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HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate C - Scientific Opinions

C2 - Management of scientific committees; scientific co-operation and networks

Scientific Committee on Food

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Statement

of the Scientific Committee on Food

on the re-allocation of some substances for consistency with new SCF guidelines for food contact materials

(expressed on 4 December 2002)

 $http://europa.eu.int/comm/food/fs/sc/scf/index_en.html\\$

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The Commission services noted that for a few substances, the current classification, sometimes dated from many years ago, was not in line with the new SCF Guidelines¹. Therefore the Committee was asked to bring the previous requests for data concerning the substances mentioned in Annex in accordance with the SCF Guidelines.

 $http://europa.eu.int/comm/food/fs/sc/scf/out82_en.pdf$

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¹ Guidelines of the Scientific Committee on Food for the presentation of an application for safety assessment of a substance to be used in food contact materials prior to its authorisation. (Document SCF/CS/PLEN/GEN/100 Final). Available at

Annex to

Statement of the SCF on some of substances listed previously in SCF_List 7

Identification of substance/compound	Assessment
Ref. No.: 12880 Name of the substance: Azelaic acid dichloride CAS number: 000123-98-8	General information Substance requested by Member States. No other information is available. Previous evaluations (by SCF) In 1984 the SCF (SCF, 1984) examined the substance and classified it in
	SCF_List 7 with the following notation: "List 7. Needed: hydrolysis and migration data. Pending these results, necessity for further studies has to be considered." Evaluation The substance remains in SCF_List: 7 but without the request for migration data if it is demonstrated that it hydrolyses into azelaic acid and hydrochloric acid,
	which have been already evaluated (SCF, 1984). Conclusion SCF_List: 7 Needed data or information In first instance hydrolysis data
	References: - SCF (Scientific Committee on Food). Opinion expressed on 14 th December 1984, 1 st Report of the SCF on certain monomers and other substances to be used in the manufacturing of plastic materials intended to come into contact with foodstuffs. 17 th series of reports of the SCF. Office of Official Publications of the European Communities, Luxembourg, 1986.

Identification of substance/ compound	Assessment
	General information Substance requested by Member States. No other information is available. Previous evaluations (by SCF) In 1991 the SCF (SCF, 1991) examined the substance and classified it in SCF_List 7 with the following notation: "List 7. Needed: provided hydrolysis can be demonstrated, data on crotonic acid are requested."
	Evaluation The substance remains in SCF_List 7 but without the request for data on crotonic acid because this substance has been evaluated in 2002 (SCF 2002). Crotonic acid has been then classified in SCF_List 3 with a restriction of 0.05 mg/kg of food. Therefore, it should be demonstratred that crotonic acid, vinyl ester, hydrolyses into crotonic acid and acetaldehyde (vinyl alcohol does not exist because it re-arranges spontaneously into acetaldehyde, which has already been evaluated, SCF, 1991). Conclusion:
	Needed data or information: In first instance hydrolysis data on crotonic acid, vinyl ester References: - SCF (Scientific Committee for Food). Opinion expressed on 19 June 1991, 3 rd addendum to the first report of the SCF on certain monomers and other substances to be used in the manufacturing of plastic materials intended to come into contact with foodstuffs. 30 th series of reports of the SCF. Office of Official Publications of the European Communities, Luxembourg 1992 - SCF (Scientific Committee on Food). Opinion expressed on 26 September 2002. Opinion of the 19 th additional list of monomers and additives for food contact materials http://europa.eu.int/comm/food/fs/sc/scf/out141_en.pdf

Identification of substance/compound	Assessment
Ref. No.: 24310 Name of the substance: sebacic acid dichloride CAS number: 000111-19-3	General information Substance requested by Member States. No other information is available. Previous evaluations (by SCF) In 1984 the SCF (SCF, 1984) examined the substance and classified it in SCF_List 7 with the following notation: "List 7. Needed: migration and hydrolysis data. Pending these results, necessity for a 28-day oral study and further studies to be considered." Evaluation The substance remains in SCF_List 7 but without the request for migration data if it is demonstrated that it hydrolyses into sebacic acid and hydrochloric acid, which have been already evaluated (SCF, 1984). Conclusion: SCF_List: 7 Needed data or information: In first instance hydrolysis data References: - SCF (Scientific Committee on Food). Opinion expressed on 14 th December 1984, 1 st Report of the SCF on certain monomers and other substances to be used in the manufacturing of plastic materials intended to come into contact with foodstuffs. 17 th series of reports of the SCF. Office of Official Publications of the European Communities, Luxembourg, 1986

Identification of substance/compound	Assessment
Ref. No.: 82640	General information Substance requested by Member States. No other information is available.
Name of the substance: 1,2-propyleneglyc ol diricinoleate	Previous evaluations (by SCF) This substances was evaluated in the past (reported in SCF, 2000) and classified in SCF_List 7 with the following notation: "List 7. Needed: hydrolysis and migration data."
<u>CAS number</u> : 056414-56-3	Evaluation The substance remains in SCF_List 7 but without the request of migration data if it is demonstrated that it hydrolyses into 1,2-propyleneglycol and ricinoleic acid, which have been already evaluated (SCF, 1978; SCF, 1991 respectively).
	Conclusion: SCF_List: 7
	Needed data or information: In first instance hydrolysis data
	References:
	- SCF (Scientific Committee on Food), 2000. In "Compilation of the evaluations of the Scientific Committee for Food on certain monomers and additives used in the manufacture of plastic materials intended to come into contact with foodstuffs until the 21 March 1997". 42nd Series of Reports of the Scientific Committee for Food. Office of Official Publications of the European Communities, Luxembourg, 2000
	- SCF (Scientific Committee on Food). Opinion expressed on 28 September 1978. Report of the SCF on the positive list of substances to be authorised in the manufacture of regenerated cellulose films intended to come in contact with foodstuffs. 6 th series of reports of the SCF .Office of Official Publications of the European Communities, Luxemburg 1978
	- SCF (Scientific Committee on Food). Opinion expressed on 19 June 1991, 3 rd addendum to the first report of the SCF on certain monomers and other substances to be used in the manufacturing of plastic materials intended to come into contact with foodstuffs. 30 th series of reports of the SCF. Office of Official Publications of the European Communities, Luxembourg 1992

Identification of substance/compound	Assessment
Ref. No.: 83280	General information Substance requested by Member States. No other information is available.
	Substance requested by Member States. No other information is available. Previous evaluations (by SCF) This substance was evaluated in the past by the SCF (reported in SCF, 2000): "List 7. Needed: hydrolysis and migration data." Evaluation The substance is classified again into SCF_List 7 but without the request of migration data it is demonstrated that it hydrolyses into 1,2-propyleneglycol and ricinoleic acid, which have been already evaluated (SCF, 1978; SCF, 1991, respectively). Conclusion: SCF_List: 7 Needed data or information: In first instance hydrolysis data References:
	 SCF (Scientific Committee for Food), 2000. In "Compilation of the evaluations if the Scientific Committee for Food on certain monomers and additives used in the manufacture of plastic materials intended to come into contact with foodstuffs until the 21 March 1997". 42nd Series of Reports of the Scientific Committee for Food. Office of Official Publications of the European Communities, Luxembourg, 2000 SCF (Scientific Committee on Food). Opinion expressed on 28 September 1978. Report of the SCF on the positive list of substances to be authorized in the manufacture of regenerated cellulose films intended to come in contact with foodstuffs. 6th series of reports of the SCF. Office of Official Publications of the European Communities, Luxembourg, 1978. SCF (Scientific Committee on Food). Opinion expressed on 19 June 1991, 3rd addendum to the first report of the SCF on certain monomers and other substances to be used in the manufacturing of plastic materials intended to come into contact with foodstuffs. 30th series of reports of the SCF. Office of Official Publications of the European Communities, Luxembourg, 1992.