

Declaration concerning food contact

FDA (Food & Drug Administration)

Roehling Industrial Gastonia, LP

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Product

Sustason[®] PPSU MG (Radel[®] R5500) purple - ASTM

We hereby declare that our above-mentioned semi-finished product, due to the resin manufacturers data, comply with the requirements of the FDA-regulation **FCN 83 of September 23, 2000, as well as, if applicable, further specific FDA regulations for additives or colorants contained (e.g. FDA 21 CFR 178.3297 Colorants for polymers).**

Restrictions

Types of food: Repeat use food contact applications with all food types, under FDA conditions of use B through H as described in Tables 1 and 2 of 21 CFR 176.170(c)

Additional: It is the responsibility of the customer to determine that all conditions and specifications outlined in FCN 83 are met, and that the products fabricated from these materials are acceptable to the FDA for use in their intended food contact applications. This declaration is valid for Sustason PPSU MG bone [NT15].

Compliance with these requirements was not checked on the semi-finished product, as these generally relate to the final article. The exact provisions of the aboved-mentioned FDA-regulation can be found at:

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm>

The quality assurance system of Roehling Industrial Gastonia, LP is certified as per DIN EN ISO 9001:2015 and serves as an important basis of the constant composition and quality of Sustason[®] PPSU MG (Radel[®] R5500) purple - ASTM.

Note:

It is customers own responsibility to test the suitability of plastic items manufactured from or with our products for the planned application in the foodstuff industry. That includes for example:

- testing, if the physical characteristics of the plastic are suitable for the planned application,
- testing, if plastic parts manufactured by the customer fulfill the prescribed migration or extraction values,
- testing for possible influence of the plastic on the composition and/or organoleptic characteristics of foodstuffs.



This information above is based on the information provided by our suppliers. We are not liable for completeness and correctness of information contained herein. Existing laws and regulations must be respected by the receivers/users of our product in their own responsibility.

All information contained in this document is provided in good faith and is based on sources believed to be reliable at the time of publication of this document. In the event of changes, for example due to legislation, manufacturing-related changes, or new scientific findings, new statements will be published on our website <https://www.roechling.com/industrial/materials/thermoplastics/high-performance-plastics/ppsu/sustason-ppsu-mg-radel-r5500-purple-astm-774120>. Previous declarations will become invalid as a result. This declaration expired 12 months after the date of issue (Print). It is the sole responsibility of our customer to ensure that the laws and regulations necessary for their intended use are complied with. Therefore, if necessary, please request a new confirmation or download it from our website <https://www.roechling.com/industrial/materials/thermoplastics/high-performance-plastics/ppsu/sustason-ppsu-mg-radel-r5500-purple-astm-774120>.

The **Food and Drug Administration** (FDA) is an [agency](#) of the [United States Department of Health and Human Services](#), one of the [United States federal executive departments](#).

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