SCIENTIFIC OPINION

Scientific opinion on the safety assessment of medium viscosity white mineral oils with a kinematic viscosity between 8.5 – 11 mm²/s at 100 °C for the proposed uses as a food additive[1]

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

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ABSTRACT

The Panel on Food Additives and Nutrient Sources added to Food (ANS) delivers a scientific opinion evaluating the safety in use of medium viscosity white mineral oil (MVMO) (kinematic viscosity between 8.5 – 11 mm²/s at 100 °C) as a food additive. In 2009, EFSA evaluated the safety of high viscosity white mineral oils (HVMO) (kinematic viscosity ≥ 11 mm²/s at 100 °C). In this evaluation, the ANS Panel considered as pivotal a 2-year feeding study in the rat on chronic toxicity and carcinogenicity of two mineral oils: MVMO and HVMO. Based on the results of the study the Panel concluded that no carcinogenic effect was observed in F344 rats tested with MVMO and HVMO. The ANS Panel considered the NOAEL for both MVMO and HVMO in the above study to be 1200 mg/kg bw/day, the highest dose tested. Presently the Panel confirmed this conclusion and established a group ADI of 12 mg/kg bw/day for HVMO (kinematic viscosity ≥11 mm²/s at 100 °C) and for MVMO (kinematic viscosity between 8.5 - 11 mm²/s at 100 °C). The Panel noted that conservative estimates indicated that the potential dietary intake of MVMO and/or HVMO from the proposed uses and use levels as food additive in high consumers would reach up to approximately 10.1 mg/kg bw/day for toddlers. This exposure is below the established group ADI. The Panel also noted that additional exposure to MVMO and/or HVMO via other sources could represent a major source of exposure. With the data presently available it is difficult to draw conclusions as to the magnitude of exposure and the number of consumers affected by this potential additional exposure.

KEY WORDS

High viscosity white mineral oils; medium viscosity white mineral oils; mineral oils (medium and low viscosity) Class I; CAS 8042-47-5; P100 oil; P70(H) oil.

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SUMMARY

Following a request from the European Commission, the Panel on Food Additives and Nutrient Sources added to Food (ANS) was asked to deliver a scientific opinion on the safety of medium viscosity white mineral oil (MVMO) with a kinematic viscosity between 8.5 – 11 mm²/s at 100 °C as food additive.

In 1995, the Scientific Committee for Food (SCF) allocated a temporary group acceptable daily intake (ADI) of 0-4 mg/kg bw/day for white paraffinic mineral oils derived from petroleum based hydrocarbons feed stocks (kinematic viscosity not less than 8.5 mm²/s at 100 °C; carbon number, not less than 25 at the 5 % boiling point; average molecular weight not less than 480 g/mol).

In 2002, the Joint FAO/WHO Expert Committee on Food Additives (JECFA) re-evaluated several types of mineral oils, including class I medium- and low-viscosity mineral oil. In a 2-year feeding study in the rat (male and female) at doses between 60 and 1200 mg/kg bw/day, some effects were observed but JECFA considered that these effects were indicators of exposure to mineral hydrocarbons rather than adverse effects. Based on the results of the 2-year study, JECFA allocated an ADI of 0-10 mg/kg bw/day.

In 2009, the ANS Panel evaluated the high viscosity white mineral oil (HVMO) with a kinematic viscosity ≥11 mm²/s at 100 °C, a carbon number >28 at 5 % distillation point and an average molecular weight >500 g/mol). In this evaluation the ANS Panel considered a study by Trimmer (Trimmer, 2001; Trimmer et al., 2004) as pivotal. The 2-year study in rats (male and female) assessed the chronic toxicity and carcinogenicity of two mineral oils: a MVMO (kinematic medium 8.97 mm²/s at 100 °C) and a HVMO (kinematic viscosity 11 mm²/s at 100 °C). The MVMO used in the Trimmer study is representative for the type of white mineral oil evaluated in the present opinion.

The study was conducted in compliance with OECD guidelines for chronic toxicity/carcinogenicity (OECD 453) and GLP principles. It consisted of three phases: a chronic toxicity phase, a carcinogenicity phase and a recovery phase. The study design also included an evaluation of the reversibility or persistence of the biological effects associated with a 12 months exposure, after a 12-month recovery period. The white mineral oils were administered in the diet at levels of 60, 120, 240 or 1200 mg/kg bw/day.

The parameters investigated included body weight, food consumption, clinical observations, serum chemistry, haematology, ophthalmology, urine parameters and organ weights, including mesenteric lymph nodes. Analyses for mineral hydrocarbons were performed on the liver, kidneys, mesenteric lymph nodes and spleen from female animals. Detailed histopathological examination of 48 tissues, including the liver, spleen, mesenteric and mandibular lymph nodes, Peyer's patches, kidney, bone marrow and male and female reproductive tissues was conducted for all animals in the control group and at the highest dose in the main (2 year) study and at the 12 month sacrifice.

Based on the results of the study the ANS Panel in 2009 concluded that no carcinogenic effect was observed in the study in F344 rats with MVMO and HVMO. Non-neoplastic effects were limited to infiltration of histiocytes in mesenteric lymph nodes and oil deposition in the liver. These effects were considered to be an indication of MVMO and HVMO exposure rather than an adverse effect. There were no adverse effects on survival, body weight, food consumption, clinical signs, clinical chemistry, haematology, and no treatment-related adverse changes were seen at necropsy or by microscopy.

The ANS Panel in 2009 considered the no-observed-adverse-effect level (NOAEL) for the mineral oils used in the above study to be 1200 mg/kg bw/day, the highest dose tested.

In 2009, the ANS Panel also concluded that, based on the available data, there would be no safety concern with respect to genotoxicity for HVMO and MVMO. The Panel currently confirmed this conclusion.

Based on the present dataset the Panel confirmed the above conclusion and established a group ADI of 12 mg/kg bw/day for HVMO (kinematic viscosity ≥11 mm²/s at 100 °C, a carbon number >28 at 5% distillation point and an average molecular weight >500 g/mol) and MVMO (kinematic viscosity between 8.5 - 11 mm²/s at 100 °C).

According to the applicant MVMO and HVMO are to be used in an interchangeable manner and only up to the maximum levels in the food categories as specified in this opinion. Therefore, the estimated exposure to MVMO also includes the potential use of HVMO and can be considered as the total estimated exposure to both classes of white mineral oils. Thus, the present exposure assessment supercedes the assessment of the HVMO performed by the ANS Panel in 2009 (EFSA, 2009).

The Panel considered the dietary exposure to MVMO and/or HVMO from the proposed uses, which ranged on average from 0.9 – 5.2 mg/kg bw/day across all population groups. High intake estimates ranged from 1.6-10.1 mg/kg bw/day across all population groups.

As regards the residue level of polycyclic aromatic hydrocarbons (PAHs) in MVMO, the applicant proposed a maximum limit for benzo[a]pyrene of 50 µg/kg in accordance with the PAH limit set for E905 microcrystalline wax (Commission Regulation (EU) N° 231/2012). The Panel noted that the scientific opinion of the Panel on Contaminants in the Food Chain on polycyclic aromatic hydrocarbons in food (EFSA, 2008) suggested that the concentrations of a range of PAHs of concern rather than a single PAH should be measured.

The Panel noted that exposure to HVMO and/or HVMO at the established ADI of 12 mg/kg bw/day would result in a daily exposure of less than 0.5 ng/kg bw/day of benzo[a]pyrene. Compared to an estimated median dietary exposure to benzo[a]pyrene of 3.9 ng/kg bw/day, which was derived from the Scientific Opinion of the EFSA Panel on Contaminants in the Food Chain (CONTAM) on polycyclic aromatic hydrocarbons (PAHs) in food, the additional exposure to benzo[a]pyrene from the use of HVMO and MVMO as food additives is considered by the Panel to be of no concern.

In conclusion, the Panel established a group ADI of 12 mg/kg bw/day for HVMO (with a kinematic viscosity at 100 °C not less than 11 mm²/s and for MVMO (with a kinematic viscosity at 100 °C between 8.5 and 11 mm²/s). The group ADI has been derived by applying an uncertainty factor of 100 to a NOAEL of 1200 mg/kg bw/day, the highest dose level tested, in a chronic toxicity and carcinogenicity study in F344 rats.

The Panel noted that the conservative estimates indicated that the potential dietary intake of MVMO and/or HVMO from the proposed uses and use levels as food additive in high consumers would reach up to approximately 10.1 mg/kg bw/day for toddlers and thus, the exposure would be below the established group ADI.

The Panel also noted that additional exposure to MVMO and/or HVMO via other sources could represent a major source of exposure. With the data presently available it is difficult to draw conclusions as to the magnitude of exposure and the number of consumers affected by this potential additional exposure.

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BACKGROUND AS PROVIDED BY THE COMMISSION

The Health and Consumers Directorate-General has received from CONCAWE (the oil companies European organization for Environment, health and Safety in refining and distribution, Brussels) a request to consider the use of white mineral oils with a viscosity at 100 °C between 8.5 and 11 mm^2/s (described by JECFA as medium viscosity, Class I) as a food additive.

According to the petitioner the toxicological data and exposure assessment were included in the dossier on high viscosity white mineral oils that was submitted to EFSA in 2006 for the evaluation of high viscosity mineral oils as food additives.

This additive is used to exert different functions in a range of foodstuffs, e.g. as a glazing agent on confectionery, meat products, fruits and vegetables; in use levels up to 950 mg/kg.

Before the introduction of European legislation on food additives, mineral oils have historically been used as food additives, e.g. glazing agents, anti-foaming agents, binders and preservatives. Moreover, in some countries they are used as processing aids, for example as external lubricants and release agents. Legislation on such processing aid used are not harmonised at European level and are subject to national legislation. The European Commission requests that EFSA provide an opinion on the safety of medium viscosity white mineral oils when used as a food additive. A possible use as a processing aid should be taken into account due to its contribution to the overall exposure.

TERMS OF REFERENCE AS PROVIDED BY THE COMMISSION

In accordance with Article 29 (1) (a) of Regulation (EC) No 178/2002, the European Commission asks the European Food Safety Authority to provide a scientific opinion on the safety of medium viscosity white mineral oils as a food additive for use in the food categories specified in the dossier.

ASSESSMENT

1. Introduction

The present scientific opinion deals with the evaluation of the safety of medium viscosity white mineral oil (MVMO) with a kinematic viscosity at 100 °C between 8.5 and 11 mm²/s as food additive.

According to the applicant, from a production and use point of view, the white mineral oils with a viscosity at 100 ^{o}C not less than 11 mm²/s, previously evaluated by EFSA (EFSA, 2009) and white mineral oils with a viscosity at 100 ^{o}C between 8.5 and 11 mm²/s are equivalent (CONCAWE, 2012a). MVMOs (with a viscosity at 100 ^{0}C between 8.5 and 11 mm²/s) are produced using the same manufacturing process, have the same reaction and fate in food and are used in the same applications as high viscosity white mineral oils (HVMOs). Therefore, MVMO and HVMO can be interchanged by the end-user based on supply availability or commercial considerations.

In Table 1 the general classification of highly refined mineral hydrocarbons intended for use in foods as defined by Joint FAO/ WHO Expert Committee on Food Additives (JECFA, 2002) is given.

Table 1: General classification of highly refined mineral hydrocarbons intended for use in foods (from JECFA, 2002)

Name	Viscosity at 100 °C (mm^2/s)	Average relative molecular weight	Carbon number at 5% distillation point
Mineral oil (high viscosity)	>11	≥ 500	≥ 28
P100	11	520	29
Mineral oil (medium and low viscosity) class I	8.5 – 11	480-500	≥ 25
P70	9.0	480	27
Medium-viscosity liquid petroleum	8.7	480	25
P70(H)	8.6	480	27

Terminology used in the classification of highly refined mineral hydrocarbons:
P100 oil, crude: paraffinic, viscosity (40°C): 100 mm^2/s;
P70 oil, crude: paraffinic, viscosity (40°C): 70 mm^2/s;
P70(H) oil, crude: paraffinic, viscosity (40°C): 70 mm^2/s, hydrotreated (catalytic hydrogenation).

2. Technical data

2.1. Identity of the substance

According to the applicant, MVMO belong to the family of substances identified as 'Unknown or Variable Composition, Complex reaction products or Biological materials (UVCBs)' (CONCAWE, 2012c). For this reason, the composition cannot be precisely identified and be only identified as $C_nH_{2(n+z-1)}$ where, on average, n = 22 - 50 and z = 0 - 5 depending on the number of carbon and hydrogen atoms present. The CAS Registry Number is 8042-47-5 and the EINECS number is 232-455-8.

The number of carbons in the molecules and the relative distribution between iso-alkanes and branched cyclo-alkanes is dependent on the crude mineral oil origin and on the manufacturing process setting the viscosity and purity of the oil. The distribution of molecules between iso-alkenes, cyclo-alkanes and poly-condensed cyclo-alkanes statistically evolves toward more condensed cyclic structures as viscosity increases (CONCAWE, 2012c).

In Table 2 the chemical characteristics, as provided by the applicant, of two representative samples of MVMO that meet the proposed specifications are shown. The applicant stated that such types of oils will be used in the proposed uses.

Table 2: Chemical characteristics of MVMO with a viscosity between 8.5 – 11 mm²/s at 100 °C (CONCAWE, 2012c)

Sample number		A	B
Nature of hydrocarbon chain		Paraffinic	
Processing method		Catalytic hydrogenation	
Viscosity at 100 °C (mm²/s)		8.7	8.9
Average molecular weight (M_n) (g/mol)		514	521
Carbon number (C_n)/molecule		36.4	37.4
Empiric formula		$C_nH_{2(n+z-1)}$ (% of various structure)	
0 rings	z= +2	14.5	15.3
1 ring	z = 0	31.5	32.5
2 rings	z = -2	22.8	23.3
3 rings	z = -4	16.8	15.6
4 rings	z = -6	9.2	8.6
5 rings	z = -8	3.9	3.6
6 rings	z = -10	1.3	1.1
Average z-number		-1.83	-1.70
Average z-number calculated from M_n and C/H ratio		-2.58	-2.56
95% confidence limit		± 0.29	± 0.29

The z-number is a parameter indicating the deficiency of hydrogen atoms relative to open chain structures; M_n: number average molecular weight.

The synonyms proposed by the applicant are: liquid paraffin (European and Japan Pharmacopoeias), mineral medium viscosity class 1 (JECFA), mineral oil (US Pharmacopoea), Paraffinum Liquidum, white mineral oil (FDA), food-grade white oil and food-grade mineral oil.

2.2. Specifications

The specifications for the MVMO (with a kinematic viscosity at 100 °C between 8.5 and 11 mm²/s) as proposed by the applicant, are given in Table 3.

Table 3: Specifications for the MVMO (with a viscosity at 100 °C between 8.5 and 11 mm²/s) as proposed by the applicant:

Definition	A mixture of highly refined paraffinic and naphthenic liquid hydrocarbons with boiling point above 350 °C; obtained from mineral crude oils through various refining steps (e.g. distillation, extraction and crystallisation) and subsequent purification by acid and/or catalytic hydro-treatment
Chemical formula	$C_nH_{2(n+z-1)}$ with, on average n = 22 – 50 and z = 0 - 5
Assay	Average molecular weight: > 480 g/mol Carbon number at 5% distillation point: not less than 25 (the boiling point at the 5% distillation point is higher than 391°C Kinematic viscosity: 8.5 -11 mm²/s at 100 °C.
Description	Colourless, transparent, oily liquid, free from fluorescence in daylight; odourless
Identification	Solubility: insoluble in water, sparingly soluble in ethanol, soluble in ether. Stable to acids and bases, burning: burns with bright flame and with a paraffin-like characteristic smell.
Purity	
Carbonizable substances	After 10 min shaking a 5 g sample with sulphuric acid in a tube at the temperature of a boiling water bath, the sulphuric acid is not darker than a very slightly coloured reference (according European Pharmacopoeia, 2011), a mixture of 0.5 ml of Blue primary solution, 1.5 ml of Red primary solution, 3.0 ml of Yellow primary solution and 2 ml of a 10 g/l solution of hydrochloric acid).
Polycyclic aromatic hydrocarbons	The UV absorbance of a dimethylsulphoxide extract of the white mineral oil is not higher than a reference (according to the European Pharmacopoeia, 2011), a solution of 7.0 mg/l naphthalene in trimethylpentane; absorbance measured at 275 nm.
Solid paraffins	The white mineral oil is clear after 4 hours storage at 0°C
Heavy metals	Lead, Not more than 1 mg/kg

Polycyclic aromatic hydrocarbons (PAHs)

The Panel noted that for the evaluation on HVMO in 2009 (EFSA, 2009), the applicant indicated that residues of polycyclic aromatic hydrocarbons (PAHs) are restricted by selective extraction and measurement of UV absorption.

Consistent with the PAH limit set for E 905 microcrystalline wax (Commission Regulation (EU) N° 231/2012[4]), the applicant proposed to set an individual limit for benzo[a]pyrene at maximum 50 µg/kg (CONCAWE, 2012c). The Panel noted that the CONTAM opinion on PAH (2008) suggested that the concentrations of a range of PAHs of concern rather than a single PAH should be measured.

The Panel noted that the indicated technique for measuring levels of PAHs (Table 3) is non-specific and high pressure liquid chromatography (HPLC) with fluorescence detection or gas chromatography-mass spectrometry (GC/MS) is preferred as it gives a better insight into contamination with specific PAHs which are of more interest than total levels.

The Panel noted that the manufacturing process for HVMO and for the MVMO is the same, therefore the Panel assumed the residue level of PAHs in both types of oils to be the same.

[4] 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 OJ L 83, 22.3.2012 p 1-295.

2.3. Manufacturing process

According to the applicant, MVMOs (with a kinematic viscosity at 100 C between 8.5 and 11 mm²/s) are produced according to the same manufacturing process already described in the EFSA opinion on HVMO (EFSA, 2009). In summary, the crude mineral oil is subjected to the processes of de-salting, distillation and refining. Final purification is achieved either via the so-called oleum process (i.e. treatment with sulphur trioxide or fuming sulphuric) or by catalytic hydrogenation.

The applicant provided data showing that the physical and chemical characteristics of HVMO and MVMO obtained either via the conventional method (i.e. solvent extraction followed by oleum treatment) or via the catalytic hydrogenation process are essentially similar. This conclusion was based on the analysis of corresponding pairs of HVMO differing not only with respect to the final purification step but also with respect to being paraffinic or naphthenic (CONCAWE, 1984).

2.4. Methods of analysis in food

According to the applicant, the methods of analysis for the chemical identification and physical-chemical characterisation of HVMO in food described in the EFSA opinion on HVMO (EFSA, 2009) are applicable to MVMO.

2.5. Reaction and fate in food

According to the applicant, the information on the reaction and fate in food of the HVMO described in the EFSA opinion (EFSA, 2009) are applicable to MVMO.

2.6. Case of need and proposed uses

According to the applicant (CONCAWE, 2012d), MVMO and HVMO are to be used in an interchangeable manner and only up to the maximum levels in the food categories as specified in this opinion (Table 4). Therefore, the estimated exposure to MVMO also includes potential use of HVMO and can be considered as total estimated exposure to both classes of white mineral oils. Thus, the present exposure assessment supercedes the assessment of the HVMO performed by the ANS Panel in 2009 (EFSA, 2009).

The uses and the use levels for MVMO and/or HVMO as provided by the applicant are listed in Table 4 (CONCAWE, 2012a;2012d).

The applicant indicated that the application as release agent in bakery products and as dusting agent for cereal grains are processing aids. The Panel noted that, therefore, these applications are out of the scope of Regulation (EC) No 1333/2008 and are not included in the exposure assessment.

Table 4: Use and use levels for MVMO and/or HVMO as proposed by the applicant (CONCAWE, 2012a;2012d)

Type of food	Application	Technological function	Maximum proposed use level (mg/kg food)
Confectionery		Glazing agent	2000
Fruit and vegetable	Protective coating for raw fruit and vegetable	Preservative	200
Bakery products	Surfaces and dividers	Release agent	1500
Cereal grains	Rice, corn, barley, rye, wheat, soybean, sorghum bean, grain surfaces	Dedusting agent	200

2.7. Exposure

2.7.1. Food consumption data used for exposure assessment

Since 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, 2011b)).

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 where the sample size was sufficiently large to allow calculation of the 95th percentile (EFSA, 2011b). 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 5:

Table 5: Population groups considered for the exposure estimates of MVMO

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[5]	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[5]	Older than 65 years	Belgium, Denmark, Finland, France, Germany, Hungary, Italy

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

2.7.2. Exposure to MVMO from its use as food additive

Exposure to MVMO from its proposed use as food additive has been calculated using the levels proposed by the applicant as listed in Table 4 combined with national consumption data for the five population groups (Table 5). Annex B (Table 9) provides information on the Foodex Food categories used for the exposure estimates.

[5] 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).

High level exposure (typically 95th percentile of consumers only) was calculated by adding the 95th percentile of exposure from one food group (i.e. the one having the highest value) to the mean exposure resulting from the consumption of all other food groups.

This is based on the assumption that an individual might be a high level consumer of one food category and would be an average consumer of the others. This approach has been tested several times by the Panel in re-evaluation of food colours and has shown reasonable correlation with high level total intakes when using the raw food individual consumption data. Therefore, this approach was preferred for the calculations based on the maximum use levels proposed by the applicant in order to avoid excessively conservative estimates.

However, the Panel notes that its estimates should be considered as being conservative as it is assumed that all considered foods contain the MVMO added at the proposed use levels.

Table 6 summarises the estimated exposure to MVMO and/or HVMO from their use as food additives as proposed by the applicant (Table 4, CONCAWE, 2012a;2012d) of all five population groups.

Table 6: Summary of anticipated exposure to MVMO and/or HVMO from their use as food additives using the use levels as proposed by the applicant in five population groups

Anticipated exposure to MVMO and/or HVMO from the proposed use as food additives (mg/kg bw/day)					
	Toddlers (12-35 months)	**Children (3-9 years)**	**Adolescents (10-17 years)**	**Adults (18-64 years)**	**Elderly (>65 years)**
Mean exposure	3.4-5.2	1.8-4.7	1.2-2.7	0.9-1.8	1.1-1.6
Exposure 95th percentile	6-10.1	4.7-9.5	3-5.6	2.3-4.0	1.6-3.0

For estimates derived using proposed use levels, mean intake of MVMO and/or HVMO from their use as food additives ranged from 0.9 – 5.2 mg/kg bw/day across all population groups. High intake estimates ranged from 1.6-10.1 mg/kg bw/day across all population groups.

2.7.3. Main food categories contributing to exposure to MVMO using the maximum use levels proposed by the applicant

Table 7 presents the main contributing food categories to the total exposure and the number of surveys in which each food groups contributes to exposure to MVMO at this level.

Table 7: Main food categories contributing to exposure to MVMO and/or HVMO using the maximum use levels proposed by the applicant and number of surveys in which each food categories is contributing.

	% contribution to total exposure (number of surveys)*				
Food Categories	**Toddlers**	**Children**	**Adolescents**	**Adults**	**Elderly**
Root vegetables	12% (1)	<10% (17)	<10% (12)	<10% (15)	<10% (7)
Fruiting vegetables	12-26% (2)	11-31% (5)	11-25% (5)	10-26% (11)	11-21% (5)
Potatoes and potatoes products	12-35% (4)	11-27% (14)	12-30% (12)	12-40% (14)	10-31% (7)
Citrus fruits	<10% (6)	<10% (17)	<10% (12)	11-12% (2)	10-12% (2)
Pome fruits	11-16% (2)	10-16% (12)	12-15% (4)	10-25% (9)	12-31% (7)
Berries and small fruits	<10% (6)	<10% (17)	<10% (12)	<10% (15)	12% (1)
Miscellaneous fruits	11-22% (3)	11-11% (2)	<10% (12)	<10% (15)	<10% (7)
Chocolate (Cocoa) products	11-31% (2)	12-37% (17)	15-44% (12)	10-29% (13)	11-15% (3)
Confectionery (non-chocolate)	17% (1)	11-41% (10)	11-36% (6)	11-19% (5)	<10% (7)

* Total number of surveys may be greater than total number of countries as listed in Table 5, as some countries submitted more than one survey for a specific age range.

2.7.4. Exposure via other sources

Further information on proposed use levels of MVMO was provided by the applicant which he considered for use as processing aids. Proposed uses comprise the use of MVMO as release and dedusting agents in bakery products and cereal grains (see Table 4).

Due to the lack of information and uncertainty associated with the frequency and amount of use of mineral oils for these practices (in particular release agents and/or dedusting and spraying agents), no firm conclusions can be drawn concerning the additional exposure from frequent consumption of products in which these substances have been used.

However, from estimates derived by the CONTAM Panel (EFSA, 2012) and data provided by the applicant in this opinion, it can be concluded that the use of mineral oils in these applications could be a major source of exposure to mineral oils and significantly add to the estimated exposure to MVMO and/or HVMO from the proposed use as food additive.

2.7.5. Exposure to contaminants

2.7.5.1. Dietary exposure to benzo[a]pyrene

Based on exposure estimates for MVMO from its use as food additive provided in Table 5, the estimated exposure to benzo[a]pyrene at a maximum concentration of 50 µg/kg[6] ranges from 0.05 – 0.51 ng/kg bw/day (see Table 8).

[6] The applicant proposed to set an individual limit for benzo[a]pyrene at max 50 µg/kg in accordance with the PAH limit set for E905 microcrystalline wax (Commission Regulation (EU) N° 231/2012) (CONCAWE, 2012c).

Table 8: Summary of anticipated exposure in five population groups to residual benzo[a]pyrene from the proposed use of MVMO as food additive using the individual limit for benzo[a]pyrene of 50 µg/kg proposed by the applicant.

Anticipated exposure to residual benzo[a]pyrene from the proposed use of MVMO as food additive (ng/kg bw/day)					
	Toddlers (12-35 months)	**Children (3-9 years)**	**Adolescents (10-17 years)**	**Adults (18-64 years)**	**Elderly (>65 years)**
Mean exposure	0.17-0.26	0.09-0.24	0.06-0.14	0.05-0.09	0.06-0.08
Exposure 95th percentile	0.3-0.51	0.24-0.48	0.15-0.28	0.12-0.2	0.08-0.15

2.8. Evaluation

The Committee for Food (SCF) allocated a temporary group acceptable daily intake (ADI) of 0 - 4 mg/kg bw/day for white paraffinic mineral oils derived from petroleum based hydrocarbons feed stocks (kinematic viscosity not less than 8.5 mm²/s at 100 °C; carbon number, not less than 25 at the 5 % boiling point; average molecular weight not less than 480 g/mol) (SCF, 1995).

In 1995, the Joint FAO/WHO Expert Committee on Food Additives (JECFA) evaluated mineral oils and waxes, including low and medium-viscosity white mineral oils (JECFA, 1995). For the class I including the medium viscosity oil P70(H), a temporary ADI of 0-1 mg/kg bw/day was allocated based on a No-Observed-Effect Level (NOEL) of 200 mg/kg bw/day for increased incidence of pigmented macrophages in male rats, reported at the highest dose level of 2000 mg/kg bw/day in a 90-day feeding study. However, JECFA considered this effect of doubtful biological significance. In 2002, JECFA re-evaluated mineral oils (low- and medium-viscosity) and allocated a full ADI of 0-10 mg/kg bw/day to class I medium- and low-viscosity mineral oils, which include P70(H), based on a NOEL of 1200 mg/kg bw/day, the highest dose level tested in combined chronic toxicity and carcinogenicity studies in rats, using an uncertainty factor of 100 (JECFA, 2002).

In 2009, EFSA evaluated HVMO with a kinematic viscosity ≥11 mm²/s at 100 °C (a carbon number >28 at 5 % distillation point and an average molecular weight >500 g/mol). In this evaluation the ANS Panel considered the data by Trimmer (Trimmer, 2001) as pivotal. This 2-year study in male and female F344 rats assessed the long-term toxicity and carcinogenicity of two white mineral oils: a MVMO [P70(H)] (kinematic medium 8.97 mm²/s at 100 °C) and a HVMO (P100) (kinematic viscosity 11 mm²/s at 100 °C). The Panel noted that the MVMO used in the Trimmer study is representative for the type of white mineral oil evaluated in the present opinion.

The study was conducted in compliance with OECD guidelines for chronic toxicity/carcinogenicity (OECD 453) and GLP principles. The study included three phases: a chronic toxicity phase, a carcinogenicity phase and a recovery phase. The chronic toxicity phase was conducted with 10 rats/sex/group that were sacrificed after 12-month exposure. The carcinogenicity phase was conducted with 50 rats/sex/group that were sacrificed after 24 months exposure. The reversibility phase was conducted with 20 rats/sex/group that were sacrificed after 24 months; these rats were first exposed to the treated diet for 12 months and then to the control diet for 12 additional months. The MVMO were administered in the diet at levels of 60, 120, 240 or 1200 mg/kg bw/day.

In addition, satellite groups of 5 females were included at each dosage level for each phase. These rats were sacrificed at 3, 6, 12, 18 and 24 months and a set of tissues was analysed for the presence of mineral hydrocarbons.

The parameters investigated included body weight, food consumption, clinical observations, serum chemistry, haematology, ophthalmology, urine parameters and organ weights, including mesenteric lymph nodes. Analyses for mineral hydrocarbons were performed on the liver, kidneys, mesenteric lymph nodes and spleen from female animals. Detailed histopathological examination of 48 tissues,

including the liver, spleen, mesenteric and mandibular lymph nodes, Peyer's patches, kidney, bone marrow and male and female reproductive tissues was conducted for all animals in the control group and at the highest dose in the main (2 year) study and at the 12 month sacrifice. From animals at 60, 120 or 240 mg/kg bw/day in the main study, only the lungs, liver, mesenteric lymph nodes, spleen and kidneys were examined; the mesenteric lymph nodes and livers of animals in all groups in the recovery study were also examined. Immune function was not examined, but standard end-points considered to reflect immune function (i.e. total and differential leukocyte count, albumin:globulin ratio, the weights and histological appearance of the thymus, spleen and mesenteric lymph nodes, histopathological evaluation of Peyer's patches and bone-marrow cellularity) were evaluated.

Administration of the HVMO did not affect survival. No treatment-related effects were seen on clinical signs, body weight, food consumption, food conversion efficiency, ophthalmic, haematological, clinical chemistry or urinary parameters, and no treatment related changes were seen at necropsy. Dietary administration of the oil was associated with increased weight of mesenteric lymph nodes and increased grade of infiltrating cell histiocytosis; increased incidence and grade of vacuolation of periportal hepatocytes; increased incidence of combined cystic degeneration or angiectasis of the livers from male rats (with no dose–response relationship); and a quantifiable, reversible accumulation of mineral hydrocarbons in the liver to a similar level regardless of dose but dependent on the type of mineral oil.

Treatment-related non-neoplastic lesions in this study were seen in the mesenteric lymph nodes. Infiltrating histiocytes were observed in the mesenteric lymph nodes of all groups, including the controls. With the P70(H) oil a slight increase in severity score from "minimal" to "mild" was observed in all treatment groups compared to the control group after 24 months of exposure. Similar severity scores were observed in the recovery groups. No significant increase in severity was seen after 12 months of exposure. With the HVMO no change in severity of infiltrating histiocytes was observed at 12 month. At 24 months, the severity was statistically significantly increased from minimal to mild in all the female groups. Higher but non-statistically significant scores were noted in the males.

A few other non-neoplastic lesions were observed in this study but were not considered to be biologically important, e.g., a dose-related increase in the incidence and grade of vacuolation of periportal hepatocytes was observed in the livers of males in all treated groups after 12 and 24 months of exposure. In view of the nature and severity of the response, the investigators did not consider the increased grade of vacuolation to be indicative of an adverse effect but rather a marker of prolonged administration of white oils. An increased incidence of combined angiectasis and cystic degeneration (focal sinusoidal dilatation) was also observed in all treated male groups compared to the control group at the 24 month sacrifice. This lesion was of minimal grade, and of similar incidence in all treated groups, and it was, according to the authors, a common finding in F344 rats. An increased incidence of mononuclear cell leukemia was observed in treated females. However, this was not considered treatment-related, as the incidence in treated groups was not dose-related and was within the range for other control female F344 rats.

Although effects were observed in the mesenteric lymph nodes and the liver, even at the lowest dose level, these did not progress to more serious changes and were not detrimental to the life or health status of the rat. These effects are considered to be an indication of exposure to white oils rather than adverse effects. The no-observed-adverse-effect level (NOAEL) for MVMO and HVMO in this study was considered to be 1200 mg/kg bw/day the highest dose tested.

Based on the results of these studies the ANS Panel in 2009, concluded that no carcinogenic effect was observed in the study in F344 rats with MVMO and HVMO. Non-neoplastic effects were limited to infiltration of histiocytes in mesenteric lymph nodes and oil deposition in the liver. These effects were considered to be an indication of white oil exposure rather than an adverse effect. There were no adverse effects on survival, body weight, food consumption, clinical signs, clinical chemistry, haematology, and no treatment-related changes were seen at gross necropsy.

The Panel noted that the CONTAM Panel evaluated the range of mineral oil hydrocarbons that have been detected in food rather than specific products (EFSA Panel on Contaminants in the Food Chain (CONTAM), 2012). The CONTAM Panel also evaluated the results of the Trimmer et al. (2004) study and acknowledged that no hepatic microgranulomas were observed in this study. At the same time the CONTAM Panel concluded that it would be prudent to assume that liver microgranulomas observed in studies with various mineral oil saturated hydrocarbons (MOSH) in the Fischer 344 rats could be relevant to humans. This endpoint was therefore used by the CONTAM Panel for the risk assessment of mineral oil saturated hydrocarbons in food.

The ANS Panel also considered that the accumulation of mineral oils in tissues is an undesirable effect of mineral oil consumption. The Panel also acknowledged that this effect could be relevant for humans and should be carefully considered. For the specific MVMO used in the Trimmer (2001) study, no adverse effects were indentified over the 2-year study in the rat, the accumulation was reversible and experimental studies have not identified adverse effects related to mineral oil accumulation. Therefore, the Panel considers that no adverse effects in man would be expected, resulting from the exposure to MVMO complying with the proposed specifications.

The Panel further noted that the CONTAM Panel in its assessment covered MOSH mixtures with carbon numbers in the range between C_{16}-C_{35} and stated that the absorption of alkanes may occur through the portal and/or the lymphatic system (EFSA Panel on Contaminants in the Food Chain (CONTAM), 2012). For n-alkanes and cyclo-alkanes the absorption varied from 90% for C_{14}-C_{18} to 25% for C_{26}-C_{29}. The absorption further decreases with increasing carbon number, until above C_{35} when it is negligible. The ANS Panel acknowledged this statement and points out that in its current assessment of the MVMO (with a kinematic viscosity at 100 ^{o}C between 8.5 and 11 mm²/s) the test mixtures under evaluation have a carbon number in the range of C_{22} to C_{50}.

In 2009 (EFSA, 2009), the ANS Panel considered the NOAEL for the HVMO used in the Trimmer (2001) study to be 1200 mg/kg bw/day, the highest dose tested. Using this NOAEL and applying an uncertainty factor of 100, an ADI of 12 mg/kg bw/day was established for HVMO (kinematic viscosity ≥11 mm²/s at 100 ^{o}C, a carbon number >28 at 5 % distillation point and an average molecular weight of >500 g/mol). In addition, the ANS Panel noted that, given that the Trimmer et al. study (2001; 2004) was conducted with both HVMO (P100) and MVMO [P70(H)], the derived ADI could have been potentially applicable as a group ADI to HVMO (kinematic viscosity ≥ 11 mm²/s at 100 ^{o}C, a carbon number >28 at 5% distillation point and an average molecular weight > 500 g/mol) and MVMO (kinematic viscosity 8.5 - 11 mm²/s at 100 ^{o}C, a carbon number >25 at 5% distillation point and an average molecular weight of 480 - 500 g/mol).

The Panel noted that the CONTAM Panel, in its opinion (EFSA Panel on Contaminants in the Food Chain (CONTAM), 2012), stated that the ADI's established by the SCF (1995), FAO/WHO (2002) were based on toxicological studies with poorly characterised products with regard to chemical composition and that ideally MOSH mixtures should be assessed by considering the molecular weight range and subclass composition (e.g. n-, branched- or cyclo-alkanes), rather than on physico-chemical properties such as viscosity.

The Panel also acknowledged the statement by the CONTAM Panel that mineral hydrocarbons are derived from crude oils and/or synthetic products and that, for many products, little is known about the composition and that even products with the same specifications may considerably vary in their composition, depending on the source of the oil and the processes used.

The Panel took note of these considerations. The Panel also acknowledged the fact that for its evaluation the CONTAM Panel did not have the Trimmer (2001) study available. In this study the test substances were adequately specified based both on chemical and physico-chemical properties and were according to the specifications set forward in Table 2.

In 2009, the ANS Panel concluded that there would be no safety concern with respect to genotoxicity for HVMO and MVMO based on the available data.

Based on the available data, the ANS Panel confirmed the above conclusion and established a group ADI of 12 mg/kg bw/day for HVMO (kinematic viscosity ≥11 mm²/s at 100 °C a carbon number >28 at 5% distillation point and an average molecular weight >500 g/mol) and MVMO (kinematic viscosity between 8.5 - 11 mm²/s at 100 C).

According to the applicant, MVMO and HVMO are to be used in an interchangeable manner and only up to the maximum levels in the food categories as specified in this opinion (Table 4). Therefore, the estimated exposure to MVMO also includes potential use of HVMO and can be considered as total estimated exposure to both classes of white mineral oils. Thus, the present exposure assessment supercedes the assessment of the HVMO performed by the ANS Panel in 2009 (EFSA, 2009).

The Panel considered the dietary exposure to MVMO and/or HVMO from the proposed uses, which ranged on average from 0.9–5.2 mg/kg bw/day across all population groups. High intake estimates ranged from 1.6-10.1 mg/kg bw/day across all population groups.

The Panel, however, noted that additional exposure to MVMO and/or HVMO via other sources could represent a major source of exposure. With the data presently available it is difficult to draw conclusions as to the magnitude of exposure and the number of consumers affected by this potential additional exposure.

As regards the residue level of PAHs in MVMO, the applicant proposed a maximum limit for benzo[a] pyrene of 50 µg/kg in accordance with the PAH limit set for E 905 microcrystalline wax (Commission Regulation (EU) N° 231/2012). The Panel noted that the CONTAM opinion on PAH (2008) suggested that the concentrations of a range of PAHs of concern, rather than a single PAH, should be measured.

The Panel noted that exposure to MVMO and/or HVMO at the established group ADI of 12 mg/kg bw/day would result in a daily exposure of less than 0.5 ng/kg bw/day of benzo[a]pyrene. Compared to an estimated median dietary exposure to benzo[a]pyrene of 3.9 ng/kg bw/day (EFSA, 2008). The Panel used the same approach for calculating Margin of Exposure (MOE) as described in the opinion on vegetable carbon E 153 (EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS), 2012). The Panel used the highest exposure estimates (toddlers, 95th percentile) of 0.5 ng/kg bw/day to derive a MOE of 7.3 million; MOEs using other exposure estimates would be higher. The Panel noted that these estimates were considerably higher than the MOE estimated from the total dietary benzo[a]pyrene exposure and were considered by the Panel to be of no safety concern.

CONCLUSIONS

The Scientific Panel on Food Additives and Nutrient Sources added to food established a group ADI of 12 mg/kg bw/day for HVMO (with a kinematic viscosity at 100 ^{o}C not less than 11 mm²/s) and for MVMO (with a kinematic viscosity at 100 ^{o}C between 8.5 and 11 mm²/s). The group ADI is based on the NOAEL of 1200 mg/kg bw/day, the highest dose level tested, in a chronic toxicity and carcinogenicity study in F344 rats, applying an uncertainty factor of 100.

The Panel noted that the conservative estimates indicated that the potential dietary intake of MVMO and/or HVMO from the proposed uses and use levels as food additives in high consumers would reach up to approximately 10.1 mg/kg bw/day for toddlers and thus, the exposure would be below the established group ADI.

The Panel stresses that, since mineral oils that are derived from crude oil, may, depending on the source of the oil and the processes used, vary in their composition, the present opinion relates only to MVMO with the specifications as defined in Table 3. The specifications for HVMO as set in the EFSA opinion in 2009 remain valid.

DOCUMENTATION PROVIDED TO EFSA

1. Letter from CONCAWE to European Commission DG Health & Consumers on 3 August 2011 together with attachment I and II. Submitted to EFSA on 15 November 2011.

2. CONCAWE (Conservation of Clean Air and Water in Europe), 1984. Assessment and comparison of the composition of food-grade white oils and waxes manufactured from petroleum by catalytic hydrogenation versus conventional treatment. CONCAWE report N°84/60. CONCAWE, Brussels, Belgium. Submitted by CONCAWE to EFSA on 26 th October 2012

3. CONCAWE (Conservation of Clean Air and Water in Europe), 2012a. Additional data (ref letBAD1211.doc/sf) submitted by CONCAWE to EFSA on 25 th May 2012.

4. CONCAWE (Conservation of Clean Air and Water in Europe), 2012b. Additional data (ref letBAD1213.doc/am) submitted by CONCAWE to EFSA on 29 th June 2012.

5. CONCAWE (Conservation of Clean Air and Water in Europe), 2012c. Additional data (ref letBAD1222.doc/sf) submitted by CONCAWE to EFSA on 26 th October 2012.

6. CONCAWE (Conservation of Clean Air and Water in Europe), 2012d. Personal communication to EFSA on 13th December 2012 follow-up to EFSA email sent on 10 th December 2012.

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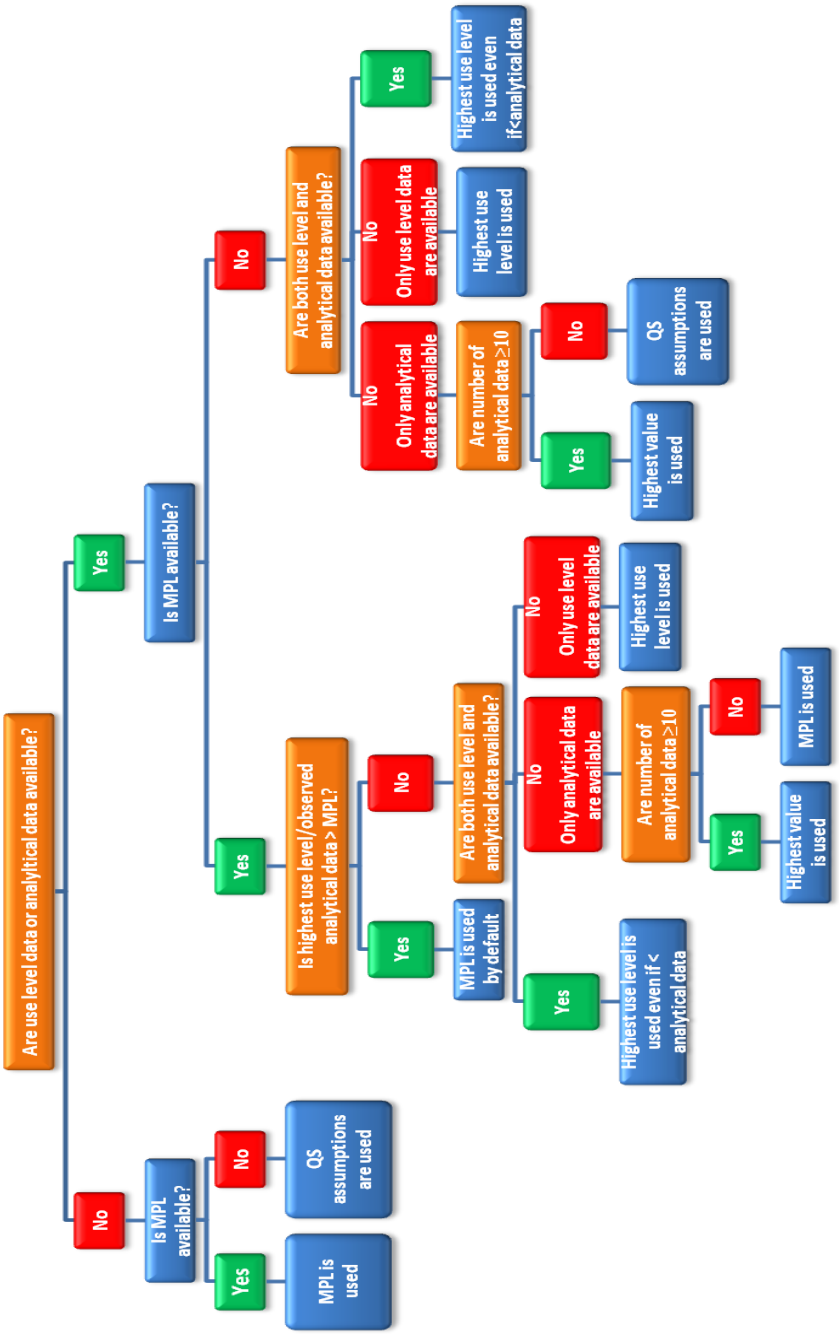
ANNEXES

A. RULES DEFINED BY THE PANEL TO DEAL WITH QUANTUM SATIS (QS) AUTHORISATION, USAGE DATA OR OBSERVED ANALYTICAL DATA FOR ALL REGULATED FOOD ADDITIVES TO BE RE-EVALUATED

Figure 1: Rules defined by the Panel to deal with usage data or observed analytical data for all regulated food additives to be re-evaluated and procedures for estimating intakes using these rules.



B. TABLE: FOODEX FOOD CATEGORIES

Table 9: Foodex Food Categories used for the exposure estimate of MVMO from the proposed food additive use

Foodex Code	Foodex Food Category	Proposed Use Level (mg/kg)
A.02.00	Vegetables and vegetable products (including fungi) (unspecified)	200
A.02.01	Root vegetables	200
A.02.02	Bulb vegetables	200
A.02.03	Fruiting vegetables	200
A.02.04	Brassica vegetables	200
A.02.05	Leaf vegetables	200
A.02.06	Legume vegetables	200
A.02.07	Stem vegetables (Fresh)	200
A.02.15	Fungi, cultivated	200
A.02.16	Fungi, wild, edible	200
A.03.01	Potatoes and potatoes products	200
A.03.02	Other starchy roots and tubers	200
A.04.01	Legumes, beans, green, without pods	200
A.05.00	Fruit and fruit products (unspecified)	200
A.05.01	Citrus fruits	200
A.05.02	Pome fruits	200
A.05.03	Stone fruits	200
A.05.04	Berries and small fruits	200
A.05.05	Oilfruits	200
A.05.06	Miscellaneous fruits	200
A.05.07	Dried fruits	200
A.10.00	Sugar and confectionary (unspecified)	2000
A.10.03	Chocolate (Cocoa) products	2000
A.10.04	Confectionery (non-chocolate)	2000

ABBREVIATIONS

ADI	Acceptable Daily Intake
ANS	Scientific Panel on Food Additives and Nutrient Sources added to Food
CONTAM	Scientific Panel on Panel on Contaminants in the Food Chain
EFSA	European Food Safety Authority
EC	European Commission
FDA	Food and Drug Administration
GC/MS	Gas chromatography-mass spectrometry
GLP	Good Laboratory practices
HPLC	High pressure liquid chromatography
HVMO	High viscosity white mineral oils
MVMO	Medium viscosity white mineral oils
JECFA	Joint FAO/WHO Expert Committee on Food Additives
M_n	Average molecular weight
MOE	Margin of exposure
MOSH	Mineral oil saturated hydrocarbons
NOAEL	No-Observed-Adverse-Effect Level
NOEL	No-Observed-Effect Level
OECD	Organisation for economic co-operation and development
PAH	Polycyclic aromatic hydrocarbon
SCF	Scientific Committee for Food
UV	Ultraviolet