Bundesamt
für Gesundheit

Office fédéral
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Ufficio federale
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Unità di direzione protezione dei consumatori

- Ai laboratori cantonali svizzeri
- All'Ufficio di controllo delle derrate alimentari del Principato del Lichtenstein
- Alle cerchie interessate

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Berna, 9 marzo 2005

Istruzione n. 4

**Il diisodecilftalato nelle derrate alimentari**

## 1. I fatti

Il laboratorio cantonale di Zurigo ha rilevato la presenza di diisodecilftalato (DIDP) in sughi al pomodoro venduti in vasetti di vetro. Come nel recente caso di contaminazione da olio di soia modificato (ESBO) di derrate alimentari conservate in vasetti di vetro, il diisodecilftalato proviene dalla sigillatura del coperchio metallico avvitabile.

Conformemente alla direttiva n. 3 del 5 novembre 2004 concernente l'ESBO nelle derrate alimentari, il laboratorio cantonale ha richiesto all'UFSP[1] un'analisi di rischio su cui basare la sua decisione.

## 2. Valutazione del caso

Il DIDP è un additivo per materie plastiche utilizzato come plastificante negli oggetti d'uso in polivinilcloruro (PVC). Normalmente è poco utilizzato in materiali destinati a entrare in contatto con derrate alimentari.

Il DIDP (CAS # 26761-40-0) non è una sostanza unica ma raggruppa i diesteri dell'acido ftalico e degli alcoli primari saturi e ramificati d'una lunghezza di catena $C_9$ a $C_{11}$ dove la catena $C_{10}$ è maggioritaria (> 90%).

Il DIDP non è classificato come additivo nella lista 2 (non esaustiva) dell'ordinanza sulle materie plastiche[2]. Pertanto il prodotto è disciplinato secondo le esigenze generali dell'articolo 6 dell'ordinanza sugli oggetti d'uso[3].

La tossicologia del DIDP è ben nota. Il DIDP non è mutageno. L'organo più sensibile ai suoi effetti tossici è il fegato. La somministrazione di dosi relativamente elevate durante test condotti su animali induce un aumento del peso del fegato e l'apparizione di vacuoli nelle cellule epatiche. Il Comitato

scientifico dell'alimentazione umana (SCF) ha determinato una dose giornaliera tollerabile di 0,15 mg/kg pc al giorno o 9 mg/persona per giorno[4,5].

Il caso di contaminazione riportato concerne quattro tipi differenti di sugo al pomodoro di un'unica marca. Le concentrazioni misurate su quattro campioni rilevano una contaminazione eterogenea. I valori misurati variano tra i 15 e i 175 mg/kg di alimento, in media 70 mg/kg. Il valore di migrazione globale (60 mg/kg) è dunque superato.

Applicando criteri analoghi a quelli applicati per la valutazione di rischio dell'ESBO (consumo di una porzione di salsa di 100 grammi tre volte alla settimana), si può calcolare che l'esposizione media di un consumatore regolare raggiunge i 3 mg/giorno, inferiore quindi alla dose giornaliera tollerabile.

**Di conseguenza si ritiene che questa contaminazione non costituisce un rischio per la salute del consumatore e che la dose giornaliera tollerabile non è superata fintantoché il tenore di DIDP rimane inferiore a 200 mg/kg di alimento.**

## 3. Misure da adottare

In considerazione del fatto che:

1) il numero di campioni analizzati è troppo esiguo per consentire una valutazione definitiva della situazione;

2) il livello di contaminazione dei campioni secondo le analisi effettuate non costituisce un rischio per la salute dei consumatori;

3) tale contaminazione non è specifica dell'addittivo DIDP ma è un problema generale di migrazione dei plastificanti nelle sigillature dei coperchi;

4) un'applicazione urgente e completa delle esigenze legali potrebbe indurre le industrie a cercare soluzioni senza testarle a sufficienza;

5) trovare una soluzione globale e durevole al problema della cessione di plastificanti da parte dei coperchi dei vasetti in vetro è nell'interesse dei consumatori;

invitiamo le autorità esecutive ad applicare misure analoghe a quelle richieste nella nostra direttiva n.3, ossia ad accordare ai distributori degli alimenti incriminati e ai fabbricanti di coperchi il lasso di tempo necessario per ricercare una soluzione definitiva e completa. **Conviene tuttavia ritirare dalla vendita gli alimenti nei quali è comprovata una presenza di DIDP superiore a 200 mg/kg.**

## 4. Considerazione importante

La presente istruzione, così come l'istruzione n. 3, non mette in causa né il principio d'inerzia dei materiali, attualmente definito mediante il valore di migrazione globale, né le modalità d'applicazione.

Invitandovi a prendere atto delle misure richieste, Vi inviamo i nostri migliori saluti.

Il capo dell'Unità di direzione protezione dei consumatori

Dr. Roland Charrière

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[1] Lettera del laboratorio cantonale di Zurigo (18.1.2005) «Migration von anderen Stoffen aus Dichtungen von Schraubdeckeln» - Istruzione n. 3 del 5.11.2004

[2] Ordinanza sulle materie plastiche, OPla, RS 817.041.1

[3] Ordinanza sugli oggetti d'uso, OUso, RS 817.04

[4] Dose giornaliera tollerata di gruppo inclusi i diesteri dell'acido ftalico e degli alcoli primari $C_7$-$C_{11}$ saturi e ramificati ($C_9$ > 90%); n. rif. 75100.

[5] Opinion on an additional list of monomers and additives for food contact materials, Scientific Committee on Food, expressed on 2 December 1999.

EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate B - Scientific Health Opinions
**Unit B3 - Management of scientific committees II**

**SCIENTIFIC COMMITTEE ON FOOD**

**SCF/CS/PM/(GEN)/M80 final**
**12/12/1999**
Annex VII to the minutes of
the 119th Plenary meeting

# OPINION
# ON AN ADDITIONAL LIST OF MONOMERS AND ADDITIVES FOR FOOD CONTACT MATERIALS

(expressed on 2 December 1999)

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SCIENTIFIC COMMITTEE ON FOOD

SCF/CS/PM/(GEN)/M80 final

# Opinion an an additional list of monomers and additives for food contact materials

(expressed on 2 December 1999)

The Committee (re)evaluated a number of monomers and additives for food contact materials. The substances examined are listed in alphabetical order in the Table, with their Reference Number (REF_N), Chemical Abstract Number (CAS_N.) and classification in a SCF list. The definition of the SCF lists is given in the Appendix. The opinion of the Committee on each of the substances is shown in the same table. Where appropriate, quantitative restrictions (R) on migration in foodstuffs or in the residual quantity in finished products appear in the Table.

The substances appearing in this table have been examined during the 80th meeting of the Working Group Food Contact Materials on 1-3 September 1999.

TABLE

| REF_N | NAME | CAS_N | SCF List | SCF ASSESSMENT |
|---|---|---|---|---|
| 19490 | LAUROLACTAM | 947-04-6 | 3 | R = 5 mg/kg of food.<br><br>Available: specific migration data; gene mutation assay in bacteria (negative); chromosomal aberration assay in cultured mammalian cells (negative); gene mutation assay in cultured mammalian cells (negative); 90-day oral rat study.<br>(RIVM/TNO SDS, July 1999 = CS/PM/2574 REV. II/19490).<br>(Adopted at the 119th SCF meeting) (2 December 1999) |
| 35160 | 6-AMINO-1,3-DIMETHYL-URACIL | 6642-31-5 | 3 | R = 5 mg/kg of food.<br><br>Available: data on specific migration of the stabiliser and its hydrolysis product from rigid PVC; two gene mutation assays in bacteria (negative); chromosomal aberration assay in cultured mammalian cells (positive only after exposure for 48 hours and without metabolic activation); gene mutation assay in cultured mammalian cells (negative); micronucleus assay (negative); 2-week oral rat study; 90-day oral rat study.<br>(RIVM/DE SDS, September 1999 = CS/PM/3323 REV.I/35160).<br><br>Remark for Commission: 6-amino-1,3-dimethyl-uracil hydrolyses in acetic acid.<br>(Adopted at the 119th SCF meeting) (2 December 1999) |

| REF_N | NAME | CAS_N | SCF List | SCF ASSESSMENT |
|---|---|---|---|---|
| 35760 | ANTIMONY TRIOXIDE | 1309-64-4 | 3 | R = 0.01 mg/kg (as Sb)<br><br>Available: data on specific migration from PET in food simulants and residual content in PET; gene mutation assay in bacteria (negative); chromosomal aberration assay in cultured mammalian cells (positive); gene mutation assay in cultured mammalian cells (negative); two micronucleus assays (negative; one assay with a single oral dose, the other assay with repeated oral doses); in vivo UDS assay (negative); 28-day oral range finding rat study; 90-day oral rat study.<br>(RIVM/DE/TNO SDS, August 1999 = CS/PM/3254 REV.II/35760).<br><br>Remark for Commission: migration limit might be exceeded at very high temperature.<br>(Adopted at the 119th SCF meeting) (2 December 1999) |
| 47540 | DI-TERT-DODECYL DISULFIDE | 27458-90-8 | 3 | R = 0.05 mg/kg of food.<br><br>Available: migration data; gene mutation assay in bacteria (negative); chromosomal aberration assay in cultured mammalian cells (negative); gene mutation assay in cultured mammalian cells (negative); acute toxicity studies with di-tert-dodecyl trisulfide (TPS20) and di-tert-dodecyl pentasulfide (TPS32); 4-week oral rat study with di-tert-dodecyl pentasulfide (TPS32); skin and eye irritation studies performed with TPS20 and TPS32; sensitisation studies performed with TPS20 and TPS32.<br>(RIVM/TNO SDS, September 1999 = CS/PM/2964 REV. II/47540).<br>(Adopted at the 119th SCF meeting) (2 December 1999) |
| 55660 | GLUTARALDEHYDE | 111-30-8 | 7 | Available: data concerning identity, physical-chemical data; no migration experiments were performed since it is intended to get an evaluation in terms of a TDI calculation; inadequate gene mutation assay in bacteria; two gene mutation assays in bacteria (one negative; one weakly positive); two gene mutation assays in bacteria (both positive, mainly in the presence of S9 mix) (two publications of 1998); chromosomal aberration assay in cultured mammalian cells (negative); gene mutation assay in cultured mammalian cells (positive and inadequate); two in vitro SCE assays (one positive and one inadequate); in vitro UDS assay (inadequate); micronucleus assay (negative; without indication that the substance reached the bone marrow); dominant lethal assay (negative); in vivo bone marrow assay (negative; without indication that the substance reached the bone marrow); in vivo sex-linked recessive lethal assay (negative); acute toxicity data; three 90-day studies with mice, rats and dogs (drinking water); 2-year combined chronic/carcinogenicity study with rats (drinking water); 2-generation reproduction study with rats (drinking water); 2 teratogenicity studies with rats and rabbits and two "limited" teratogenicity studies with mice (only summary available) and rats (industrial BIO-TEST); metabolism studies with rats and rabbits (only overview available); 13-week inhalation studies with rats and mice; 2-year inhalation carcinogenicity studies with rats and mice; conclusions drawn in other scopes.<br><br>Needed: migration data according to SCF guidelines.<br>(RIVM/TNO SDS, June 1999 = CS/PM/3283 REV. II/55660).<br>(Adopted at the 119th SCF meeting) (2 December 1999) |

| REF_N | NAME | CAS_N | SCF List | SCF ASSESSMENT |
|---|---|---|---|---|
| 75100 | PHTHALIC ACID, DIESTER WITH PRIMARY SATURATED C7-C11 BRANCHED ALCOHOLS, MORE THAN 60% C9 | 28533-12-0 | 2 | Group-TDI = 0.15 mg/kg b.w. (with PM/75105)<br><br>Available: acute oral toxicity; 3-week oral rat study; 4-week oral rat study; 13-week oral rat studies; 13-week oral dog studies; 2-year oral mouse toxicity/carcinogenicity study (only abstract available); 2-year oral rat toxicity/carcinogenicity study and additional study for male rat specific a-2u-globulin mechanism (only abstract available); gene mutation assay in bacteria (negative); chromosomal aberration assay in cultured mammalian cells (negative); gene mutation assay in cultured mammalian cells (negative); mammalian cell transformation assay (negative); UDS assay (negative); peroxisome proliferation studies; metabolism study; two-generation reproduction study in rats; two teratogenicity studies in rats (one is limited); studies on the estrogenic activity; conclusion of another scope (CSTEE opinion).<br>(RIVM SDS, September 1999 = CS/PM/2584 REV. III/75100).<br><br>Reason for the group-TDI: both substances are mixtures overlapping each other; toxicity profile of the substances is the same (same target organs) and comparable NOAEL's were established.<br>(Adopted at the 119th SCF meeting) (2 December 1999) |
| 75105 | PHTHALIC ACID, DIESTER WITH PRIMARY SATURATED C9-C11 BRANCHED ALCOHOLS, MORE THAN 90% C10 | 26761-40-0 | 2 | Group-TDI = 0.15 mg/kg b.w. (with PM/75100)<br><br>Available: acute oral toxicity; eye irritation study with rabbits; limited 8-day oral rat study; 2-week inhalation study; 90-day oral rat study; 90-day oral dog study; gene mutation assay in bacteria (negative); gene mutation assay in cultured mammalian cells (negative); mammalian cell transformation assay (negative); peroxisome proliferation studies; metabolism study; 2-generation reproduction study with rats; inadequate teratogenicity study with rats; teratogenicity study with rats; study on the estrogenic activity; conclusion of another scope (CSTEE opinion).<br>(RIVM SDS, September 1999 = CS/PM/2583 REV. III/75105).<br><br>Reason for the group-TDI: both substances are mixtures overlapping each other; toxicity profile of the substances is the same (same target organs) and comparable NOAEL's were established.<br>(Adopted at the 119th SCF meeting) (2 December 1999) |
| 81220 | POLY-[[6-[N-2,2,6,6-TETRAMETHYL-4-PIPERIDINYL)-N-BUTYLAMINO]-1,3,5-TRIAZINE-2,4-DIYL][(2,2,6,6-TETRAMETHYL-4-PIPERIDINYL)IMINO]-1,6-HEXANEDIYL[(2,2,6,6-TETRAMETHYL-4-PIPERIDINYL)IMINO]]-ALPHA-[N,N,N',N',-TETRABUTYL-N''-(2,2,6,6-TETRAMETHYL-4-PIPERIDINYL)-N''-[6-(2,2,6,6-TETRAMETHYL-4-PIPERIDINYLAMINO)-HEXYL]-[1,3,5-TRIAZINE-2,4,6-TRIAMINE]-OMEGA-N,N,N',N'-TETRABUTYL-1,3,5-TRIAZINE-2,4-DIAMINE | 192268-64-7 | 3 | R = 5 mg/kg of food<br><br>Available: molecular mass distribution curve, specifications; specific migration; gene mutation assay in bacteria (negative); chromosomal aberration assay in cultured mammalian cells (negative); gene mutation assay in cultured mammalian cells (negative); 28-day oral rat study; gene mutation assay with two migrating by-products (negative).<br>(RIVM/DE SDS, September 1999 = CS/PM/3272 REV. I/81220).<br>(Adopted at the 119th SCF meeting) (2 December 1999) |

| REF_N | NAME | CAS_N | SCF List | SCF ASSESSMENT |
|---|---|---|---|---|
| 95000 | TRIMETHYLOLPROPANE TRIMETHACRYLATE-METHYL METHACRYLATE COPOLYMER | 28931-67-1 | 7 | Available: incomplete data on use; incomplete data on residual monomers and the fraction with molecular mass < 1000 D.<br><br>Needed: data on other uses than in thin polypropylene films; basis for the determination of the fraction with molecular mass < 1000 D; in vivo mammalian bone marrow cytogenetic assay and in vivo UDS assay on trimethylolpropane trimethacrylate (PM/25840).<br>(RIVM/DE SDS, July 1999 = CS/PM/3324/9500).<br>(Adopted at the 119th SCF meeting) (2 December 1999) |
| 95270 | 2,4,6-TRI-TERT-BUTYL-PHENYL-2-BUTYL-2-ETHYL-1,3-PROPANEDIOL PHOSPHITE | 161717-32-4 | 3 | R = 2 mg/kg food (sum of phosphite, phosphate and the hydrolysis product (TTBP))<br><br>Available: 100% hydrolysis of ULTRANOX®640 in 10% ethanol (aqueous foods); migration of ULTRANOX®640 from HDPE and PP into 95% ethanol maximum 2.73 mg/kg food; migration of ULTRANOX®640-phosphate from HDPE and PP into 95% ethanol maximum 0.1 mg/kg food; migration of the hydrolysis product 2,4,6-tri-tert-butyl phenol from HDPE and PP maximum 0.34 mg/kg food; migration of the hydrolysis product 2,4,6-tri-tert-butyl phenol from HDPE and PP maximum 0.34 mg/kg food; solubility in 95% ethanol 0.2%, in isooctane 12%, in olive oil 4%; gene mutation assay in bacteria (negative); chromosomal aberration assay in cultured mammalian cells (negative); gene mutation assay in cultured mammalian cells (negative); micronucleus assay (negative); 28-day oral rat study (no NOAEL established); 90-day oral rat study (no NOAEL established); supplementary 90-day oral rat study; delayed neurotoxicity study.<br>(RIVM/DE/TNO SDS, July 1999 = CS/PM/3198 REV. III/95270).<br><br>Remark for Commission: in aqueous food simulants to be measured as 2,4,6-tri-tert-butylphenol.<br>(Adopted at the 119th SCF meeting) (2 December 1999) |

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## APPENDIX

## DEFINITION OF THE SCF LISTS

**List 0**
Substances, e.g. foods, which may be used in the production of plastic materials and articles, e.g. food ingredients and certain substances known from the intermediate metabolism in man and for which an ADI need not be established for this purpose.

**List 1**
Substances, e.g. food additives, for which an ADI (=Acceptable Daily Intake), a t-ADI (=temporary ADI), a MTDI (=Maximum Tolerable Daily Intake), a PMTDI (=Provisional Maximum Tolerable Daily Intake), a PTWI (=Provisional Tolerable Weekly Intake) or the classification "acceptable" has been established by this Committee or by JECFA.

**List 2**
Substances for which a TDI or a t-TDI has been established by this Committee.

**List 3**
Substances for which an ADI or a TDI could not be established, but where the present use could be accepted.
Some of these substances are self-limiting because of their organoleptic properties or are volatile and therefore unlikely to be present in the finished product. For other substances with very low migration, a TDI has not been set but the maximum level to be used in any packaging material or a specific limit of migration is stated. This is because the available toxicological data would give a TDI which allows that a specific limit of migration or a composition limit could be fixed at levels very much higher than the maximum likely intakes arising from present uses of the additive.

**LIST 4 (for monomers)**

**Section 4A**
Substances for which an ADI or TDI could not be established, but which could be used if the substance migrating into foods or in food simulants is not detectable by an agreed sensitive method.

**Section 4B**
Substances for which an ADI or TDI could not be established, but which could be used if the levels of monomer residues in materials and articles intended to come into contact with foodstuffs are reduced as much as possible.

**LIST 4 (for additives)**
Substances for which an ADI or TDI could not be established, but which could be used if the substance migrating into foods or in food simulants is not detectable by an agreed sensitive method.

**List 5**
Substances which should not be used.

**List 6**
Substances for which there exist suspicions about their toxicity and for which data are lacking or are insufficient.
The allocation of substances to this list is mainly based upon similarity of structure with that of chemical substances already evaluated or known to have functional groups that indicate carcinogenic or other severe toxic properties.

> **Section 6A**: Substances suspected to have carcinogenic properties. These substances should not be detectable in foods or in food simulants by an appropriate sensitive method for each substance.
>
> **Section 6B:** Substances suspected to have toxic properties (other than carcinogenic). Restrictions may be indicated.

**List 7**
Substances for which some toxicological data exist, but for which an ADI or a TDI could not be established. The required additional information should be furnished.

**List 8**
Substances for which no or only scanty and inadequate data were available.

**List 9**
Substances and groups of substances which could not be evaluated due to lack of specifications (substances) or to lack of adequate description (groups of substances ).
Groups of substances should be replaced, where possible, by individual substances actually in use. Polymers for which the data on identity specified in "SCF Guidelines" are not available.

**List W**
"Waiting list". Substances not yet included in the Community lists, as they should be considered "new" substances, i.e. substances never approved at national level. These substances cannot be included in the Community lists, lacking the data requested by the Committee.

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