

THIS IS A FAX MESSAGE FROM :
INVERESK RESEARCH INTERNATIONAL LTD.,
TRANENT, EH33 2NE, SCOTLAND.
OUR FAX NUMBER IS : 0875 614555



FOR ATTENTION OF → Connie Dillon
COMPANY → B F Goodrich Company
TOWN AND COUNTRY → Cleveland, USA
FAX NUMBER → 0101 216 447 6459
FROM → Dr C P Patrick
DATE → 5 June 1992
NUMBER OF PAGES → 2
INCLUDING THIS PAGE

(IF YOU RECEIVE LESS THAN THIS PLEASE TELEPHONE : 0875 614545)

MESSAGE FOLLOWS:

Dear Connie

GEON 87697

I have attached NATEC's comments on colouring agents in food-contact plastics.

According to NATEC, there is a positive list of additives in Austria but not in Switzerland.

NATEC's advice on Austria and Switzerland is to submit a request to the relevant authority for an opinion on the product's acceptability. This request would need to include migration data - are any available on GEON 87697?

Kind regards

Yours sincerely

pp *Joan Rafter*

C P Patrick, PhD
Regulatory Affairs

Enc

Form No: ADM/012

BFG15804

21632001

133/-14
NATEC
NATEC Institut
für naturwissenschaftlich-technische Dienste GmbH

Inveresk Research International Ltd.
Dr. C.P. Patrick
Regulatory Affairs
Trenton, EH33 2NE

SCOTLAND

Fax No. 0044 - 875 - 614 555

Behringstraße 154
Postfach 5015 68
D-2000 Hamburg 50
Telefon: (040) 88 30 9-0
Telefax: (040) 88 30 91 70
Telec: 2 164 283 ntec d
Bankkonten:
Deutsche Bank AG 6 522 445
(BLZ 200 700 00)
Dresdner Bank AG 0 908 338 400
(BLZ 200 800 00)

Ihre Ref.: Unsere Ref.: Telefon: Datum:
Dr.Bie/Dr (040) 8 83 09-151 05/06/1992

Dear Dr. Patrick,
Thanks for your fax message dated June 3, 1992, which we should like to answer as follows:

- 1) Colourants for plastics are regulated in recommendation IX. The general requirement of this recommendation is that the pigments are so tightly bound into the plastics materials that in practice "nothing" is solubilised in the foodstuff. Therefore, the amounts of different heavy metals being soluble in 0.1 N HCl are limited to portions between 0.005 and 0.05 % related to the pigments. Furthermore, the contents of primary aromatic amines, solubilized by 1 N HCl must not exceed 0.05 % (as aniline). The requirements are generally fulfilled by good quality materials. There are some further limitations for adjuvants to the colourants - if used at all.

No (drafted) EC regulations on colourants for plastics are known up to now; it may be expected that colourants may be included into the additive list (drafted only at present) or in a respective amendment.

2) Austrian and Swiss authorities

The addressees are as follows:

Bundesanstalt für Lebensmittel-
untersuchung und -forschung
Kinderspitalgasse 15
A - 1090 Vienna

Bundesamt für Gesundheitswesen
Abt. Lebensmittelwissenschaft
Postfach
CH - 3000 Bern 14

It should be mentioned that the process of expressing an opinion may be rather lengthy in some cases. Compliance with German regulations is of some advantage in any case. For migration tests the usual simulants would have to be used.

We hope to have answered your questions satisfactorily.

Kind regards,

NATEC Institut
für naturwissenschaftlich-
technische Dienste GmbH

Dr. K. Rigge

i.V. Dr. A.-D. Bieber
Key Member of The European Foundation for Quality Management

BFG15805



Mitglied der SGS-Gruppe, Sitz der Gesellschaft: Hamburg - Armengraben Hamburg 14087
Geschäftsführer: Dr.-Ing. Klaus Paulus - Erlangenort und Geschäftstand Hamburg
Die Veröffentlichung von Ergebnissen unserer Arbeiten und Gutachten sowie die Verwendung für Werbezwecke bedürfen - selbst auszugewählte - unserer schriftlichen Genehmigung.

IRI SCOTLAND 12B

00875 81455

05/06/92 18:48

21632002