

DECLARATION OF COMPLIANCE

Thermoflex SA
 Route de Denges 34
 CH-1027 Lonay
 E-mail : info@thermoflex.ch



Product: **810.00 glass PS transparent 0.15 L**

1. Regulatory requirements

The above-described articles meet the relevant requirements of the regulation 10/2011/EC (latest amended by reg. 2020/1245/EU) as well as the relevant requirements laid down in Article 3, 11(5), 15 and 17 of regulation 1935/2004/EC (latest amended by reg. 2019/1381/EU). Good manufacturing practice according to regulation 2023/2006 is applied.

Based on the information given by our suppliers:

- a) we confirm the compliance of the components contained in the articles (PS 678E; PS 1540; PS 124) with the plastic regulation 10/2011 (as amended). According to the above-mentioned regulation the overall migration should not exceed 10 mg/dm² or 60 mg/kg
- b) following monomers and additives that can be contained in the components are subject to restrictions as set out in annex I and II to the plastic regulation 10/2011/EC and its amendments:

monomer/additive	Ref.no./FCM (according to reg. 10/2011/EC)	SML
Zn-salts	89040 /106	5 mg/kg calculated as Zn

- c) The plastics the articles are made from do not contain dual use additives according to reg. 10/2011/EC which are mentioned in the respective EU regulations 1333/2008/EC or 1334/2008/EC

2. Migration and organoleptic testings

Migration tests on the article material performed by an independent institute showed that overall migration (see 1.) and specific migration* (see b.; SML) fall considerable below the respective SML given by regulation 10/2011 including amendments. Sensorical testings showed no significant deteriorations.

Ratio of food contact area to volume of the food simulant: 12 dm²/l.

2.1 NIAS

NIAS (not intentionally added substances) are unavoidable in plastic materials and articles, since they are the result of the manufacturing process or are part of the polymer itself (oligomers) and can't be removed.

Based on our safety assessment including the information provided by our raw material suppliers as well as assessing migration of NIAS by performing NIAS screenings we can confirm that the articles if used under the conditions specified under pt. 3 comply with the requirements of article 3 of regulation 1935/2004/EC.

3. Intended food contact

The abovementioned articles are intended to be used for the consumption of foodstuff. Aqueous, acidic, alcoholic and fatty foodstuff is allowable under following conditions: cold or hot filling up to 90 °C which might be followed by room temperature storage up to 24 hours. In case of printed articles please consider different contact conditions as described under pt. 6*.

The articles are not suitable for deep-freezing.

Due to possible material softening the maximum filling temperature should not exceed 90 °C.

4. Functional barrier

The above-mentioned articles do not contain a functional barrier.

The above-mentioned articles do not contain varnishes or coatings in the meaning of reg. 2018/213/EU.

5. Packaging and packaging waste / Heavy metals

Based on the information given by our suppliers we confirm that the plastic material the above-mentioned articles are made from comply with dir. 94/62/EC as amended as concerns the defined limits of heavy metals.

6. Printing colours

The printing colours we use in the case of printed articles comply with the requirements of the EuPIA/CEPE exclusion list and the CONEG requirements concerning heavy metal content. For further information please contact our Quality department.

*Printed articles are suitable for aqueous, acidic and max. 50% alcoholic foodstuff under following conditions: Cold up to room temperature filling which might be followed by room temperature storage up to 2 hours.

Printed articles are not suitable for deep-freezing.

7. Line measures for capacity serving measures

Articles given in the overview above and tagged with ** are marked with a line measure and meet the requirements of directive 2014/32/EU (OJ L 96, latest amended by dir. 2015/13).

The positions of existing line measures are monitored and lie within the range given by dir. 2014/32/EU annex X(MI-008) chapter II.

8. General

This declaration is valid from the stated version date until this document is superseded. It will be renewed in case of regulatory and/or legal changes as well as possible changes in our products. We therefore recommend our customers to verify the regulatory status periodically by accessing our Quality department.

Lonay, 12.01.2024



Thermoflex SA
Philippe Besson
Director