FEICA The European voice of the **adhesive** and **sealant industry**

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# Guidance for evaluating the food contact status of adhesives containing mineral oil hydrocarbons

FEICA, the Association of the European Adhesive & Sealant Industry, is a multinational association representing the European adhesive and sealant industry. With the support of its national associations and several direct and affiliated members, FEICA coordinates, represents and advocates the common interests of our industry throughout Europe. In this regard FEICA aims to establish a constructive dialogue with legislators in order to act as a reliable partner to resolve issues affecting the European adhesive and sealant Industry.

This guidance, provided by the FEICA Paper & Packaging Working Group, is primarily provided for the benefit of FEICA members and the members of its national association members who are manufacturing adhesives for the food packaging and food service item sector in the European Union. In addition, this guidance can also be of interest to users of food contact adhesives, such as packaging producers and their downstream users as well as other stakeholders involved in regulatory or legislative matters of food contact.

## Content

## 1. Executive Summary

Beginning in 2011, safety concerns were raised after studies indicated that consumers could be exposed to mineral oil hydrocarbons (MOH) in foodstuffs, with the likely major sources being food packaging and food additives, processing aids and lubricants. A European Food Safety Authority (EFSA) opinion[1] published in this context placed a main focus on mineral oil migration from recycled paper. Mineral oil from printing inks used on graphical / newsprint paper was identified as a major contributor to the presence of mineral oils in recycled paper and therefore to the migration into packed food. Supporting studies were published by the Official Food Control Authority of the Canton of Zurich, Switzerland, and the German Institute for Risk Assessment.[2]

Despite the fact that several new studies have been published since the EFSA opinion, the topic of mineral oil hydrocarbons remains complex for the entire packaging supply chain.

For adhesives, the lack of official analytical methods, especially for migration testing, means that testing is performed in different ways, with some of the test results not reflecting the real migration potential. This is complicated further by adhesive raw materials such as mineral oils, waxes, resins and oligomers being difficult to analyse for MOH, especially in complex matrices such as adhesives.

This guidance aims to support adhesives producers and adhesives users in ensuring that the intended adhesive application complies with article 3 of the EU Framework Regulation for food contact materials and articles.[3] The document provides clarifications as to how to risk assess mineral oil hydrocarbon migration from adhesives and, where testing is needed, how to perform the testing and evaluate the results.

A decision tree is also included to help users evaluate adhesives for their intended application.

[1] EFSA Panel on Contaminants in the Food Chain (CONTAM). 'Scientific Opinion on Mineral Oil Hydrocarbons in Food'. *EFSA Journal* 10, no. 6 (2012): 2704. Updated in August 2013.
[2] 'Messung von Mineralöl-Kohlenwasserstoffen in Lebensmitteln und Verpackungsmaterialien'. Kantonales Labor Zürich & Bundesamt für Risikobewertung, 2012.
[3] Regulation EU (No) 1935/2004.

## 2. Types of mineral oil hydrocarbons

The term 'mineral oil', without any qualification or further definition, encompasses a wide range of different mixtures of hydrocarbon compounds. Highly purified mineral oils and paraffin waxes[4] have been used in cosmetic and medical applications for decades. They are in use as food additives[5] and in food contact applications. These mineral oil compounds are approved in relevant regulations[6] and supported by adequate toxicological data.

Seeing how some mineral oil compounds are part of our daily life, while simultaneously, safety concerns are raised, it becomes clear that an accurate differentiation in the toxicological evaluation and risk assessment of 'mineral oil(s)' is key.

The EFSA[1] defines mineral oil hydrocarbons (MOH) or mineral oil products as: *'hydrocarbons containing 10 to about 50 carbon atoms'* and considers crude mineral oils as by far the predominant source of the MOH, even though equivalent products can be synthesised from coal, natural gas or biomass.

EFSA's definition of MOH therefore includes substances which are already evaluated as non-hazardous or not harmful to humans or the environment, such as those described above.

The EFSA opinion divides MOH into two main types:

- Mineral oil *saturated* hydrocarbons (MOSH), which comprise linear and branched alkanes and alkyl-substituted cyclo-alkanes
- Mineral oil *aromatic* hydrocarbons (MOAH), which comprise mainly alkyl-substituted polyaromatic hydrocarbons

EFSA acknowledges that even this categorisation lacks a precise chemical structure definition for MOSH and MOAH. Rather, the MOSH and MOAH fractions are defined based on the fractions that are visible in the commonly used analytical method.[7,8]

This choice of grouping acknowledges the immense variety and structural complexity of the individual chemical substances contained in MOH. In other words, it is not possible for current analytical techniques to resolve either MOH or MOSH or MOAH into individual substances for structural identification or quantification purposes.[1,9]

The MOSH and MOAH designations are therefore a generic terminology that is used to describe two analytical fractions and are an overall descriptor of types of hydrocarbons, independent of whether they originate from petroleum, synthetic materials or biomass.

Two related terms that are found both in the EFSA opinion as well as the wider discourse on mineral oil migration are 'POH' and 'POSH', which refer to *polyolefin oligomeric hydrocarbons* and *polyolefin oligomeric saturated*[10] *hydrocarbons*, respectively. PO(S)H do not originate from mineral oil compounds but from polyolefin polymers such as polyethylene (PE) and polypropylene (PP). In the

[4] Essentially, solid (wax) forms of mineral oil derived hydrocarbons.
[5] For example, E 905, 'Microcrystalline wax'.
[6] For example, food contact materials 93, 94, 95 in Regulation (EU) No 10/2011.
[7] See section 6 for details on the analytical method.
[8] The August 2020 draft for a German mineral oil ordinance defines MOAH similarly as: "alkylated aromatic hydrocarbons with carbon numbers C16 to C35 which contain one or more rings, with the exception of diisopropylnaphthalenes; the carbon numbers are linked to the elution ranges or to the retention times of the corresponding n-alkanes in the gas chromatographic analysis on a dimethylpolysiloxane-coated separation column".
[9] This also has implications for toxicological assessments. Without an identification of chemical structures, the common approach to perform toxicological testing with pure reference substance is not possible. See section 4 for details.
[10] The facts that oligomers from polyolefins are not cyclic structures and that they are saturated means that there is not a 'POAH' fraction.

definitions of the EFSA opinion, PO(S)H are not considered to be MOH (or MOSH): 'The term MOH excludes [..] oligomeric hydrocarbons released from polyolefins (largely consisting of branched alkanes)'. [1]

Since POSH also contain a distribution of multiple chemical structures that are of similar polarity to that of MOSH, it is typically not possible today to analytically separate PO(S)H from MOSH in a quantitative way.[1,11] Where polyolefinic materials are present, whether due to plastic materials or due to adhesives that contain polyolefinic compounds, consideration therefore needs to be given to the fact that a detection result for 'MOSH' may be in part or entirely due to the detection of PO(S)H.

## 3. Sources of mineral oil hydrocarbons in food

The EFSA opinion[1] identified a wide range of potential sources of mineral oil hydrocarbons in food.

- **Food contact materials**
    - Food packaging materials made from recycled paper and board
    - Offset printing inks applied to paper and board for food packaging
    - Mineral oils used as additives and processing aids in the manufacture of plastics for food contact (e.g., internal lubricants in polystyrene, polyolefins)
    - Wax coatings applied to paper and board
    - Jute or sisal bags containing mineral batching oil[12]
    - Lubricants used as processing aids in food and beverage can manufacture
    - Wax coatings directly applied to food
    - Adhesives used in food packaging

- **Contaminants**
    - Environmental contaminants: lubricating oil from engines without catalyst (mainly diesel), unburned fuel oil, debris from tyres and road bitumen
    - Harvesting machinery: diesel oil, lubricating oil
    - Lubricating oils in pumps, syringe type dosing machinery and other industrial installations used in food processing
    - Cleaning agents, solvents consisting of pure MOH or C10-C14 mixtures

- **Food additives, processing aids and other uses**
    - Release agents for bakery ware and sugar products
    - Oils for surface treatment of foods, such as rice, confectionery
    - Mineral oils in feeds, e.g., binders for minor additives added as powder
    - Defoamers
    - Paraffinic waxes (e.g., for chewing gum or coating of certain fruits)
    - Pesticide formulations
    - Anti-dusting agents for cereals

[11] European Commission. Joint Research Centre. Guidance on Sampling, Analysis and Data Reporting for the Monitoring of Mineral Oil Hydrocarbons in Food and Food Contact Materials. LU: Publications Office, 2019.
[12] 'Opinion of the Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food (AFC) on Mineral Oils in Jute and Sisal Bags'. EFSA Journal 3, no. 1 (2004): 162.

This list demonstrates that while adhesives can contribute to mineral oil migration into food, they are only one – and often a minor – source.

## 4. Potential health issues

Due to the highly complex mixture of chemical substances in MOH, there is a lack of reference standards for toxicological studies and information relating to actual health effects on a per-chemical-structure basis. Although the EFSA opinion[1] identified potential concerns about MOH in food, it acknowledged considerable uncertainties in assessing potential risks and concluded that further studies were needed.

According to the EFSA opinion, MOSH and MOAH exhibit the following properties:[1]

- MOSH, mainly the fraction comprising carbon chains of 16-35 atoms ( 'C16-C35'), may accumulate in the human body,[13] but have not been associated with adverse health consequences[14]

- MOAH with three or more non- or single-alkylated aromatic rings (polycyclic aromatic hydrocarbons, PAHs) may be mutagenic and carcinogenic, and are therefore considered of higher concern than the MOSH fraction[15]

EFSA has assessed a small number of MOH[16] and authorised their use in the Union list of the Plastics Regulation (EU) No 10/2011. As they are included among chemicals that are authorised for use in plastics intended for food contact, these MOH can also assumed to be suitable for the manufacture of adhesives intended for food packaging, if migration limits are met.[17]

## 5. Regulation

Only limited specific regulations pertaining to mineral oil migration into food exist.

As described above and in the Technical Appendix of this document, certain mineral oil compounds have been evaluated by EFSA and included in the Union List of the Plastics Regulation (EU) 10/2011 or Food Additives and Flavourings Regulation (EC) No 1333/2008. These regulations specify requirements and content / migration limits to be met.

A draft Ordinance in Germany[18] foresees the requirement for a barrier to be applied between recycled fibre-based products and food, unless by other measures it can be ensured that no transfer

[13] In particular, in lymph nodes, the spleen, and the liver.
[14] See also: K. Fleming, 'Mineral Oil Hydrocarbons (MOH) And Human Pathology' in 'Proceedings of the Mineral Oil CRoss Industry IssueS (MOCRINIS) Workshop September 2013', Concawe (2013).
[15] This is consistent with toxicologists typically focusing on *polycyclic aromatic hydrocarbons* (PAH) and especially 3-7 ring PAH. Some of these 3-7 ring polycyclic aromatic compounds have been confirmed to be carcinogenic.
[16] See the Technical Appendix of this document for the full list of EFSA assessed MOH including their descriptions and specifications.
[17] See FEICA Guidance paper 'Guidance for a food contact status declaration for adhesives' for a detailed explanation on the use of the Plastics Regulation (EU) No 10/2011 as a reference for the choice of adhesive raw materials.
[18] 'Twenty-Second Ordinance Amending the Consumer Goods Ordinance - Draft of the Federal Ministry of Food and Agriculture'. Federal Ministry of Food and Agriculture (Germany), 2020. See also WTO notification at https://members.wto.org/crnattachments/2021/SPS/DEU/21_2072_00_e.pdf and https://members.wto.org/crnattachments/2021/SPS/DEU/21_2072_00_x.pdf

of MOAH[19] into food occurs. Such measures include limiting the amount of MOAH present in the final article, restricting the food contact conditions (e.g., to only frozen food) and/or restricting the application to food types into which no migration occurs in practice (e.g., table salt). The proposed detection limits for MOAH are 0.5 mg/kg food or 0.15 mg/kg food simulant.

The technical guide on paper and board in food contact under the Council of Europe Resolution CM/Res(2020)9 mentions MOH in Annex II but does not yet specify a migration limit ('under discussion'). This guide states that 'producers or other operators […] are recommended to keep migration of MOH as low as reasonably feasible and to ensure that migration of genotoxic, carcinogenic MOAH does not occur.'

Swiss Ordinance 817.023.2 mentions mineral oils that contain MOAH in the list of non-evaluated substances[20] for which a migration limit of 0.01 mg/kg is defined.

## 6. Testing for migration of mineral oil hydrocarbons originating from adhesives

Food contact materials such as food packaging must be evaluated regarding the transfer of substances (so-called 'migration') from the packaging material into foodstuff. FEICA has published a guidance for the migration testing of adhesives.[21]

Adhesives, when part of a food contact material, may in certain cases contribute to migration values of mineral oil hydrocarbons. Such migration stems from low molecular weight fractions in their constituents, such as resins, waxes or oils.

Because it is often not possible or practical to test migration on samples of real food, migration into food must be approximated. This can be achieved either via *migration modelling* based on knowledge of the concentration of a migratable substance in a food contact article or packaging, or via *migration testing* with *food simulants*.

Direct extraction of the adhesive is not a viable approach to determine possible migration, as the low molecular weight fractions of the adhesive would be dissolved in the extract. This would lead to a much greater, and unrealistic, transfer of substances compared to the migration that can be expected in the real food contact scenario.[22] In addition, an adhesive generally never surrounds the food in its entirety and in most cases is not in direct contact with the food at all.

Migration into dry foodstuff, in particular, occurs predominantly via the gas phase.[1] Powder-form simulants such as MPPO[23] (food simulant 'E' in the Plastics Regulation, sometime referred to by the trade name 'Tenax') can be an appropriate choice for migration testing.[24] After the migration test, the food simulant can be analysed for migrated MOH compounds by extraction.

[19] Definition of MOAH: 'Aromatic mineral oil hydrocarbons: alkylated aromatic hydrocarbons with carbon numbers C16 to C35 which contain one or more rings, with the exception of diisopropylnaphthalenes; the carbon numbers are linked to the elution ranges or to the retention times of the corresponding n-alkanes in the gas chromatographic analysis on a dimethylpolysiloxane-coated separation column'.
[20] Printing ink section of the Ordinance (Annex 10, substance no 1902).
[21] FEICA Guidance Paper 'Migration testing of adhesives intended for food contact materials'.
[22] FEICA commissioned study 'Extraction, migration simulation and storage test regarding oligomeric hydrocarbons from hotmelt adhesives used in cardboard packaging', 2021.
[23] poly(2,6-diphenyl-p-phenylene oxide), particle size 60-80 mesh, pore size 200 nm.
[24] This simulant is also recommended for dry foodstuffs in the technical guide 'Paper and board used in food contact materials and articles', under the umbrella of Council of Europe Resolution CM/Res(2020)9.

To choose adequate simulants for the migration into other types of food, Regulation (EU) No 10/2011 can be consulted for foodstuff in contact with plastics, and the technical guides of CM/Res(2020)9 for foodstuff in contact with paper and board.

The most frequently used analytical method for the determination of MOH is based on on-line coupled HPLC-GC-FID[25], as described by the Zurich Cantonal Laboratory (KLZH) and Germany's Federal Institute for Risk Assessment (BfR).[26] The procedure was developed and optimised by the Joint Research Centre (JRC) for analysis of mineral oil hydrocarbons in foodstuff as well as in recycled paper and cardboard.[27]

The liquid chromatographic separation via HPLC separates two fractions of MOH substances, based on a difference in their polarity. Substances in the non-polar fraction are assigned as MOSH, whereas the substances in the polar fraction are assigned as MOAH. However, it must be noted that the subsequent GC-FID determination of these two fractions is neither able to resolve the complex substance mixtures in each fraction into individual chemical compounds, nor does the flame ionisation detection method allow assigning chemical structures.[1]

The HPLC-GC-FID analytical method should not be applied on an extract of the pure adhesive or on the adhesive itself as this may result in unrealistically high MOSH and MOAH readings. This is the case because the HPLC-GC-FID analysis cannot quantitatively differentiate between substances from mineral oils and substances from non-mineral oil sources, such as oligomers from polyolefins (i.e., POH / POSH) and tackifier resins.[1,28,29] A FEICA commissioned study[22] confirmed this specifically for hotmelt adhesives.

## 7. Risk assessment of mineral oils

As described above, certain mineral oil hydrocarbon compounds have been positively assessed by EFSA. Adhesives manufacturers can refer to the Union List of the Plastics Regulation (EU) No 10/2011 for guidance on mineral oil hydrocarbons authorised for use in plastics, and their specifications and restrictions.[30]

In the absence of EU harmonised specific measures for adhesives in food contact, adhesive manufacturers may also use non-listed substances, including substances that contain mineral oil. In this case, an in-house risk assessment in accordance with internationally recognised scientific principles needs to be performed. A useful aid for such a risk assessment is the FCA guideline on non-listed substances.[31]

In many cases, depending on the nature of the packaging material and its production process, adhesives will not be the only or the main source of mineral oil hydrocarbons migrating from

[25] High performance liquid chromatography – gas chromatography – flame ionisation detector. FID is chosen as a detection method despite its inability to provide structural information and its limited sensitivity since it is the only method that does not require a reference sample for calibration.
[26] 'Messung von Mineralöl-Kohlenwasserstoffen in Lebensmitteln und Verpackungsmaterialien'. Kantonales Labor Zürich & Bundesamt für Risikobewertung, 2012.
[27] For an updated summary of methods, see: European Commission. Joint Research Centre. Guidance on Sampling, Analysis and Data Reporting for the Monitoring of Mineral Oil Hydrocarbons in Food and Food Contact Materials, 2019.
[28] Lommatzsch, Martin, Maurus Biedermann, Koni Grob, and Thomas J. Simat. 'Analysis of Saturated and Aromatic Hydrocarbons Migrating from a Polyolefin-Based Hot-Melt Adhesive into Food'. Food Additives & Contaminants: Part A 33, no. 3 (2016): 473–88.
[29] Biedermann-Brem, S., N. Kasprick, T. Simat, and K. Grob. 'Migration of Polyolefin Oligomeric Saturated Hydrocarbons (POSH) into Food'. Food Additives & Contaminants: Part A, 2 December 2011, 1–12.
[30] See also the Annex of this document for a list of EFSA-authorised materials.
[31] FCA guideline on 'Risk Assessment of non-listed substances (NLS) and non-intentionally added substances (NIAS) under the requirements of Article 3 of the Framework Regulation (EC) 1935/2004'.

packaging. The compliance of the final packaging with (EC) No 1935/2004 can therefore be verified only by the manufacturer of the final packaging material because only they have control over all components of the packaging.

To assist in this process, adhesive manufacturers should provide packaging manufacturers with *adequate information* about the adhesives they supply. FEICA has published a guidance on food contact status declarations for adhesives that can serve as a reference.[32]

## 8. FEICA's recommendations for the adhesive industry

Adhesive manufacturers should perform an evaluation of the intended formulation of their adhesives. They can do so by following the decision tree provided in the FEICA guidance for a food contact status declaration for adhesives.[33]

With respect to mineral oil hydrocarbons, the adhesive manufacturer can check whether the mineral oil hydrocarbons used in the formulations, and which pose a risk for migration, are listed in Regulation (EU) No 10/2011[34] (FCM 93, 94, 95). If this is the case, the restrictions and specifications[35] provided by the Plastics Regulation shall be applied. If the mineral oil hydrocarbon compound does not meet the definitions of a listed FCM, the adhesive manufacturer should follow the steps explained below to ensure that their adhesives are fit for the intended use.

### Water-based adhesives, including water-based pressure sensitive adhesives

Certain water-based adhesives may contain MOH originating from a contained defoamer (typically, maximum concentrations of defoamers are not higher than 0.5 wt% in the adhesive).

Typical applications for water-based adhesives include construction and closing of paper and paperboard packaging, labelling, cold seals, self-adhesive labels and paper lamination.

**Recommendations:**

1. Consider whether a mineral-oil-free defoamer can be used.
2. If a mineral-oil-based defoamer is required, choose a defoamer that is based on authorised mineral oil compounds.
3. If this is not possible, request compositional information and/or toxicological data from the supplier of the defoamer used in the adhesive and perform a risk assessment for the adhesive in the intended application. If necessary, reduce the content of the mineral oil defoamer in the formulation.

**Food contact status declaration**

Unless covered by an authorisation (FCM), the mineral oil defoamer must be listed as a substance with a specific migration limit (SML) of 'not detectable' (10 ppb) in the SML table.

FEICA recommends providing information regarding maximum expectable concentration to facilitate the risk assessment by the downstream user.

[32] FEICA Guidance paper 'Guidance for a food contact status declaration for adhesives'.
[33] FEICA Guidance paper 'Guidance for a food contact status declaration for adhesives'.
[34] As explained in the FEICA guidance for a food contact status declaration for adhesives, due to the absence of an EU harmonised measure on adhesives, the Plastics Regulation (EU) No 10/2011 and its Union List of approved substances can be used as a reference.
[35] Column 10 of the Union List.

If a risk from the migration of mineral oil hydrocarbons into the food beyond applicable migration limits cannot be excluded, a functional barrier has to be recommended.

### Hotmelt adhesives

Certain hotmelts such as some ethylene vinyl acetate and polyolefin-based hotmelts may contain mineral oil hydrocarbons. POSH from paraffinic waxes or hydrocarbon resin raw materials, which are not mineral oil compounds, may also be detected in the MOH fraction, leading to a possibility of misinterpretation of the migration results.[36]

Typical applications include case and carton sealing and lamination.

**Recommendations:**

1. If hydrocarbon compounds are to be used, choose types that are evaluated (covered by FCM 97, 93 or 94).
2. If this is not possible, request compositional information and/or toxicological data from the supplier of the mineral oil hydrocarbon component and perform a risk assessment for the adhesive in the intended application. If necessary, reduce the content of the mineral oil hydrocarbon components.

**Food contact status declaration**

Unless covered by an authorisation (FCM), mineral oil hydrocarbons must be listed as a substance with a specific migration limit (SML) of 'not detectable' (10 ppb) in the SML table.

FEICA recommends providing information regarding maximum expectable concentration to facilitate the risk assessment by the downstream user.

If a risk from the migration of mineral oil hydrocarbons into the food beyond applicable migration limits cannot be excluded, a functional barrier has to be recommended.

### Hotmelt pressure-sensitive adhesives

Most hotmelt pressure-sensitive adhesives (PSA) contain mineral oils (10-30 wt% in the formulation). Manufacturing hotmelt PSA entirely without oil is difficult, but it is possible to use highly refined oils with a minimal amount of low molecular weight aromatic compounds.

Typical applications include labelling, tapes, packaging tapes and resealable packaging.

**Recommendations:**

1. If hydrocarbon compounds are to be used, choose types that are evaluated (covered by FCM 97, 93, 94, 95)
2. If this is not possible, request compositional information and/or toxicological data from the supplier of the mineral oil hydrocarbon component and perform a risk assessment for the adhesive in the intended application.

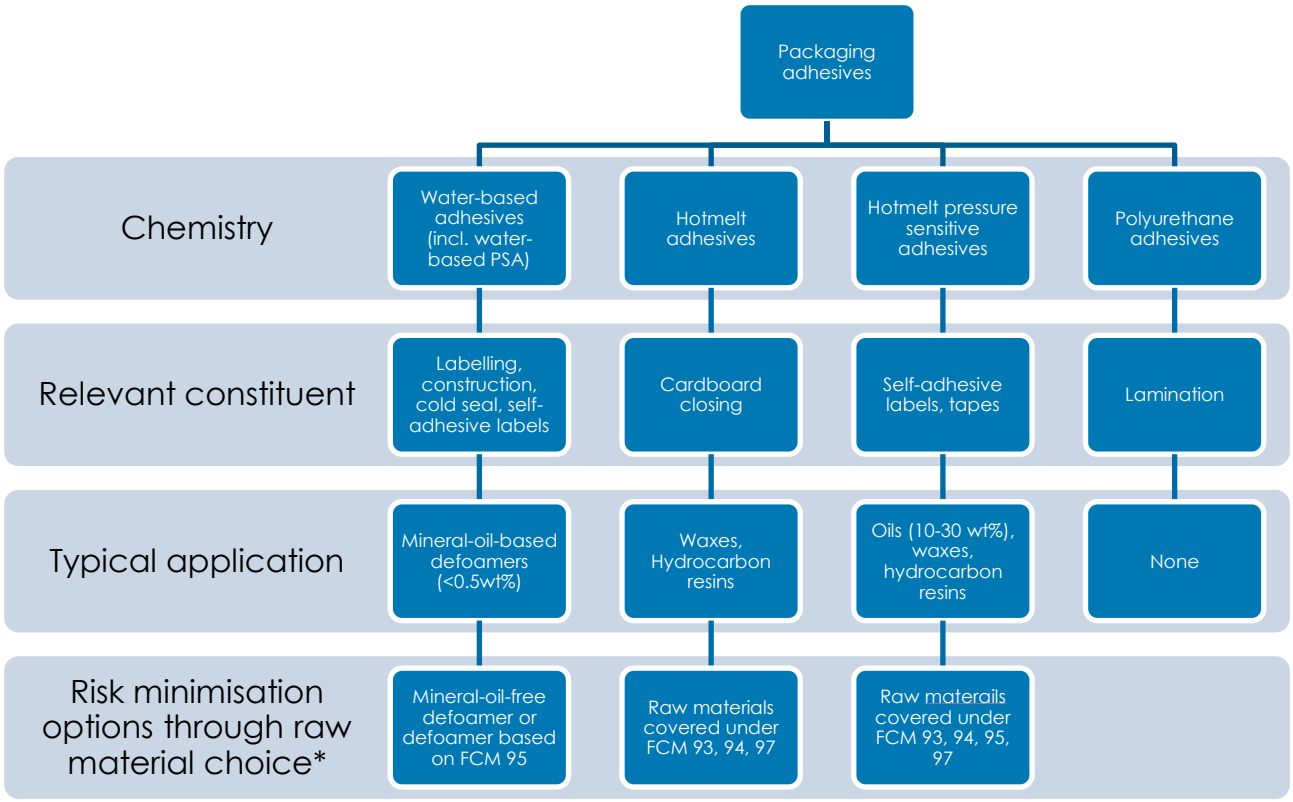
[36] See section 6.

**Food contact status declaration**

Unless covered by an authorisation (FCM), mineral oil hydrocarbons must be listed as a substance with a specific migration limit (SML) of 'not detectable' (10 ppb) in the SML table.

FEICA recommends providing information regarding maximum expectable concentration to facilitate the risk assessment by the downstream user.

If the risk of migration of mineral oil hydrocarbons into the food beyond applicable migration limits cannot be excluded, a functional barrier has to be recommended.




* See detailed recommendations in section 8.

## 9. Summary

Mineral oil hydrocarbons (MOH) are composed of thousands of different chemical compounds, with large variations in toxicological characteristics. MOH can be grouped into saturated hydrocarbons (MOSH) and aromatic hydrocarbons (MOAH).

Certain MOAH, especially those with three to seven non- or single-alkylated aromatic rings,[1] may be mutagenic and carcinogenic and are therefore considered by the European Food Safety Authority (EFSA) of substantially higher concern than the MOSH fraction.

Specific MOH compounds have been assessed by EFSA and are listed and authorised in the Union list of the Plastics Regulation (EU) No 10/2011 or as a food additive in Regulation (EC) No 1333/2008.

The analytical test methods currently available for MOSH and MOAH determination are not able to separate these fractions into individual chemical substances. The methods were developed for the analysis of paper and board or for the analysis of foodstuff. This means that there is no method available that is specifically adapted to adhesives.

**Applying the current analytical methods for MOSH / MOAH determination will always result in misleading values when analysing adhesives directly (or their extracts). Only migration testing with adequate food simulants (see section 6) can provide a realistic picture of mineral oil transfer into foodstuff. As sample preparation and interpretation of the analytical results can be difficult for adhesives, cooperation between the adhesives supplier, the user and the laboratory performing the testing is important.**

FEICA collaborates with specialists of adhesive manufacturers and all stakeholders in the packaging supply chain to further the understanding of all aspects of mineral oil migration.

FEICA encourages adhesive manufacturers to carry out a complete risk assessment of all ingredients in an adhesive formulation. Aside from EFSA-reviewed mineral oil hydrocarbons (FCM 93, 94, 95), unlisted mineral oil compounds can also be used in adhesive formulations if a risk assessment supports this use.

Effective communication in the supply chain is essential to ensure that the adhesive users (i.e., packaging manufacturers) receive sufficient information about adhesives to allow them to carry out their own risk assessment and demonstrate compliance with Article 3 of the Framework Regulation for the final packaging. FEICA has published a guidance on food contact status declarations for adhesives to support adhesive manufacturers in this regard.[37]

A decision tree is provided in the Annex of this guidance document to assist users in their evaluation of adhesives relative to mineral oil compounds for the intended application and final packaging.

[37] FEICA Guidance paper 'Guidance for a food contact status declaration for adhesives'.

## 1. Mineral oil hydrocarbon compounds evaluated by EFSA

The following mineral oil hydrocarbons are authorised in the **Union List of Regulation (EU) No 10/2011**:

- **White mineral oils, paraffinic, derived from petroleum-based hydrocarbon feedstock** (FCM 95)
  No specific migration limit (SML) is defined
  The product must comply with the following specifications:
  – hydrocarbons with carbon number less than 25, not more than 5% (w/w)
  – viscosity not less than 8.5 $mm^2/s$ at 100 °C
  – average molecular weight not less than 480 Da

- **Waxes, refined, derived from petroleum-based or synthetic hydrocarbon feedstock** (FCM 94)
  No specific migration limit (SML) is defined
  The product must comply with the following specifications:
  – hydrocarbons with carbon number less than 25, not more than 5% (w/w)
  – viscosity not less than 11 $mm^2/s$ at 100 °C
  – average molecular weight not less than 500 Da

- **Waxes, paraffinic, refined, derived from petroleum-based or synthetic hydrocarbon feedstock** (FCM 93)
  An SML of 0.05 mg/kg food is specified
  In addition, these waxes are not to be used for articles in contact with fatty foods
  The product must comply with the following specifications:
  – hydrocarbons with carbon number less than 25, not more than 40% w/w
  – viscosity at 100°C min 2.5 $mm^2/s$
  – average molecular weight not less than 350 Da

In addition, one mineral oil hydrocarbon compound is approved as a **food additive in Regulation (EC) No 1333/2008**:

- **Microcrystalline wax** (E 905)
  Approved for use in the surface treatment of confectionery (excluding chocolate), chewing gum, melons, papayas, mangoes, avocados and pineapples.
  Maximum level: *quantum satis*

## 2. Hydrocarbon resins

Since, as described in this document, hydrocarbon resins may influence the MOSH and MOAH analysis, this section provides an overview of EFSA-reviewed and authorised, toxicologically evaluated hydrocarbon resins.

The following hydrocarbon resins are authorised in the **Union List of Regulation (EU) No 10/2011**:

- **Petroleum hydrocarbon resins, hydrogenated** (FCM 97)
  No specific migration limit (SML) is defined
  The product must comply with the following specifications:
  - Viscosity at 120 °C: > 3 Pa·s
  - Softening point: > 95 °C as determined by ASTM Method E 28-67
  - Bromine number: < 40 (ASTM D1159)
  - The colour of a 50 % solution in toluene < 11 on the Gardner scale
  - Residual aromatic monomer ≤ 50 ppm

## 3. Further hydrocarbon compounds

Since, as described in this document, hydrocarbon compounds may influence the MOSH and MOAH analysis, this section provides an overview of EFSA-reviewed and authorised, toxicologically evaluated hydrocarbon compounds.

The following hydrocarbon compounds are authorised in the **Union List of Regulation (EU) No 10/2011**:

- **Polyethylene wax** (FCM 549)
  No specific migration limit (SML) is defined

- **Polypropylene wax** (FCM 550)
  No specific migration limit (SML) is defined

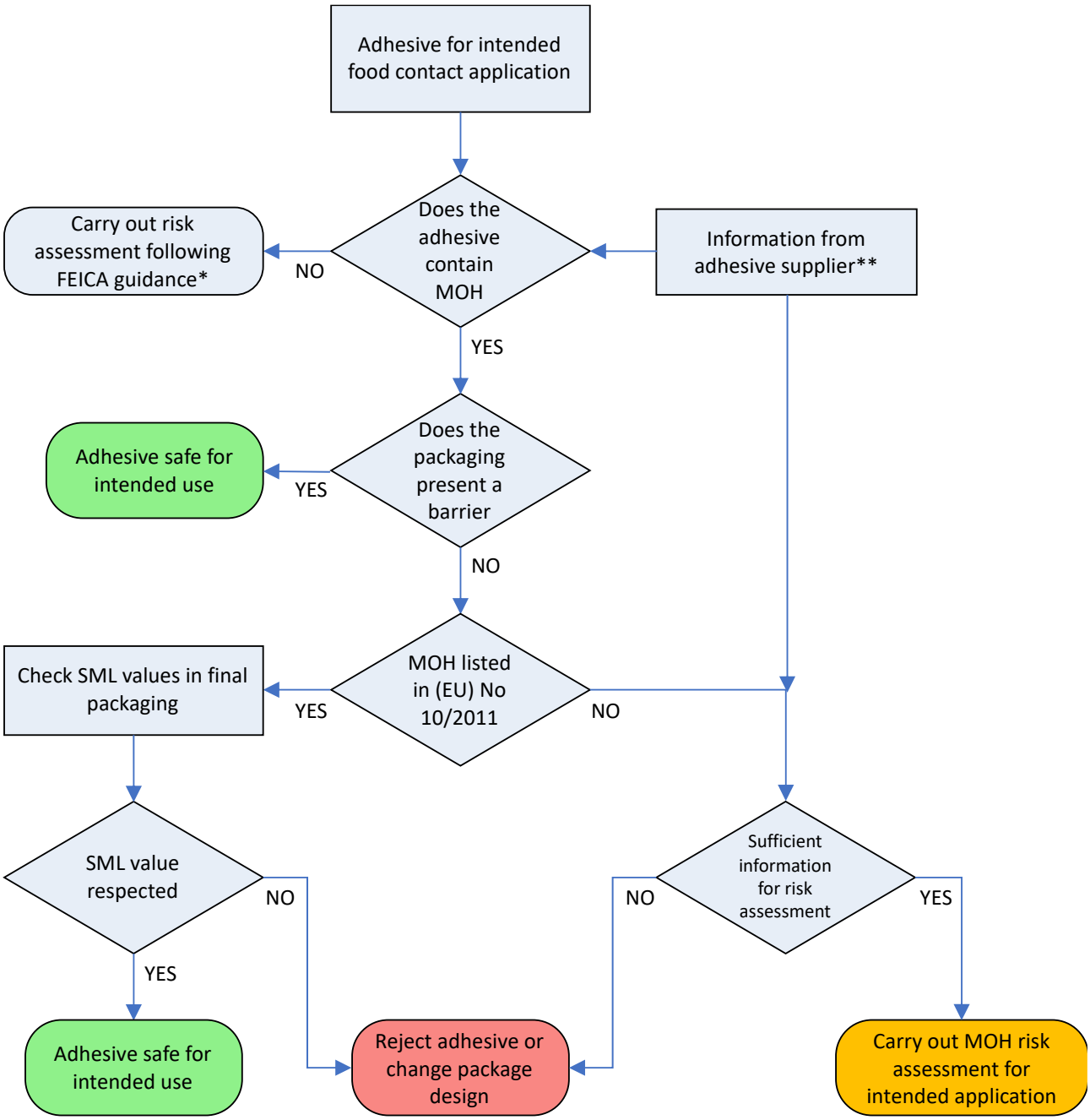
- **Isobutylene-butene copolymer** (FCM 577)
  No specific migration limit (SML) is defined

- **p-cresol-dicyclopentadiene- isobutylene, copolymer** (FCM 732)
  An SML of 5 mg/kg food is specified

- **Hydrogenated homopolymers and/or copolymers made of 1-hexene and/or 1-octene and/or 1-decene and/or 1-dodecene and/or 1-tetradecene (Mw: 440 – 12000)** (FCM 789)
  No specific migration limit (SML) is defined
  The product must comply with the following specifications:
  - Average molecular weight not less than 440 Da
  - Viscosity at 100 °C not less than 3.8 cSt ($3.8 \times 10^{-6}$ m2/s)

- **Ethylene-vinyl acetate copolymer wax** (FCM 969)
  No specific migration limit (SML) is defined
  The product must comply with the following specifications:
  - To be used only as a polymeric additive up to 2 % w/w in polyolefins
  - The migration of low molecular weight oligomeric fraction below 1,000 Da shall not exceed 5 mg/kg food

## 4. Decision Tree for Downstream User Evaluation of Adhesives




* FEICA Guidance paper 'Guidance for a food contact status declaration for adhesives'.
** From food contact status declaration of the adhesive or another source.

## 5. Contact

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