



01 September 2009

## CMR348

### **Statement on the regulatory status of Sasol Polymers Polypropylene intended for use in food contact applications**

#### **Europe**

The grade of polypropylene listed above complies with the regulations of the Commission of the European Communities relating to plastic materials and articles intended to come into contact with food as published in *Commission Directive 2002/72/EC* and amended by *Commission Directive 2004/19/EC*, *Commission Directive 2007/19/EC* and *Commission Directive 2008/39/EC*. Compliance is claimed on the basis of the following:

- Only monomers listed in Annex II (Sections A and B) to *Directive 2002/72/EC* are used in the production of this grade.
- Only additives listed in Annex III (Sections A and B) to *Directive 2002/72/EC* (as amended by Annex II to *Directive 2004/19/EC*, Annex II to *Directive 2007/19/EC* & Annex I to V of *Directive 2008/39/EC*) are used in the production of this grade. Where applicable additives are used in concentrations below the maximum permitted concentration ("QM") specified in the directives listed above.

Users of this grade are informed that:

- A Specific Migration Limit ("SML") or concentration limit ("QM") is imposed on certain additives by the directives listed above. To enable polymer converters to fulfil their obligations in term of the regulations, polymer producers are obliged to disclose information pertaining to additives on which limits are imposed. Polymer converters are therefore informed that the grade of polypropylene listed above contains at least one additive which is subject to a SML and/or a QM. For more detailed information in this regard please contact Sasol Polymers.
- The directives listed above require that plastic materials and articles in contact with foodstuffs shall have an overall migration limit ("OML") not exceeding 10 mg/dm<sup>2</sup> of the area in contact with the foodstuffs (in some instances an alternative OML of 60 mg/kg of foodstuffs packaged in the article is specified). The OML applies to all additives and adjuvant substances present in the final article, including those added during conversion.

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- Migration behaviour of additives from polymers into packaged foodstuff is dependant on polymer material composition, packaging article geometry, nature of foodstuff and conditions under which the foodstuff is packed, stored and used. Verification of compliance to SML's and OML's must therefore be done by polymer converters or foodstuff packagers based on the specific design and specific use of the final article in accordance with *Article 8 of Directive 2002/72/EC*, i.e. either by calculation, migration modelling or migration testing in accordance with *Directive 82/711/EEC* (as amended with *Directive 93/8/EEC* and *97/48/EEC*) and *Directive 85/572/EEC* (as amended by *Directive 2007/19/EC*).

### **United States of America**

The grade of polypropylene 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 on the basis of the following:

- The basic polymer used in this grade meets the requirements of paragraph (a) (1) (i) or paragraph (a) (3) (i) of *21 CFR 177.1520*.
- The additives used in this grade meet the requirements of paragraph (b) of *21 CFR 177.1520* in that they are permitted for use by the applicable regulations in *21 CFR 170* through *189*. The additives in this grade are permitted in articles intended for use with:
  - Foods of types I to IX as listed in Table 1 of *21 CFR 176.170*.
  - Conditions B to H as listed in Table 2 of *21 CFR 176.170*.

For further information or clarification of any part of this statement please do not hesitate to contact us.

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#### **Disclaimer:**

- 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.*
- This statement will remain valid until replaced by a newer version from Sasol Polymers on the above mentioned topic.*
- 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 polypropylene granules 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 Sasol Polymers polypropylene 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 polypropylene after it has been converted into articles (mouldings, film, etc). Users are advised to subject articles made from Sasol Polymers polypropylene to relevant calculations and/or migration modelling and/or migration testing before suitability for food contact applications is claimed.*