

LANXESS Deutschland GmbH / 50569 Cologne, Germany

To whom it may concern

Food Contact Status Summary

Lewatit[®] IN 42

This grade complies with the relevant requirements of:

- **Regulation (EC) No 1935/2004** of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food

- **Commission Regulation (EU) No 10/2011** of 14 January 2011 on plastic materials and articles intended to come into contact with food, 321/2011 (01/04/2011), 1282/2011 (28/11/2011), 1183/2012 (30/11/2012), 202/2014 (03/03/2014), 865/2014 (08/08/2014), 2015/174 (05/02/2015), 2016/1416 (24/08/2016), 2017/752 (28/04/2017), 2018/79 (18/01/2018), 2018/213 (12/02/2018), 2018/831 (05/06/2018), 2019/37 (10/01/2019), 2019/988 (17/06/2019), 2019/1338 (08/08/2019), 2020/1245 (20/09/2020)

- **Commission Regulation (EC) No 2023/2006** of 22 December 2006 on good manufacturing practice for materials and articles intended to come into contact with food (GMP) as amended.

No monomers subject to Specific Migration Limit (SML) are used.

No additives subject to restriction (Specific Migration Limit or Quantitative Maximum) are used.

This grade contains catalyst residues containing aluminium. Indicative specific migration tests carried out on this type of polymer on films, under conditions 10 days / 60°C, in food simulant B (considered as the most severe for such components) show that Specific Migration Limit of 1 mg/kg food or food simulant (expressed as aluminium) is not exceeded for this grade. As the conversion process can affect migration, only the converter can guarantee the compliance of his own articles with the above limits.

Indicative overall migration tests carried on this type of polymer on film or thin plaque, under the conditions 10 days / 40°C, in the food simulants A, B and D2 show that the Overall Migration Limit of 10 mg/dm² is not exceeded for this grade. As the conversion process can affect migration, only the converter can guarantee the compliance of his own articles to the OML.

Calcium stearate (E470) is approved as food additive (dual-use additive). It is present, as additive, in the above grade.

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LANXESS Deutschland GmbH

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FDA:

Under 21 CFR 177.1520(c)1.1a, this resin may be safely used in articles used for packing or holding food during cooking.

All adjuvants used in the manufacture of this resin are cleared for use in 21 CFR 170-189 by specific citation, generally recognized as safe (GRAS), prior sanctioned or under a specific Food Contact Notification (FCN).

No further restrictions apply to the finished polymer.

China:

Standard GB 31603-2015

This grade has been manufactured according to the requirements laid down by the General Hygiene Norm GB 31603-2015.

Standards GB 4806.1-2016 and GB 9685-2016

This grade is in compliance with the Standards GB 4806.1-2016 (General Safety Requirements for Food Contact Materials & Articles) and GB 9685-2016 (National Food Safety Standard: Standard for Uses of Additives in Food Contact Materials and Their Products).

For more details about eventual restrictions related to the use of particular monomers or additives, please refer to the EU DoC of the present Certificate. The restrictions listed in the new Chinese Standards are indeed fully aligned with those of the Annex 1 of the Regulation (EU) 10/2011.

Standard GB 4806.6-2016

This grade also fulfils the requirements of the Standard GB 4806.6-2016 (Plastic Resin Standard).

For more details about eventual restrictions related to SML, SML(T) and QM, please refer to the EU DoC of the present certificate. The restrictions applying to Plastics Resins are indeed fully aligned to those set by the Regulation (EU) 10/2011.

Standard GB 4806.7-2016

Indicative results performed on resins similar to this one show that if used under normal conditions, the articles produced should meet the requirements of Standard 4806.7-2016 (Plastic Articles Standard). It remains however the responsibility of the converter to assess the compliance of his articles with this standard.

Please note:

It pertains to downstream users of materials intended to come into contact with food, to ensure that the final materials or articles do not bring about an unacceptable change in the composition of the food, or bring about deterioration in the organoleptic characteristics which render it unfit.

The user of **Lewatit® IN 42** is responsible to check the ability of the resin for the intended use and **Lewatit® IN 42** must be pre-treated by the user in accordance with the manufacturer's instructions.

Dr. Katrin Wieland
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Lewatit® IN 42 corresponds with the technical data and recommendations given in the relevant Lewatit Product Information and Technical Information.

For further information concerning the application, please contact your local LANXESS Affiliate.

Yours sincerely,
LANXESS Deutschland GmbH

i. V. Katrin Wieland

Dr. Katrin Wieland
Global Product Stewardship

* This information and our technical advice - whether verbal, in writing or by way of trials - are given in good faith but without warranty, and this also applies where proprietary rights of third parties are involved, statements regarding consistency are valid. Our advice does not release you from the obligation to check its validity and to test our products as to their suitability for the intended processes and uses. The application, use and processing of our products and the products manufactured by you on the basis of our technical advice are beyond our control and, therefore, entirely your own responsibility. Our products are sold in accordance with the current version of our General Conditions of Sale and Delivery.

Our products to be delivered according to an order confirmation have been registered according to EC Regulation 1907/2006 (REACH Regulation), or are excluded from the REACH Regulation, or are exempted from registration according to the REACH Regulation.

For the US this letter is only of consultative character: In the United States of America the LANXESS business is conducted by LANXESS Corporation, Pittsburgh, PA. Customers in the US are kindly asked to address their requests directly to this legal entity.

