



**FOOD SURVEY
INFORMATION SHEET**

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**A 4-YEAR ROLLING PROGRAMME OF SURVEYS ON CHEMICAL MIGRANTS FROM
FOOD PACKAGING MATERIALS AND ARTICLES**

**SURVEY 4: MIGRATION OF SELECTED INK COMPONENTS FROM PRINTED
PACKAGING MATERIALS INTO FOODSTUFFS AND SCREENING OF PRINTED
PACKAGING FOR THE PRESENCE OF MINERAL OILS**

Summary

- The Food Standards Agency (FSA) has an ongoing programme of surveys looking at the components of food packaging and articles that may migrate from these materials into food;
- The fourth survey in this programme looked at whether there was any migration of components from printing inks used on carton-board packaging into food;
- The FSA also looked at whether there were any mineral oils, which are found in some printing inks and adhesives, present in some of the carton board samples taken for this survey;
- The FSA carried out a risk assessment on the findings from this survey and did not identify any specific food safety concerns;
- The FSA's advice is that there is no need for consumers to change their eating habits with respect to food that has been packaged in virgin or recycled carton-board;
- The European Food Safety Authority (EFSA) is expected to issue an opinion on mineral oils in spring 2012. The FSA will take this opinion into account and commission further work on mineral oils in food and food packaging if necessary. The FSA will also review its advice to consumers and change it if appropriate.

Background

1. Printing inks and related materials, such as primers, lacquers and varnishes (subsequently referred to as 'printing inks') are used on packaging for labelling information to consumers, such as ingredients listings. Printing inks contain a number of components such as colorants and pigments, binders (materials that hold the printing inks together), additives (e.g. plasticisers which make the ink flexible within the packaging) and photoinitiators (chemicals used in printing inks to speed up the drying process of the ink using ultra violet light).
2. Mineral oils are a group of substances consisting of different complex chemical structures. Mineral oils are classified on the basis of their physical characteristics, such as viscosity (consistency) and density, rather than on the basis of their precise chemical structure.
3. Mineral oils can be found in small quantities in some adhesives, where they are used as defoamers. Mineral oil-based inks have previously been used for food packaging and continue to be primarily used to print newspapers. Recycled newspapers can be used in the manufacture of carton-board food packaging materials. If foodstuffs are packaged in such materials then, depending on the overall type of packaging, mineral oils may migrate into these foodstuffs.

The law on printing inks and mineral oils

4. Components of food packaging and other articles (for example, spoons and saucepans) that may migrate into food are covered by European Union (EU) legislation. This legislation sets limits, called specific migration limits (SMLs), for the amount of these components permitted in food as a result of migration.
5. There are no SMLs for printing inks and mineral oils in carton-board food packaging. However as a final component of a packaging material, printing inks and mineral oils must meet the more general requirements of Framework Regulation (EC) No. 1935/2004¹. This requires that under normal and foreseeable conditions of use, packaging materials do not transfer their components into food at levels which could:
 - endanger human health; or
 - bring about an unacceptable change in the composition of food; or
 - bring about deterioration in the organoleptic characteristics (i.e. texture, taste, aroma) of the food.
6. Printing inks should also be manufactured according to other EU legislation, specifically Commission Regulation (EC) No. 2023/2006, on Good Manufacturing Practice. Annex I of this relates to inks.² The FSA is not aware of any current intention of the EU to set limits for components of printing inks or mineral oils in paper and board food packaging.

7. A small number of mineral oils can also be used as food additives such as glazing agents to coat food. Food additives are substances intentionally added to food to carry out a specific function, for example preservatives used to increase the shelf life of food. The UK Mineral Hydrocarbons in Food Regulations 1966 (SI 1966/1073)³, prohibit the use of mineral oils directly added to food with the exception of the following:
- chewing gum;
 - lubricants or greasing agents used on surfaces and which come into contact with food during its preparation;
 - the rind of whole pressed cheese;
 - as an additive in any food allowed according to EU food additives legislation (Regulation 1333/2008).

The safety evaluation of printing inks and mineral oils

8. Toxicologists make assessments of the potential risk that specific substances may pose to consumers. For food, Acceptable Daily Intakes (ADIs) are set to quantify the amount of a substance that a person may consume daily over a lifetime without any appreciable health risks. SMLs are set to ensure that consumers intake of the substance in question will be within its ADI.
9. There are independent risk assessment bodies who undertake such work. EFSA carries out risk assessments in Europe. Internationally, the Joint FAO/WHO Expert Committee on Food Additives (JECFA) undertakes risk assessments. JECFA is sponsored and administered by the Food and Agriculture Organisation of the United Nations (FAO) and World Health Organisation (WHO).
10. Some printing inks have been evaluated by EFSA (see Annex 1, Table 1). The most extensive toxicological evaluation of mineral oils was carried out by JECFA in 2002⁴.
11. JECFA assigned ADIs to different mineral oils as follows:
- High viscosity mineral oils - ADI of 0 – 20 mg/kg body weight per day;
 - Medium and low viscosity mineral oils (class I)- ADI of 0 – 1 mg/kg body weight per day; and
 - Medium and low viscosity mineral oils (class II and III)- ADI of 0 – 0.01 mg/kg body weight per day.
12. Some mineral oils assessed by JECFA contain aromatic chemical structures. Some chemicals containing aromatic structures have previously been associated with possible health effects. Although JECFA and EFSA have not previously carried out a toxicological evaluation of aromatic mineral oils, EFSA has requested data on aromatic mineral oils to help inform its forthcoming risk assessment.

13. In 2010, EFSA set an ADI of 12mg/kg body weight per day for high viscosity mineral oils (for food additive use). An EFSA Working Group has been set up to look at mineral oils.⁵ It is expected that findings will be presented in spring 2012.
14. The JECFA ADIs set for medium and low viscosity mineral oils (class I to III) were set on a temporary basis due to insufficient toxicological data. Part of the EFSA Working Group's review of mineral oils will assess whether there is now sufficient toxicological data to set a full ADI. However, it is too early to speculate upon EFSA's conclusions and its relevance to this survey.

Available analytical methodology for mineral oils

15. New laboratory methods have been developed for studying mineral oils. However, due to their chemical complexity, this is not straightforward. A limitation of the current laboratory methodology is that the different types of mineral oils present in carton-board food packaging cannot be separately identified. Significant expertise is also required to interpret the test results. This means that this new methodology does not comply with all the standardisation requirements under EU legislation on analytical methodology.
16. The Canton of Zurich laboratory has the most experience and expertise in the analysis of mineral oils and the method used for this survey represents the best available at the current time. They have developed a method for identifying mixtures of different mineral oils contained within the following groups: MOSH (mineral oils saturated hydrocarbons) and MOAH (mineral oils aromatic hydrocarbons). The individual mineral oils within these mixtures cannot be identified by the current laboratory methodology.
17. Previous work in this laboratory reported that these mineral oils can migrate from carton-board food packaging into food and that these mineral oils are similar in size to the low and medium viscosity mineral oils for which JECFA set the lowest ADI (temporary) of 0.01mg/kg bw/day. The Zurich laboratory used this ADI to derive a non-statutory migration limit of 0.6mg/kg for the mineral oils found in this previous work. The BfR (the German Federal Institute for Risk Assessment) reported that they did not have sufficient data to carry out a food safety risk assessment for consumers on the levels of mineral oils detected.⁶

FSA study on printing inks and mineral oils

18. The FSA has an ongoing four year programme of surveys on food packaging and articles. The last year of this survey focused on the migration of selected ink components from printed carton-board packaging materials into food.
19. The survey samples were also used to look for mineral oils in a selection of carton-board packaging materials. This was prompted by previous work which indicated that mineral oils are typical components of carton-board packaging

materials. Previous FSA research and surveillance on printing inks and mineral oils is provided in Annex 3.

20. A total of 350 food products packaged in virgin and recycled carton board were purchased for this survey from a variety of retail outlets throughout the UK. All samples were heavily printed. The sample details, including brand names, batch numbers and best before dates and the retail outlets from which the samples were obtained are provided in Annex 1, Table 2.
21. The foodstuffs were tested for 20 printing ink substances selected on the basis of previous knowledge of their potential to migrate from food packaging into food. Analysis of the packaging materials was carried out to ascertain whether the printing ink components in the food had migrated from the packaging material. It cannot be discounted that the ink components detected may have come from a source other than the packaging, for example the use of waste paper as compost, the components of which may then transfer into food at low levels. However, this is unlikely. The standard operating procedure (SOP) for the analysis of the packaging and foods for printing inks is shown in Annex I. The majority of the selected substances are photoinitiators but some are plasticisers and binders. The selected substances and the background to their selection are provided in Annex 1, Table 1.
22. The FSA survey did not analyse mineral oils in foods because this part of the survey was only intended to be a screening exercise to ascertain whether mineral oils were present in carton-board packaging material. Due to the limited availability of laboratories to analyse mineral oils in food packaging, the contractor carried out the work at the Canton of Zurich laboratory whose staff have the expertise and analytical capability in this area where previous work had been done. The FSA carried out a preliminary risk assessment.

Results

Printing Inks

23. Details of the selected ink components measured in the foodstuffs are given in Annex 1, Table 3. Twenty seven of the 350 samples tested contained one or more of the selected ink components assigned to each for the purposes of this survey. Benzophenone (a photoinitiator) was detected in 37 (11%) of the samples. Other samples contained mixtures of one or more of 1-hydroxycyclohexyl phenyl ketone, ethyl-4-dimethylaminobenzoate, 2,2-dimethoxy-2-phenylacetophenone, methyl-2-benzoylbenzoate, 2-ethylhexyl-4-dimethylaminobenzoate and 4-phenylbenzophenone.

Mineral Oils

24. The results of this study show that some of the packaging materials contain mineral oils and that the levels found are similar to those reported in previous published literature. MOSH was detected in all 51 samples tested.

Concentrations of MOAH exceeded the limit of detection in 17 of the 51 samples tested.

25. The MOSH and MOAH concentrations in the packaging samples are given in Annex 2, Table 2.
26. It has not been possible in all cases to determine whether the carton-board packaging had been recycled. Therefore, it was not possible to make a comparison of the levels of mineral oils found in recycled carton-board and non-recycled carton-board packaging in this study.

FSA risk assessment

Printing Inks

27. There is limited toxicological data available for many of the substances included in this survey. An FSA risk assessment of the levels found in the foodstuffs has been made using available toxicological data and the published EFSA opinion on benzophenone⁷. Data from related substances has been used where appropriate in the absence of data on specific substances. Based upon our risk assessment, the results do not indicate that any of the selected ink components in the foodstuffs analysed give rise to any concerns in relation to human health. No action has therefore been taken by the FSA on these results.

Mineral Oils

28. The FSA has also carried out an initial risk assessment on the levels of mineral oils detected in the food packaging to consider whether there was a potential risk to consumers. Our risk assessment assumed that all the mineral oils detected in the packaging could potentially migrate into food. It also assumed that portions of certain foods were consumed on a daily basis. This approach tended to over-estimate the potential risk to consumers from exposure to mineral oils.
29. The current limited toxicological data on many mineral oils means that there is uncertainty in assessing the risk to consumers from the results of this study. Nevertheless, on the basis of the levels of mineral oils found in the food packaging and the assumptions used in our risk assessment, the FSA does not consider that the presence of mineral oils in the packaging at the levels found indicate any specific food safety concerns (see Annex 4 for further details).

Conclusion

30. The Canton of Zurich laboratory assumed that the lowest ADI of 0.01mg/kg applied to all the mineral oils in packaging and food. From this assumption, they derived their own migration level of 0.6mg/kg for all mineral oils.

However, the current laboratory methodology cannot identify which type, or how many, of the different mineral oils assessed by JECFA (with ADIs ranging from 0.01-20mg/kg) are present in the packaging. It is therefore not currently possible to determine whether the chemical nature of the mixture of different mineral oils comprising MOSH and MOAH are the same as the mineral oils assigned ADIs by JECFA, and therefore which of the ADIs, if any, should apply. The FSA has not applied the ADI of 0.01mg/kg to all mineral oils and therefore did not derive a 0.6mg/kg level from its risk assessment.

31. The printing ink results from this survey do not identify any concerns in relation to human health and demonstrate a reduction in the number of food samples containing benzophenone, compared with FSA work undertaken in 2006⁸. The FSA position is that consumer's exposure to mineral oils in carton-board food packaging is not a risk to consumer's health. The FSA's advice is that there is no need for consumers to change their eating habits with respect to food that has been packaged in virgin or recycled carton-board.
32. The FSA will consider the EFSA opinion on mineral oils, due to be published in spring 2012. We will also continue to monitor developments in laboratory methodology. Further work on mineral oils in foods in contact with carton-board may be considered in the light of these future developments.

Annex 3 Other FSA research and surveillance on printing ink and mineral oils

Printing inks

The FSA published a survey on the photoinitiator benzophenone in carton-board food packaging in October 2000.⁸ 49 out of 350 samples of printed carton-board were found to contain measurable amounts benzophenone. No adverse health effects were expected in an individual's lifetime from the levels found in the survey.

The FSA published a follow-up survey entitled "Benzophenone and 4-hydroxybenzophenone migration from food packaging into foodstuffs" in 2006⁹. This survey tested 350 foodstuffs that had been packaged in printed paper or board (virgin or recycled). 4-hydroxybenzophenone was not confirmed in any of the samples tested. Benzophenone was confirmed in 61 of the 350 samples tested. Levels found were not considered a health concern.

The FSA published a research report assessing the migration potential of substances, including reaction and breakdown products, from inks and coatings used in food contact applications in 2007¹⁰. The report provides a list of the significant impurities and breakdown products and ranks them according to their toxicity, potential abundance, mobility and molecular weight.

The FSA is also currently carrying-out a piece research to establish screening test procedures capable of measuring the extent of set-off of a wide range of ink components to the food contact surface of packaging.¹¹ We anticipate this will be published early in 2012.

Mineral oils

The FSA carried out surveillance in 2003 on mineral oils in food contact materials¹². Consumer intakes of wax and oils migrating into food were within the range of ADIs set by JECFA. However, this surveillance did not analyse for MOSH and MOAH and focused on paraffinic waxes which are high viscosity mineral oils. Nevertheless, levels of mineral oils found were within the ADIs set by JECFA for this type of mineral oil.

The FSA is also currently carrying-out a related piece of research to gain knowledge of typical substances that would always be present in plastic and paper & board materials before they are recycled as a result of their first use, but which should be effectively removed by the recycling process¹³. This research has just begun and we anticipate it will be published in two years time. Unfortunately it has not been possible to include mineral oils in this study. However, it will provide information on the safety of recycled materials for consumers.

Annex 4 - Risk assessment on mineral oils in packaging.

A risk assessment based upon assumptions on migration and consumption of food was used to assess the concern from the results of this survey and provide an estimate of the food safety risk to consumers.

Assumptions on packaging

The level of MOSH and MOAH measured at the time of analysis represents the total amount of MOSH and MOAH in the packaging. We have no information on the level in the packaging at the time of production up until the analysis was carried out. The possibility that higher levels were initially present and decreased before measurement cannot be excluded and could lead to an underestimation of the potential risk.

All the MOSH and MOAH measured in the packaging migrates into the food. This assumes all the material can migrate, it all ends up in the food, that all food types will take up food and ignores the possibility that inner packaging could act as a barrier. These will tend to overestimate the potential risk.

Assumptions on exposure

Using the assumed migration detailed above, it has also been assumed that a portion of food from that source is consumed every day. This is likely to be unrealistic as most individuals will have a varied diet and therefore this assumption will tend to overestimate the potential risk. In addition, estimated portion sizes are higher than daily consumed data, where available. Therefore, it is probable that the portion sizes will also tend to overestimate risk.

Assumptions on toxicity

MOSH and MOAH measured do not directly correspond to mineral oil categories for which toxicological data is available, or the types of mineral oils for which ADIs were set by JECFA. In the absence of toxicological data on MOSH and MOAH themselves, it is necessary to extrapolate from the toxicological databases on specified tested mineral oils. As always, when extrapolating there are uncertainties, but there is no underlying reason why this data should not be used.

Using the different ADIs set for mineral oils allows a range to be applied to the potential risk. The upper estimate of this risk is likely to be an overestimate due to the fact that not all the mineral oils in the MOSH and MOAH fraction is equivalent to low-medium viscosity mineral oil. There is also a requirement for re-evaluation of the temporary ADI for low-medium viscosity mineral oils set by JECFA based upon new toxicological data, which is likely to be submitted in the future.

Risk assessment

These estimates of risk do not identify specific food safety concerns. However given the assumptions and limitations described, this estimate of the risk indicates a need

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for further data to allow for refinement of the risk assessment rather than indicating a significant risk from the levels measured in the packaging.

Further information

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This survey has been placed on the Agency's website.

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