



**DANISH  
TECHNOLOGICAL  
INSTITUTE**

Curex APS  
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1999.09.06  
SCH

### **FDA COMPLIENCE FOR CUREX PE 50**

From Curex APS we have received copies of:

- Letter from KELLER AND HECKMANN LLF, Washington. USA
- Results from a section of extraction tests from different laminates containing CUREX PE 50
- FDA 21 § 177.1395
- Extraits from the preamble to FDA 21 CFR 170.39

On this basis, we have concluded, that the tested laminates from a material technological point of view, may be considered generally recognised as safe for use with nonalcoholic foods at temperatures between 120 °F and 180 °F, and therefore, such use may be said to comply with the Federal Food, Drug, and Cosmetic Act, and all applicable food additive regulations.

The above mentioned is carried out according to the general terms and conditions regarding commissioned work accepted by the Danish Technological Institute. See enclosure.

With Kind Regards  
The Danish Technological Institute  
Centre for Packaging and Transport

Paul Schlemmer  
Head of section

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23. august 1999  
1-0654  
SCH/bwa

## **RE.: FOOD COMPLIANCE FOR MATERBATCH CUREX PE 50**

From Curex ApS, Ringvejen 70, 7900 Nykøbing Mors, Denmark we have received copies of Food Contact Documentation related to masterbatch CUREX PE 50 as follows:

Letter from DTC/ATV , DK 2970 Hørsholm, Denmark  
Letter from INSTITUT NEHRING GmbH, 38102 Braunschweig, Germany  
PRODUCT INFORMATION for CUREX PE 50  
Material Safety Data Sheet for CUREX PE 50  
Information about the content of CUREX PE 50 from CUREX.

### **COMPLIANCE WITH EU REGULATIONS FOR FOOD CONTACT MATERIALS**

On this basis we can conclude that, when added to a polyethylene film of maximum 125 gr/m<sup>2</sup> by up to 4 % CUREX PE 50 the use of CUREX PE 50 is in full compliance with EU regulation regarding "PLASTIC MATERIALS AND PLASTIC ARTICLES ALLOWED TO GET IN CONTACT WITH FOOD <sup>1)</sup> "  
The conclusion will hereafter be that a film may maximum contain 4 % CUREX PE 50, if it is presumed that the total quantity added to the film will migrate.

### **COMPLIANCE WITH GERMAN REGULATIONS FOR FOOD CONTACT MATERIALS**

On the same basis we can conclude that, when added to a polyethylene film of maximum 125 gr/m<sup>2</sup> by up to 4 % CUREX PE 50 , the use of CUREX PE 50 is in full compliance with the German "BEDARFSGEGEN-STÄNDEVERORDNING

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<sup>1)</sup> Council Directives 78/142/EEC from 1978, 82/711 EEC from 1982, 84/500 EEC from 1984, 85/572/EEC from 1985, 89/109/EEC from 1989, 89/397/EEC from 1989, 93/99/EEC from 1993, and Commission Directives 80/590/EEC from 1980, 80/766/EEC from 1980, 81/432/EEC from 1981, 90/128EEC from 1990, 92/39/EEC from 1992, 93/8/EEC from 1993, 93/9/EEC from 1993, 93/10/EEC from 1993, 93/111/EEC from 1993, 95/3/EEC from 1995, 96/11/EC from 1996.

IN DER FASSUNG VOM 23.12.1997" according to Kunststoff-Richtlinie 90/128/EWG.

The addition of 4 % CUREX PE 50 is therefore allowed and without reservation and covers the use of CUREX PE 50 according to the Synoptic Document for both monomers and additives.

The above mentioned is carried out according to the general terms and conditions regarding commissioned work accepted by the Danish Technological Institute. See enclosure.

With Kind regards  
The Danish Technological Institute  
Centre for Packaging and Transport



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