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Low molecular weight hydrocarbon compounds in paper and packaging adhesives

(mineral oil hydrocarbons)

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For several years there have been reports[1] of analytical evidence of the presence low molecular weight hydrocarbon compounds (mainly chain length C10 to C50) in foods. In general, literature refers to such low molecular weight hydrocarbon compounds as MOH because they also form the main part of mineral oil.

Commission Recommendation (EU) No 2017/84 defines mineral oil hydrocarbons (MOH) as "chemical compounds derived mainly from crude oil, but also produced synthetically from coal, natural gas and biomass".

MOH are used in many chemical products, e. g. in waxes, white oils or machinery lubricants. In addition, they have also been used for many decades in products for medical or cosmetic applications as well as in the production of organically farmed foods.

Low molecular weight hydrocarbon compounds can be split into the following types:

- Saturated hydrocarbon compounds (MOSH = Mineral Oil Saturated Hydrocarbons), e. g. paraffinic, linear and branched alkanes as well as naphthene-like cyclic alkanes.
- Aromatic hydrocarbon compounds (MOAH = Mineral Oil Aromatic Hydrocarbons), mainly alkylated polycyclic aromatic hydrocarbons.

It should be noted that MOSH and MOAH are analytical fractions, consisting of many individual substances.

Moreover, newer literature also mentions the following sub groups in connection with MOSH and MOAH:

- Saturated polyolefin oligomers of hydrocarbons (POSH = Polyolefin Oligomeric Saturated Hydrocarbons; ROSH = Resin Oligomeric Saturated Hydrocarbons).
- Iso-paraffins with short main chain and long side chains (PAO = Poly Alpha Olefins)
- Refined mineral oil products (MORE = Mineral Oil Refined Products), MOSH from approved mineral oil products, such as paraffin waxes.

MOH in technical quality usually consist of 65 % to 85 % MOSH and 15 % to 35 % MOAH. White oils and paraffin waxes for food applications are characterised by a minimal MOAH content. POSH and ROSH which are formed during polymerisation of polyolefins and hydrocarbon resins are predominantly oligomers. Their signals often overlap with those of MOSH and MOAH.

MOH in foods

Examination results and sources of contribution

Since low molecular weight hydrocarbon compounds are used in many products and processes it is not astonishing to find them also in foods. Since 2011 there are more and more media reports about low molecular weight hydrocarbon compounds in foods, especially because of 2 studies which have been published by the official test laboratory of the canton Zurich[1]. These studies covered analysis of 119 samples of dry food packed in card board boxes (with and without inner plastic bag). Low molecular weight hydrocarbon compounds were found in all foods, partly in high concentrations (4 to 28 mg/kg MOSH and 0.7 to 6.1 mg/kg MOAH, depending on food type and contact time). The authors of the studies consider the measured concentrations as a threat to human health.

The amounts of hydrocarbons found have been attributed to migration from recycled card board, where they originate predominantly from the use of mineral oil containing printing inks from newsprint. These mineral oil parts cannot yet be removed completely during processing of secondary fibres.

Trace contamination from unspecified sources

Since MOH are used in almost all areas of life they are ubiquitous in the environment. Consequently, MOH from many other partly undefined sources can end up in food. Known sources are e. g. hydrocarbons from car or truck fuel (e. g. diesel), compressor oils from compressed air lines, lubricants and sealants from mixers and conveyor belts and also release agents used in the production of metal or plastic containers. Paraffinic hydrocarbons specifically approved for contact with food may partly also be used with these products[3, 4]. Paraffins are also used e. g. in micro emulsions in eco-farming for fruit tress as non-toxic insecticides[5]. Commission regulation (EU) No 2021/1165 allows certain paraffins oils under "Annex I - 4. Active substances not included in any of the above categories"[6]. They can also be the source for MOSH contamination in food.

Plants, e. g. apples, form a natural paraffin wax layer on the skin, peel or husk, they can also be detected as MOSH.

Benchmark values for mineral oil hydrocarbons in food

To gain an overview on the actual values of MOH found in foods the food surveillance authorities in Germany and the Food Federation Germany "Lebensmittel-verband Deutschland e.V." published in April 2019 the first benchmark values obtained from their joint project, covering MOH and analogues in food[7]. These benchmark values were developed from data obtained for MOH in foods by the authorities since 2016.

The benchmark values offer guidance about the source-independent content on mineral oil-like

hydrocarbons (MOH in the sum of MOSH and MOSH analogues (e. g. POSH, PAO, MORE) and MOAH) in certain food types which are to be expected if competent good manufacturing practise is followed; this includes ubiquitarian sources[7].

The values are "recommendations and give guidance for practical use. By definition they are not to be interpreted or used as threshold limit levels. The levels apply to end consumer products and products on the market and represent the state-of-the-art for good agricultural, manufacturing and packaging practice for the respective process chains at the current point in time"[7]. The list covers to date (January 2024) nine food categories and will continue to be updated and extended to further categories.

Health risks associated with low molecular weight hydrocarbon compounds

MOSH and MOAH have different properties and can cause the following problems:

- Shorter chain saturated hydrocarbons (MOSH, especially C16 to C35) are easily absorbed by the body and can accumulate in the organs. Animal studies have shown that such MOSH can accumulate and cause damage in the liver and lymph nodes[8].
- The MOAH fraction is a more complex mixture of predominantly alkylated aromatic hydrocarbons, including some carcinogenic and mutagenic species. Especially the 3 to 7 ring aromatic substances are of particular toxicological concern. Their potential to cause harm is therefore higher than that of MOSH. For this reason, the rejected draft[10] (rejected by the German Second Chamber of parliament "Bundesrat" on 16/12/2022) of the German regulation on mineral oils[9] looked particularly at the MOAH fraction. From our point of view, the assumption of the source being recycling paper was too one-sided. But minimisation of MOAH as contaminant will continue to be relevant.

Risk assessment of the German Federal Office for Risk Assessment (BfR)

The BfR does not consider the measured MOH contamination in foods to be an imminent health risk but they are fundamentally undesirable. Therefore, migration of low molecular weight hydrocarbon compounds into food, e. g. from recycled paper and card board, should be minimised as far as technically possible[8].

There are currently no toxicological studies on the MOH mixtures found in foods via the oral route[8]. Consequently, no appropriate risk assessment is possible at the moment. The BfR cannot exclude at this point that the MOAH fraction contains carcinogenic aromatic substances.

In a BfR opinion on "Highly refined mineral oils in cosmetics" it states that intake via the skin is not considered critical. With lip care products "oral exposure has to be considered" but no negative effects are expected if only MOH are used which have been authorised for use in food.

For the health assessment of such compounds the portion resorbed by the body is decisive. It has to be remembered that such absorbed mixtures are only slowly excreted and therefore may accumulate in the human body.

Statement by the European Food Safety Authority (EFSA)

In a scientific opinion of EFSA on 12th July 2023[15] the authority concludes that "Mineral oil hydrocarbons (MOH) are hydrocarbons mainly derived from crude mineral oil that can enter food from multiple intended and unintended sources. Due to their complexity and variable composition of MOH, their complete chemical characterisation is not possible." Although "there was minimal acute toxicity associated with MOSH", the authority makes several recommendations for MOSH, including improvement of analytical methods, further investigation of sources, formation, biotransformation and additional data on toxicology and human tissue concentrations.

For MOAH the authority stresses that "the genotoxicity of MOH is associated with the presence of some MOAH with three or more aromatic rings." The authority recommends that more data is collected for MOAH, e. g. on sources of contamination, the influence of alkylation on genotoxicity and carcinogenic potential and more detailed information on MOAH in the technical specification of white oils and waxes used as food additives.

The EU Commission had already issued recommendation (EU) No 2017/842 on the monitoring of mineral oil hydrocarbons in food and in materials and articles intended to come into contact with food. Data was collected from 2017 by member states.

Legal situation

EU law

Regulation (EC) No 1935/2004 defines the general requirements for materials and articles which can come in contact with food. At European level there is no specific measure with regards to low molecular weight hydrocarbon mixtures. Regulation (EU) No 10/2011[3] also regulates some MOH mixtures in relation to their use as additives in plastic materials in contact with food. The following MOH mixtures are listed in Annex I (Union list) of (EU) No 10/2011 as additives or polymer production aid:

- **Food Contact Material (FCM) 93:**
  Hydrocarbon wax/oil low viscosity (paraffinic, refined, derived from petroleum based or synthetic hydrocarbon feedstocks)

  The material must comply with the following specification:

  - Average molecular weight not less than 350 Da.
  - Viscosity at 100 °C not less than 2.5 cSt (2.5 × 10-6m²/s).
  - Content of hydrocarbons with Carbon number less than 25 not more than 40 % (w/w).

  NB:
  The specific migration limit (SML) of this material is set at 0.05 mg for 1 kg of food. In addition the material must not be used for articles in contact with fatty foods for which simulant D1 and/or D2 is laid down.

  In the course of a new assessment on this material by EFSA in February 2023 it was concluded that there should be no safety concerns if the migration is below 5 mg/kg[12.]

- **Food Contact Material (FCM) 94:**
  Hydrocarbon wax/oil high viscosity (refined, derived from petroleum based or synthetic hydrocarbon feedstocks)

  The material must comply with the following specification:

  - Average molecular weight not less than 500 Da.
  - Viscosity at 100 °C not less than 11 cSt (11 × 10-6 m²/s).
  - Content of mineral hydrocarbons with Carbon number less than 25, not more than 5 % (w/w).

  NB:
  A specific migration limit (SML) has not been set.

- **Food Contact Material (FCM) 95:**
  White mineral oil (paraffinic, derived from petroleum based hydrocarbon feedstock)

  The material must comply with the following specification:

  - Average molecular weight not less than 480 Da.
  - Viscosity at 100 °C not less than 8.5 cSt (11 × 10-6 m²/s).
  - Content of mineral hydrocarbons with Carbon number less than 25, not more than 5 % (w/w).

  NB:
  A specific migration limit (SML) has not been set.

In addition, hydrocarbon resins which can also contribute to the MOSH and MOAH fraction are also covered as FCM 97.

- **Food Contact Material (FCM) 97:**
  Petroleum hydrocarbon resin, hydrogenated

  The material must comply with the following specification:

  - 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

  NB:
  A specific migration limit (SML) has not been set.

According to regulation (EC) No 1333/2008 of the European Parliament and the Council of 16th December 200816 on food additives microcrystalline waxes (E 905, FCM 94) are permitted without restrictions on the amount (quantum satis) for surface treatment only: fruit (melons, papayas, mangoes, avocados and pineapples), chewing gum, "05.4 Decorations, coatings and fillings, except fruit-based fillings covered by category 4.2.4" and "05.2 Other confectionery including breath freshening micro-sweets", Such use must follow Good Manufacturing Practise.

Commensurate with Regulation (EU) No 231/2012[4] 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, waxes are defined as "Refined mixtures of solid, saturated hydrocarbons, obtained from petroleum or synthetic feedstocks". The molecular weight average must be at least 500 Da, the viscosity must be not less than 1.1 × 10^{-5} m² s^{-1} at 100 °C or not less than 0.8 × 10^{-5} m² s^{-1} at 120 °C, if solid at 100 °C. The carbon number at 5 % distillation point must not be more than 5 % of molecules with carbon number less than 25. Further restrictions are set for the presence of polycyclic aromatic hydrocarbons.

At the end of April 2022 the Standing Committee on Plants, Animals, Food and Feed (SC PAFF) published detection limits for MOAH in foods[13], which are de facto new limits for MOAH as contaminants in food. The values for the various food categories are listed in the table below:

Food type	Detection limit in mg/kg
dry foods with a low fat/oil content (≤ 4% fat/oil)	0.5
foods with a higher fat/oil content (> 4% fat/oil)	1
fats/oils	2

As of August 2024 an amendment of the regulation (EU) No 2023/915 on maximum levels for certain contaminants in food[28] is in preparation to include new limits of MOSH and MOAH.

German legislation

The draft published on 19/08/2022[9] which was rejected by the Second Chamber of the German parliament (Bundesrat) on 16/12/2022[10] for an "ordinance on mineral oil" (Zweiundzwanzigste Verordnung zur Änderung der Bedarfsgegenständeverordnung, 22nd amendment on the German Ordinance on Commodities) emphasized avoiding migration of MOH from recycled paper through use of barrier layers. However, such barrier layers would impede paper recycling. Had the ordinance as set out in the draft become law, the migration of MOAH of an article made from recycled paper would not have been allowed above the set detection limits (0.5 mg/kg in foods themselves or 0.15 mg/kg for food simulants).

During the session of the "Bundesrat" on 16/12/2022 when the new ordinance was refused, the German government was asked to work on a technically feasible and economically reasonable provision to minimize migration of MOAH in printing inks from the paper and board circuit[11].

French legislation

France has a national regulation[17] which prohibits the use of mineral oil compounds in packaging if they have a potential to disrupt recycling. A Decret[18] and two Arretes[19, 20] further elaborate this. Initially, the rules only apply to printing inks.

Swiss legislation

The Ordinance of the FDHA on Materials and Articles in contact with food[21] contains a section on commodities made of recycled paper and board (section 9). Art. 27 demands that only unprinted production scrap of fresh fibres which fulfil the requirements applicable to them can be used, or it can be proven that the migration of components fulfils the requirements of Art. 49 of the Food and Commodity Regulation[22]. The latter can also be achieved by the use of a suitable barrier layer or adsorbent agent.

According to section 10, art. 28 of this ordinance paraffins and waxes must fulfil the requirements of the Pharmacopoea Helvetica and have to be free of carcinogenic substances.

For non-evaluated mixtures a migration limit of 0.01 mg per kg of food (10 ppb) applies provided they are not CMR substances.

Legislation in the USA

Although the provisions for mineral oil components in the USA according to relevant FDA rules are not applicable in Europe they are sometimes asked for, especially if commodities are also delivered to countries which follow US FDA rules.

In these cases the requirements for MOH as direct or indirect food additive are of relevance. White mineral oils are cleared through paragraphs 21 CFR 172.878 and 21 CFR 178.3620. 172.828 describes the criteria for use as direct food additive (for use in feed additives paragraph 21 CFR 573.680 is applicable). Specifications for applications for indirect food contact are included in 21 CFR 175.105. Furthermore, substances Generally Recognized As Safe (GRAS) and details from paragraphs 176.170, 176.200, 176.210, 177.2800, 178.1200, 178.2010, 178.3650, 178.3710, 178.3720, 178.3740, 178.3860 and FCN (food contact notifications) can be used for assessments.

Low molecular weight hydrocarbon compounds in paper and packaging adhesives

MOH are also found in various adhesive systems. They may be components of the formulation or substances are introduced as components of raw materials into the formulation.

- **Water-based adhesives/dispersions**

  Water-based adhesives can contain MOH based formulation components, e. g. defoamers. Typically, the maximum concentration of the defoamer in the formulation does not exceed 0.5 %. MOH based raw materials used in defoamers for adhesives for food contact commodities should fulfil the requirements of FCM 95.

  Typical application of such adhesives are packaging, lamination and labelling.

- **Hot melt adhesives**

  Ethylene vinyl acetate and polyolefin hot melts for food contact commodities can contain MOH, e.g. from paraffin waxes used as component in the adhesive. Such raw materials should fulfil the requirements of FCM 93 or 94.

  Typical applications for these hot melts are carton closing and lamination.

  The European adhesive association FEICA published a study in October 2021, carried out by the laboratory Lommatzsch & Säger[23], demonstrating that typical packaging hot melts fulfil the requirements of the EU framework regulation.

- **Pressure sensitive adhesives**

  Pressure sensitive adhesives for food contact commodities may contain approximately 10 % to 30 % MOH in the formulation in addition to polymers and resins, e. g. white oils (FCM 95).

  Typical applications of these adhesives are self-adhesive labels and packaging tapes.

How is the adhesive industry affected?

So far the discussion on sources of MOH in food concentrates mainly on printing inks and their influence on the quality of recycled paper board for food packaging. But there are already publications which also name adhesives as potential source of MOH.

In reaction to such publications there are more and more food packaging producing companies or those using food packaging asking for “mineral oil free” adhesives. Such requests don’t distinguish between MOH from FCM and MOH from non-FCM as they cannot be analytically distinguished.

Besides, it cannot be excluded that the legislator will pass regulation on low molecular weight hydrocarbon compounds and mixtures used in areas close to food – there could be consequences, e. g. regarding the availability of adhesive raw materials. Such German legislation from the Federal Ministry of Food and Agriculture (BMELV) in the form of the so-called “mineral oil ordinance” has already been rejected by the “Bundesrat” on 16/12/2022 as mentioned above. Instead the German government was asked to work on a technically feasible and economically reasonable provision to minimize migration of MOAH in printing inks from the paper and board circuit[10, 11].

How can adhesive companies contribute to the reduction of MOH in food contact commodities?

In connection with adhesives there are basically two entry paths for MOH into foods:

a) Migration of MOH from adhesives utilised in the manufacture and use of food contact commodities.
b) Migration of MOH from recycled paper and board where MOH containing adhesives have been applied in the used paper products

The means to reduce or substitute MOH for the two entry paths mentioned above are described below.

Adhesives for manufacture and conversion of food contact commodities

In order to estimate the risk of migration of MOH into foods it is recommended as a first step to carry out a risk assessment of the intended application for the adhesive, i. e. it should be questioned if, considering the barrier properties of the packaging material, there exists a direct migration potential (absolute or functional barrier – e. g. glass or plastic).

If there is the risk of migration the used mineral oil components must be checked whether they have been toxicologically assessed, i. e. if they are listed in e. g. Annex I (Union list) regulation (EU) No 10/2011. If this is not the case then further measures should be considered:

Transmit information to the downstream user/customer:
The adhesive manufacturer should list the non-evaluated low molecular weight hydrocarbon compounds or mixture as substance with a restriction (10 ppb) and the maximum expected concentration, serving as basis for a risk assessment of the downstream user/customer. The information template[24] suggested by the Technische Kommission Papier- und Verpackungsklebstoffe (TKPV) should be used for this.

Adhesives for paper products which are recycled

Apart from the direct migration of MOH from food contact adhesives into food, the path via paper recycling should also be considered.

Because there are no methods to completely remove MOH in the paper recycling process, it is possible that adhesive components enter food via recycling paper, although only in small amounts.

In contrast to the plasticiser diisobutyl phthalate (DIBP) which voluntarily hasn’t been used by the German

adhesive industry since 2009 as part of their responsible care it is not technically feasible to completely substitute MOH in adhesives in the short term; however, the adhesive industry works with full stretch to reduce non-evaluated MOH in recycling paper. Thus, the German adhesive industry also supports the environmentally rational paper recycling, also for the manufacture of food contact packaging made of paper & board.

In May 2023 FEICA published an update on the "Guidance for evaluating the food contact status of adhesives containing mineral oil hydrocarbons"[25] on the topic of mineral oil which also supports the measures suggested by the German adhesive association "Industrieverband Klebstoffe e.V.".

The statement also agrees with the toolbox[26] published in December 2017 by the German food association "Lebensmittelverband e.V." (previously BLL "Bund für Lebensmittelrecht und Lebensmittelkunde e.V."). This toolbax contains some background information and practical guidance which can be used by companies to minimise MOH in foods in their manufacturing process.

In spite of these important contributions to paper recycling by the German and European adhesive industry there remains the problem that MOH from imported paper products enter the recycling circuit, with the risk of further accumulation in the recycling process.

The use of a barrier preventing migration of undesirable substances between recycled paper board and the food is not only a technically wise but also a short term solution to protect the consumer. This solution is favoured by the German Federal Ministry of Food, Agriculture and Consumer Protection8 but it also has some disadvantages for paper recycling because of the use of plastic materials as barriers.

Summarised assessment

Generally, it needs to be considered regarding the topic of MOH in foods that there exist many potential sources, thus this has to be tackled as a problem of contaminants in a holistic manner, as already described by the representatives of the surveillance authorities[27]. An important step towards this is the already mentioned monitoring project by the EU, which started in 2017[2]. It is very probable that further studies are necessary to assist the risk assessment in order to establish future generally accepted limits.

In this context the established benchmark values by the German surveillance authorities in connection with the Food Federation Germany "Lebensmittelverband Deutschland e.V." are an important contribution.

After discussion of the mineral oil problem by the public for many years, it is now generally recognised that aromatic hydrocarbons which are included in the MOAH fraction have a higher potential to harm human health than aliphatic hydrocarbons from the MOSH fraction. For this reason the regulatory activity deals almost exclusively with the MOAH fraction.

However, it should be noted that parts of the MOSH fraction have been toxicologically assessed by EFSA and approved for use in food contact. This important distinction between the hazardous aromatic and the less hazardous saturated hydrocarbons is unfortunately not taken into account in the public discussion.

Until limits are agreed for MOH all players in the food supply chain should continue to use the ALARA principle (as low as reasonably achievable) to further reduce the amounts of such contaminants. As already mentioned above, the emphasis should be on the reduction of MOAH because they are considered to be more hazardous than saturated MOH.

References:

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2 Recommendation (EU) No 2017/84 of the Commission on the monitoring of mineral oil hydrocarbons in food and in materials and articles intended to come into contact with food

3 Regulation (EU) No 10/2011 of the Commission on 14th January 2011 on plastic materials and articles intended to come into contact with food (including amendments, last on 10th August 2023 by (EU) No 2023/1627)

4 Regulation (EU) No 231/2012 of the Commission on 9th March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 (including amendments, last on 22th January 2024 by (EU) No 2024/346).

5 Oekologischer Landbau, Julius-Kuehn.de (Autoren: Stefan Kühne, Britta Friedrich JKI, Institut für Strategien und Folgenabschätzung, Kleinmachnow)

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18 Décret no 2020-1725 du 29 décembre 2020 [Journal Officielle de la République Française vom 30. Dezember 2020]

19 Arrêté du 1er octobre 2021 [Journal Officielle de la République Française vom 27. Oktober 2021]

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