



Mitsubishi Engineering-Plastics Corp.

Shiodome Sumitomo-Bldg, 25F, 9-2, Higashi-Shinbashi
1-Chome, Minato-ku, Tokyo 105-0021, Japan

April 12, 2016

To : Whom it may concern

Mitsubishi Engineering-Plastics Corp.
Environment and Quality Assurance Department

THAI POLYCARBONATE CO., LTD.
QC-RD Department

Re : FDA Compliance Statement on IUPILON

This is to certify that the products called IUPILON S-3001R (5313) is in compliance with the requirements of CFR 21 §177.1580 of U. S. Food and Drug Administration (FDA) of 2009 for use in contact with food.

THAI POLYCARBONATE CO., LTD.

QC-RD Department

Padaeng Industrial Estate 1 Padaeng Road,

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Tel : (038) 684816-7, (038) 685613-23

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Mr. Winai C.
(QC & RD Dept. Manager)



April 12, 2016

To : Whom it may concern

Mitsubishi Engineering-Plastics Corp.
Environment & Quality Assurance Department

THAI POLYCARBONATE CO., LTD.
QC-RD Department

Food Contact Declaration Europe

Product grade : S-3001R Color 5313

The composition of above mentioned product(s) meet the relevant requirements laid down in Regulation (EC) No 1935/2004 Commission Regulation (EC) No 2023/2006 and Commission Regulation (EU) No 10/2011 (as amended up to Regulations (EU) No 1183/2012 and (EU) No 202/2014) on materials and articles intended to come into contact with food and can be safely used as a raw material in the production of repeated use food contact applications (all food types) over a long period of time at room temperature¹.

The monomers and/or additives used in the manufacturing of mentioned lupilon grade(s) are listed in Annex I of Commission Regulation (EU) No 10/2011 (as amended). These intermediate materials contain substances as listed below, each with a specific migration limit (SML) as indicated:

Substance	CAS RN	SML [mg/kg food]
bisphenol A	80-05-7	0.6
4-tert-butylphenol	98-54-4	0.05

This intermediate material is not to be used for the manufacture of polycarbonate infant feeding bottles. The monomer carbonyl chloride used has a concentration limit in the final product of 1 mg/kg. The residual carbonyl chloride concentration in lupilon is < 1 mg/kg.

Substances also authorized as direct food additives ("Dual use additives") are either not used for the manufacturing of these intermediate materials, kind of not migrating, or only present in quantities that in case of their migration don't allow relevant contribution to exceeding the limits laid down in Regulation (EC) No 1333/2008 (amended by Commission Regulation (EU) No 257/2010)) or as flavourings and certain food ingredients with flavouring properties for use in and on foods (Regulation (EC) No 1334/2008).

In accordance with Article 12 of Commission Regulation (EU) No 10/2011, the overall migration shall not exceed 10 mg/dm² from plastic materials and articles, with the exception of plastic materials and articles intended to contact infant or child food (60 mg/kg).

Compliance with the overall and specific migration limits as described above must be measured from the final article intended to come into contact with foodstuff.

It is the responsibility of the legal entity responsible for placing on the market of the final article to ensure that the usage of such article is safe, lawful and technically suitable.

¹In accordance with good manufacturing practice, finished articles containing polycarbonate polymer shall be thoroughly cleansed before their first use in contact with food.



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This declaration has been prepared and issued on the basis of currently applicable laws and regulations and our best knowledge and expertise currently available; the addressee or recipient is advised to regularly request updates hereof. This declaration replaces all previous ones relating to these intermediate materials.

The General Conditions of Sale of the entity selling this intermediate material apply to and are part of all our quotations, offers, agreements, sales, deliveries and all other similar dealings, unless explicitly agreed otherwise by means of a duly and mutually executed document.

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