

Date: 09/19/2023

From: Whirl-Pak®

Subject: EU Compliance Statement

The film used to manufacture Whirl-Pak® bags is manufactured in accordance with Commission Regulation (EC) No. 2023/2006.

The film used to manufacture Whirl-Pak® bags complies with Regulation (EC) No. 1935/2004. Regulation 1935/2004 contemplates the promulgation of more specific regulations for subclasses of materials intended for food packaging, including plastics.

Commission Regulation (EU) No. 10/2011, as amended, is the specific regulation governing the use of plastics for food contact. The regulation contemplates a prescriptive and a proscriptive regulator regime. That is, materials used to manufacture the plastic must be allowed in Annex I and the package must not exceed migration limits that are stated in Annex I when used in contact with food.

The film used to manufacture this product uses materials in compliance with Annex I of 10/2011. However, 10/2011 also requires the products meet both the global migration limit of 60 mg/kg of food or 10 mg/dm² of the plastic, as well as the SML restrictions for the specific ingredients in testing conditions that are both representative of the food used, i.e. the correct food simulant is used for extraction testing, and the end use conditions, i.e. repeat contact, long term storage, etc., for the application in which the end user seeks to use the products.

Because it is not possible for Whirl-Pak to predict how the products are used or filled or what final material is placed in the products, it is not possible for Whirl-Pak to provide statements or guarantees that Whirl-Pak® products will comply with all applicable SML and OML restrictions. It is the responsibility of the end-user carry to out testing to comply with these requirements.

The specific SML material used in formulating the film are included in the table below. Nothing in the manufacturing process is expected to affect these results. Please note this is for the inside film layer only. The materials on the outside of the bag are not intended to come into contact with food and are not covered by this statement, as the film provides a functional barrier between these materials and the inside of the bag.

LLDPE Film				
FCM Substance No.	EEC Ref No	CAS No	Restriction	Dual Use
21	salt of 42500	not listed in table	None listed	Yes
69	744000	not listed in table	30 mg/kg - lipophilic substance	No
264	22660	111-66-0	15 mg/kg	No

271	52720	112-84-5	none	No
402	96240	1314-13-2	25 mg/kg - expressed as Zinc	No
433	68320	2082-79-3	6 mg/kg	No
511	salt of 91920	7664-93-9	1 mg/kg - expressed as Barium	No
615	92080	14807-96-6	None listed	Yes
734	46380	68855-54-9	None listed	No

If you have any questions, or need assistance, please email our Customer Support team at contact@whirl-pak.com. For Frequently asked questions please visit our website www.whirl-pak.com/frequently-asked-questions