

Regulatory Support:

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sasol

Sasol Base Chemicals
Product Stewardship and Technical Services

Declaration of Compliance – LF2220M

Description of product

| | |
|---------------------------|---|
| Identity of manufacturer: | Sasol South Africa (Pty) Ltd (Reg. no. 1968/013914/07), a company incorporated and existing under the laws of South Africa |
| Origin of product: | Sasol Base Chemicals produces polyethylene at its operations situated at Sasol Midland Site, Bergius Street, Sasolburg, Republic of South Africa. |
| Grade name: | LF2220M |
| Type of polymer: | Low density polyethylene |
| CAS number: | 9002-88-4 |

European food contact

The grade listed above complies with *Commission 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 compositional requirements of *Commission Regulation (EU) No 10/2011* of 14 January 2011 (as amended by *Regulation EU 1183/2012*, *Regulation EU 1282/2011*, *Regulation EU 202/2014*, *Regulation 2015/174*, *Regulation (EU) 2016/1416* and *Regulation (EU) 2017/752* relating to plastic materials and articles intended to come into contact with food.

Compliance to the compositional requirements of *Commission Regulation (EU) No 10/2011* is claimed based on the fact the grade listed above is produced from authorised substances listed in the *Union list of authorised monomers, other starting substances, macromolecules obtained from microbial fermentation, additives and polymer production aids* specified in Annex I Table 1 of the regulation.

Users of this grade are reminded of their obligations to demonstrate compliance of the final food contact article made from the grade listed above. Such demonstration of compliance may be based on migration testing as specified in Annex V of the regulation using an appropriate stimulant as specified in Annex III of the regulation.

As migration testing is complex, costly and time consuming it should be admissible that compliance can be demonstrated also by calculations, including modelling, other analysis, and scientific evidence or reasoning if these render results which are at least as severe as the migration testing.

To fulfil its obligation of providing sufficient information to allow the downstream business operators to ensure compliance, Sasol Base Chemicals discloses that the grade listed above contains substances subject to a specific migration limit.

| FCM substance No | 271 | 433 | 638 | 504 |
|---|-----------|--|---------------------|--|
| Ref. No | 52720 | 68320 | 23590 | 86240 |
| CAS No | 112-84-5 | 2082-79-3 | 25322-68-3 | 7631-86-9 |
| Substance name | Erucamide | Octadecyl-3-(3,5-di-tert butyl-4-hydroxyphenyl)-propionate | Polyethylene Glycol | Silicon dioxide |
| Use as additive or polymer production aid (yes/no) | Yes | Yes | Yes | Yes |
| Use as monomer or other starting substance or macromolecule obtained from microbial fermentation (yes/no) | No | No | Yes | No |
| FRF applicable (yes/no) | No | Yes | No | No |
| SML [mg/kg] | - | 6 | - | - |
| SML(T) [mg/kg] (Group restriction No) | | - | - | - |
| Restrictions and specifications | | - | - | For synthetic amorphous silicon dioxide: primary particles of 1 – 100 nm which are aggregated to a size of 0,1 – 1 µm which may form agglomerates within the size distribution of 0,3 µm to the mm size. |
| Duel Use Additive | No | No | Yes (E551) | Yes (E1521) |

This grade contains duel use additive as specified in Regulation (EC) No 1333/2008 on food additives and Regulation (EC) No 1334/2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods. Please see the table above for more information.

United States of America food contact

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*. 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 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.

The information contained in the table above is confidential in nature. Distribution to third parties without prior written permission from Sasol Base Chemicals is prohibited.



Stephen Jugmohan
Product Steward : Regulatory

Disclaimer:

- a) *This statement replaces all earlier statements from Sasol on the above mentioned topic(s). Please contact Sasol regularly for up-to-date regulatory information.*
- b) *This statement will remain valid until replaced by a newer version from Sasol on the above mentioned topic.*
- c) *Sasol 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 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 and does not include:*
 - 1) *Modification of the polymer by the addition of any other product to it.*
 - 2) *Modification of the polymer resulting from processing.*
 - 3) *Modification of the polymer resulting from storage.*
- e) *This statement does not claim or guarantee that any Sasol 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 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' products to relevant calculations and/or migration modelling and/or migration testing before suitability for food contact applications is claimed.*