

28 April 2011

HKR102

Statement on the regulatory status of Sasol Polymers' products intended for use in food contact applications

Identification

Grade name:	HKR102
Type of polymer:	Polypropylene homopolymer
CAS number:	9003-07-0
Identity of manufacturer:	Sasol Polymers, a division of Sasol Chemical Industries Limited (Reg. no. 1968/013914/06), a company incorporated and existing under the laws of South Africa.
Origin of product:	Sasol Polymers produces polypropylene at its operations situated at Polymer Road, Sasol Works, Secunda, Republic of South Africa.

Europe

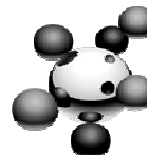
The grade listed above complies with *Regulation (EC) No 1935/2004 of 27 October 2004* (the "framework regulation" on food contact materials). Compliance is claimed based on the following:

- The grade is manufactured in accordance with the broad guidelines for good manufacturing practice as outlined in *Commission Regulation (EC) No 2023/2006 of 22 December 2006* (although no formally audited GMP system is in place at present).
- Adequate documentation-, quality assurance- and quality control measures are in place to ensure adherence to specification, consistency of composition and batch traceability.
- The grade complies with the requirements of *Commission Directive 2002/72/EC of 06 August 2002* relating to plastic materials and articles intended to come into contact with foodstuffs; more information provided below.

The grade listed above complies with *Commission Regulation (EU) No 10/2011 of 14 January 2011* as amended by *Commission Directives (EU) No 321/2011 of 1 April 2011*. Compliance is claimed based on the following:

- Only monomers listed in Annex I to *Commission Regulation (EU) No 10/2011* (as amended) are used in the production of this grade.
- Only additives listed in Annex I *Commission Regulation (EU) No 10/2011* (as amended) are used in the production of this grade.
- Where applicable additives are used in concentrations below the maximum permitted concentration ("QM") specified in the directive.
- The grade listed above contains no additive which is subject to a Specific Migration Limit ("SML") under the directive.

Users of this grade are reminded of their obligations under *Commission Regulation (EU) No 10/2011*; namely to ensure compliance of packaging articles to the overall migration limit ("OML") and specific migration limits ("SML"). Verification of compliance must be done in accordance with Annex V of *Commission Regulation (EU) No 10/2011*, i.e. either by calculation, migration modelling or migration testing in accordance with Annex V of *Commission Regulation (EU) No 10/2011* and with reference to *Directive 82/711/EEC* (as amended by *Directive 93/8/EEC* & *97/48/EEC*) using an appropriate food simulant as specified in *Directive 85/572/EEC* (as amended by *Directive 2007/19/EC*).



United States of America

The grade listed above complies with the regulations of the US Food and Drug Administration (FDA) governing the use of plastic materials in contact with food as published in the *Code of Federal Regulations 21 CFR*. Compliance is claimed based on the following:

- The basic polymer present in this grade is allowed in food contact applications under paragraph (a)(1)(i) of 21 CFR 177.1520.
- The basic polymer present in this grade is suitable for cooking & non-cooking applications as specified in paragraph (c)1.1a of 21 CFR 177.1520.
- All adjuvant substances added to the basic polymer are permitted by virtue of being GRAS (generally recognised as safe), having prior sanction or being explicitly approved for use under 21 CFR 170 through 189. The adjuvant substances in this grade are permitted in articles intended for use with:
 - Food types I - IX as specified in Table 1 of 21 CFR 176.170
 - Conditions A - H as specified in Table 2 of 21 CFR 176.170
- Please note that additional restrictions might apply for various applications. Please refer to CFR 21 for more information in this regard.

Disclaimer:

a) This statement replaces all earlier statements from Sasol Polymers on the above mentioned topic(s). Please contact Sasol Polymers regularly for up-to-date regulatory information.

b) This statement will remain valid until replaced by a newer version from Sasol Polymers on the above mentioned topic.

c) Sasol Polymers provides this information in good faith, but makes no representation as to its comprehensiveness or accuracy. Individuals receiving this information must exercise their independent judgement in determining its appropriateness for a particular purpose. Accordingly, Sasol Polymers will not be responsible for damages resulting from use of or reliance upon this information.

d) This statement only applies to virgin polymer granules or powders as supplied by Sasol Polymers and does not include:

- Modification of the polymer by the addition of any other product to it.
- Modification of the polymer resulting from processing.
- Modification of the polymer resulting from storage.

e) This statement does not claim or guarantee that any Sasol Polymers product is suitable for any specific food contact application. No blanket "food contact approval" of polymer materials and/or articles made from polymer materials is possible under the applicable regulations. Migration of substances from polymers depends to a large extent on the geometry of the article made from the polymer, the foodstuff packed in the articles and the conditions under which the foodstuff is packaged, stored and used. Sasol Polymers cannot predict or guarantee the migratory behaviour of its polymers after it has been converted into articles (mouldings, film, etc). Users are advised to subject articles made from Sasol Polymers' products to relevant calculations and/or migration modelling and/or migration testing before suitability for food contact applications is claimed.

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