statement, combined with our own assessment, we can conclude that the product complies with the requirements of the following legislations.

A. Europe

Material group	Legislation
COLOURANTS & PIGMENTS Country: Europe - CoE AP(89)1 Status: Compliant	Council of Europe Resolution AP (89) 1 on the use of colorants in plastic materials coming into contact with food.
GENERAL Country: Europe - Framework Regulation (EC) No 1935/2004 (amended by 2019/1381) Status: Compliant	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. (Amended by REGULATION (EC) No 2019/1381). Stating compliance with the Framework Regulation not only covers the safety aspects set out in Article 3(1)(a), but also covers: GMP (Article 3), labelling requirements (Article 15) and Traceability (Article 17).
Country: Europe - GMP Regulation (EC) No 2023/2006 Status: Compliant	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
PLASTICS Country: Europe - 10/2011 up to 2020/1245 Status: Compliant	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) 2020/1245 Of 2 September 2020.

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	
Material group	Legislation
COLOURANTS & PIGMENTS Country: Germany - BfR IX Colorants (As of 01.06.2019) Status: Compliant	BfR Recommendation IX Colorants for Plastics and other Polymers Used in Commodities. (As of 01.06.2019)
Country: Netherlands - Hoofdstuk XI –Kleurstoffen en pigmenten (26 april 2022) Status: Compliant	Regeling van de Minister van Volksgezondheid, Welzijn van 14 maart 2014, kenmerk 328583-117560-VGP, houdende vaststelling van de Warenwetregeling verpakkingen en gebruiksartikelen die in contact komen met levensmiddelen (Warenwetregeling verpakkingen en gebruiksartikelen), geamendeerd tot aan regeling van de Minister van Volksgezondheid, Welzijn en Sport van 26 april 2022, 3348384-1027396-VG Hoofdstuk XI –Kleurstoffen en pigmenten

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 (assigned fatty food simulant) - 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 $70\text{ °C} \leq T \leq 100\text{ °C}$ for a maximum of $t = 120/2^{((T-70)/10)}$ minutes.	Test OM 2 covers also food contact conditions described for OM0, 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 reportable non-listed substances with restrictions.

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

Substance identification	Restrictions and specifications	Screening method
FCM: 356 * EEC ref: 18820 CAS: 0000592-41-6 1-hexene	SML: 3 mg/kg FRF: no Compliance Notes:	Method= (1)
FCM: 186 * EEC ref: 14020 CAS: 0000098-54-4 4-tert-butylphenol	SML: 0,05 mg/kg FRF: no Compliance Notes:	Method= (5)
FCM: 483 * EEC ref: 68860 CAS: 0004724-48-5 n-octylphosphonic acid	SML: 0,05 mg/kg FRF: Compliance Notes:	Method= (5)
FCM: 433 * EEC ref: 68320 CAS: 0002082-79-3 octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate	SML: 6 mg/kg FRF: Compliance Notes:	Method= (12)

Legend screening methods: (1) 100% migration calculation, (2) Overall migration test, (3) Migration modelling, (4) Migration testing, (5) Other (like for instance suppliers information), (12) Migration result (from 100% migration calculation, migration modelling, migration testing or all possible combinations)

i. Group restrictions: Annex I – table 2

No group restrictions are present.

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

No notes on verification of compliance are present.

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

Name / Element	Restriction	Screening method
Aluminium *	SML: 1 mg/kg	Migration result (calculated from members)

Antimony *	SML: 0,04 mg/kg	Migration result (calculated from members)
Arsenic *	SML: 0,01 mg/kg	Migration result (calculated from members)
Barium *	SML: 1 mg/kg	Migration result (calculated from members)
Cadmium *	SML: 0,002 mg/kg	Migration result (calculated from members)
Chromium *	SML:(1) 0,01 mg/kg(2) 3,6 mg/kg	Other
Cobalt *	SML: 0,05 mg/kg	Migration result (calculated from members)
Copper *	SML: 5 mg/kg	Migration result (calculated from members)
Europium *	SML: 0,05 mg/kg	Migration result (calculated from members)
Gadolinium *	SML: 0,05 mg/kg	Migration result (calculated from members)
Iron *	SML: 48 mg/kg	Migration result (calculated from members)
Lanthanum *	SML: 0,05 mg/kg	Migration result (calculated from members)
Lead *	SML: 0,01 mg/kg	Migration result (calculated from members)
Lithium *	SML: 0,6 mg/kg	Migration result (calculated from members)
Manganese *	SML: 0,6 mg/kg	Migration result (calculated from members)
Mercury *	SML: 0,01 mg/kg	Migration result (calculated from members)
Nickel *	SML: 0,02 mg/kg	Migration result (calculated from members)
Terbium *	SML: 0,05 mg/kg	Migration result (calculated from members)
Zinc *	SML: 5 mg/kg	Migration result (calculated from members)

D. 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

E. Compliance confirmation

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

The compliance assessment is performed for 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 Test temperature: 60 °C

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 551	Silicon dioxide	0,040 %
E 172	Iron oxides and hydroxides	-
E 173	Aluminium	-
E 170	Calcium carbonate	-
FL 4.064	4-(1,1-Dimethylethyl)phenol	-

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 types of food: aqueous acidic and alcoholic foods (up to 10% alcohol) and foods that containing fats and oils.

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 $70\text{ °C} \leq T \leq 100\text{ °C}$ for maximum $t = 120/2^{((T-70)/10)}$ minutes.

Any other limitations of use

Compliant with the provisions within Regulation (EU) No 10/2011 for infants and young children: 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.

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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.