



Hine Labels Limited
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Hope Street
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EU Regulatory Statement

Products:

Printed pouches based on the following substrates:

- Primed 12 µm PET/Solventless Adhesive/70 µm Natural PE
- Primed 12 µm Met PET/Solventless Adhesive/70 µm Natural PE
- Primed 12 µm PET/Solventless Adhesive/70 µm White PE

Intended applications: Long term storage of food at room temperature and below (non-retortable applications)

EUROPEAN REGULATIONS

Framework regulation (EC) No. 1935/2004:

Based on the information received from our suppliers and as detailed below, the above flexible pouches are in compliance with the applicable requirements of Regulation (EC) no.1935/2004 on Materials and Articles intended to come into contact with food including Article 3 (General Requirements) and Article 17 (Traceability).

Good Manufacturing Practice Regulation (EC) No. 2023/2006:

The above pouches are manufactured under a quality assurance system which meets the requirements of Regulation (EC) No. 2023/2006 on Good Manufacturing Practice for materials and articles intended to come into contact with food.

Commission regulation (EU) No.10/2011 on plastic materials intended to come into contact with food:

The primed Polyester and Polyethylene layers are in compositional compliance with EU Regulation 10/2011 including its updates 1282/2011, 1183/2012, 202/2014, 174/2015, 2016/1416, 2017/752, 2018/79, 2018/213 and 2018/831. Levels of overall and specific migration from these films meet the requirements of the regulation for the intended applications of the pouches.

Printing inks:

The composition of the UV inkjet digital inks employed with the above pouches comply with the EuPIA Guidelines on Printing Inks applied to the non-food contact surface of food packaging materials and articles. All components of the inks are listed in Annex 6 of the Swiss Ordinance SR 817.023.021. This positive list includes evaluated substances (Section A) and non-evaluated substances (Section B) whose migration into food is restricted to below 0.010 mg/kg (10 ppb).

Absence of any Set-Off Migration / Presence of a Functional Barrier

In the manufacturing process for these flexible pouches, there is no contact of the ink-jet printed outer polyester (PET) surface with the inner polyethylene food contact surface prior to pack filling. Therefore, there is no possibility of any set-off migration occurring. Migration modelling studies undertaken on the above flexible pouch films have predicted that for the proposed applications of the pouches, the 12µm PET layer present in all 3 pouch types will act as a functional barrier to migration of any residual low molecular weight ink components into food at levels of migration above 0.010 mg/kg (with full cure of the inks under good manufacturing practice).

Adhesives:

The composition of the adhesives used meets the requirements of Article 3 of Regulation 1935/2004.

ADDITIONAL INFORMATION

EU REACH (Registration, Evaluation, Authorization and Restriction of Chemicals)

The above flexible pouches are not manufactured or formulated with any of the Substances of Very High Concern (SVHC) as per the European REACH candidate list at levels above 0.1%.

Heavy Metals

Mercury, lead, cadmium, and hexavalent-chromium based compounds are not intentionally used in the formulation of any of the components of the pouches.

Phthalates

Phthalate esters are also not associated with any or the components of the pouches.

Date: 6th Day of February 2019

Signed:

Printed: Bill Hine

Position: Managing Director
(Authorised Hine Labels Ltd. signatory)