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Re-evaluation of name of hydrogenated poly-1-decene (E 907) as food additive

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Abstract

The Panel on Food Additives and Flavourings added to food (FAF) provided a scientific opinion re-evaluating the safety of hydrogenated poly-1-decene (E 907) when used as a food additive. Hydrogenated poly-1-decene (E 907) is authorised as a food additive in the EU in accordance with Annex II to Regulation (EC) No 1333/2008. Hydrogenated poly-1-decene is of low acute toxicity and does not raise concern for genotoxicity. Toxicity and carcinogenicity, as well as reproductive and developmental toxicological studies, were not available; therefore, the Panel based the derivation of the acceptable daily intake (ADI) on the no observed adverse effect level (NOAEL) identified in the subchronic study in rats and established an ADI of 20 mg/kg bw per day. Dietary exposure to hydrogenated poly-1-decene (E 907) from its use as a food additive was calculated based on *regulatory maximum level exposure assessment scenario*. Mean exposure to hydrogenated poly-1-decene (E 907) from its use as a food additive ranged from no exposure in infants to 2.35 mg/kg bw per day in toddlers. The high exposure to hydrogenated poly-1-decene (E 907) ranged from 0 mg/kg bw per day in infants and adults to 6.69 mg/kg bw per day in toddlers. The exposure estimates in the *regulatory maximum level exposure assessment scenario* did not exceed the ADI of 20 mg/kg bw per day for all population groups. The Panel concluded that the exposure to hydrogenated poly-1-decene (E 907) does not raise a safety concern when used at the maximum permitted levels.

Keywords: hydrogenated poly-1-decene, E 907, food additive, safety, risk assessment, dietary exposure, acceptable daily intake

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Summary

The present opinion deals with the re-evaluation of hydrogenated poly-1-decene (E 907) when used as a food additive.

Hydrogenated poly-1-decene (E 907) is authorised as a food additive in the European Union (EU) in accordance with Annex II to Regulation (EC) No 1333/2008 on food additives and specific purity criteria have been defined in the Commission Regulation (EU) No 231/2012

Hydrogenated poly-1-decene (E 907 was evaluated by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) twice, in 1997 and 2001 (JECFA, 2001) and by the Scientific Committee for Food (SCF) in 2001 (SCF, 2001). JECFA and the SCF established an acceptable daily intake (ADI) of 0–6 mg/kg body weight (bw).

Hydrogenated poly-1-decene is a member of a more general family of hydrocarbons known as polyolefin saturated hydrocarbons (POSH) which in turn is a subgroup of mineral oil saturated hydrocarbons (MOSH) and more generally mineral oil hydrocarbons (MOH). MOH and MOSH were evaluated by the EFSA CONTAM Panel (EFSA CONTAM Panel, 2012a; Cravedi et al., 2017).

Hydrogenated poly-1-decene is poorly absorbed from the gastrointestinal tract following oral administration and is mainly excreted in the faeces.

Hydrogenated poly-1-decene is of low acute toxicity and does not raise concern for genotoxicity.

In a rat subchronic study, doses of 80, 550 and 4,160 mg/kg per day were tested. The Panel identified 4,160 mg/kg bw per day as no observed adverse effect level (NOAEL), the highest dose tested.

Considering that chronic toxicity and carcinogenicity, as well as reproductive and developmental toxicological studies, were not available, the Panel based the derivation of the ADI on the NOAEL identified in the subchronic study in rats. According to EFSA guidance (EFSA SC, 2012), a time-adjustment factor of 2 and default factor of 100 was applied to the NOAEL of 4,160 mg/kg per day, resulting into an ADI of 20 mg/kg bw per day.

Dietary exposure to hydrogenated poly-1-decene (E 907) from its use as a food additive was calculated based on maximum permitted levels (MPLs) set out in the EU legislation (defined as the *regulatory maximum level exposure assessment scenario*. Due to limited information on actual use levels (only one use level reported by industry referring to a niche product of chewing gum), a refined exposure assessment could not be calculated. Mean exposure to hydrogenated poly-1-decene (E 907) from its use as a food additive ranged from no exposure in infants to 2.35 mg/kg bw per day in toddlers. The 95th percentile of exposure to hydrogenated poly-1-decene (E 907) ranged from 0 mg/kg bw per day in infants and adults to 6.69 mg/kg bw per day in toddlers.

The exposure estimates in the *regulatory maximum level exposure assessment scenario* did not exceed the ADI of 20 mg/kg bw per day for all population groups.

In conclusion, the Panel established the ADI of 20 mg/kg bw per day for hydrogenated poly-1-decene (E 907) and concluded that the exposure to hydrogenated poly-1-decene (E 907) does not raise a safety concern when used at the maximum permitted levels.

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1. Introduction

The present opinion deals with the re-evaluation of hydrogenated poly-1-decene (E 907) when used as a food additive.

1.1. Background and Terms of Reference as provided by the European Commission

1.1.1. Background

Regulation (EC) No 1333/2008[1] 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 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[2]. This Regulation also foresees that food additives are re-evaluated whenever necessary in the 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[3] of 2001. The report "Food additives in Europe 2000[4]" 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 a highest priority.

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

1.1.2. Terms of Reference

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, procedures 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.

1.2. Information on existing authorisations and evaluations

The food additive hydrogenated poly-1-decene (E 907) is authorised in the EU in accordance with Annex II of Regulation (EC) No 1333/2008 on food additives; specific purity criteria have been defined in Commission Regulation (EU) No 231/2012.[5]

The substance was evaluated in 2001 by the Scientific Committee on Food (SCF, 2001) and the Joint FAO/WHO Expert Committee on Food Additives (JECFA, 2001, 2006). Both committees established an ADI of 0–6 mg/kg bw per day on the basis of a no observed adverse effect level (NOAEL) of 550 mg/kg bw per day derived from a 90-day study in rat.

[1] 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. 16–33.
[2] Commission Regulation (EU) No 257/2010 of 25 March 2010 setting up a programme 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, 26.3.2010, p. 19–27.
[3] COM(2001) 542 final.
[4] Food Additives in Europe 2000, Status of safety assessments of food additives presently permitted in the EU, Nordic Council of Ministers, TemaNord 2002, 560.
[5] 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.

Hydrogenated poly-1-decene is a member of a more general family of hydrocarbons known as polyolefin saturated hydrocarbons (POSH) which in turn is a subgroup of mineral oil saturated hydrocarbons (MOSH) and more generally mineral oil hydrocarbons (MOH). In 2012, the EFSA CONTAM Panel carried out an extensive evaluation of MOH in food (EFSA CONTAM Panel, 2012a). MOH were described as mixtures of thousands of different molecules, generally, but not exclusively, derived from crude oil and composed of open-chain and cyclic saturated hydrocarbons and aromatic hydrocarbons. MOSH consist of open-chain, often branched hydrocarbons (paraffins) and cyclic saturated hydrocarbons (broadly named naphthenes), which are generally alkylated. POSH consists largely of branched hydrocarbons of synthetic origin including, among others, the hydrogenated poly-1-decene. In contrast to POSH in general, hydrogenated poly-1-decene is a well-defined mixture (see Section 3.1.1)

In 2016, the EFSA CONTAM Panel published an external scientific report on the bioaccumulation of MOSH in rats (Cravedi et al., 2017 also published as Barp et al., 2017; and Nygaard et al., 2019).

The chemical hydrogenated poly-1-decene is registered under REACH Regulation (EC) No 1907/2006[6] with the following identifiers (ECHA, online): EINECS (EC) No 500-183-1 and CAS No 68037-01-4. (ECHA, online).

2. Data and methodologies

Data

The Panel on Food Additives and Flavourings (FAF) was not provided with a newly submitted dossier and EFSA launched a public call for data.[7] The Panel based its assessment on information submitted to EFSA following the public calls for data, information from previous evaluations and additional available literature up to 16 January 2020. Attempts were made at retrieving relevant original study reports on which previous evaluations or reviews were based however these were not always available to the Panel.

Food consumption data used to estimate the dietary exposure to hydrogenated poly-1-decene (E 907) were derived from the EFSA Comprehensive European Food Consumption Database (Comprehensive Database[8]).

The Mintel's Global New Products Database (GNPD) was checked to identify the uses of poly-1-decene (E 907) in food and beverage products and food supplements. The Mintel's GNPD is an online database that contains the compulsory ingredient information present on the label of numerous products.

Methodologies

This opinion was formulated following the principles described in the EFSA Guidance on transparency with regard to scientific aspects of risk assessment (EFSA Scientific Committee, 2009) and following the relevant existing guidance documents from the EFSA Scientific Committee.

The FAF Panel assessed the safety of hydrogenated poly-1-decene (E 907) as a food additive in line with the principles laid down in Regulation (EU) 257/2010 and in the relevant guidance documents: Guidance on submission for food additive evaluations by the SCF (2001) and taking into consideration the Guidance for submission for food additive evaluations in 2012 (EFSA ANS Panel, 2012).

When the test substance was administered in the feed or in the drinking water, but doses were not explicitly reported by the authors as mg/kg bw per day based on actual feed or water consumption, the daily intake was calculated by the Panel using the relevant default values as indicated in the EFSA Scientific Committee Guidance document (EFSA Scientific Committee, 2012) for studies in rodents or, in the case of other animal species, by JECFA (2000). In these cases, the dose was expressed as 'equivalent to mg/kg bw per day'.

Dietary exposure to poly-1-decene (E 907) from its use as a food additive was estimated combining food consumption data available in the EFSA Comprehensive European Food Consumption Database with the maximum levels according to Annex II to Regulation (EC) No 1333/2008[9]. Different scenarios

[6] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). OJ L 396, 30.12.2006.

[7] Call for scientific data on food additives permitted in the EU and belonging to the functional classes of emulsifiers, stabilisers and gelling agents. Published: 22 November 2009. Available from: http://www.efsa.europa.eu/en/dataclosed/call/ans091123

[8] Available online: http://www.efsa.europa.eu/en/food-consumption/comprehensive-database

[9] Commission 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.

were used to calculate exposure (see Section 3.3.1). Uncertainties on the exposure assessment were identified and discussed.

3. Assessment

3.1. Technical data

3.1.1. Identity of the substance

Hydrogenated poly-1-decene (E 907)

According to Commission Regulation (EU) No 231/2012[10]), hydrogenated poly-1-decene (E 907) has chemical formula $C_{10n}H_{20n+2}$ (n = 3–6) and average molecular weight 560 g/mol; no EINECS (EC) or CAS numbers are reported. The substance must have a purity equal to or greater than 98.5%, a content of compounds with carbon number less than 30 not higher than 1.5%, a level of the heavy metals nickel and lead not higher than 1 mg/kg each, and the following oligomer composition: C_{30}, 13–37 %; C_{40}, 35–70 %; C_{50}: 9–25 %; C_{60}, 1–7 %. The presence of readily carbonisable substances must be compliant with a specific test. The substance is described as a viscous liquid (viscosity: 5.7–6.1 $\times$ 10^{-6} m^2 s^{-1} at 100°C), insoluble in water, slightly soluble in ethanol, and soluble in toluene, that burns with a bright flame and a paraffin-like characteristic smell.

In JECFA (2006), hydrogenated poly-1-decene is described as 'Hydrogenated poly-1-decene is a mixture of branched isomeric hydrocarbons, prepared by hydrogenation of mixtures of trimers, tetramers, pentamers, and hexamers of 1-decenes. Minor amounts of molecules with carbon number less than 30 may be present'. The substance is described as a colourless, odourless, viscous liquid, employed as a glazing or release agent. In JECFA (2006), the substance is identified with CAS No 68037-01-4.

The use of hydrogenated poly-1-decenes (INS No 907) as glazing agent is also reported in Codex Alimentarius (2018).

According to ECHA Registry (ECHA website), the substance with CAS No 68037-01-4 has EC No 500-183-1 and the chemical names of dec-1-ene, homopolymer, hydrogenated, or dec-1-ene, oligomers, hydrogenated.

3.1.2. Specifications

The specifications for hydrogenated poly-1-decene (E 907) as defined in the Commission Regulation (EU) No 231/2012 and by JECFA (2006) are listed in Table 1.

Table 1: Specifications for hydrogenated poly-1-decene (E 907) according to Commission Regulation (EU) No 231/2012 and JECFA (2006)

	Commission Regulation (EU) No 231/2012	**JECFA (2006)**
Synonyms	Hydrogenated polydec-1-ene Hydrogenated poly-*alpha*-olefin	Hydrogenated polydec-1-ene Hydrogenated poly-α-olefin INS No 907
Definition	—	Hydrogenated poly-1-decene is a mixture of branched isomeric hydrocarbons, prepared by hydrogenation of mixtures of trimers, tetramers, pentamers, and hexamers of 1-decenes. Minor amounts of molecules with carbon number less than 30 may be present
	EINECS (EC) No: —	CAS No: 68037-01-4
	Chemical name: —	Chemical name: —
	Chemical formula: $C_{10n}H_{20n+2}$, where n = 3–6	Chemical formula: $C_{10n}H_{20n+2}$, where n = 3–6
	Molecular weight (g/mol): 560 (average)	Formula weight (g/mol): 560 (average)

[10] 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.

	Commission Regulation (EU) No 231/2012	JECFA (2006)
	Assay: not less than 98.5% of hydrogenated poly-1-decene, having the following oligomer distribution: C_{30}: 13–37% C_{40}: 35–70% C_{50}: 9–25% C_{60}: 1–7%	Assay: not less than 98.5% of hydrogenated poly-1-decene, having the following oligomer distribution: C_{30}: 13–37% C_{40}: 35–70% C_{50}: 9–25% C_{60}: 1–7%
Description	—	Colourless, odourless, viscous liquid
Functional uses	—	Glazing agent, release agent
Identification	Solubility: insoluble in water; slightly soluble in ethanol; soluble in toluene	Solubility: insoluble in water; slightly soluble in ethanol; soluble in toluene
	Burning: burns with a bright flame and a paraffin-like characteristic smell	Burning: the product burns with bright flame and a paraffin-like characteristic smell
	Viscosity: between 5.7×10^{-6} and 6.1×10^{-6} m^2s^{-1} at 100 °C	Viscosity: between 5.7 and 6.1 mm^2/s (100 °C)
Purity	Compounds with carbon number less than 30: not more than 1.5 %	Compounds with carbon number less than 30: not more than 1.5 %
	Readily carbonisable substances: after 10 min shaking in a boiling water bath, a tube of sulfuric acid with a 5-g sample of hydrogenated poly-1-decene is not darker than a very slight straw colour	Readily carbonisable substances: passes test
	Nickel: not more than 1 mg/kg	Nickel: not more than 1 mg/kg
	Lead: not more than 1 mg/kg	Lead: not more than 1 mg/kg

EINECS: European Inventory of Existing Commercial Chemical Substances; CAS: Chemical Abstract Service.

The Panel noted that, according to the EU specifications for hydrogenated poly-1-decene (E 907), impurities of the toxic elements nickel and lead are accepted at concentrations up to 1 mg/kg each. Contamination at such levels could have a significant impact on the exposure to these metals, for which the exposure already are close to the health-based guidance values or benchmark doses (lower Confidence Limits) established by EFSA (EFSA CONTAM Panel, 2010, 2012b, 2015).

3.1.3. Manufacturing process

Hydrogenated poly-1-decene is synthesised from pure 1-decene - itself made from ethylene, readily available at high levels of purity. It is mixture of synthetic branched-chain hydrocarbons produced by oligomerisation of pure 1-decene to the tri-, tetra-, penta- and hexa-decene molecules, followed by hydrogenation to full saturation of the oligomers; both processes are carried out in the presence of a catalyst; the crude mixture is purified by filtration through activated clay (SCF, 2001; WHO, 2000, 2001; JECFA, 2001). The final product consists of a mixture of isomeric hydrocarbons (isoparaffins) between 30 to 60 carbon atoms. The impurities (not more than 1.5 %) are saturated hydrocarbons below C_{30}.

3.1.4. Methods of analysis in food

No specific methods of analysis of hydrogenated poly-1-decene in food has been provided by Interested Parties.

The presence in food of mineral oil hydrocarbons and their chemical nature were extensively described by EFSA CONTAM Panel (2012a). Likewise, the analytical methods developed to detect and quantify the aforesaid chemicals in food are described in the aforementioned scientific evaluation.

The methods for measuring mineral oil hydrocarbons – which include isoparaffins – in food are commonly based on high-resolution gas chromatography with flame ionisation detection (GC-FID): such is the method of assay reported in JECFA (2006) for hydrogenated poly-1-decene (INS No 907). FID is chosen because of calibration problems met with other detection techniques (e.g. mass spectrometry). However, FID is not selective, a drawback in view of the broad patterns of unresolved peaks of unidentified components formed by mineral oils (Biedermann et al., 2009; Cravedi et al., 2017) reported

that comprehensive two-dimensional GC (GC × GC) is an effective method for separating complex mixtures of hydrocarbons: equipped with either a FID or a time-of-flight mass spectrometer (TOF-MS), the technique enables the characterisation of mineral oil saturated hydrocarbons by separating cyclic from open chain compounds and by grouping open chain hydrocarbons by the degree of branching and the cyclic ones by the degree of alkylation.

According to Grob (2018), on-line coupled high-performance liquid chromatography (HPLC) and GC-FID) (HPLC–GC-FID)) appears to be the method of choice and its successful application was reported already in 1984 (Grob et al., 1984). The aforesaid methodology makes use of solvent effects and retention gap technology: raw food extracts or solutions of edible oils could be directly injected, which not only provided a high-performance pre-separation, but also avoided contamination during sample preparation with virtually ubiquitous mineral oil hydrocarbons.

Up to 2008, the online HPLC–GC method was limited to the analysis of mineral oil saturated hydrocarbons (Grob, 2018); the method was upgraded to enable routine measurement of the aromatic hydrocarbons after 2008 (Biedermann et al., 2009). During most of the period, the detection limit was in the range of several mg/kg food: this sensitivity was considered to be sufficient, since the selected concentrations were often more than two orders of magnitude higher. In the meantime, such high contamination virtually subsided and the detection limits were lowered to below 1 mg/kg food, eventually by enrichment or removal of interfering components by improving the HPLC pre-separation phase (Zurfluh et al., 2014).

3.1.5. Stability of the substance, and reaction and fate in food

Hydrogenated poly-1-decene is thermally and microbiologically very stable and is characterised by low volatility with a boiling range starting at 320°C (SCF, 2001). Hydrogenated poly-1-decene is not expected to be subject to oxidative reactions under the anticipated conditions of use.

3.2. Authorised uses and use levels

Maximum levels of hydrogenated poly-1-decene (E 907) have been defined in Annex II to Regulation (EC) No 1333/2008[11] on food additives, as amended. In this document, these levels are named maximum permitted levels (MPLs).

Currently, hydrogenated poly-1-decene (E 907) is an authorised food additive in the EU with MPL at level of 2000 mg/kg in all four food categories listed in Table 2.

Table 2: MPLs of hydrogenated poly-1-decene (E 907) in foods according to Annex II to Regulation (EC) No 1333/2008

Food category number	Food category name	E-number/ Group	Restrictions/exception	MPL (mg/L or mg/kg as appropriate)
04.2.1	Dried fruit and vegetables	E 907	Only dried fruit as glazing agent	2,000
05.2	Other confectionery including breath freshening microsweets	E 907	Only as glazing agent for sugar confectionery	2,000
05.3	Chewing gum	E 907	As glazing agent only	2,000
05.4	Decorations, coatings and fillings, except fruit-based fillings covered by category 4.2.4	E 907	As glazing agent only	2,000

MPL: maximum permitted level.

[11] 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

3.3. Exposure data

3.3.1. Reported use levels or data on analytical levels of hydrogenated poly-1-decene (E 907)

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. Therefore, information on actual use levels is required for performing a more realistic exposure assessment.

In the framework of Regulation (EC) No 1333/2008 on food additives and of Commission Regulation (EU) No 257/2010 regarding the re-evaluation of approved food additives, EFSA issued a public call[12] for occurrence data (usage level and/or analytical data) on hydrogenated poly-1-decene (E 907). In response to this public call, updated information on the actual use of hydrogenated poly-1-decene (E 907) in foods was made available to EFSA by industry. No analytical data on the concentration of hydrogenated poly-1-decene (E 907) in foods were made available by the Member States.

Summarised data on reported use levels in foods provided by industry

Industry provided EFSA with one use level of hydrogenated poly-1-decene (E 907) for one out of the four food categories in which hydrogenated poly-1-decene (E 907) is authorised.

This use level was made available by the International Chewing Gum Association (ICGA) and referred to a niche product of chewing gum with added sugar. The minimum, typical and maximum use levels provided for this niche product were 500, 1,000 and 2,000 mg/kg, respectively.

The Panel considered that there is no need to perform a refined exposure assessment based on this limited information available on the use levels of hydrogenated poly-1-decene (E 907).

3.3.2. Summarised data extracted from the Mintel's Global New Products Database

The Mintel's GNPD is an online database which monitors new introductions of packaged goods in the market worldwide. It contains information of over 2.5 million food and beverage products of which more than 900,000 are or have been available on the European food market. Mintel started covering EU's food markets in 1996, currently it contains data from 25 out of its 28 Member States and Norway.[13]

For the purpose of this Scientific Opinion, the Mintel's GNPD[14] was used for checking the labelling of food and beverages products and food supplements for hydrogenated poly-1-decene (E 907) within the EU's food market as the database contains the compulsory ingredient information on the label.

According to the Mintel's GNPD, hydrogenated poly-1-decene (E 907) was labelled on a few products (n = 8) of glazed assorted confectionery between January 2014 and May 2019.

Appendix A lists the percentage of the food products labelled with hydrogenated poly-1-decene (E 907) out of the total number of food products per food subcategory according to the Mintel's GNPD food classification. The percentages ranged from 0.01% in the Mintel's GNPD food subcategory 'Baking ingredients & Mixes' to 1.1% in the subcategory 'Mixed Assortments'. The average percentage of foods labelled to contain hydrogenated poly-1-decene (E 907) was 0.002%.

3.3.3. Food consumption data used for exposure assessment

EFSA Comprehensive European Food Consumption Database

Since 2010, the EFSA Comprehensive European Food Consumption Database (Comprehensive Database) has been populated with national data on food consumption at a detailed level. Competent authorities in the European countries provide 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 on the 'Use of the EFSA Comprehensive European Food Consumption Database in Exposure Assessment' (EFSA, 2011a). Consumption surveys added in the Comprehensive Database in 2015 were also taken into account in this assessment.[15]

The food consumption data gathered by EFSA were collected by different methodologies and thus direct country-to-country comparisons should be interpreted with caution. Depending on the food

[12] https://www.efsa.europa.eu/en/data/call/170223
[13] Missing Cyprus, Luxembourg and Malta.
[14] http://www.gnpd.com/sinatra/home/ accessed on 17/5/2019.
[15] Available online: http://www.efsa.europa.eu/en/datexfoodcdb/datexfooddb.htm

category and the level of detail used for exposure calculations, uncertainties could be introduced owing to possible subjects' underreporting and/or misreporting of the consumption amounts. Nevertheless, the EFSA Comprehensive Database includes the currently best available food consumption data across Europe.

Food consumption data from infants, toddlers, children, adolescents, adults and the elderly were used for the exposure assessment. For the present assessment, food consumption data were available from 33 different dietary surveys carried out in 19 European countries (Table 3).

Table 3: Population groups considered for the exposure estimates of hydrogenated poly-1-decene (E 907)

Population	Age range	Countries with food consumption surveys covering more than 1 day
Infants	From more than 12 weeks up to and including 11 months of age	Bulgaria, Denmark, Finland, Germany, Italy, UK
Toddlers[a]	From 12 months up to and including 35 months of age	Belgium, Bulgaria, Denmark, Finland, Germany, Italy, Netherlands, Spain, UK
Children[b]	From 36 months up to and including 9 years of age	Austria, Belgium, Bulgaria, Czech Republic, Denmark, Finland, France, Germany, Greece, Italy, Latvia, Netherlands, Spain, Sweden, UK
Adolescents	From 10 years up to and including 17 years of age	Austria, Belgium, Cyprus, Czech Republic, Denmark, Finland, France, Germany, Italy, Latvia, Netherlands, Spain, Sweden, UK
Adults	From 18 years up to and including 64 years of age	Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Hungary, Ireland, Italy, Latvia, Netherlands, Romania, Spain, Sweden, UK
The elderly[b]	From 65 years of age and older	Austria, Belgium, Denmark, Finland, France, Germany, Hungary, Ireland, Italy, Romania, Netherlands, Sweden, UK

(a): The term 'toddlers' in the Comprehensive Database corresponds to 'young children' in Regulations (EC) No 1333/2008 and (EU) No 609/2013

(b): The terms 'children' and 'the elderly' correspond, to 'other children' and the merge of 'elderly' and 'very elderly' in the Comprehensive Database, respectively (EFSA, 2011a).

Consumption records were codified according to the FoodEx classification system (EFSA, 2011b). Nomenclature from the FoodEx classification system has been linked to the food categorisation system (FCS) as presented in Annex II of Regulation (EC) No 1333/2008, part D, to perform an exposure assessment. In practice, the FoodEx food codes were matched to the FCS food categories.

Food categories considered for the exposure assessment of hydrogenated poly-1-decene (E 907)

The food categories in which the use of hydrogenated poly-1-decene (E 907) is authorised were selected from the nomenclature of the EFSA Comprehensive Database (FoodEx classification system), at the most detailed level possible (up to FoodEx Level 4) (EFSA, 2011b).

For all four food categories, the use of hydrogenated poly-1-decene (E 907) is restricted to its use as a glazing agent (Table 2). Since the glazed food products are not referenced in the FoodEx classification system, this restriction could not be taken into account, and therefore the whole food categories were considered in the exposure assessment. This has resulted in an overestimation of the exposure. The restriction 'only dried fruit' in FC 04.2.1 and the restriction 'only sugar confectionery' in FC 05.2 were considered.

3.4. Exposure estimates

3.4.1. Exposure to hydrogenated poly-1-decene (E 907) from its use as a food additive

The Panel estimated the chronic dietary exposure to hydrogenated poly-1-decene (E 907) for the following population groups: infants, toddlers, children, adolescents, adults and the elderly. Dietary exposure to hydrogenated poly-1-decene (E 907) was calculated by multiplying concentrations of hydrogenated poly-1-decene (E 907) per food category (Table 2) with their respective consumption

amount per kilogram body weight for each individual in the Comprehensive Database. The exposure per food category was subsequently added to derive an individual total exposure per day. These exposure estimates were averaged over the number of survey days, resulting in an individual average exposure per day for the survey period. Dietary surveys with only 1 day per subject were excluded as they are considered as not adequate to assess repeated exposure.

The exposure was calculated for all individuals per survey and per population group, resulting in distributions of individual exposure per survey and population group (Table 3). Based on these distributions, the mean and 95th percentile of exposure were calculated per survey and per population group. The 95th percentile of exposure was only calculated for those population groups with a sufficiently large sample size (EFSA, 2011a). Therefore, in the present assessment, the 95th percentile of exposure for infants from Italy and for toddlers from Belgium, Italy and Spain was not estimated.

Exposure assessment to hydrogenated poly-1-decene (E 907) was carried out by the FAF Panel based on MPLs as set down in Annex II to Regulation (EC) No 1333/2008 and listed in Table 2 (defined as the *regulatory maximum level exposure assessment scenario*). The Panel considered the exposure estimates derived from this scenario as the most conservative, since it is assumed that the population will be exposed to the food additive present in food at the MPL.

A refined exposure assessment was not performed in the present evaluation, due to the limited information on actual use levels of hydrogenated poly-1-decene (E 907).

Dietary exposure to hydrogenated poly-1-decene (E 907)

Table 4 summarises the estimated exposure to hydrogenated poly-1-decene (E 907) from its use as a food additive in six population groups (Table 3). Detailed results per population group and survey are presented in Appendix B.

Table 4: Summary of dietary exposure to hydrogenated poly-1-decene (E 907) from its use as a food additive in the regulatory maximum level exposure assessment scenario, in six population groups (minimum–maximum across the dietary surveys in mg/kg bw per day)

	Infants (12 weeks–11 months)	Toddlers (12–35 months)	Children (3–9 years)	Adolescents (10–17 years)	Adults (18–64 years)	The elderly (≥ 65 years)
• Mean	0[(a)]–0.55	0.14–2.35	0.15–2.19	0.03–1.01	0.02–0.37	0.02–0.22
• 95th percentile	0–3.37	1.81–6.69	1.03–5.72	0.30–3.81	0–1.63	0.03–0.97

bw: body weight.
(a): In one dietary survey, no consumption of the foods belonging to the food categories included in the exposure assessment was reported.

Mean exposure to hydrogenated poly-1-decene (E 907) from its use as a food additive at the MPL ranged from no exposure in infants to 2.35 mg/kg bw per day in toddlers. The 95th percentile of exposure to hydrogenated poly-1-decene (E 907) ranged from < 0.01 mg/kg bw per day in infants and adults to 6.69 mg/kg bw per day in toddlers.

Main food categories contributing to exposure to hydrogenated poly-1-decene (E 907)

The main contributing food category to the total mean exposure estimates for all population groups was FC 05.2 Other confectionery, including breath freshening microsweets. For infants, toddlers, adults and the elderly, also FC 04.2.1 Dried fruits and vegetables contributed significantly to the total mean exposure to hydrogenated poly-1-decene (E 907) (see Appendix C for more details).

Appendix C can be found in the online version of this output ('Supporting information' section): https://doi.org/10.2903/j.efsa.2020.6034.

Uncertainty analysis

Potential sources of uncertainty in the exposure assessment of hydrogenated poly-1-decene (E 907) have been discussed above. In accordance with 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 in Table 5.

Table 5: Qualitative evaluation of influence of uncertainties on the dietary exposure estimate

Sources of uncertainties	Direction[(a)]
Consumption data: different methodologies/representativeness/underreporting/misreporting/ no portion size standard	+/–
Methodology used to estimate high percentiles (95th) long-term (chronic) exposure based on data from food consumption surveys covering only a few days	+
Food categories selected for the exposure assessment: inclusion of all four food categories without considering the restriction/exception (as glazing agent only)	+
Regulatory maximum level exposure assessment scenario:– exposure calculations based on the MPL according to Annex II to Regulation (EC) No 1333/2008	+

(a): +, uncertainty with potential to cause overestimation of exposure; –, uncertainty with potential to cause underestimation of exposure.

Due to limited information on actual use levels, only the *regulatory maximum level exposure assessment scenario* was performed in the present evaluation. The Panel considers the exposure estimates derived following this scenario as conservative since it is assumed that the population will be exposed to the food additive present in food at the MPL. This overestimation was even greater because it was assumed that all foods in the authorised food categories were glazed.

3.5. Biological and Toxicological data

Hydrogenated poly-1-decene is part of the MOSH family which includes linear and branched alkanes with carbon numbers varying over a large range.

Hydrogenated poly-1-decene as a food additive is described as 'not less than 98.7% of hydrogenated poly-1-decene having the following range of oligomer distribution: C30 13–37%, C40 35–70%, C50 9–25% and C60 1–7%'. Therefore, studies on *n*-alkanes with different carbon numbers branched and non-branched have been considered in the assessment. In particular, the 2012 EFSA opinion on MOSH (EFSA CONTAM Panel, 2012a) and an EFSA external scientific report on MOSH (Cravedi et al., 2017), which reported on different toxicological and bioaccumulation studies, were considered relevant.

3.5.1. Absorption, distribution, metabolism and excretion

Absorption, distribution, metabolism and excretion (ADME) of *n*-alkanes has been extensively described in the EFSA CONTAM opinion on MOSH (EFSA CONTAM Panel, 2012a). For the *n*-alkanes, the absorption varies from 90% for carbon numbers in the range C_{14}–C_{18} to 25% for C_{26}–C_{29} and the absorption further decreases with increasing carbon number. Information on branched alkanes suggests that the uptake is lower than *n*-alkanes. Alkanes are metabolised to corresponding fatty-alcohols and then fatty acids. The oxidase metabolism of alkanes follows the same metabolic pathway as fatty acids which include integration into lipid fraction as phospholipids and neutral lipids such as triglycerides, and incorporation into lipoproteins. MOSH with carbon numbers between C_{16} and C_{35} may accumulate in different tissues including adipose tissues, lymph nodes and liver.

Bioaccumulation of broad MOSH mixtures in rats was also demonstrated in two series of experiments (Cravedi et al., 2017, also published as Barp et al., 2017 and Nygaard et al., 2019). However, the Panel noted that these studies have been performed with test materials that only to some extent overlap with the composition of hydrogenated poly-1-decene as a food additive and therefore the evidence was not considered relevant for this assessment.

One study investigating the absorption, toxicokinetic, tissue distribution and excretion of hydrogenated poly-1-decene is available.

^{3}H-radiolabelled hydrogenated poly-1-decene (purity < 97%) were studied in male Fischer rats (Huntington Life Sciences, 1999 as cited by JECFA, 2001) in the following experimental settings: (a) rats (33/group, body weight 200–250 g) received single oral doses of 30, 210 or 1,500 mg/animal in order to determine radiolabel in plasma, several tissues (fat, kidney, liver, lymph node, spleen, gut wall), intestinal contents, urine, faeces, carcass, skin and fur for 168 h after dosing, (b) three rats received 30 mg/animal intravenously and radiolabel was determined in plasma 168 h after dosing, (c) three rats received an oral daily dose of 210 mg/animal of unlabelled compound for 14 days followed by a single oral dose of ^{3}H-radiolabelled compound to investigate influence of repeated dosing, (d) three rats with cannulated bile ducts received a single oral dose of 210 mg/rat to study biliary, urinary and faecal excretion.

The pattern of excretion of ^{3}H-radiolabelled hydrogenated poly-1-decene was similar following single or repeated oral doses. After 48 h 70% of radioactivity was found in the faeces, 0.16% in the urine and 0.01% in the bile. After 168 h, 93-102% of a dose was excreted in the faeces and less than 1% in the urine.

Transient oiliness of the fur at the base of the tail was observed approximately 6 h after administration of 210 mg/animal and 1 h after administration of 1,500 mg/animal. The oiliness decreased during 48–72 h after dosing and disappeared after 96 h.

Overall, data on MOSH with different carbon numbers showed that absorption and accumulation depended on the number of carbons. Absorption and accumulation of *n*-alkanes with carbon numbers above C_{35} were negligible. MOSH with carbon number ranging from C_{16} to C_{35}, which are however less representative for hydrogenated poly-1-decene as food additive, accumulated mainly in liver and spleen The Panel noted only one study investigating the ADME of hydrogenated poly-1-decene. According to this study, only a small amount of hydrogenated poly-1-decene was absorbed and was systemically available as indicated by a high excretion in the faeces (92–102% of the dose), low biliary excretion (less than 1%) and low excretion via urine (less than 1%).

3.5.2. Acute toxicity

Available acute oral toxicity data related to branched chain aliphatic hydrocarbons with carbon chain lengths from C_9 to C_{13}. The oral LD_{50} in rats of these compounds ranged from 10,000 to 34,000 mg/kg bw (Mullin et al., 1990 as cited in JECFA, 2000 and SCF, 2001).

The Panel concluded that poly-1-decene is of low acute toxicity.

3.5.3. Short-term and subchronic toxicity

In a 28-day dose range finding study, F-344 rat (5/sex per group) received 0, 8,000, 20,000 or 50,000 mg hydrogenated poly-1-decene /kg diet (equal to at least 990, 2,480 or 6,240 mg/kg bw, respectively) (Pharmaco LSR, 1994 by SCF, 2001, and Cooper et al. 1994 as cited by JECFA, 2000, 2001). The test compound was reported as NEXBASE 2006 FG comprising 32% trimer, 47% tetramer, 17% pentamer, 4% hexamer. Haematological and clinical chemistry analyses were not performed. The findings were limited to a dose-related decrease in absolute and relative weights of the mandibular lymph node in males and females, which was statistically significant only in high-dose females, and to a dose-related decrease in weights of mesenteric lymph nodes which was more pronounced in females.

F-344 rats (10/sex per group) received 0 (basal diet), 1,000, 7,000 or 50,000 mg hydrogenated poly-1-decene /kg diet (equivalent to at least 80, 550 or 4,160 mg/kg bw per day, respectively) for 90 days (Pharmaco LSR, 1996 as cited by the SCF, 2001 and Cooper 1995 as cited by JECFA, 2000, 2001). The test compound was reported as NEXBASE 2006 FG comprising 32% trimer, 47% tetramer, 17% pentamer, 4% hexamer (SCF, 2001). Two additional groups of F-344 rats (5/sex per group) received 0 or 50,000 mg hydrogenated poly-1-decene /kg diet for 90 days and thereafter a control diet with no hydrogenated poly-1-decene added for 4 weeks (recovery groups). All animals survived until scheduled terminations. Soft faeces and poor hair condition were observed in males and females from mid- and high-dose groups. The Panel considered the soft stools and the poor hair condition as treatment-related but not adverse. High-dose males and females had oily and ungroomed fur. Body weights of the treated groups were comparable to controls. Feed intake in the high-dose group was reported to be slightly increased and feed conversion efficiency to be slightly reduced (statistical analysis was not available). Haematological examination revealed several differences to the controls. The Panel noted, that the majority of the values for the affected parameters were within normal ranges for this age and strain, the changes were not evident at the end of the recovery period, lacked dose dependency (except for haemoglobin concentration), and there were no changes indicative of possible haematological effects in the bone marrow. Therefore, the Panel considered haematological findings unlikely to be of toxicological significance. Clinical chemistry examination, urinalysis and necropsy did not reveal any differences to the controls. Absolute and relative liver weights were statistically significantly lower in high-dose males as compared to controls but this liver weight change was not accompanied by histological changes, therefore the Panel considered this effect as not adverse. In high-dose females, low incidence of single hepatocyte necrosis (3/10 vs 0/10) was recorded which according to the Panel is a normal background finding and not of toxicological relevance. Absolute and relative liver weights were not affected in the end of recovery period. Therefore, the Panel considered the effect on the liver as toxicologically not significant. Microscopically no accumulation of hydrogenated poly-1-decene was seen in the liver, spleen, lymph nodes and gastrointestinal tract at doses up to 4,160 mg/kg bw per day.

The Panel noted that the effects on the appearance of the coat, haematology and liver were considered as adverse by JECFA and the SCF and therefore they identified a NOAEL of 550 mg/kg bw per day. However, the Panel considered the effects seen at the dose of 4,160 mg/kg bw per day were not of toxicological relevance and identified 4,160 mg/kg bw per day as the NOAEL.

3.5.4. Genotoxicity

Hydrogenated poly-1-decene was previously evaluated by JECFA (2000). No studies of genotoxicity conducted with the test material were available for evaluation to JECFA; however, the results of tests for genotoxicity with related isoparaffinic compounds of lower molecular mass showed that they had no effect on a variety of end-points (Xerox Corp., 1981 and 1983; Exxon Corp, 1978; Philips Petroleum Co, 1990 as cited in JECFA, 2000). Consequently, the Committee concluded that tests for the genotoxicity of hydrogenated poly-1-decene were not required.

In the EFSA CONTAM opinion, genotoxicity of MOSH mixtures, *n*-alkanes and branched alkanes (n-paraffin and isoparaffin) was assessed (EFSA CONTAM Panel, 2012a). The EFSA CONTAM Panel concluded that alkanes mixtures are not genotoxic, neither *in vitro* nor *in vivo*. Although few genotoxicity data were available for the single alkanes, CONTAM Panel concluded that refined paraffinic mineral oils with very low content of aromatics are not mutagenic in the *Salmonella* Typhimurium mutagenicity tests with and without metabolic activation and that alkanes did not induce morphological transformation in primary Syrian Hamster embryo cells in culture.

A structure–activity analysis of 1-decene and hydrogenated poly-1-decene (CAS 68037-01-4) by the OECD QSAR ToolBox (version 3.3), using a series of profilers for DNA reactivity and genotoxicity, did not identify structural alerts for in vitro (Ames test, micronucleus and chromosomal aberrations) and in vivo genotoxicity (micronucleus test), DNA binding and genotoxic carcinogenicity (Appendix D).

Overall, based on the results of genotoxicity tests of structural analogues, and the outcome QSAR analysis, the Panel concluded that hydrogenated poly 1-decene does not raise concern for genotoxicity.

3.5.5. Chronic toxicity and carcinogenicity

No studies were available.

3.5.6. Reproductive and developmental toxicity

No studies were available.

3.5.7. Hypersensitivity, allergenicity and food intolerance

No studies were available.

3.6. Discussion

Hydrogenated poly-1-decene (E 907) is a glazing agent authorised as a food additive in the EU. In 2001, it was evaluated by both JECFA Safety Evaluation of certain food additives and contaminants (2001) and the SCF (2001). Both committees established an ADI of 0–6 mg/kg bw.

Hydrogenated poly-1-decene is a member of a more general family of hydrocarbons known as POSH which in turn is a subgroup of MOSH and more generally MOH. MOH and MOSH were evaluated by the EFSA CONTAM Panel (EFSA CONTAM Panel, 2012a; Cravedi et al., 2017).

Specifications for hydrogenated poly-1-decene have been defined in the EU in Commission Regulation (EU) 231/2012 and by JECFA. The purity of hydrogenated poly-1-decene is specified to not be less than 99.5% by JECFA, and 98.5% by the EU regulation.

Hydrogenated poly-1-decene is part of the MOSH family which includes linear and branched alkanes with carbon numbers varying over a large range. Hydrogenated poly-1-decene is described as 'not less than 98.7% of hydrogenated poly-1-decene having the following range of oligomer distribution: C_{30} 13–37%, C_{40} 35–70%, C_{50} 9–25% and C_{60} 1–7%'. Therefore, the EFSA CONTAM opinion on MOH (EFSA CONTAM Panel, 2012a) and an EFSA external scientific report on MOSH (Cravedi et al., 2017) were taken into consideration. According to these reports, MOSH with carbon numbers between C_{16} and C_{35} may accumulate in different tissues including adipose tissues, lymph nodes and liver. However, the Panel noted that these studies have been performed with test materials that only to some extent overlap with the composition of hydrogenated poly-1-decene as food additive and therefore the evidence was not considered relevant for this assessment.

The Panel noted only one study investigating the ADME of hydrogenated poly-1-decene. According to this study, only a small amount of hydrogenated poly-1-decene was absorbed and was systemically available as indicated by a high excretion in the faeces (92-102% of the dose), low biliary excretion (less than 1%) and low excretion via urine (less than 1%).

Poly-1-decene is of low acute toxicity.

Based on the results of genotoxicity tests of structural analogues and the outcome of the QSAR analysis, the Panel concluded that hydrogenated poly 1-decene does not raise concern for genotoxicity.

In a rat subchronic study doses of 80, 550 and 4,160 mg/kg per day were tested and the Panel identified 4,160 mg/kg bw per day as NOAEL, the highest dose tested. No accumulation has been found in tissues up to the highest dose. Considering that chronic toxicity and carcinogenicity, as well as reproductive and developmental toxicological studies were not available, the Panel based the derivation of the ADI on the NOAEL identified in the subchronic study in rats. According to EFSA guidance (EFSA SC 2012) a time-adjustment factor of 2 and default factor of 100 was applied to the NOAEL of 4,160 mg/kg per day, resulting into an ADI of 20 mg/kg bw per day.

The dietary exposure to hydrogenated poly-1-decene (E 907) from its use as a food additive was calculated based on MPLs set out in the EU legislation (defined as the *regulatory maximum level exposure assessment scenario*). Due to limited information on actual use levels (only one use level reported by industry referring to a niche product of chewing gum) and the fact that not analytical data were submitted by Member States a refined exposure assessment could not be calculated. This limited use of hydrogenated poly-1-decene (E 907) is in line with the information from the Mintel GNPD database (Appendix A). Based on the aforementioned information the Panel presumed that hydrogenated poly-1-decene as food additive is rarely used.

Mean exposure to hydrogenated poly-1-decene (E 907) from its use as a food additive ranged from no exposure in infants to 2.35 mg/kg bw per day in toddlers. The 95th percentile of exposure to hydrogenated poly-1-decene (E 907) ranged from < 0.01 mg/kg bw per day in infants and adults to 6.69 mg/kg bw per day in toddlers.

The exposure estimates in the *regulatory maximum level exposure assessment scenario* did not exceed the ADI of 20 mg/kg bw per day for all population groups (Table 4). The Panel noted that the estimated exposure based on this scenario is conservative, as this scenario assumes that all foods belonging to the food categories in which the use of hydrogenated poly-1-decene (E 907) is authorised according to Annex II to Regulation No 1333/2008 contain hydrogenated poly-1-decene (E 907) as a food additive at the MPL. Furthermore, hydrogenated poly-1-decene (E 907) is only authorised as a glazing agent in these food categories. Since the glazed food products are not referenced in the FoodEx classification system, this restriction could not be taken into account, and therefore the whole food categories were considered in the exposure assessment. This has resulted in an overestimation of the exposure.

4. Conclusions

Based on the toxicological database available, the Panel established the ADI of 20 mg/kg bw per day for hydrogenated poly-1-decene (E 907) and concluded that the exposure to hydrogenated poly-1-decene (E 907) does not raise a safety concern when used at the maximum permitted levels.

5. Recommendations

The Panel recommended that:

- The European Commission should consider setting lower maximum limits for toxic elements (nickel and lead) in the EU specifications of hydrogenated poly-1-decene (E 907) in order to ensure that its use as a food additive will not be a significant source of exposure to these toxic elements in food.

Documentation provided to EFSA

1) ICGA (International Chewing Gum Association), 2017. Data on usage levels of hydrogenated poly-1-decene (E 907) in foods in response to the EFSA call for additives usage levels and/or concentration data in food and beverages intended for human consumption (Batch 6). Submitted to EFSA on 30th November 2017.

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Abbreviations

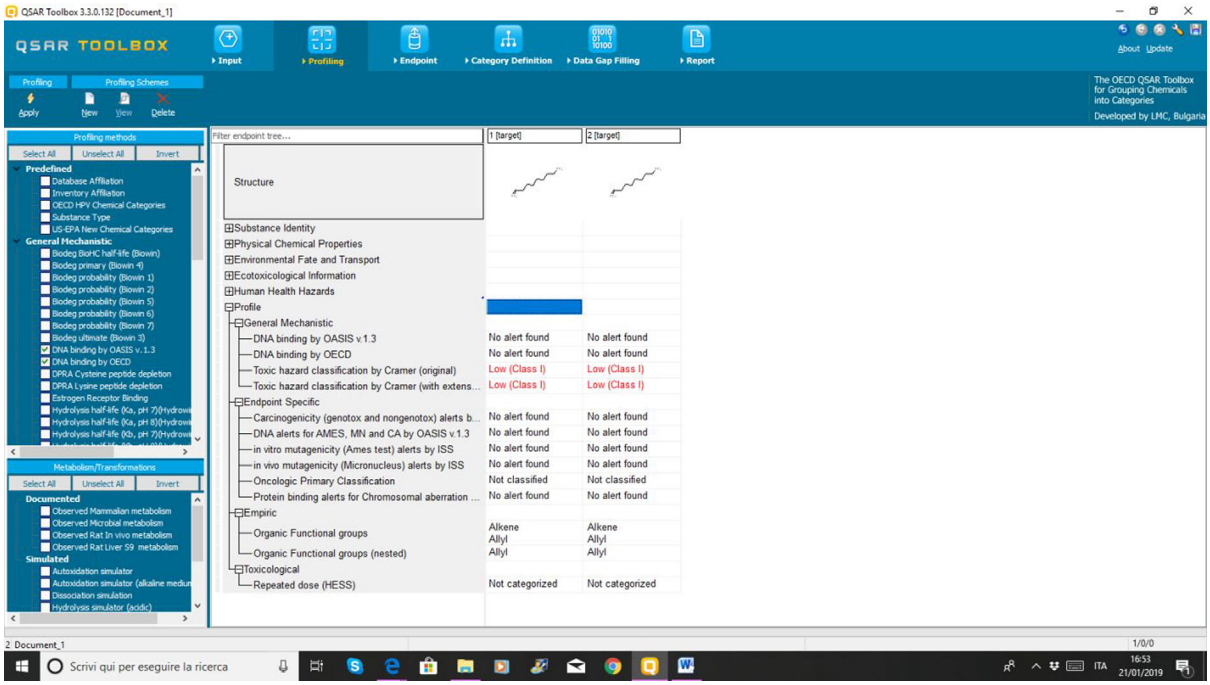
ADI	acceptable daily intake
ADME	absorption, distribution, metabolism and excretion
AI	adequate intake
bw	body weight
CAS	Chemical Abstract Service
ECHA	European Chemicals Agency
EINECS	European Inventory of Existing Commercial chemical Substances
FAF	Food Additives and Flavourings
FCS	food categorisation system
FID	flame ionisation detection
GC	gas chromatography
GNPD	Global New Products Database
HPLC	high-performance liquid chromatography
ICGA	International Chewing Gum Association
JECFA	Joint FAO/WHO Expert Committee on Food Additives
IC	ion chromatography
IPCS	International Program on Chemical Safety
LD_{50}	lethal dose, 50% i.e. dose that causes death among 50% of treated animals
MOH	mineral oil hydrocarbons
MOSH	mineral oil saturated hydrocarbons
NOAEL	no observed adverse effect level
POSH	polyolefin saturated hydrocarbons
REACH	Registration, Evaluation, Authorisation and restriction of Chemicals
SCF	Scientific Committee for Food
TOF-MS	time-of-flight mass spectrometry
WHO	World Health Organization

Appendix A – Number and percentage of food products labelled with hydrogenated poly-1-decene (E 907) out of the total number of food products present in the Mintel GNPD per food subcategory between 2014 and 2019

Appendix B – Summary of total estimated exposure of hydrogenated poly-1-decene (E 907) from its use as a food additive per population group and survey: mean and 95th percentile (mg/kg bw per day)

Appendix C – Main food categories contributing to exposure to hydrogenated poly-1-decene (E 907) (> 5% to the total mean exposure)

Appendix D – QSAR ToolBox 3.3 – Results with 1-decene (CAS 872-05-9) and hydrogenated poly-1-decene (CAS 68037-01-4)



Appendixes A–D can be found in the online version of this output ('Supporting information' section): https://doi.org/10.2903/j.efsa.2020.6034.