1. Improved Performance requirements
   - Faster printing/turn around: Objective to reduce overall printed product cost
   - Better print quality: Reduce quality gap between Flexo and offset (Faster printing & better quality)
   - Improved adhesion: on plastics PP, PE, PET, PA, Aluminum in all application fields including Flexo, Offset and Digital

2. Technology Shift:
   - Food packaging: Shift from rigid to more flexible materials and films reduction in weight.
   - Flexo: Continued growth due to increasing penetration of narrow web label machines and emerging medium (wide) web packaging applications
   - Digital: Technology overtaking screen printing

3. Regulatory:
   - VOC legislations continues to drive research into alternative technologies to Solvent-based systems
   - Food packaging regulations?
   - Printers get concerned regarding possible issues/claims and so start moving their products to low migration if they do not have dedicated presses to avoid contamination.
   - Same concern is seen with some ink formulators and start formulating “regulatory compliant” product..
1. UV/EB food packaging printing and varnishing

Advantages of UV/EB Printing in Food Packaging

- In-line finishing (laminating, die cutting, folding, etc...)
- Higher productivity
- Just in time delivery
- Diversification and innovation in packaging design (high quality)
- Production of eye catching packaging (desire of Brand owners)
- More cost effective process for short runs (trend in EU)
- Can be used on a variety of substrates (paper & board, foil, metal ...)
- Practically no volatile organic compounds (VOC) (a)
- Less space requirements
- Less storage of finished products
- ....
1. UV/EB food packaging printing and varnishing

Incentives to use UV/EB in *flexo* printing

- Printing on PLASTICS (rigid and flexible)
- Practically No solvent emission (No VOC) (b)
- **Print quality** comparable to offset
- Immediate drying
- High gloss
- Ink viscosity constant
  - Print consistency
  - ready to use inks
  - no control and viscosity adjustment
- Quick start up of the press : time saving and waste reduced
- No drying on the press : absence of frequent cleaning of the press
- Multipurpose inks : no need of different series for different machines speed and different substrates
1. UV/EB food packaging printing and varnishing

Incentives to use UV/EB in *offset* printing

- Immediate drying: no set off, in-line finishing
- No anti-setoff powder needed
- High speed print on non porous substrates (plastics, metal …)
- High gloss stable after UV varnishing (No dry back)
- No drying on the press: frequent cleaning of the press not necessary
- Highly resistant inks. (heat, rub, solvents…)
- Less expensive drying process in metal deco

**FOOD PACKAGING:**

- On paper & board, conventional oil based inks only “dry” by penetration, therefore, a water based varnish need to be applied!
- No conventional oil based inks for plastic substrates
Today’s Constraints

• Potential for odor and taste transfer
• Potential for migration of existing raw materials
• Lack of efficient migration testing protocol for acrylates
• Upcoming tightening of food legislations on composition and migration levels
• Lack of consistency, reliability in all stage of the printing (from resin manufacturers, ink formulators and printers)

For wide web flexo printing
• Acceptable adhesion difficult to achieve on uncoated polyolefin substrates at high printing speeds (up to 500 m/min)
• Limited availability of UV equipment
2. Overview Food Contact Regulations in US

- FDA Regulates food additives
  - Food additive = substance “reasonably expected to become a component of food under the intended conditions of use”
  - Printing inks components are generally considered to be food additives … unless the contrary can be demonstrated

- Food additives must be covered by
  - an effective Food Contact Notification (FCN)
  - a Threshold of Regulation exemption letter
  - or fall within an exemption

- "no migration" position
  - Must be demonstrated based on appropriate extraction studies or equivalent data
  - the ink is not considered to be a food additive -> no need to be listed
2. Overview Food Contact Regulations in US

FDA—Food additive regulations

- FDA §175.300 for coatings

- No FDA chapter specifically for inks but:
  - Inks in contact with paper -> chapters on paper (§176.170 – §176.180)
  - Inks in direct contact with the food -> chapter on coatings (§175.300)
  - Inks separated from the food by a functional barrier -> chapter on adhesives (§175.105)
  - Colorants -> look in §178.3297 ("Colorants for polymers")

- A lot of cross-references and interpretation
FDA—Food Contact Notifications

- Different from a Food additive petition
- For substances that have been demonstrated to be safe for their intended use
- Assessment based on the exposure (consumption factors)
- Proprietary to the notifying company(ies)
- Process challenged every years by US authorities (expensive!)

**FCN 772**
- TMPTA, TMP(EO)TA, BADGEDA, TRPGDA
- Mutagenicity & migration data
- Migration limit of 1 ppm thanks to low consumption factor (5%)
- No Specific regulation for Ink but:

* Several European regulations that apply to:

- To materials and articles (M&A) which are intended to be brought into contact with food or can reasonably be expected to be brought into contact with food or to transfer their constituents to food under normal or foreseeable circumstances.

→ Example of regulation:


- **Art 3**: "Materials and articles.... shall be manufactured in compliance with **good manufacturing practice** so that, under normal or foreseeable conditions of use, they do not transfer their constituents to food in quantities which could:

  • could endanger human health, bring about unacceptable change in food composition, deteriorate organoleptic characteristics

- **Art.16**: Declaration of Compliance (conformity)

- **Art.17**: Proof of Traceability at all stages
What is Good manufacturing practices?
According Regulation (EC) 2023/2006 (article 3(a):

"good manufacturing practice (GMP) means those aspects of quality assurance which ensure that materials and articles are consistently produced and controlled to ensure conformity with the rules applicable to them and with the quality standards appropriate to their intended use by not endangering human health or causing an unacceptable change in the composition of the food or causing a deterioration in the organoleptic characteristics thereof”

Entry into force:
This Regulation shall enter into force on the 20th day following that of its publication in the Official Journal of the European Union. It shall apply from 1 August 2008.

ISO 9000 procedures can thus be an excellent carrier for 'good manufacturing practice' but should not be confused with 'good manufacturing practice as such'

Annex referring to inks
Specifications For Development of New Products

Directive 2002/72/EC: relating to plastic materials and articles intended to come in contact with food

- Overall migration limit (OML): 60 mg/kg food
- Specific migration limit (SML) for individual substances
  (positive list of monomers and starting materials)

Inks/OPV are not under scope of 2002/72/EC but may contribute to OML and SML!

4th amendment 2007/19/EC

- No Carcinogenic, Mutagenic, Reprotoxic (CMR) cat. 1-2 (Dir 67/548/EEC)
- No CMR cat. 3 not evaluated by EFSA
  (EFSA = European Food Safety Authority )
- Compliance with Specific Migration Limits (SML) for EFSA-listed substances (“worst case calculation” or migration test)
- Non EFSA listed substance: migration < 10 ppb

OVERALL THERE IS A CLEAR POTENTIAL FOR LIABILITY
Product Profile

- Develop a full range of resins/oligomers and reactive diluents to give printing ink manufacturers the possibility to formulate UV/EB curable inks or varnishes for indirect food packaging complying with previously mentioned regulations and guidelines having:
  - Good Printability
  - Low odor
  - Low taste transfer
  - Low migration (acrylates and additives!)
  - Evaluated toxicity
  - Manufacture under GMP with traceability
  - Provide confidence/Safety in reliability of the process
Development

→ Start with Raw Material Selections
  – No CMR cat. 1-2
  – No CMR cat. 3 not evaluated by EFSA
  – Worst Case Migration of EFSA-listed resin components < Allowed Specific Migration Limits
  – Not EFSA listed additives: migration testing < 10 ppb
  – Higher purity
  – Higher molecular weight
Unique Production Process

• Higher conversion degree

• Additional Treatment, purification to minimize residuals
  – (eg. solvent and acrylic acid)

• Extended Quality Control:
  Internal specifications on potential contaminants are set and documented.
Production under Good Manufacturing Practices (GMP)

- Batch to batch cross contamination is avoided by
  - optimizing the production sequence
  - and/or by producing in campaigns
  - and/or cleaning reactor and piping before production.

- Traceability in all stages (RM, process, finished products)

- A specific layout of production log sheets

- Any deviation from the instructions, recipe or process change is reported to the Product Stewardship and Regulatory Affairs department, which then re-assesses compliance
End Product Properties

- Higher conversion degree
- Limit mono and di-acrylates
- Lower residuals (eg. solvent and acrylic acid)
- Low migration, low odor
- Toxicity evaluated
3. Development of Acrylates for UV/EB Food Packaging Printing & Varnishing

A range of new acrylates:

- Raw material selection: supplier – listed RM
- Purity criteria for raw materials.
- Purity criteria for end product.
- Produced under GMP (Good Manufacturing Practice) as obliged since 1 August 2008.
- Migration assessed in set-off (< 10 ppb); acrylates & additives
- Toxicity assessed
- Conformity statements delivered under secrecy agreement to customer or end user.

LOW ODOR and LOW MIGRATING ACRYLATES giving printing ink manufacturers the possibility to formulate UV/EB curable inks or varnishes for indirect food packaging complying with previously mentioned regulations and guidelines! LEO products are the only Authorized Acrylates resins which are clearly mentioned in Nestle list.
### 3. Development of Acrylates for UV/EB Food Packaging Printing & Varnishing

#### Actual product range

<table>
<thead>
<tr>
<th>EBECRYL®</th>
<th>Type</th>
<th>Viscosity at 25°C (mPa.s)</th>
<th>Offset</th>
<th>Flexo</th>
<th>OPV</th>
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<tbody>
<tr>
<td>LEO 10501</td>
<td>3-functional diluting acrylate</td>
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<td>LEO 10551</td>
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<td>220</td>
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<tr>
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<td>modified epoxy acrylate</td>
<td>200000</td>
<td>√</td>
<td>√</td>
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<tr>
<td>LEO 10801</td>
<td>6-functional polyester acrylate</td>
<td>50000</td>
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</tbody>
</table>
4. Conclusion and Perspective

- A range of Low Odor/Low Migration acrylates have been developed for UV/EB food packaging printing and varnishing.

- These products are designed to formulate UV/EB-inks and varnishes meeting the most **stringent legal requirements**:
  
  - Raw material selection (conformity statement from suppliers)
  - Purity criteria for raw materials
  - Purity criteria for end product
  - Produced under GMP as required
  - Migration assessed (< 10 ppb)
  - Toxicity assessed
  - Conformity statements can be delivered
  - Only clearly mentioned in Nestle list as authorized Acrylates resins
Thank you

Our Vision:
Delivering Technology
Beyond Our Customer’s Imagination™

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