



Brief Summary of the first Day

Dr. Christoph Hutzler

German Federal Institute for Risk Assessment (BfR)

Department for Chemical and Product Safety

Session I: Health risks through mineral oil in food?

Toxicity and bioaccumulation of mineral oil saturated hydrocarbons

M. Binaglia (EFSA)

Analysis of mineral oils in food

M. Biedermann ((Kantonales Labor Zürich)

EU monitoring on mineral oil hydrocarbons in food and in materials and articles intended to come into contact with food

E. Hoekstra (JRC)

Concept of the BfR MEAL Study with the inclusion of MOSH and MOAH

S. Ptok (BfR)

Mineral oil-based printing inks as a food contamination source and their alternatives

A. Reichart (UBA)

Regulatory measures on mineral oil in food contact materials and in food

U. Galle-Hoffmann (BMEL)

Toxicity of MOSH after oral exposure:

- Summary of the 2012 opinion of CONTAM panel.
- EFSA funded Study on the toxicity and bioaccumulation of rats.

Scientific debate should take place on the following aspects:

- Relevance of classification of MOSH based on viscosity and carbon numbers.
 - Relevance of Fischer rats as a laboratory model to test MOSH.
 - Scientific basis of the currently established ADIs.
 - Relevance of human bioaccumulation as a toxicological endpoint.
 - Scientific basis of the currently established ADIs.
-
- Need for further data on exposure to MOSH and MOAH

Analytik und Befunde über die letzten 30 Jahre

Analytik

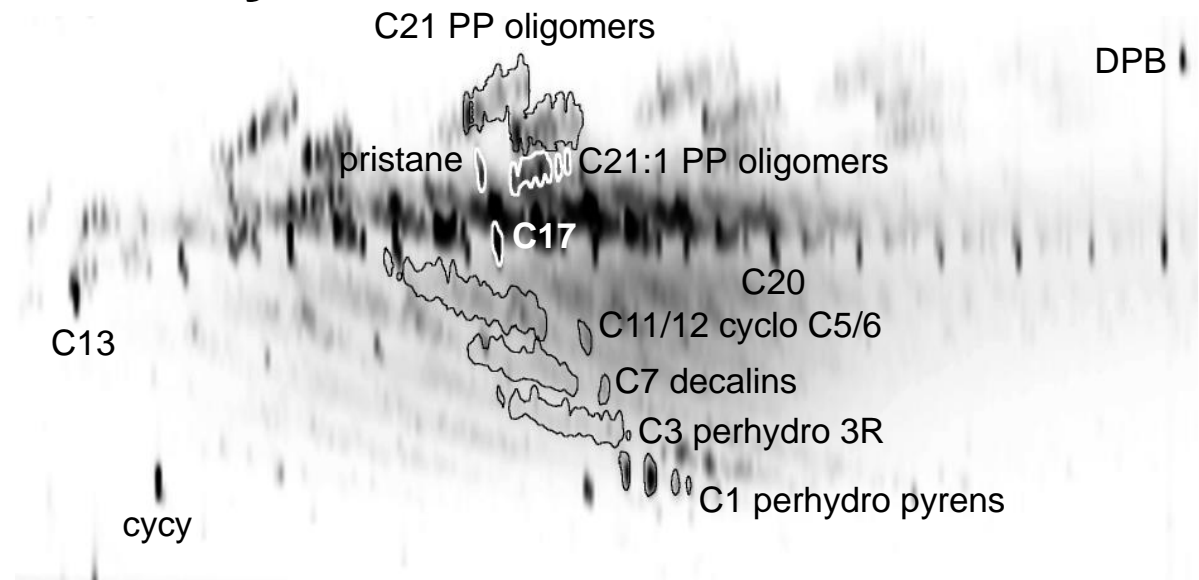
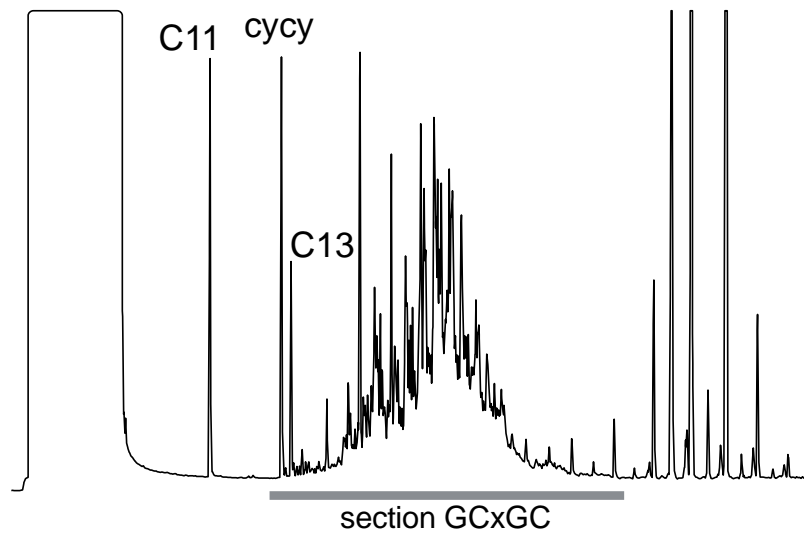
- On-line LC-GC FID robuste Methode zur Quantifizierung von MOSH und MOAH.
- Charakterisierung der MOSH und MOAH Fraktion über umfassend zweidimensionale GCxGC FID/MS oder GC MS → Oligomere (Polyolefine, Polystyrole), synthetische Kohlenwasserstoffe, Mineralölmarker
- Auswertung der Chromatogramme setzt entsprechendes Training, Wissen und Erfahrung voraus.

Befunde

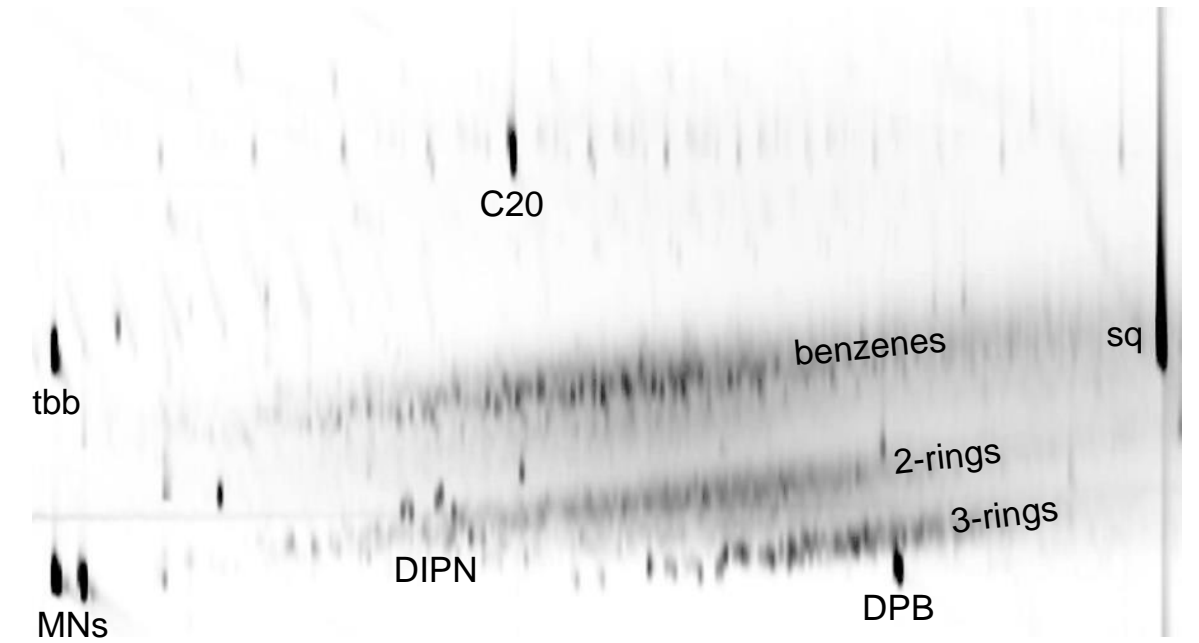
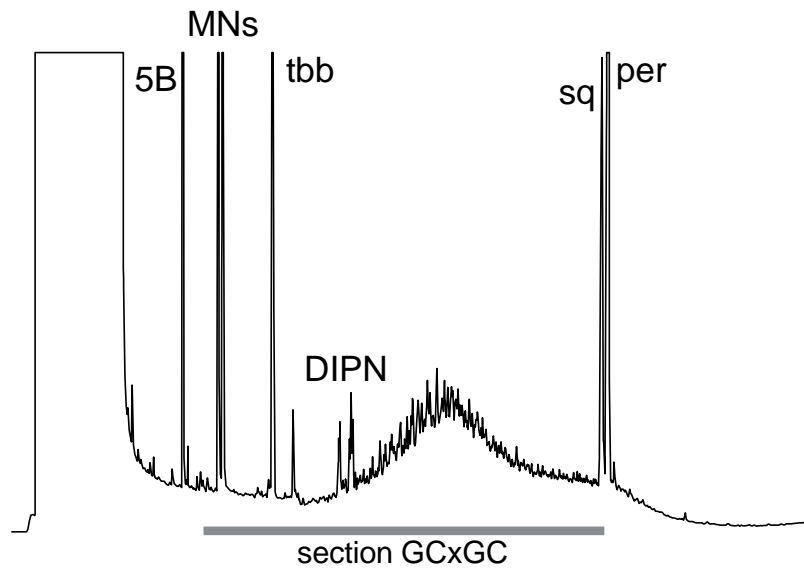
- Vielfältige Quellen/Ursachen für Mineralölkontaminationen
- Über die letzten 30 Jahre zahlreiche Quellen erkannt und eliminiert, z.B. Trennmittel, Batching Öle, Staubbinder auf pflanzlicher Basis
- Migrationsbarrieren für MOSH/MOAH und andere Komponenten aus dem Recyclingkarton

State of the Art der Mineralölanalytik

MOSH rice a



MOAH rice b



© by Maurus Biedermann

European monitoring of mineral oil

Guidelines – work of Task Force

➤ Members are appointed by MSs: NRL, OCL

➤ **Guidelines**

✓ **Set definition of MOH, MOSH, MOAH, POSH**

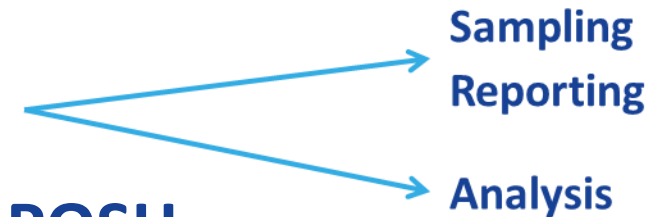
✓ **List of authorised MOH food additives and processing aids**

✓ **Collection of chromatograms of MOH sources**

➤ **Getting an overview of MSs' planned monitoring activities**

➤ **Develop training for official control laboratories (OCL)**

➤ **Develop reference materials for proficiency test**





2017 – 2018



- Alle 350 Lebensmittel der Foodlist werden auf MOSH/MOAH untersucht
- Hintergrundbelastungen von MOSH/MOAH werden berücksichtigt, indem alle LM der Foodlist analysiert werden
- stratifizierte Proben (regional und/oder saisonal und/oder biologisch/konventionell) werden für jedes Lebensmittel zu einer Probe zusammengefasst analysiert

Ansätze zur Minimierung des Eintrags von MOH in den Recyclingkreislauf

- Mineralölfreie Druckfarben sind im Rollenoffset-heatset und im Bogenoffsetdruck in der Praxis angekommen
- Aromatische Kohlenwasserstoffe sind weitestgehend eliminiert
- Wenn die technischen Schwierigkeiten im Rollenoffset-coldset in den Forschungsvorhaben behoben werden können, werden Druckereien diese Farben anwenden
- Mineralölgehalt in den Farben wird deutlich sinken

Regulation

- Es gibt keine unregulierten Lebensmittel und Lebensmittelkontaktmaterialien

Verordnung (EG) Nr. 852/2004 Hygieneverordnung Lebensmittelhygiene-Verordnung (LMHV)

Verordnung (EG) Nr. 1935/2004 „Rahmenverordnung“

Verordnung (EG) Nr. 2023/2006 „GMP-Verordnung“

Verordnung (EG) Nr. 178/2002 „Basisverordnung“

Verordnung (EWG) Nr. 315/93 -> Grundlage zu ALARA-Prinzip

- **Entwurf der 22. VO zur Änderung der BedarfsgegenständeV**
Überarbeiteter Entwurf sieht eine **Barrierepflicht** vor

derzeit Ressortabstimmung der aus der Anhörung resultierenden letzten Anpassungen

Entwurf der 21. VO zur Änderung der BedarfsgegenständeV

- Druckfarben zur Bedruckung von Lebensmittelbedarfsgegenständen
- **Notifizierung** bei EU-Kommission (Info-Richtlinie) im Juli 2016, vorübergehend zurückgestellt
- EU-Lebensmittelmonitoring als Grundlage für weitere Maßnahmen

Session II: Mineral oil in cosmetic products

Refining of mineral oil for use in cosmetic products and pharmaceuticals

D. Sothmann (Mineralölwirtschaftsverband)

The toxicology of mineral oil at dermal exposure

J.-C. Carrillo (CONCAWE)

Health risks through mineral oil components in cosmetic products?

A. Luch (BfR)

Aufreinigung eines typischen niedrig viskosen Medizinischen Weißöls (INCI: Paraffinum Liquidum)



Methode						Medizinisches Weissöl
MOAH		300000 ppm	80000 ppm	100000 ppm	20000 ppm	250 ppm
IP 346		6,6 %	0,4 %	0,5%	0,2%	< 0,1%
ASTM E 1687-10				0,09	0,06	0,02
PAH						0,7 ppb

© by Dierk Sothmann

- Aufreinigungsschritte und deren begleitende Charakterisierung beispielhaft für Medizinisches Weißöl.
- Aufreinigung von Wachsen führt zu MOAH-Restgehalten von typischerweise 1-5 %.
- Unterschiedliche MOAH-Restgehalte von Petrolatum bedingt durch Reinheit der Edukte.

Dermal Toxicity

IP 346

- ▶ Eliminated animal testing
- ▶ DMSO-PAC selectivity based on steric hindrance
- ▶ Regulatory standard method validated with animal data
- ▶ Vital specification to allow product for further processing



Refining Methods

**Mouse Skin
Painting Bioassay**

- ▶ Boiling range of PAC
- ▶ Hydrogenation
- ▶ Solvent extraction
- ▶ Acid treatment

- ▶ Skin is the most sensitive route
- ▶ Toxicity depends on MOAH Structure
- ▶ Two types of MOAH
- ▶ Bad MOAH is > 3 ring PAC

© by J.-C. Carrillo

Do We Need A Sophisticated MOAH Method?

Assessment of cosmetic products

IP 346 method shows good predictivity of carcinogenic potential

- Cave: - Not all MOAH compounds extracted
- Content of PAH classified as carcinogen unknown

→ Further refinement of raw material improves Margin of Exposure

No incidence for dermal Exposure to MOSH from cosmetic products.

Exposure to MOSH via lip care products and lipsticks (worst case)

Daily amount of lip care products:	57 mg/person per day (SCCS)
MOSH content:	8.2 – 74 % (BfR data)
Intake (100 %):	4.7 – 42 mg/person/day
Bodyweight 60 kg:	0.08 – 0,7 mg/kg bw / day

Estimated daily dietary intake of MOSH 0.03 to 0.3 mg/kg bw per day (EFSA, 2012)

For lip care products only highly refined mineral oil based ingredients should be used for which an ADI value had been derived.

Use of petrolatum in lip care products?

Session II: Other regulation areas

The PetCo working group and its activities

C. Tissier (ECHA)

Paraffin hydrocarbons – pharmaceutical use and quality requirements

J. Norwig (BfArM)

The Petroleum and Coal stream Substances (PetCo) Working Group

- PetCo working group is a platform for exchange to ensure that the work on PetCo substances is moved forward using the developed approach as a basis and progress are made in improving the registration dossiers and further regulating PetCo substances where necessary
- **Prioritisation based on uses (widespread uses)** *At least one professional, consumer use or article service life Intermediate uses and fuel uses excluded from regulatory action*
- Blocks and analytical data are the starting point of the prioritisation but uncertainties around blocks
- Hazard assessment for both HH and ENV and which data to generate, on what. Testing on representative structure of the blocks? Testing on the whole substance?
- How to address the categories. Ongoing work on some categories by ECHA

Comparison of the Analytics of MOAH

- Ph.Eur. - DMSO extraction detects **polycyclic aromatic hydrocarbons**
- DAB 8 - UV absorption is detecting the **aromatic electrons**
- ¹H-NMR - is detecting the **aromatic protons** and excludes the aliphatic side chains
- HPLC-GC-FID - detects the **aromatic molecule** including the aliphatic side chains

Conclusion

- Highly purified **liquid and solid paraffins** are used in pharmaceuticals
- **Soft paraffins** show a significant higher content of MOAH.
They are only allowed for topical application, not for oral use
- **Yellow soft paraffin** is suggested to be eliminated from the Pharmacopoeia
- **Fischer Tropsch Products** are proposed to be included in the Pharmacopoeia (D already done)
- **DAB 8 - UV Analytics** could be reinstated in the Pharmacopoeia in order to estimate total MOAH
- to be discussed: ¹H-NMR could become a reference method



Thank you for your attention!

Dr. C. Hutzler

German Federal Institute for Risk Assessment (BfR)

Max-Dohrn-Str. 8-10 • D-10589 Berlin

Tel. +49 30 - 184 12 - 3782 • Fax +49 30 - 184 12 - 47 41

christoph.hutzler@bfr.bund.de • www.bfr.bund.de