SAFRIPOL
preferred polymer partner

SAFRIPOL | HEAD OFFICE
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TO WHOM IT MAY CONCERN

This is to inform you that the composition of our polyethylene material:

Safrene® M 6650

as supplied from our factory complies with the requirements for use in contact with food of:

EU	Commission Regulation (EU) No 10/2011 (14.1.2011) on plastic materials and articles intended to come into contact with food, ANNEX1, Table 1, up to and including Commission Regulation (EU) 2019/1338. (The EU Commission Directive 2002/72/EC and its amendments, EU-Directives 2004/1/EC, 2004/19/EC, 2005/79/EC, 2007/19EC, 2008/39/EC and EU Commission Regulation (EC) No 975/2009 and 2011/8/EU Commission Directive are repealed).
USA	The U.S. Food, Drug and Cosmetic Act as amended under Regulation 21 CFR (see details below) of the U.S. Food and Drug Administration [FDA] (1.4.2011).

With reference to Article 11, item 3 of Commission Regulation (EU) No 10/2011:

- No substances, which are subject to a restriction in food based on Regulation (EC) No 1333/2008 (16.12.2008) and subsequent amendments up to and including Commission Regulation (EU) 2019/891, are present in this product.

In reference to Article 3 of Regulation (EC) No 1935/2004 concerning the generic product safety requirements of materials and articles intended to come into contact with foodstuffs:

- This resin is manufactured in accordance with good manufacturing practice as outlined in Commission Regulation (EC) No 2023/2006.

- This resin, when used unmodified as supplied by Safripol (Pty) Ltd, is of a suitable purity for articles intended for use in contact with foodstuffs. However, good manufacturing practice needs to be applied during processing of the polymer, including adherence to the maximum recommended processing temperatures.

- All monomers and additives used in the manufacturing of this resin are listed in Commission Regulation (EU) No 10/2011 and/or are allowed for use in food contact articles under the relevant national food-contact regulations applicable to many countries in Europe.

- Safripol does not on a routine basis perform organoleptic tests on articles produced from this resin. Please note that it is the responsibility of the manufacturers of the finished food contact article and/or the industrial food packers to ensure that the article in its final application does not bring about a deterioration of the organoleptic characteristics of the foodstuff.

- Parameters such as applied processing conditions and any modification of the resin during processing is beyond the control of Safripol, Thermal emissions (like aldehydes, ketones and organic acids) are generated during processing of polyethylene under typical processing conditions. Since these emissions could have an impact on the organoleptic properties of the final products, it remains the responsibility of the manufacturer of the finished food contact article and the industrial food packer to make sure that the requirements of Regulation (EC) No 1935/2004, Article 3, pertaining to the final articles, are met.

- Systems and procedures are implemented in the manufacture of this resin in order to fulfill the requirements of Article 17 of Regulation (EC) No 1935/2004 regarding traceability.

We like to draw your attention to the fact that the Commission Regulation (EU) No 10/2011, which applies to all EU-Member States, includes a limit of 10 mg/dm² on the overall migration from finished plastic articles into food.

In accordance with Commission Regulation (EU) No 10/2011 the migration should be measured on finished articles placed into contact with the foodstuff or appropriate food simulants in accordance with ANNEX III of Commission Regulation (EU) No 10/2011 for a period and at a temperature which are chosen by reference to the contact conditions in actual use, according to the provisions in Article 22 Commission Regulation (EU) No 10/2011.

Please note that it is the responsibility of both the manufacturers of finished food contact articles as well as the industrial food packers to make sure that these articles in their actual use are in compliance with the imposed overall migration requirements.

Further, when used unmodified and processed in accordance with good manufacturing practice for food contact applications, the above-mentioned material will comply with the U.S. Food, Drug and Cosmetic Act as amended under Regulation 21 CFR 177.1520(c)3.1c of the U.S. Food and Drug Administration (FDA). However, this product is limited to use in contact with food only under conditions B – H as described in Table 2 of 21 CFR 176.170(c). This statement refers to the extraction limitations only, not to the products physical utility.

The regulations should be consulted for complete details.

Yours faithfully,

G Claasen
Technology & Innovation Executive