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**Desmopan 786 – Food contact  
Your fax of April 28 1999**

Preliminary note regarding food contact plastics: for the time being and the foreseeable future rules of EU member states relevant in this area are quite complicated and require lengthy explanation.

Monomers used for the manufacture of plastics are regulated by EC Directives and their transformations into national ordinances, e.g. in Germany the " Ordinance on Consumer Goods " (Bedarfsgegenständeverordnung).

For all further plastics constituents (additives, polymerisation aids, colourants etc.) there are no finalized EC Directives covering all of them, therefore these components have to comply with the existing national rules/positive lists, partly deviating from each other. In Germany for instance, the "BGA" Recommendations still are to be observed for additives etc.

With respect to its monomer constituents Desmopan 786 complies with

- Commission Directives (90/128/EEC), (92/39/EEC), (93/9/EEC), (95/3 EEC) and (96/11/EEC) of February 23, 1990, of May 14, 1992, of March 15, 1993, of February 14, 1995 and of March 5, 1996 relating to plastics materials and articles intended to come into contact with foodstuffs (Official Journal of the European Communities, No. L 349/26 of 1990, No. L 168/21 of 1992, No. L 90/26 of 1993, No. L 41/44 of 1995 and No. L 61/26 of 1996)
- the amended German "Regulation on Articles for Food Contact Applications" of 12/23/1997(Federal Law Gazette, No. 1, Jg. 1997, pages 5 et seq).

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Eintragung: Amtsgericht Leverkusen HRB 1122

The main sections of the above EC Directives and German Regulation contain

- the limit on the "global migration" of < 60 mg/kg of foodstuff
- the list of authorized monomers
- specific restrictions on individual monomers (specific migration limits, SML, or maximum residual content in finished plastic articles,  $Q_m$ ).

Regarding the monomers used in Desmopan 786, the following limits must be observed:

Diphenylmethane 4,4'-diisocyanate - max. residual content in the article : < 1 mg/kg  
expressed as NCO

Propylene oxide - max. residual content in the article : < 1 mg/kg of plastic

Trimethylolpropane - specific migration limit: < 6 mg/kg of foodstuff

At the moment, there are no recognised methods of analysis with sufficient precision for verifying these threshold values. This position seems unlikely to change in the near future. Methods of analysis are only adopted as European standards at CEN once lengthy standardization procedures have been carried out following completion of the necessary collaborative trials. For this reason, we are only able to make provisional and non-binding statements about our products based on our own investigations and product knowledge.

We are working on the assumption that the global migration and monomer specific limits can be met when Desmopan 786 is used for food contact applications at room temperature and contact times up to 24 h hours.

With respect to its additives and/or further constituents Desmopan 786 also complies with Recommendation XXXIX "Plastics materials and articles on Polyurethanes", of the former German Federal Health Office (BGA), renamed into "Bundesinstitut für gesundheitlichen Verbraucherschutz und Veterinärmedizin (BgVV), status: 01.06.98 (196. Communication: Bundesgesundh. Bl. 41, 360 (1998)).

Furthermore the migration test of primary aromatic amines on the finished part belongs to the responsibility of the articles manufacturer.

Our experience shows that the guidelines or requirements defined in this context are reliably fulfilled.

Best regards  
Bayer AG

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