Mineral oil hydrocarbons in food: adhesives for food packaging as a source

Executive Summary

In 2011, health concerns were raised after studies were published indicating that consumers could be exposed to mineral oil hydrocarbons (MOH) in foodstuffs as a result of migration of the oils from printing inks in recycled paper. The studies were published by the Official Food Control Authority of the Canton of Zurich, Switzerland.

Types of mineral oil hydrocarbons

The term mineral oil is imprecise and encompasses a wide range of mixtures of hydrocarbons. Mineral oil hydrocarbons (MOH) are generally classified into two categories:

- 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.

However, even this categorisation is difficult due to a lack of a precise definition of MOSH and MOAH.

Sources of mineral oil hydrocarbons in food

The European Food Safety Authority Panel on Contaminants in the Food Chain (CONTAM Panel) identified the following potential sources of mineral oil hydrocarbons in food (EFSA 2012 “Scientific Opinion on Mineral Hydrocarbons in Food”, The EFSA Journal 10(6):2704, pp 140 - 141):.

Food contact materials:

- Food packaging materials made from recycled paper and board.
- Off-set printing inks applied to paper and board for food packaging.
- Mineral oils used as additives in the manufacture of plastics for food contact (e.g. internal lubricants in polystyrene, polyolefins).
- Wax paper and board.
- Jute or sisal bags with mineral batching oil.
- Lubricants for can manufacture.
- Wax coating directly applied to food.
- In addition, some types of adhesives may contain mineral oil components. Systematic studies on the migration from adhesives have not been carried out.
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.
- Authorised paraffinic waxes (e.g. for chewing gum or coating of certain fruits).
- Pesticide formulations.
- Anti-dusting agents for cereals.

Potential health issues

MOSH and MOAH exhibit the following properties:

- MOSH, mainly the fraction comprising carbon chains of 16 - 35 atoms (C16 - C35), may accumulate in the human body, especially in lymph nodes, the spleen and the liver. However, this has not been associated with adverse health consequences.
- The MOAH fraction may be both mutagenic and carcinogenic, and is considered by the European Food Safety Authority Panel to be of more concern than the MOSH fraction.

Because of the diverse nature of MOH, there is a lack of reference standards for exposure and information relating to actual health effects in practice. Although the European Food Safety Authority identified potential concern about MOH in food, it acknowledged considerable uncertainties in assessing any potential risks and concluded that further studies were needed (see Technical Appendix).

Some mineral oils are approved by the European Food Safety Authority for food contact (see Technical Appendix). These mineral oils should not contain any MOAH, only MOSH. In contrast, so-called “technical grade” mineral oils are not approved for food contact and typically contain 15 - 35% MOAH. These grades contain also a high amount of MOSH.

Testing for mineral oil hydrocarbons

The most frequently used testing method is the Koni Grob test, published by the Zurich Cantonal Laboratory (KLZH) and Germany’s Federal Institute for Risk Assessment (BfR). However, this test method is not able to differentiate between MOH and other substances with a similar chemical structure, such as long-chain alcohols or acids. As a result, detected levels of MOSH and POSH (polyolefin oligomeric saturated hydrocarbons) can be overestimated. The use of a mass spectrometer (MS) detector would provide a more accurate measurement and a more realistic picture of the actual levels of MOH.
Conclusions from the EFSA Opinion

In June 2012 the European Food Safety Authority (EFSA) published its “Scientific Opinion on Mineral Hydrocarbons in Food” (The EFSA Journal 2012; 10(6):2704). This concluded there is a need for:

- Further studies on the possible hazards posed by the various mineral oil fractions.
- Improved analytical methods and monitoring systems to enable better assessment of the risks caused by mineral oil hydrocarbons.
- An investigation into how applicable the findings of animal studies regarding MOH are to humans.
- A detailed evaluation of the toxicological impact of mineral oil hydrocarbons.

The role of adhesives

The potential contribution of adhesives to the presence of mineral oils in food arises through the use of adhesives for food packaging. Depending on the nature of the packaging material and its production process, adhesives will not be the main source of mineral oils in the packaging. As a result, full compliance to article 3 of the Framework Regulation ((EC) No. 1935/2004 on materials and articles intended to come into contact with food) can only be addressed by the manufacturer of the final packaging material because only they have oversight of all the components of the packaging. To assist in this process, adhesive companies are obliged to provide packaging manufacturers with information about the adhesives they supply.

Adhesives manufacturers refer to Regulation (EU) No. 10/2011 for guidance on mineral oil hydrocarbons. The regulation covers white mineral oil, two paraffin waxes and hydrogenated hydrocarbon resin (FCM 95, 94, 93 and 97 respectively, as explained in the Technical Appendix).

FEICA’s response

FEICA represents Europe’s adhesive manufacturers. These manufacturers are committed to continuous improvement in the health and safety aspects of their products. Consequently, FEICA has been working in collaboration with specialists from the adhesive manufacturers and the various players in the packaging supply chain to:

- Ensure adhesive manufacturers provide packaging manufacturers with as much information as possible about the adhesives used to allow them to carry out their own risk assessments.
- Encourage adhesive manufacturers to substitute unlisted mineral oil hydrocarbons with authorised ones (FCM 93, 94, 95, 97).

To this end, FEICA’s technical experts and the specialists from the adhesive manufacturers have developed a set of recommendations to help the industry reduce or eliminate the amount of suspect mineral oil hydrocarbons coming into contact with foodstuffs. These recommendations are summarised in the Technical Appendix.
Technical Appendix

The European Food Safety Authority opinion

The European Food Safety Authority opinion, published 6th June 2012, specifies the types of mineral oil hydrocarbons approved for food contact, as detailed in this excerpt:

“Regulation (EC) No. 1935/2004 lays down the general provisions and principles for food contact materials and articles. There are no specific measures regarding mineral oil hydrocarbons, except for the provisions on their use as additives in plastic materials and articles intended to come into food contact laid down by Regulation (EU) No. 10/2011. The following mineral oil components are covered by the positive list of additives:

a. FCM substance No. 95: White mineral oils, paraffinic, derived from petroleum-based hydrocarbon feedstock. No specific migration limit (SML) is defined (i.e. its use is restricted only by the overall migration limit of 60 mg/kg food or 10 mg/dm² food contact surface). 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 mm²/s at 100°C;
   - average molecular weight not less than 480 Da.

b. FCM substance No. 94: Waxes, refined, derived from petroleum-based or synthetic hydrocarbon feedstock. No SML is specified (i.e. its use is restricted only by the overall migration limit). 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 mm²/s at 100°C;
   - average molecular weight not less than 500 Da.

c. FCM substance No. 93: Waxes, paraffinic, refined, derived from petroleum-based or synthetic hydrocarbon feedstock. An SML of 0.05 mg/kg food is specified. In addition, these oils 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 mm²/s;
   - average molecular weight not less than 350 Da.”

d. FCM substance No. 97: Petroleum hydrocarbon resins, hydrogenated
   - 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

In addition, one mineral oil component is approved as food additive and has an “E” number: Microcrystalline wax (E 905) is approved for use in the surface treatment of confectionery (excluding chocolate), chewing gum, melons, papaya, mango and avocado.

Mineral oils in adhesives used for food packaging

The following types of adhesives used in packaging applications may contain mineral oil components.
**Water-based adhesives**

Water-based adhesives for some specific applications may contain MOH from the defoamer (typically maximum concentrations are not higher than 0.5%). Usually these defoamer are food contact compliant (FCM 95).

Typical applications: Packaging construction, labelling, paper lamination.

**Hotmelts**

Some hotmelts contain mineral oil hydrocarbons, for example some ethylene vinyl acetate and polyethylene-based hotmelts for case and carton sealing. Sometimes, MOH can be detected coming from the paraffinic waxes. Where migration cannot be excluded, these mineral oil components should comply with relevant food contact legislation (FCM 93, 94, 95).

Typical applications: Case and carton sealing, lamination.

**Pressure-sensitive adhesives**

a. Most hotmelt pressure-sensitive adhesives contain mineral oils. Normally, block polymers are used, which may contain 10 – 30% mineral oil. For food contact applications where migration can be expected to occur, this should be a white mineral oil compliant with FCM 95.

Typical applications: Labelling, tapes, packaging tapes, resealable packs.

b. Water based pressure-sensitive adhesives may contain MOH from the defoamer (see waterbased adhesives above)

Typical applications: Coldseals, self-adhesive labels

**FEICA’s recommendations for the adhesive industry**

As a first step, adhesive manufacturers should make a risk assessment of the intended use of their adhesives, for example what type of barrier will there be between the adhesive and the foodstuff. If there is a risk of migration, the adhesive manufacturer needs to check whether the mineral oil components are compliant with Regulation [EU] No. 10/2011 (FCM Nos 93, 94, 95, 97).

If this is not the case, the adhesive manufacturer should follow these steps to ensure that their adhesives are fit for their intended use.

**Water based adhesives with expected food contact:**

- Check whether the mineral oil can be replaced by another oil or silicones that are compliant with the relevant food contact legislation.
- If this is not possible, request compositional information from the supplier of the defoamer used in the adhesive and reduce the content of the mineral oil defoamer as much as possible in order to reduce any cyclic naphthenic and/or aromatic hydrocarbons.
Food Contact Status: List mineral oil defoamer as a substance with restriction (10ppb), in the specific migration limit (SML) table with a maximum expected concentration (in order to enable risk assessment by the downstream user).

**Hotmelts with expected food contact:**

- Check whether mineral oil components can be replaced by components complying with FCM Nos 93, 94, 95 or 97.
- If this is not possible, request more detailed raw material information from the supplier (e.g. carbon number distribution, content of aromatic hydrocarbons, etc.) and reduce the content of the mineral oil components as much as possible.

Food Contact Status: If the risk of migration of mineral oil components into the food cannot be excluded, a functional barrier is recommended.

**Pressure sensitive adhesives (hotmelt) with expected food contact**

- Check whether mineral oil components can be replaced by components complying with FCM Nos 93, 94, 95 or 97.
- In the case of block polymers, the replacement of oil is more difficult and the use of more refined oil with less naphthenic / aromatic components should be considered.
- If mineral oil components cannot be avoided, request more detailed raw material information from the supplier (e.g. carbon number distribution, content of aromatic hydrocarbons etc.)

Food Contact Status: If the risk of migration of mineral oil components into the food cannot be excluded, a functional barrier is recommended.

**Pressure sensitive adhesives (water based) with expected food contact:**

- Check whether the mineral oil can be replaced by another oil or silicones that are compliant with the relevant food contact legislation.
- If this is not possible, request compositional information from the supplier of the defoamer used in the adhesive and reduce the content of the mineral oil defoamer as much as possible in order to reduce any cyclic naphthenic and/or aromatic hydrocarbons.

Food Contact Status: List mineral oil defoamer as a substance with restriction (10ppb), in the specific migration limit (SML) table with a maximum expected concentration (in order to enable risk assessment by the downstream user).
References


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