European Food Safety Authority

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SCIENTIFIC OPINION

# Scientific Opinion on the re-evaluation of montan acid esters (E 912) as a food additive[1]

**EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS)**[2, 3]

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## ABSTRACT

Following a request from the European Commission, the EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS) was asked to deliver a scientific opinion re-evaluating the safety of montan acid esters (E 912) when used as a food additive. Montan acids are extracted from oxidised montan wax and esterified with ethylene glycol, 1,3-butanediol or triols, to form montan acid esters. Montan acid esters are authorised only for the surface treatment of fresh fruits. No data, specifically for montan acid esters, on toxicokinetics and reproductive and developmental toxicity were available. The available data on short-term and subchronic toxicity, genotoxicity and chronic toxicity and carcinogenicity were limited. Important deficiencies in the available studies on chronic toxicity and carcinogenicity were noticed. The data requested in the 1990s (i.e. chromosomal aberration *in vitro*, reproduction and teratogenicity studies, material characteristics, impurities, presence of PAHs) were not submitted. Furthermore no data were submitted following an EFSA public call for data in 2012. The Panel identified some summary data in the European Chemicals Agency database (ECHA) on registered substances that might have been relevant for the assessment of montan acid esters but the original study reports were not made available to EFSA. Based on these limitations in the toxicological database the Panel concluded that montan acid esters as a food additive could not be evaluated.



## KEY WORDS

Fatty acid, montan wax; montan acid wax; waxes, montan fatty acids; fatty acids, montan-wax, ethylene esters; glyceryl montanate; montan wax acid, butylene glycol montanate; 1,3-butanediol diester.

[1] On request from the European Commission, Question No EFSA-Q-2011-00708, adopted on 16 May 2013.

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## SUMMARY

Following a request from the European Commission, the EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS) was asked to deliver a scientific opinion on the re-evaluation of montan acid esters (E 912) as a food additive.

The Panel was not provided with a newly submitted dossier on montan acid esters and no new data were submitted following a public call for data. The present evaluation is based on previous evaluations and on additional literature that became available since then. Not all original studies on which previous evaluations were based were available for re-evaluation but the Panel had access to information submitted to the EU Scientific Committee on Food (SCF).

Montan acid esters (E 912) are waxes of various chemical compositions. Montan acids are isolated from montan wax, a bituminous product extracted from lignite, and then esterified with diols such as ethylene glycol and 1,3-butylene glycol or with triols such as glycerol.

The Panel noted that benzene is used as solvent in the manufacturing process. Benzene is genotoxic and is classified by the International Agency for Research on Cancer (IARC) and EU as a human carcinogen.

The Panel recommended that benzene should not be used for the manufacturing of montan acid esters.

The Panel noted that the specifications did not include properties such as melting point and solubility, which would help identify the substance. The Panel considered that the starting materials for the production of the montan acid esters would justify either a requirement for limits for poly-aromatic hydrocarbons (PAHs), or proof that the extraction procedure and the subsequent oxidation steps in the manufacturing process would prevent any residual contamination with such substances.

No data on absorption, distribution, metabolism, and excretion (ADME) of montan acid esters were available for the present evaluation.

Feeding studies in the dog and the rat have been performed with different types of test mixtures that fall within the definition of montan acid esters, E 912. In a 90-day study in the rat and in two 90-day studies in the dog no treatment related effects were found at doses up to 1660 mg/kg bw/day for the dog and up to about 4000 mg/kg bw/day for the rat.

The Panel considered that the two 2-year studies on montan acid esters (Wax E and Wax KPS) were not suitable for risk assessment due to the limitations in the studies or the material tested. Two types of commercial montan acid esters (Wax E and WE4) gave negative results in the Ames test.

No reproductive and developmental toxicity studies are available.

The Panel noted that:

- no data on toxicokinetics and reproductive and developmental toxicity of montan acid esters were available,
- the available data on short-term and subchronic toxicity, genotoxicity and chronic toxicity and carcinogenicity were limited,
- the data requested by the SCF in the late 1990s (i.e. chromosomal aberration study *in vitro*, reproduction and teratogenicity studies, description of the material, including impurities, absence of PAHs and/or a specification) have not been submitted,
- No data were submitted following an EFSA public call for data in 2012. The Panel identified some summary data in the European Chemicals Agency (ECHA) database on registered

substances that might have been relevant for the assessment of montan acid esters but the original study reports were not made available to EFSA.

Based on these limitations in the toxicological database the Panel concluded that montan acid esters as a food additive could not be evaluated.

The Panel noted that benzene is reported to be used as solvent in the manufacturing process. Benzene is not authorised as an extraction solvent in the production of foodstuffs and ingredients (EU Directive No 2009/32/EU),. Benzene is genotoxic and is classified by IARC and EU as a human carcinogen and therefore it should not be used for the manufacturing of montan acid esters.

## TABLE OF CONTENTS

## BACKGROUND AS PROVIDED BY THE EUROPEAN COMMISSION

Regulation (EC) No 1333/2008[4] of the European Parliament and of the Council on food additives requires that food additives are subject to a safety evaluation by the European Food Safety Authority (EFSA) before they are permitted for use in the European Union. In addition, it is foreseen that food additives must be kept under continuous observation and must be re-evaluated by the EFSA.

For this purpose, a programme for the re-evaluation of food additives that were already permitted in the European Union before 20 January 2009 has been set up under the Regulation (EU) No 257/2010[5]. This Regulation also foresees that food additives are re-evaluated whenever necessary in light of changing conditions of use and new scientific information. For efficiency and practical purposes, the re-evaluation should, as far as possible, be conducted by group of food additives according to the main functional class to which they belong.

The order of priorities for the re-evaluation of the currently approved food additives should be set on the basis of the following criteria: the time since the last evaluation of a food additive by the Scientific Committee on Food (SCF) or by EFSA, the availability of new scientific evidence, the extent of use of a food additive in food and the human exposure to the food additive taking also into account the outcome of the Report from the Commission on Dietary Food Additive Intake in the EU[6] of 2001. The report "Food additives in Europe 2000[7]" submitted by the Nordic Council of Ministers to the Commission, provides additional information for the prioritisation of additives for re-evaluation. As colours were among the first additives to be evaluated, these food additives should be re-evaluated with the highest priority.

In 2003, the Commission already requested EFSA to start a systematic re-evaluation of authorised food additives. However, as a result of the adoption of Regulation (EU) 257/2010 the 2003 Terms of Reference are replaced by those below.

## TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

The Commission asks the European Food Safety Authority to re-evaluate the safety of food additives already permitted in the Union before 2009 and to issue scientific opinions on these additives, taking especially into account the priorities, procedure and deadlines that are enshrined in the Regulation (EU) No 257/2010 of 25 March 2010 setting up a programme for the re-evaluation of approved food additives in accordance with the Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives.

[4] Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives, OJ L 354, 31.12.2008, p. 16.
[5] Commission Regulation (EU) No 257/2010 of 25 March 2010 setting up the program for the re-evaluation of approved food additives in accordance with Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives, OJ L 80, 26.03.2010, p.19.
[6] Report from the Commission on Dietary Food Additive Intake in the European Union, Brussels, 01.10.2001, COM (2001) 542 final.
[7] Food Additives in Europe 2000, Status of safety assessments of food additives presently permitted in the EU, Nordic Council of Ministers. TemaNord 2002:560.

## ASSESSMENT

### 1. Introduction

The present opinion deals with the re-evaluation of the safety of montan acid esters (E 912) when used as a food additive.

Montan acid esters (E 912) are waxes of various chemical compositions authorised as a food additive in the EU according to Annex II of EC Regulation 1333/2008.

The Panel on Food Additives and Nutrient Sources added to Food (ANS) was not provided with a newly submitted dossier on montan acid esters and no new data were submitted to the European Food Safety Authority (EFSA) following a public call for data in 2012[8]. The Panel based its evaluation on previous evaluations and on additional literature that became available since then. The Panel noted that not all original studies on which previous evaluations were based were available for re-evaluation. The Panel had access to information submitted to the EU Scientific Committee on Food (SCF).

### 2. Technical data

#### 2.1. Identity of the substance

Montan acid esters (E 912) are complex mixtures that are described as "*montan acids and/or esters with ethylene glycol and/or 1,3-butanediol and/or glycerol*" (TemaNord, 2002).

In Figure 1 the structural formula of montanic acid (octacosanoic acid, $C_{28}H_{56}O_2$, CAS Registry Number 506-48-9) is shown. From this basic structure the different montan acid esters can be derived.

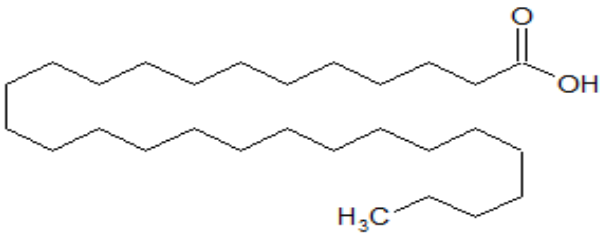


Figure 1. Structural formula of montanic acid

Montan wax acids (CAS Registry Number 68476-03-9) are prepared from crude montan wax and may be esterified with ethylene glycol, 1,3-butanediol or triols such as glycerol, to form the food additive E 912.

The Panel noted that montan acid esters (E 912) are a group of substances with different CAS Registry Numbers. These CAS Registry Numbers include, among others, CAS Registry Number 73138-45-1 (ethylene glycol monomontanate), CAS Registry Number 68476-38-0 (glyceryl montanate), CAS Registry Number 73138-44-0 (montan wax acid, 1,3-butanediol diester), CAS Registry Number 93763-20-3 (fatty acids, montan- wax, esters with 1, 3- butanediol).

The source material, montan wax (CAS Registry Number 8002-53-7; EINECS Number 232-313-5) consists of non-glyceride carboxylic acid esters ($C_{24}$- $C_{30}$; 62 - 68 % w/w), free long-chain organic acids (22–26 %), long-chain alcohols, ketones, and hydrocarbons (7–15 %), and resins (Heinrichs, 2005).

[8] Call for scientific data on montan acid esters (E 912). (http://www.efsa.europa.eu/en/dataclosed/call/120215a.htm).

Because of its origin, montan wax is classified as a mineral wax. Chemically however, it is more related to the hard vegetable waxes, such as carnauba wax, than to petroleum waxes. The composition of the montan wax varies depending on the geographical area (Bennett, 1975; Matthies, 2001).

Synonyms for montan acid esters (E 912) are: fatty acid, montan wax; montan acid wax; waxes, montan fatty acids; fatty acids, montan-wax, ethylene esters; ethylene glycol monomontanate; glyceryl montanate; montan wax acid; butylene glycol montanate; 1,3-butanediol diester.

A list of a number of esters of montan acids is given in Annex 1.

## 2.2. Specifications

Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council lays down specifications for montan acid esters (E 912) used as food additives. These specifications are listed in Table 1. The Joint FAO/WHO Expert Committee on Food Additives (JECFA) has not yet set specifications for montan acid esters (E 912).

**Table 1:** Specifications established for montan acid esters (E 912) by Commission Regulation (EU) No 231/2012.

| Montan acid esters (E 912) | Commission Regulation (EU) No 231/2012 |
|---|---|
| **Definition** | Montan acids and/or esters with ethylene glycol and/or 1,3-butanediol and/or glycerol |
| Chemical name | Montan acid esters |
| **Description** | Almost white to yellowish flakes, powder, granules or pellets |
| **Identification** | |
| Density (20 °C) | 0.98-1.05 g/cm$^3$ (20°C) |
| Drop point[1] | Greater than 77 °C |
| **Purity** | |
| Acid value[2] | Not more than 40 |
| Glycerol | Not more than 1 % (by gas chromatography) |
| Other polyols | Not more than 1 % ( by gas chromatography) |
| Other wax types | Not detectable (by differential scanning calorimetry and/or infrared spectroscopy) |
| Arsenic | Not more than 2 mg/kg |
| Chromium | Not more than 3 mg/kg |
| Lead | Not more than 2 mg/kg |

[1] The drop melting point of wax is the temperature at which the wax passes from a semi-solid state to a liquid state and drops from the thermometer used in making the determination under defined conditions.

[2] The Acid Value (AV) is defined as the mass of KOH (in mg) required to neutralise the acid groups contained in 1 g Dry Substance (DS).

The Panel noted that the above specifications do not include properties such as melting point and solubility. For ethylene glycol montanate (CAS Registry Number 73138-45-1) a melting point of about 76-78°C, a boiling point in the range of >120-150°C (decomposition) and a density of 1.01-1.03 g/cm³ (20°C) have been described. Ethylene glycol montanate has a very low solubility in water (EC, 2000).

The Panel also noted that there is a need to extend the specifications of montan acid esters (E 912) with respect to the percentage of free acids and the level of calcium in the final substance, the

residuals carried over from the manufacturing process (e.g. components of the lignite, residues of resins, residues of asphaltenes[9], residues of extraction solvents e.g. benzene).

The Panel noted that benzene is reported to be used as solvent in the manufacturing process. Benzene is not authorised as an extraction solvent in the production of foodstuffs and ingredients (EU Directive No 2009/32/EU)[10]. Benzene is genotoxic and is classified by the International Agency for Research on Cancer (IARC) and EU as a human carcinogen and therefore it should not be used for the manufacturing of montan acid esters.

The Panel considered that the starting materials for the production of the montan acid esters would justify either a requirement for limits for undesired residuals carried over from the manufacturing process (e.g. PAHs), or proof that the extraction procedure and the subsequent oxidation steps in the manufacturing process would prevent any residual contamination with such substances.

### 2.3. Manufacturing process

Montan wax is produced by solvent extraction of lignite[11] or brown coal. The lignite is crushed, screened to remove fine powder, and dried. The crude wax is then extracted with a solvent mixture and recovered by distillation of the solvent. Various solvents may be used; in one method, described by Bennett (1975), an azeotropic mixture of about 85 % benzene and 15 % ethyl alcohol is used. The solvents are evaporated in several steps and the wax melt is pelleted or poured into moulds. The crude montan wax is a black-brown, hard, brittle product with a conchoidal fracture[12] pattern. Crude montan wax is refined by removing resins and asphaltenes with various organic solvents, distillation and fractionation.

For the production of montan acids, the montan wax is oxidised with chromosulphuric acid mixtures. In this process, residues of resin and dark asphalt are oxidised to carbon dioxide or low molar mass, water-soluble compounds in a multistage oxidation process. The wax esters are simultaneously hydrolysed, the wax alcohols formed are oxidised to wax acids and the hydroxycarboxylic acids are oxidised to dicarboxylic acids. The resulting high carboxylic acid-containing product can then be esterified with different diols and triols to meet various technological needs, sometimes together with mild saponification with calcium hydroxide (Heinrichs, 2005).

### 2.4. Methods of analysis in foods

No official method for analysing montan acid esters in food has been identified in a literature search.

Regulation (EC) No 183/93[13] (1993) describes a method for determination of wax esters. The principle for the determination of phytyl- and geranylgeranyl fatty acids relies on the '*addition of a suitable internal standard to the fat or oil, then fractionation by chromatography on a hydrated silica gel column. Recovery of the fraction eluted first under the test conditions (whose polarity is less than that of the triglycerides), then direct analysis by capillary column gas-liquid chromatography*'.

A method for the determination of montan acid esters coating on fruits was described by Kröller (1973). A Differential Scanning Calorimetry (DSC) method for detecting coatings (beeswax, candelilla, wax, carnauba wax and shellac) on apples has been described (Ritter et al., 2001).

[9]Asphaltenes consist primarily of carbon, hydrogen, nitrogen, oxygen, and sulphur, as well as trace amounts of vanadium and nickel. The C:H ratio is approximately 1:1.2

[10] Directive 2009/32/EC of the European Parliament and of the Council of 23 April 2009 on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients. OJ L 141, 6.6.2009, p -3-11.

[11] Lignite: yellow to dark brown coal formed from peat at shallow depths and temperatures lower than 100°C.

[12] 'Conchoidal fracture' describes the way brittle materials break when they do not follow any natural planes of separation.

[13] Commission Regulation (EEC) No 183/93 of 29 January 1993 amending Regulation (EEC) No 2568/91 on the characteristics of olive oil and olive-residue oil and on the relevant methods of analysis. OJ L 22, 30.1.1993, p. 58.

Tada et al. (2007) described a method for the determination of the different constituents of 10 ester-type gum bases used as natural food additives in Japan (urushi wax[14], carnauba wax, candelilla wax, rice-bran wax, shellac wax, jojoba wax, bees wax, Japan wax, montan wax, and lanolin).

### 2.5. Reaction and fate in food

No data on the reaction and fate of montan acid esters (E 912) in food have been submitted following a public call for data or found in the literature. The Panel considered that, generally, compounds of this chemical nature are stable in food matrices and that therefore it is unlikely that degradation or reaction with food components will take place to any significant extent.

### 2.6. Case of need and proposed uses

Maximum Permitted Levels (MPLs) of montan acid esters have been defined in the Annex II of EC Regulation 1333/2008[15]on food additives for use in foodstuffs.

Currently, montan acid esters are authorised glazing agents in the EU permitted at *quantum satis* in a limited number of foods.

Table 2 summarises foods that are permitted to contain montan acid esters and the corresponding MPLs as set by Annex II of EC Regulation 1333/2008.

**Table 2:** MPLs of montan acid esters in foods according to the Annex II of EC Regulation 1333/2008.

| Category number | Foods | Restrictions/exception | Maximum level (mg/L or mg/kg as appropriate) |
|---|---|---|---|
| 04.1.1 | Entire fresh fruit and vegetables | only surface treatment of citrus fruit, melons, papaya, mango, avocado and pineapple | *quantum satis* |

### 2.7. Reported use levels or data on analytical levels of montan acid esters

Most food additives in the EU are authorised at a specific MPL. However, a food additive may be used at a lower level than the MPL. For those additives where no MPL is set and which are authorised as *quantum satis*, information on actual use levels is required. In the framework of Regulation (EC) No 1333/2008 on food additives and of Regulation (EU) No 257/2010 regarding the re-evaluation of approved food additives, EFSA issued a public call for scientific data on montan acid esters including present use and use patterns (i.e. which food categories and subcategories, proportion of food within categories/subcategories in which it is used, actual use levels (typical and maximum use levels), especially for those uses which are only limited by *quantum satis*).

EFSA received no information on the usage of montan acid esters following the public call for data in 2012.

According to the SCF, the actual use levels of montan acid esters do not exceed 140 mg/kg fruit (SCF, 1992).

### 2.8. Information on existing authorisations and evaluations

The SCF has evaluated montan acid esters in various contexts.

[14] *Urushi*: Japanese word which denotes a lacquer produced in East Asia from the sap of *kiurushi* trees (Lacquer tree, species of genus *Toxicodendron* ).
[15] Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives. OJ L 354, pp 16-33.

Prior to 1992 the SCF concluded that a 'temporary acceptance' should be given to substances where there was no reasoned doubt on their safety. Since, based on the available data at that time, montan acid esters did not show adverse effects at dietary levels of up to 5 %, the SCF concluded a temporarily acceptable use applied to the surface treatment of citrus fruits with montan acid esters at levels up to 140 mg/kg fruit; no Acceptable Daily Intake (ADI) was allocated (SCF, 1992).

In 1996 the Commission received another application for an extended use of montan acid esters to cover also uses on confectionery and other foods where other waxes (beeswax, candelilla wax and carnauba wax) were authorised (CS/ADD/MsAd/137, dossier EC 137.01).

The Food Additives Working Group of the SCF discussed the new application between 1996 and 1998 and concluded that, at a minimum, data should be submitted on an *in vitro* chromosomal aberration study, reproductive and developmental toxicity studies and a clear description of the material, including impurities, absence of PAHs and/or a specification. Until now these data have not been submitted to EFSA.

JECFA has not evaluated montan acid esters (these additives were on the agenda of the fifty-third meeting, but were removed from the agenda as no information was submitted; JECFA, 1999). Codex Alimentarius does not list montan acid esters in its list of food additives[16].

The SCF also evaluated the montan acid esters as an additive in plastic materials in contact with food (FCM). The substance was found acceptable with no specific migration limit (SML) (SCF, 1999). According to Directive No 2002/72/EC[17], montan acid esters (substance Ref. No 67840) are permitted for FCM.

## 2.9. Exposure

### 2.9.1. Food consumption data used for exposure assessment

In 2010, the EFSA Comprehensive European Food Consumption Database (Comprehensive Database) has been built from existing national information on food consumption at a detailed level. Competent authorities in the European countries provided EFSA with data on the level of food consumption by the individual consumer from the most recent national dietary survey in their country (cf. Guidance of EFSA 'Use of the EFSA Comprehensive European Food Consumption Database in Exposure Assessment' (EFSA, 2011a).

Overall, the food consumption data gathered at EFSA were collected by different methodologies and thus direct country-to-country comparison should be made with caution.

For calculation of chronic exposure, intake statistics have been calculated based on individual average consumption over the total survey period excluding surveys with only one day per subject. High level consumption was only calculated for those foods and population groups were the sample size was sufficiently large to allow calculation of the 95$^{th}$ percentile (EFSA, 2011a). The Panel estimated chronic exposure for the following population groups: toddlers, children, adolescents, adults and the elderly. Calculations were performed using individual body weights.

Thus, for the present assessment, food consumption data were available from 26 different dietary surveys carried out in 17 different European countries as mentioned in Table 3.

[16] http://www.codexalimentarius.net/gsfaonline/additives/index.html#M
[17] Commission Directive No 2002/72/EC of 6 August 2002 relating to plastic materials and articles intended to come into contact with foodstuffs. OJ L 220, 15.8.2002, p. 18.

**Table 3:** Population groups considered for the exposure estimates of montan acid esters

| Population | Age range | Countries with food consumption surveys covering more than one day |
|---|---|---|
| Toddlers | from 12 up to and including 35 months of age | Bulgaria, Finland, Germany, Netherlands |
| Children[18] | from 36 months up to and including 9 years of age | Belgium, Bulgaria, Czech Republic, Denmark, Finland, France, Germany, Greece, Italy, Latvia, Netherlands, Spain, Sweden |
| Adolescents | from 10 up to and including 17 years of age | Belgium, Cyprus, Czech Republic, Denmark, France, Germany, Italy, Latvia, Spain, Sweden |
| Adults | from 18 up to and including 64 years of age | Belgium, Czech Republic, Denmark, Finland, France, Germany, Hungary, Ireland, Italy, Latvia, Netherlands, Spain, Sweden, UK |
| The elderly[18] | Older than 65 years | Belgium, Denmark, Finland, France, Germany, Hungary, Italy |

Consumption records were codified according to the FoodEx classification system (EFSA, 2011b).

Exposure was estimated using the food additives intake model (FAIM), available on the EFSA website[19].

### 2.9.2. Exposure to montan acid esters from its use as food additive

Exposure to montan acid esters from its use as food additive has been calculated based on information contained in the twenty-sixth series report of the SCF (SCF, 1992) combined with national consumption data for the five population groups (Table 4). The Panel noted that the peel of the fruit on which montan acid esters are permitted, is not normally consumed, except for the rare consumption of the peel of citrus fruits as marmalade and as a condiment in food. The Panel further noted that there is no information on migration of montan acid esters; however, the Panel considered that due to the high molecular weight and the lipophilicity of the substance, migration through the peel is likely to be negligible.

Therefore, in the present exposure estimation, only the exposure via the peel of citrus fruits is taken into account. The exposure from the use of citrus peel as a condiment in food is considered negligible.

The Panel noted that its estimates should be considered as being conservative as it is assumed that:

1) all citrus fruit contains montan acid esters at a level of 140 mg/kg fruit according to the SCF,

2) all "jams, marmalades and other fruit spreads" consumed are citrus fruit marmalade, and

3) citrus marmalade has a citrus fruit content of 60 % (including peels).

Table 4 summarises the estimated exposure to montan acid esters from its use as food additive of all five population groups.

[18] The terms "children" and "the elderly" correspond respectively to "other children" and the merge of "elderly" and "very elderly" in the Guidance of EFSA on the 'Use of the EFSA Comprehensive European Food Consumption Database in Exposure Assessment' (EFSA, 2011b).

[19] (http://www.efsa.europa.eu/en/topics/topic/additives.htm).

**Table 4:** Summary of anticipated exposure to montan acid esters from its use as food additive using reported use levels (140 mg/kg) in five population groups (mg/kg bw/day)

| | Toddlers (12-35 months) | Children (3-9 years) | Adolescents (10-17 years) | Adults (18-64 years) | Elderly (>65 years) |
|---|---|---|---|---|---|
| **Estimated exposure using highest application rate cited in literature** | | | | | |
| Mean exposure | 0.003-0.01 | 0.002-0.03 | 0.001-0.01 | 0.003-0.01 | 0.003-0.02 |
| Exposure 95$^{th}$ percentile | 0.08-0.18 | 0.04-0.18 | 0.03-0.12 | 0.03-0.09 | 0.04-0.09 |

For estimates derived using a use level of 140 mg/kg reported by the SCF (1992), mean intake of montan acid esters from use as food additives ranged from 0.001-0.03 mg/kg bw/day across all population groups. High intake estimates ranged from 0.03-0.18 mg/kg bw/day across all population groups.

### 2.10. Uncertainty analysis

Uncertainties in the exposure assessment of acid montan esters have been previously discussed in the present opinion, in the previous chapter. According to the guidance provided in the EFSA opinion related to uncertainties in dietary exposure assessment (EFSA, 2007), the following sources of uncertainties have been considered and summarised below:

**Table 5:** Qualitative evaluation of influence of uncertainties

| Sources of uncertainties | Direction * |
|---|---|
| Consumption data: different methodologies / representativeness / under reporting / misreporting / no portion size standard | +/- |
| Extrapolation from food consumption survey of few days to estimate chronic exposure | + |
| Linkage between reported use levels and food items in the consumption database: uncertainties on which precise types of food the use levels refer. | +/ |
| Occurrence data: maximum reported use levels within a food category | + |
| Exposure model: uncertainty in possible national differences in use levels of food categories, data set not fully representative of foods on the EU market, exposure calculations based on the maximum reported use levels (no use of typical use levels when available) | + |

* + = uncertainty with potential to cause over-estimation of exposure;
- = uncertainty with potential to cause

## 3. Biological and toxicological data

No new toxicological or biological information was submitted following the public call for data in 2012.

A literature search was conducted on montan acid esters in the most commonly available online databases for toxicological and biological information (PubMed, Toxline, BIOSIS and Web of Science), but no relevant new information was identified.

Montan acid esters have been evaluated previously by the SCF (SCF, 1992) and by TemaNord (TemaNord, 2002). The present opinion briefly describes the major studies evaluated in these opinions.

### 3.1. Absorption, distribution, metabolism and excretion

No data on ADME of montan acid esters were available for the present evaluation; no data were available to the SCF in 1992; no data were submitted following a call for data.

### 3.2. Toxicological data[20]

#### 3.2.1. Acute oral toxicity

$LD_{50}$ values of more than 20 000 mg/kg bw were obtained in oral studies with albino mice for two types of montan acid esters [Wax E: mixture of mono- and diesters of montan acids with ethylene glycol (CAS Registry Number 73138-45-1) and Wax OP: montan wax acid butylene glycol diester, CAS Registry Number 93763-20-3 with added calcium hydroxide (about 2 % CaO)]. Each of the test mixture was administered by gavage as a 20 % suspension in starch mucilage, to 10 cross-bred albino mice of unspecified sex. The animals received the highest administrable dose of 20 g wax/kg bw. This amount was well tolerated by all the mice. The mice were observed for 6 days after application, and none of the animals died (Anon, 1963; Scholz and Weigand, 1963).

An $LD_{50}$ value of more than 15 000 mg/kg bw in rats has been reported for another type of montan acid esters [Wax KPS: mixture of mono- and diesters of montan acids with equimolar parts of ethylene glycol and 1,3-butylene glycol (CAS Registry number 73138-44-0)] by Scholz and Weigand (1969).

No other studies on the acute toxicity of montan acid esters were identified in the literature.

#### 3.2.2. Short-term and subchronic toxicity

Leist (1980) tested montan acid ester [Wax WE4: mixture of mono-, di- and tri-esters of montan acids with glycerol (CAS Registry Number 68476-38-0)] in a 90-day subchronic toxicity study in SPF Wistar rats. No information was given on whether the tests were carried out according to OECD guidelines and/or Good Laboratory Practice (GLP). Four groups of 15 rats of each sex received a diet containing the test substance at concentrations of 0, 2000, 10 000 and 50 000 mg/kg feed (equivalent to 0, 147, 743 and 3916 mg test substance/kg bw/day for the males and 0, 160, 787 and 4090 mg test substance/kg bw/day for the females, as calculated by the authors based on feed intake). Behaviour and state of health were examined daily except on weekends, and body weight and feed consumption were measured twice a week. Haematological and clinical-chemical analyses and urinalyses were performed in the middle (exact time not further specified by the authors) and at the end of the study. At the post-mortem examinations the animals were examined macroscopically for changes in organs, and the heart, lungs, liver, kidneys, spleen, testicles/ovaries, adrenal glands, thyroid gland, brain and pituitary gland were weighed and their relative organ weights were calculated. Microscopic slides were prepared from organs and tissues of all the animals. Histopathological examination was carried out on the organs of the controls and of the highest dose groups, as well as any organs from other groups which showed macroscopic changes. The behaviour, state of health, body weight gain and feed/water consumption were not affected by the test substance. Significant differences were observed in several of the haematological parameters compared to the controls. The Panel noted that haemoglobin was increased in both sexes, and there were increases in erythrocytes in males receiving 10 000 mg/kg diet and 50 000 mg/kg diet, and in leucocytes in males at the highest dose in the middle of the study. Significant increases in haemoglobin, leucocytes and erythrocytes in males, and in leucocytes in females at the highest dose, were also observed at the end of the study. All the haematological changes were within the normal range of biological variation, and the differential white cell counts exhibited no changes. Furthermore, no pathological changes were found in the haematopoietic organs.

Significant changes were found in several clinical chemical parameters. Alkaline phosphatase was increased in males receiving the test substance at 10 000 mg/kg diet, and serum potassium was decreased in males receiving 2000 g/kg diet. Urea and uric acid were decreased and increased, respectively, in males receiving the test substance at 50 000 mg/kg diet; in females, urea was increased

[20] Information on the waxes used in the toxicological studies is listed in Annex 1.

at the dose of 10 000 mg/kg diet, and potassium was increased in females receiving 50 000 mg/kg diet. However, all recorded changes within the groups receiving the test substance were within the normal range for the strain of rats used, and were thus not interpreted to be biologically relevant. There were no abnormal urinalysis findings. At the post-mortem examinations, no treatment-related statistically significant changes were found in organ weights and no adverse macroscopic differences were detected.

The authors concluded that in the rat, no treatment-related effect from the administration of the test substance was observed up to dose levels of about 50 000 mg test substance/kg diet for 90 days, corresponding to 3916 mg/kg bw/day for males and 4090 mg/kg bw/day for females as calculated by the authors. The Panel agreed with this conclusion.

In a study in Beagle dogs (4 males and 4 females/dose), two types of montan acid esters (Wax E and Wax OP) were tested in short-term toxicity tests. The respective test substances were mixed in the diet at concentrations of 5000, 20 000 and 50 000 mg/kg feed (corresponding to 200, 735 and 1600 mg/kg bw/day and 173, 644 and 1660 mg/kg bw/day for the two products respectively; values calculated as average dose from the test diet consumed). A non-nutritive cellulose-like substance[21] was used in the diet of the control animals. The diet was given *ad libitum* for one hour a day, seven days a week for 140 days.

Two dogs, one exposed to Wax E at a level of 5000 mg/kg feed and the other exposed to Wax OP at a level of 50 000 mg/kg feed, lost and gained weight sporadically throughout the investigation, but all the other dogs appeared normal. No significant differences were found in the average body weights of each group of dogs or the amount of food consumed. No significant differences were found between the groups with respect to the haematology and clinical chemistry results. No treatment-related effects appeared in the urinalysis or in the macroscopic post-mortem examination. Moreover, the ratios of the weights of various organs to body weight were within normal limits and were not significantly different among the groups. It was concluded by the authors that no significant effects were produced by either of the waxes in the study (Doerr et al., 1967). The Panel agreed with this conclusion.

In another study with the same design as above, Beagle dogs (4 males and 4 females/dose) and 4 of each sex as untreated control, received montan acid esters (Wax KPS) in their feed, at the same dose levels as above, for 90 consecutive days. None of the measured parameters (feed consumption, body weight, blood, serum, blood glucose, enzyme activity, urine, histopathological examination of the eye, together with *N. opticus*, and other organs) showed any treatment-related effects (Scholz and Brunk, 1967).

No other short-term or subchronic toxicity studies are available on montan acid esters.

### 3.2.3. Genotoxicity

**In *vitro* assays**

Two types of montan acid esters (Wax E and Wax WE4) were tested for their mutagenic potential in *Salmonella typhimurium* strains TA1535, TA1537, TA1538, TA98 and TA100, and in *Escherichia coli* strain WPuvrA. Concentrations of 4, 20, 100, 500, 2500 and 10 000 µg/plate were tested, and the tests were performed with (S-9 fraction of Aroclor 1254-induced Sprague-Dawley rats) and without metabolic activation. The test was carried out according to guideline OECD 471. No bacterial toxicity was observed, but visible precipitation of the test substances on the plates was observed with 500 µg/plate of WE4 and 2500 µg/plate of Wax E. For the second experiment, 2500 µg/plate of Wax WE4 and 5000 µg/plate of Wax E were chosen as the highest doses. No bacterial mutagenicity was observed in any of the tests with or without metabolic activation (Jung and Weigand, 1986; Müller, 1987).

[21] Alphacel: a polysaccharide linked with 4-O-beta-D-Glucopyranosyl-D-glucose units (as in cellobiose).

### 3.2.4. Chronic toxicity and carcinogenicity

***Studies with montan ester waxes***

Scholz and Weigand (1963) tested montan acid esters (Wax E) in a 2-year chronic toxicity study in groups of 25 cross-bred albino rats of each sex. The test mixture was mixed in the pelleted diet, which the rats received daily (7 days a week) as the only feed. The diet contained the test substances in concentrations of 0, 5000, 20 000 and 50 000 mg/kg feed (corresponding to 225, 900 and 2250 mg/kg bw/day for the males and to 290, 1160 and 2900 mg/kg bw/day for the female rats). The weight of each animal was monitored once a week in the first 4 weeks of the trial and then at 14-day intervals. The behaviour of the animals and the general state of health of each animal was checked each day. Haematology (15/sex/dose; haemoglobin, erythrocyte, leucocyte) and urinalysis (15/sex/dose; protein, appearance, sediment) was examined at the beginning of the study, 2 times during the study and at the end of the study. Absolute and relative organ weights (all animals; heart, lung, liver, kidney, spleen), gross pathology (all animals) and histology (all animals; heart, lung, liver, kidney, spleen) were evaluated.

After 15 and 28 weeks no abnormalities were found. No detailed data of females after 15 weeks and no detailed data of males after 28 weeks for haematology and urinalysis were given. After 104 weeks 40 males and 30 females had died during the study (scattered throughout all groups including the control group), mostly because of pulmonary infections. Urinalysis showed erythrocytes in the sediment for 3, 4 and 5 animals in respectively the 5000, 20 000 and 50 000 mg/kg feed dose group; the controls showed no erythrocytes in the sediment. An increase in proteins in the urine was seen through all groups including the control group. Haematology, organ weights, gross pathology and histology showed no abnormalities. Tumours occurred at about the same frequency in all groups. The majority of the tumours were fibroadenomas of the mammary glands. The authors concluded that the results indicate that administration of the two types of montan acid ethylene glycol diester (Wax E) in the feed, up to concentrations of 50 000 mg/kg for two years, did not lead to any sign of treatment-related toxic effects.

In another study (Anon., 1963), montan acid esters (Wax OP) was tested in a 2-year chronic toxicity study in 4 groups of 25 cross-bred albino rats of each sex. The test mixture was mixed in the pelleted diet, which the rats received daily (7 days a week) as the only feed. The diet contained the test substances in concentrations of 0, 5000, 20 000 and 50 000 mg/kg feed (equivalent to 225, 900 and 2250 mg/kg bw/day for the males and to 290, 1160 and 2900 mg/kg bw/day for the female rats). After 15 weeks and after 28 weeks 5 animals/sex/dose were sacrificed. After 104 weeks all the surviving animals were sacrificed. All animals in the test groups were fed normally (the control diet) for 5 to 9 days prior to sacrifice. Clinical observations and feeding behaviour was controlled daily. Body weight of each animal was monitored once a week in the first 4 weeks of the trial and then at 14-day intervals. Haematology (15/sex/dose; haemoglobin, red and white cell count, differential cell count) and urinalysis (same 15/sex/dose; protein, appearance, sediment) was examined at the beginning of the study, two times during, and at the end of the study. Absolute and relative organ weights (all animals; heart, lung, liver, kidney, spleen), gross pathology (all animals) and histology (all animals; heart, lung, liver, kidney, spleen) were evaluated. At 15 weeks the exposed males showed increased protein-levels in the urine. According to the authors this effect was also seen in the control group, however the detailed haematology and urinalysis data of females and controls at 15 weeks and of males and controls at 28 weeks were not given. At 28 weeks one female of the 20 000 mg/kg feed dose-level had died during the study. After 104 weeks 34 males and 35 females had died during the study (scattered throughout all dose groups and the control group), mostly because of pulmonary infections. Urinalysis showed erythrocytes in the sediment for 2, 2 and 3 animals in respectively the 5000, 20 000 and 50 000 mg/kg feed dose group; this effect was not seen in the control group. Other differences between exposed animals and controls were not found.

Tumours occurred at about the same frequency in all groups. Even in the 50 000 mg/kg feed group, the tumour frequency was not higher than in the lower dosage groups. The majority of the tumours were

fibroadenomas of mammary glands. The authors concluded that the results indicate that administration of montan acid esters (Wax OP) in the feed, up to concentrations of 50 000 mg/kg for two years, did not lead to any sign of treatment-related toxic effects.

The Panel noted the limitations for both studies as regards the low numbers of surviving animals per group, high number of animals with pulmonary infections and the associated death, no detailed data on haematology and urine analyses and the limited number of organs (5) evaluated histopathologically. The Panel considered that these limitations introduced such a high level of uncertainty that these studies were not suitable for risk assessment.

Scholz and Weigand (1969), in a similar study as those described above, tested Wax KPS. Wax KPS is a mixture of the esters of the chromic acid oxidation product of crude montan wax with ethylene glycol and 1.3-butylglycol (1:1), the impurities are $K_2SO_4$ (0.1 %) and $Cr_2(SO_4)_3$. In this study groups of 40 Wistar rats/sex/dose were fed a standard diet for two years containing 0, 10 000 or 50 000 mg test substance/kg diet (corresponding, on average, to about 0, 690 or 3300 mg/kg bw/day for males and 0, 690 and 3800 mg/kg bw/day for females, calculated from the food intake data). No compound-related effects were noted on body weight gain, haematology, urinalysis, and organ weights. Macroscopically, inflammation and sporadic tumours were found in the lungs in controls and also in the treated animals. Histopathological evaluation was done on a wide range of organs and tissues (heart, liver, kidney, adrenal gland, lung, spleen, cerebrum, cerebellum, N. Opticus, testicles, epididymis, ovary, uterus, pancreas, small intestine, colon, thymus, urinary bladder). No treatment related effects were observed. The Panel noted that the specification for the test compound did not appear to be entirely consistent with that set forward by Commission Regulation No 231/2012 for montan acid esters (E 912), particularly in terms of chromium content. Therefore the Panel considered that, based on the information available, the study cannot provide a suitable basis for the risk assessment of montan acid esters (E 912).

### 3.2.5. Reproductive and developmental toxicity

No studies on reproductive and developmental toxicity on montan acid esters were submitted to the SCF or identified in the literature search. No data were submitted following a public call for data in 2012 (http://www.efsa.europa.eu/en/dataclosed/call/120215a.htm).

### 3.2.6. Hypersensitivity

No studies on the hypersensitivity of montan acid esters were available or identified in a recent literature search.

## 4. Discussion

The Panel was not provided with a newly submitted dossier on montan acid esters and no new data were submitted following a public call for data. The present evaluation is based on previous evaluations and on additional literature that became available since then. Not all original studies on which previous evaluations were based were available for re-evaluation, but the Panel had access to information submitted to SCF.

Montan acid esters (E 912) are waxes of various chemical compositions. Montan acids are isolated from montan wax, a bituminous product extracted from lignite, and then esterified with diols such as ethylene glycol and 1,3-butylene glycol or with triols such as glycerol.

The Panel noted that benzene is used as solvent in the manufacturing process. Benzene is genotoxic and is classified by IARC and EU as a human carcinogen. The Panel recommended that benzene should not be used for the manufacturing of montan acid esters.

The Panel noted that the specifications did not include properties such as melting point and solubility, which would help identify the substance. The Panel considered that the starting materials for the

production of the montan acid esters would justify either a requirement for limits for PAHs, or proof that the extraction procedure and the subsequent oxidation steps in the manufacturing process would prevent any residual contamination with such substances.

No data on ADME of montan acid esters were available for the present evaluation.

Feeding studies in the dog and the rat have been performed with different types of test mixtures that fall within the definition of montan acid esters, E 912. In a 90-day study in the rat and in two 90-day studies in the dog no treatment related effects were found at doses up to 1660 mg/kg bw/day for the dog and up to about 4000 mg/kg bw/day for the rat.

The Panel considered that the two 2-year studies on montan acid esters (Wax E and Wax KPS) were not suitable for risk assessment due to the limitations in the studies or the material tested as described earlier.

Two types of commercial montan acid esters (Wax E and Wax WE4) gave negative results in the Ames test.

No reproductive and developmental toxicity studies are available.

The Panel noted that:

- no data on toxicokinetics and reproductive and developmental toxicity of montan acid esters were available,
- the available data on short-term and subchronic toxicity, genotoxicity and chronic toxicity and carcinogenicity were limited,
- the data requested by the SCF in the late 1990s (i.e. chromosomal aberration study *in vitro*, reproduction and teratogenicity studies, description of the material, including impurities, absence of PAHs and/or a specification) have not been submitted.
- No data were submitted following an EFSA public call for data in 2012. The Panel identified some summary data in the ECHA database on registered substances that might have been relevant for the assessment of montan acid esters but the original study reports were not made available to EFSA.

Based on these limitations in the toxicological database the Panel concluded that montan acid esters as a food additive could not be evaluated.

## CONCLUSIONS

Based on these limitations in the toxicological database the Panel concluded that montan acid esters as a food additive could not be evaluated.

The Panel noted that benzene is reported to be used as solvent in the manufacturing process. Benzene is not authorised as an extraction solvent in the production of foodstuffs and ingredients (EU Directive No 2009/32/EU). Benzene is genotoxic and is classified by the International Agency for Research on Cancer (IARC) and EU as a human carcinogen and therefore it should not be used for the manufacturing of montan acid esters.

## DOCUMENTATION PROVIDED TO EFSA

1. Pre-evaluation document prepared by DTU Food, National Food Institute (Technical University of Denmark). November 2010.

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## GLOSSARY AND/OR ABBREVIATIONS

| | |
|---|---|
| ADI | Acceptable Daily Intake |
| ANS | Scientific Panel on Food Additives and Nutrient Sources added to Food |
| AV | Acid Value |
| CAS | Chemical Abstracts Service |
| DS | Dry Substance |
| DSC | Differential Scanning Calorimetry |
| EC | European Commission |
| ECHA | European Chemicals Agency |
| EU | European Union |
| EFSA | European Food Safety Authority |
| FCM | Materials in contact with food; Food contact materials |
| GLP | Good Laboratory Practice |
| IARC | International Agency for Research on Cancer |
| JECFA | Joint FAO/WHO Expert Committee on Food Additives |
| $LD_{50}$ | Lethal Dose, 50 % i.e. dose that causes death among 50 % of treated animals |
| MPL | Maximum Permitted Level |
| NOAEL | No-Observed-Adverse-Effect Level |
| OECD | Organisation for Economic Co-operation and Development |
| PAHs | Poly-Aromatic Hydrocarbons |
| SCF | Scientific Committee on Food |
| SML | Specific Migration Limit |

# ANNEX 1

## Substances used in the toxicological studies

| Name | CAS Registry number | EINECS number | Chemical formula | Toxicity studies |
|---|---|---|---|---|
| Wax E | 73138-45-1 | 277-291-8 | Ethylene glycol monomontanate ($C_{30}H_{60}O_{3)}$ | Chronic toxicity and carcinogenicity.<br>Reproductive and developmental toxicity |
| Wax KPS | 73138-44-0 | 277-290-2 | Mixture of mono- and diesters of montan acids with equimolar parts of ethylene glycol and 1,3-butylene glycol | Acute toxicity<br>Chronic toxicity and carcinogenicity |
| Wax OP | 93763-20-3 | 297-837-9 | Partially saponified 1,3-butanediol montanate | Chronic toxicity and carcinogenicity |
| Wax WE 4 | 68476-38-0 | | Mixture of mono-, di- and tri-esters of montan acids with glycerol | Genotoxicity *in vitro* |