

Certificate

Product Certification Services

Harlan Laboratories Ltd.

for

**MX-Nylon Grades:
S6001, S6007, S6011,
S6121, S6022, S6003LD**

Products of

MITSUBISHI GAS CHEMICAL CO., INC.
TOKYO / JAPAN

AND

MGC ADVANCED POLYMERS, INC.
VA / USA

Issued by

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CERTIFICATE

of compliance with

European Regulation (EU) No 10/2011;
US FDA CFR, Title 21, §177.1500, §177.1390, §177.1395 and FCN 870;
Mercosur GMC/RES. N° 02/12 and GMC/RES. N° 32/07;
Swiss SR 817.023.21

for the

**MX-Nylon Grades:
S6001, S6007, S6011, S6121, S6022 and S6003LD**

The detailed compositions of the above mentioned **MX-Nylon Grades** were disclosed by **Mitsubishi Gas Chemical Co. Inc., Tokyo, Japan** on August 7th, 2014 and were evaluated by Harlan Laboratories Ltd., Global Registration and Strategic Consulting, CH-4452 Itingen, Switzerland for compositional compliances with the following food contact material regulations:

- (EU) No 10/2011 (on plastic materials and articles intended to come into contact with food; last amended by Regulation (EU) No 202/2014)
- US FDA CFR, Title 21, §177.1500, (Nylon Resins; (a)(10)(ii); dated April 1st, 2013)
- US FDA CFR, Title 21, §177.1390, (Laminate structures for use at temperatures of 250° F and above; (c)(1)(i)(e); dated April 1st, 2013)
- US FDA CFR, Title 21, §177.1395, (Laminate structures for use at temperatures between 120 °F and 250 °F; (b)(1); dated April 1st, 2013)
- US FDA Food Contact Notification No 870 (dated April 7th, 2009)
- Mercosur GMC/RES. N° 02/12 and GMC/RES. N° 32/07 ("Lista Positiva De Monómeros, Otras Substancias De Partida Y Polímeros Autorizados Para La Elaboración De Envases Y Equipamentos Plásticos En Contacto Con Alimentos" and "Lista Positiva De Aditivos Para Materiales Plásticos Destonados A La Elaboración De Envases Y Equipamentos En Contacto Con Alimentos")
- Swiss SR 817.023.21 (Ordinance on Materials And Articles; version of April 1st, 2013).

Based on these evaluations **MX-Nylon Grades S6001, S6007, S6011, S6121, S6022 and S6003LD** have found to be in compliance with the above mentioned regulations provided that the limitations as mentioned on page 2 and 3 are met.



Dr. W. Nef
Regulatory Affairs Manager

Itingen, October 14th, 2014
Expiration date: October 14th, 2017
Harlan Laboratories Project D95822b / NEW

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Limitations:

▪ General:

This certificate is based on the information provided to Harlan Laboratories Ltd., Global Registration and Strategic Consulting and on the present legislation as mentioned on page 1. The validity expires in case of any modification of the formulation or any relevant change of the corresponding legislation.

▪ European Union (EU) No 10/2011 / Mercosur and Swiss SR 817.023.21

The final article coming into contact with foodstuffs must comply with the general provisions for food contact materials and must not endanger human health or bring about an unacceptable change in the composition of the food or bring about a deterioration in the organoleptic characteristics thereof.

It must also comply with the overall migration limit of 10 mg/dm² contact surface or 60 mg/kg food and the Specific Migration Limits of 0.05 mg/kg food for 1,3-Benzenedimethanamine (CAS-No 1447-55-0).

▪ When used as Nylon Resin according to CFR 21, §177.1500

Limitations/Specifications:

The food-contact polymer may be used to manufacture films having an average thickness not to exceed 40 microns (0.0016 inch) for use in processing, handling, and packaging of food of types V and IX listed in table 1 of §176.170(c) of this chapter under conditions of use C, D, E, F, G, and H in table 2 of §176.170(c).

▪ When used in laminate structures for use at 250° F and above according to CFR 21, §177.1390 or §177.1395:

Limitations/Specifications:

It is safe to use MX Nylon Grades that comply with the test and use specification as mentioned in item 10.3 of the table in § 177.1500(b) and that are in compliance with the corresponding limits when extracted with water and heptane under the conditions of time and temperature specified for condition of use A, as set forth in Table 2 of § 176.170(c).

▪ When used in as modifier for polyethylene terephthalate (PET) polymers according to Food Contact Notification No 870:

- (a) At levels not to exceed 30 percent by weight of the modified PET in contact with food types I, II, IV-B, VI-A, VI-B, VII-B and VIII and under Conditions of Use C through G, as described in Tables 1 and 2, respectively. Chloroform soluble extractives shall not exceed 0.08 mg/cm² (0.5 mg/inch²) of food-contact surface of the modified PET article when exposed to water at 95°C (203° F) for 1 hour followed by 49°C (120°F) for 24 hours.

- (b) At levels not to exceed 10 percent by weight of the modified PET in contact with foods containing greater than 8 percent ethanol, food type VI-C, at temperatures not exceeding 71°C (160°F). Chloroform soluble extractives shall not exceed 0.08 mg/cm² (0.5 mg/inch²) of food contact surface of the modified PET article when exposed to 50 percent ethanol at 71°C (160°F) for 1 hour followed by 49°C (120°F) for 24 hours.