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15/05/1992

Dr.Bie/Dr

Re.: PVC GT 001 - our project NA 92 9320

Dear Dr. Patrick,

Please find enclosed our assessment of PVC, product code GT 001.

According to this assessment the composition of the PVC material does not fully comply with German regulations. As the additives are still subject to the regulation via recommendations, the user in principle is free to deviate from the recommendation, but on his own risk. In such case positive assessment may be used, if there are only slight deviations or if substances of very low toxicity are used.

We feel the use of the first two substances as specified in the assessment for the reasons shown is more than a slight deviation only and therefore the composition is considered not acceptable according to present German regulations.

We should furthermore point to the fact that for some of the additives there are criteria for purity or certain parameters. Moreover, as derived from EC directive 90/128, the global migrate is limited to 10 µg/dm² (normally no problem for rigid PVC) and the transfer of monomeric vinyl chloride is limited to 10 µg per kg foodstuff (1.7 µg/dm²). In doubt these parameters would have to be checked on the final article or a representative test specimen.

We regret not having been in a position to issue a in total positive assessment.

NAME	RI	✓
GT		
GNS		

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Geschäftsführer: Dr.-Ing. Klaus Paulsen - Erläuterungsort und Gerichtsstand Hamburg
Die Veröffentlichung von Ergebnissen unserer Arbeiten und Gutachten sowie die Verwendung für Werbezwecke
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Assessment of PVC GT 001
with regard to German Regulations for Plastics Intended
for Food Contact Applications

NA 92 9320

According to the order of Messrs. IRI - Inveresk Research International, Tranent, Scotland, dated March 25, 1992, the composition of a PVC material, product code GT 001, intended for food contact applications, was assessed with regard to compliance with relevant regulations in the Federal Republic of Germany.

Plastics intended for food contact applications in Germany are regulated generally by the "Lebensmittel- und Bedarfsgegenständengesetz" (LMBG, food and commodities law) and in detail for the monomers by the Bedarfsgegenstände-verordnung (commodities ordinance) and for the additives by the "Empfehlungen" (recommendations) of the German BGA. For rigid PVC recommendation II applies.

The composition of the PVC material was communicated to us by IRI via fax on March 17, 1992, and some supportive information supplied subsequently.

It is concluded that most components in the amounts used comply with the respective regulations, yet very few components exceed the limitations in recommendation II, some others are not listed in recommendation II at all, part of which is listed elsewhere.

In detail

Substanz N-60 (711472) ed. 1. 1. 92
- Nonylphenoxy polyethylenoxy alkylphenol ethoxylate (CAS No. 9016-45-9) is used in an amount of 1.25 %. Limit in Rec. II: 0.2 %

unspecific
- 4,4'-Isopropylidenediphenol alkyl(C₁₂ - C₁₅)phosphite: not listed in Rec. II, but contained in the drafted EC list of additives, SCF list 9 ("Substances ... which could not be evaluated due to lack of adequate specificity. These groups should be replaced by individual substances actually in use").



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