

The Chemical Company

BASF SE, 67056 Ludwigshafen, Germany

G-KT/SI

Mr. Dr. Jens Hamprecht

Sep 8, 2011 / vg

EV/CS - E100

Dr. Sabine Vogt

Phone: +496216049143

Fax: +496216093253

E-Mail: [plastics.safety@basf.com](mailto:plastics.safety@basf.com)**Request-no.: 31571/01****Your request of Sep 8, 2011**

Dear Mr. Hamprecht

**ECOFLEX® F BLEND GRADES**

European Union:

Presuming appropriate processing the product can be used in the countries of the European Community for food contact materials or articles according to article 3 of Regulation (EC) No 1935/2004 (Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27th October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC).

Compliance with the provisions of Regulation (EC) No 1935/2004 especially the suitability of the articles for the given application, the effect on smell and taste of the food, and observance of any given limitations, must be ensured by the person who introduces the articles into circulation (see the last paragraph).

The specific restrictions mentioned in Commission Regulation (EU) No. 10/2011 and amendments have to be ensured.

European Union:

The composition of the product complies with the requirements of the Commission Regulation (EU) No. 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food as amended.

The following restrictions have to be ensured:

- Hexamethylenediisocyanate (FCM-No. 372) SML (T) = N.D.  
(1mg/kg in the final product, expressed as isocyanate moiety)

BASF SE  
67056 Ludwigshafen, DeutschlandTelefon: +49 621 60-0  
Telefax: +49 621 60-42525  
E-Mail: [info.service@basf.com](mailto:info.service@basf.com)  
Internet: [www.basf.com](http://www.basf.com)Sitz der Gesellschaft:  
67056 Ludwigshafen  
Registergericht:  
Amtsgericht Ludwigshafen  
Eintragsnummer: HRB 6000Euro-Bankverbindungen:  
Commerzbank Aktiengesellschaft  
Konto-Nr. 0201000700, BLZ 545 400 33  
IBAN DE26 5454 0033 0201 0007 00  
SWIFT COBADEFF545Deutsche Bank Aktiengesellschaft  
Konto-Nr. 0013302500, BLZ 545 700 94  
IBAN DE72 5457 0094 0013 3025 00  
SWIFT DEUTDESM545

Aufsichtsratsvorsitzender: Eggert Voscherau

Vorstand: Kurt Bock, Vorsitzender;  
Martin Brudermueller, stellv. Vorsitzender;  
Hans-Ulrich Engel, Michael Heinz,  
Andreas Kreimeyer, Stefan Marcinowski,  
Harald Schwager, Margret Suckale

The Chemical Company

- 1,4-Butanediol (FCM-No. 254) SML (T) = 5 mg/kg
- Terephthalic acid (FCM-No. 785) SML (T) = 7.5 mg/kg
- Tetrahydrofuran \* (FCM-No. 246) SML = 0.6 mg/kg

Additional information and/or restrictions are mentioned in Commission Regulation (EU) No. 10/2011 for the substances above under the respective FCM-No. (<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:012:0001:0089:EN:PDF>).

The meaning of the abbreviations is:

ND = non-detectable, a detection limit of 0,01 mg/kg food is applicable unless specified differently

SML = specific migration limit expressed in mg per kg food

SML (T) = specific migration limit for a group of substances expressed in mg per kg food

FCM-No = unique identification number of the substance

\* Polyesters like ECOFLEX® can decompose if excessive thermal treatment is applied. Depending on the processing conditions tetrahydrofurane (THF) may be formed leading to a residual content in the finished article. Therefore the referenced specific migration limits must be ensured by the person who introduces the articles into commerce.

We confirm, that the product is manufactured according to the requirements of Commission Regulation (EC) No 2023/2006 of 22 December 2006 on good manufacturing practice for materials and articles intended to come into contact with food. BASF SE meets the demands for risk minimization in the value chain which are required.

USA:

Since September 18, 2009 the Food Contact Notification No. 907 (amending No. 372 and 780) is effective for the referenced ECOFLEX® grade. Hence, this ECOFLEX® grade fully complies with the requirements of the Federal Food, Drug and Cosmetic Act, 21 CFR in contact with all types of food under Conditions of Use C to G, as described in Tables 1 and 2 on FDA website: <http://www.cfsan.fda.gov/~rdb/opa-fcn3.html>.

The listing of effective notifications for food contact substances is available on the agency's internet site at <http://www.cfsan.fda.gov>.

Toys:

The composition of the product complies with the requirements of European Standard EN 71 Safety of Toys, part 3: "Migrations of certain elements".

Heavy metals:

The sum of lead, cadmium, chromium-VI and mercury does not exceed the maximum value of 100 ppm (i.e. 0.01%) as required by the CONEG (Coalition of North Eastern Governors) for the January 1, 1994. Thus, also the maximum value for these elements laid

The Chemical Company

down in Directive 94/62/EEC is met.

**F o r n o t i c e :** Appropriate processing conditions for the articles have to be applied. The suitability of the articles for the application concerned, including their effect on smell and taste of the food, and observance of any given limitations (for example overall migration, specific limits and other analytical requirements) must be tested and ensured in each case by the person who introduces the articles into circulation.

BASF SE makes no warranties, express or implied, concerning the suitability of BASF plastics for use in any medical device and pharmaceutical applications.

Yours sincerely

BASF SE  
Global Regulatory Affairs

i. A. S. U. 

---

The data indicated above are the results of our investigations and correspond to the state-of-the-art. The data refer to the state of the laws at the date of issue.

This confirmation expires after 12 months or in case of regulatory changes.

Please ask for a new confirmation if needed.

It is the responsibility of those to whom we supply our products to ensure that any proprietary rights and existing laws and legislation are observed.

The certificate is exclusively for our customers and respective competent authorities. It is not intended for publication either in printed or electronic form (e.g. via Internet) by others.

Thus, neither partial nor full publication is allowed without written permission.