

Certificate

US-American and EU food regulatory assessment of the purging compound "Lusin® Clean 1061"

Client:

Chem-Trend Deutschland GmbH

D - 82216 Maisach-Gernlinden

Order:

PA/4735/13

Sample:

Purging compound "Lusin® Clean 1061"

The product "Lusin® Clean 1061" shall be used as purging compound for the cleaning of screws, cylinders and nozzles of thermoplastic injection moulding machines and extruders. The product is designed for the removal of polymer residues in case of a material or colour change in machines used for the production of articles intended for direct food contact.

After disclosure of the formulation of the purging compound "Lusin® Clean 1061" by the client, the used components were evaluated according to US-American legislation for food contact materials (21 Code of Federal Regulation, 21 CFR) and according to European requirements for food contact materials (Fraunhofer IVV test report PA/4220/13, dated 11.4.2013). Additionally details on the production process were provided by the client for the evaluation.

Based on the evaluation of the food regulatory status of the components used for the formulation of "Lusin® Clean 1061" it can be concluded that all components are either affirmed as GRAS (generally recognized as safe), or approved as direct food additives or permitted as indirect food additives according to 21 CFR § 177 "Indirect Food Additives: Polymers".

Furthermore, the formulation of the purging compound "Lusin® Clean 1061" is in compliance with the European Plastics Regulation (EU) No 10/2011 (last amendment by Regulation (EU) No 1183/2012). Therefore, the application of "Lusin® Clean 1061" as purging compound is in compliance with the safety requirements according to Art. 3 of the EU Framework Regulation (EC) No 1935/2004.

In conclusion, the product "Lusin® Clean 1061" can be safely used as purging compound for the cleaning of screws, cylinders and nozzles of thermoplastic injection moulding machines and extruders that are used for the production of articles intended for direct food contact applications.

Fraunhofer Institute Process Engineering and Packaging

Freising, 26.9.2013

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