

# Voice of crafts and SMEs in Europe

**REACH-restriction for substances in tattoo inks and permanent make-up**

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# Issue/ Objective

Since the introduction of the restriction in Annex XVII to (EC) No 1907/2006 (REACH), the availability of REACH compliant mixtures for the use in tattoos or permanent make-up (tattoo inks) continues to be a major challenge for the European industry.

- Insufficient commercial supply of tattoo inks for the European Tattoo and PMU industry
- Limited or no availability of conform and safe inks due to
  - Some specifications are technical not feasible (impurity limits) or unavailability of complying raw materials
  - Lack of standardized analytical methods
  - Missing guidelines for practical implementation of the requirements for the manufactures
  - Incoherent enforcement on the international market/ of the member states
- Increased (personal) imports from non/less regulated markets

# Labeling

**Labeling under REACH is a major challenge in PMU & Tattoo industries.**

Conflicts of labelling requirements under REACH and established national regulations and uncertainties on the execution of REACH requirements lead to major complications.

- Because of the size of the bottles not all information can be included on the label
  - It is not possible to provide all information in the languages of all member states
  - Label complaints from control bodies although the labels show full conformity with REACH
- Guidelines for industries are required
- Actions for harmonised enforcement of REACH are required
- Labeling according to the Cosmetics regulation should be accepted

For example, some control bodies require tattoo ink labels to state “REACH compliant”. The EU restriction does not require such a criterion and enforcement authorities in other member states complain that this wording is incorrect. In some cases, this has already led to the officially ordered disposal of tattoo inks that were flawless as such.

# Provisions on Labeling - Annex XVII to (E.C) No 1907/2006

7. Suppliers placing a mixture on the market for use for tattooing purposes shall ensure that, after 4 January 2022, the mixture is marked with the following information:

- (a) the statement "Mixture for use in tattoos or permanent make-up";
- (b) a reference number to uniquely identify the batch;
- (c) the list of ingredients in accordance with the nomenclature established in the glossary of common ingredient names pursuant to Article 33 of Regulation (EC) No 1223/2009, or in the absence of a common ingredient name, the IUPAC name. In the absence of a common ingredient name or IUPAC name, the CAS and EC number. Ingredients shall be listed in descending order by weight or volume of the ingredients at the time of formulation. "Ingredient" means any substance added during the process of formulation and present in the mixture for use for tattooing purposes. Impurities shall not be regarded as ingredients. If the name of a substance, used as ingredient within the meaning of this entry, is already required to be stated on the label in accordance with Regulation (EC) No 1272/2008, that ingredient does not need to be marked in accordance with this Regulation;

- (d) the additional statement "pH regulator" for substances falling under point (d)(i) of paragraph 1;
- (e) the statement "Contains nickel. Can cause allergic reactions." if the mixture contains nickel below the concentration limit specified in Appendix 13;
- (f) the statement "Contains chromium (VI). Can cause allergic reactions." if the mixture contains chromium (VI) below the concentration limit specified in Appendix 13;
- (g) safety instructions for use insofar as they are not already required to be stated on the label by Regulation (EC) No 1272/2008.

The information shall be clearly visible, easily legible and marked in a way that is indelible.

The information shall be written in the official language(s) of the Member State(s) where the mixture is placed on the market, unless the Member State(s) concerned provide(s) otherwise.

Where necessary because of the size of the package, the information listed in the first subparagraph, except for point (a), shall be included instead in the instructions for use.

# Labeling issues

Example 1: Vet lab 1807-015186 22 HB426

Example 2: Vet lab 1807-015186 22 HB427

- MT.DERM GmbH was inspected in March 2023 from responsible regulatory authorities (Bezirksamt Berlin Tempelhof-Schöneberg, VetLab 18).
- **10 ml** bottles were collected and analysed
- No toxicological complains
- Label complaints
  - Warning statement “Contains Nickel” is missing on the label. This statement is included in the manual only
  - “List of ingredients” is missing on the label. This information is included in the manual only
  - “Best before use” information is not written in national language. It is not allowed to use symbols from cosmetic regulation



Untersuchungsbefund und Beurteilung	
Bezeichnung der Probe*:	amiea organidine Romantique PMU Rot 585
Art der Probe*:	Monitoring-Planprobe
Einsender*:	BA Tempelhof-Schöneberg R07
Proben-Nr. des Einsenders*:	22-07-03-0003
Untersuchungsauftrag/Bemerkung*:	Verkehrsfähigkeit, chemisch, Kennzeichnung (Gebrauchsanweisung innenlegend)
Entnahmebetrieb*:	MT, Derm GmbH Blohmstr. 37-61 12307 Berlin
Entnahmedatum*:	03.05.2022

**Not REACH complaint**

**Not REACH complaint**

**Not complaint to TatVO**

# Urgent need of Analytical Standards

As a manufacturer we want to comply with the REACH regulations and thereof defined impurity limits. To place safe products on the market universal applicable standards are required for manufacturers & analytical laboratories.


- Missing standards & guidance led to major uncertainties for the operating stakeholders
- Analytical data must be reliable and comparable

For example, a RAPEX notification was initiated based on data from full copper analysis. In contrast, the EU restriction states that only “soluble” copper is to be considered.

- Existing analytical methods not develop for Tattoo inks
- For Data interpretation the specific situation of tattoo in the body and pigment ingredients of the formulation must be considered
- Different sample preparations e.g. extraction or total decomposition led to different results
- Soluble Copper and soluble Chromium IV should only be analysed with extraction methods; e.g. in Chromium oxide green inks total decomposition method could led to false positive results

<b>Alert number: A12/00008/22</b>	
Published on 07/01/2022 - Report 2022-1	
Notifying country: Sweden	
• Legal provisions of notification A12/00008/22 has been modified	
<b>Product description</b>	Blue tattoo ink.
<b>Packaging description</b>	Plastic bottle.
<b>Country of origin</b>	United Kingdom
<b>Risk type</b>	Chemical
<b>Risk description</b>	The product contains an excessive amount of copper (measured value: 250 ppm). Copper can cause liver and kidney damage and might affect fertility.
<b>Legal provisions (at EU level) and European standards against which the product was tested and did not comply</b>	The product does not comply with the REACH Regulation.
<b>Measures taken by economic operators (Importer)</b>	Withdrawal of the product from the market Date of entry into force 12/11/2021

<b>Product category</b>	Chemical products
<b>Product</b>	Tattoo ink
<b>Name</b>	Eternal Ink True Blue
<b>Brand</b>	Eternal Ink
<b>Batch number</b>	013182



# Aldehydes

- New limit for Acetaldehyde/ Formaldehyde: **0.5 ppm**
  - Root cause for formaldehyde/ acetaldehyde in Tattoo inks are liquid components itself, formation during storage, sterilization processes as well as preservatives or some bottle materials.
  - Purity requirements of substances like Glycerol, Propylene Glycol, Ethanol are defined in Monographies of Ph.Eur.
  - Limit for aldehydes (including formaldehyde) in the Pharmacopoea Europaea (**Ph.Eur.**): **10 ppm**
- Technical unavoidable entry of aldehydes from liquid components with highest purity/ safety certification

Sigma-Aldrich

www.sigmaaldrich.com

## Certificate of Analysis

**Product Name:** Ethanol  
tested according to Ph. Eur.  
**Product Number:** 29221  
**Batch Number:** BCKK2520  
**CAS Number:** 64-17-5  
**Formula:** CH<sub>3</sub>CH<sub>2</sub>OH  
**Formula Weight:** 46.07  
**Quality Release Date:** 30 MAY 2023  
**Recommended Retest Date:** MAR 2028

TEST	SPECIFICATION	RESULT
VOLATILE IMPURITIES	GC: METHANOL MAX. 200 PPM V/V,	METHANOL <5 PPM,
	ACETALDEHYDE/ACETAL MAX. 10 PPM V/V, BENZENE MAX. 2 PPM V/V, TOTAL OF OTHER IMPURITIES MAX. 300 PPM	ACETALDEHYDE/ACETAL <5 PPM, BENZENE <1 PPM, TOTAL OF OTHER IMPURITIES <5 PPM

## Specification



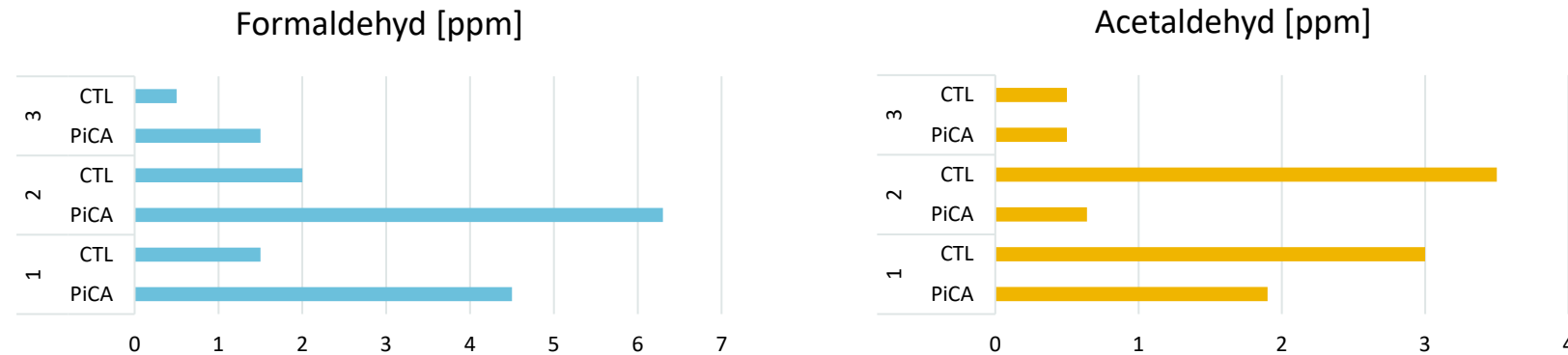
Item number: 7530  
Glycerol  
**SOLVAGREEN® ≥98 %, anhydrous, Ph. Eur.**  
CAS No.: 56-81-5  
formula: C<sub>3</sub>H<sub>8</sub>O<sub>3</sub>  
density: 1,26  
molecular weight: 92,09 g/mol  
print date: 18.04.2023

### Guarantee analysis

Assay	98,0-101,0 %
Identity	complies
Appearance of solution	complies
Refractive index n <sub>D</sub> <sup>20</sup>	1,470-1,475
Relative density (20 /20 °C)	1,263-1,2651
Acidity/alkalinity	≤0.2 ml (0.1 M NaOH)
Ester	≥8 ml (0.1 M HCl)
Colour	complies
Sulphated ash	≤0,01 %
Halogen compounds	≤0,0035 %
Water (KF)	≤2,0 %
Chloride (Cl)	≤0,001 %
Aldehydes	≤0,001 %
Sugar	complies

# Analytics of Aldehydes- comparison of different Laboratories

- A major issue in (aldehyde) analytics in Tattoo inks are missing standards for measurements and sample preparation
- Different laboratories generate different outcomes in measured aldehydes and other analytes



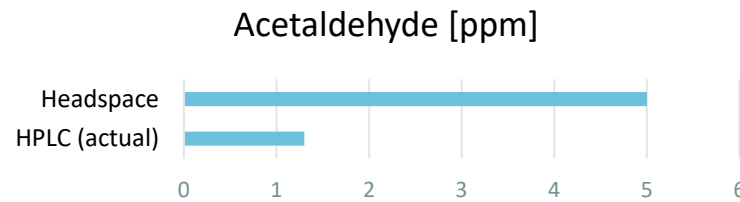
Measurement performed on 3 different research samples.  
CTL GmbH: various extraction methods, analysis with GC-MS and HPLC.  
PiCA GmbH: watery extraction and derivatization, analysis with GC-MS.



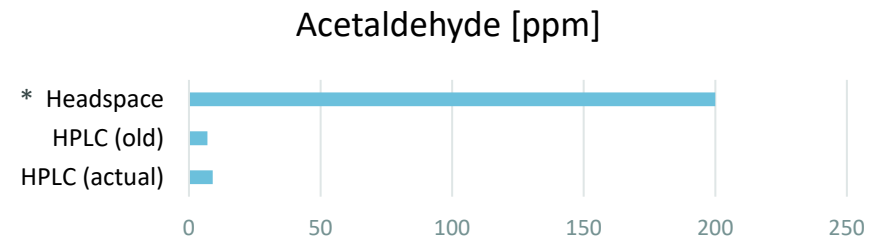
# Analytics of Aldehydes – comparison of different methods

- Depending on applied method and derivatization (sample preparation), different aldehyde levels are measured

→ Harmonized analytical standards are required



Research sample; data provided by CTL GmbH

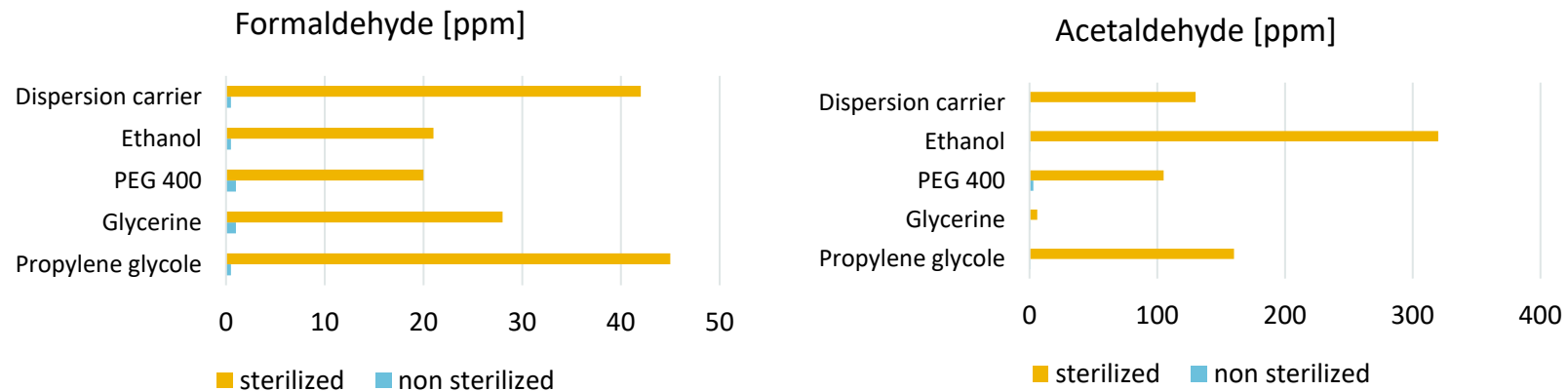


Research sample; data provided by CTL GmbH

\* False positive result due to formation of acetaldehyd through measurement

# Formation of Aldehydes - Sterilization

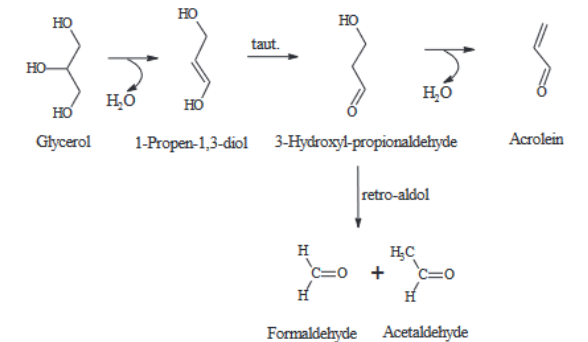
- We found potential formation of aldehydes during sterilization processes
- Validated gamma sterilization process according to ISO 11137-2 “sterilization of health care products” with 15/35 kGy min./max. dose).
- Lowest effective dose to attain a SAL (sterility assurance level) of  $< 10^{-6}$



\*Dispersion carrier = pre mix/ master batch of all liquids for ink formulation

\* All data from MT.Derm GmbH on ingredients with PH.Eur. quality

# Formation of Aldehydes

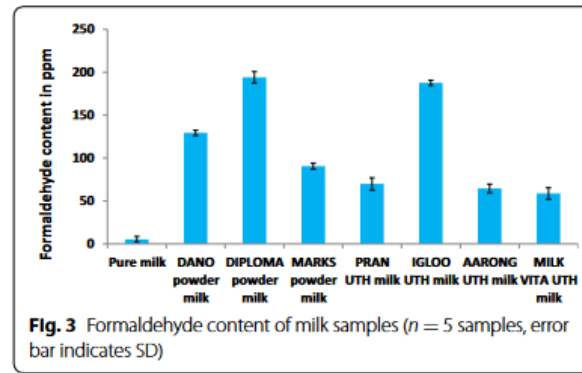
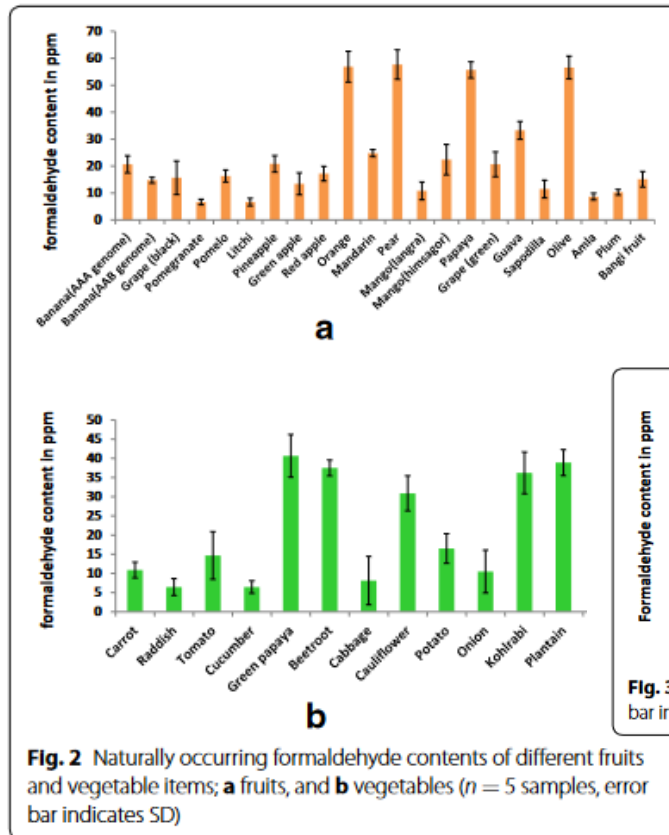


- Glycerol and Propylene Glycols are known to decompose into formaldehyde & acetaldehyde under thermal conditions (oxy(dehydration)).
  - This effect is known to be triggered by temperature and energy levels (e.g. e-cigarettes)
  - A negative effect under specific environmental conditions like UV/ sunlight exposure or elevated temperatures during transportation/storage at the customer site can not be excluded
- Root cause for potential aldehyde formation during sterilization and different environmental conditions should be investigated
- The risk to customers from microbiological contamination due to ineffective sterilization should be weighed against the risk from potential aldehyde formation

<sup>\*</sup>Uchiyama, S., Ohta, K., Inaba, Y., Kunugita, N., 2013. Determination of Carbonyl Compounds Generated from the E-cigarette Using Coupled Silica Cartridges Impregnated with Hydroquinone and 2,4-Dinitrophenylhydrazine, Followed by High-Performance Liquid Chromatography. *Analytical Sciences* 29, 1219-1222.  
<sup>\*</sup>Deleplanque, J., Dubois, J.L., Devaux, J.F., and Ueda, W., 2010. Production of acrolein and acrylic acid through dehydration and oxydehydration of glycerol with mixed oxide catalysts. *Catalysis Today* 157, 351-358.

# Natural Sources of Formaldehyde

- Formaldehyde is naturally produced by fruit, vegetables, meat, fish, ...
- Formaldehyde limits seem to extend in processed food items
- Endogenous formaldehyde is generated from different methylated compounds by demethylases, and from interconversion of glycine and serine that is catalyzed by pyridoxal phosphate



UTH = ultra high temperature processing

Das LG, Presse, Karte, A-Z, Kontakt, Impressum, Datenschutz, Barrierefreiheit

Bayerisches Landesamt für Gesundheit und Lebensmittelsicherheit

SARS-CoV-2, Arbeitsschutz, Lebensmittel, Produkte, Gesundheit, Tiergesundheit, Fort-/Weiterbildung

Startseite >> Lebensmittel >> Chemie >> Toxische Reaktionsprodukte >> Formaldehyd

Suche

Chemie **Formaldehyd in Lebensmitteln** Verwandte Themen

Inhaltsstoffe

Pflanzenschutzmittel

Arzneimittelrückstände

Schimmelpilzgifte

Verwendung von Formaldehyd

Abgabe von Formaldehyd aus Lebensmittelkontaktmaterialien

Formaldehyd in Lebensmitteln und tägliche Aufnahmemenge mit der Nahrung

Melanin

Marktüberwachung im Rahmen des stofflichen Verbraucherschutzes

Formaldehyd

Verbraucherprodukte

Eignungsuntersuchungen

[https://www.lgl.bayern.de/lebensmittel/chemie/toxische\\_reaktionsprodukte/formaldehyd/index.htm](https://www.lgl.bayern.de/lebensmittel/chemie/toxische_reaktionsprodukte/formaldehyd/index.htm)

# Endogenous Formaldehyde turnover



European Food Safety Authority

EFSA Journal 2014;12(2):3550

SCIENTIFIC REPORT OF EFSA

**Endogenous formaldehyde turnover in humans compared with exogenous contribution from food sources<sup>1</sup>**

**European Food Safety Authority<sup>2,3</sup>**

European Food Safety Authority (EFSA), Parma, Italy

- Essential metabolic intermediate present in all cells
- Formaldehyde blood concentrations in humans is 2.6 mg/L
- The **daily endogenous turn over** of formaldehyde has been estimated to be around **878-1310 mg/kg**

# Microbiological safety

- ResAP(2008)1: “ Sterile in this context means the absence of viable organisms, including viruses.”
- Preservatives should only be used to ensure preservation after opening & not for correction of insufficient microbiologic purity
- Many preservatives are known to be formaldehyde releasers and therefore are restricted under REACH
- **REACH: microbiological quality/risk is not considered**

→To ensure consumer safety harmonized standards for analytics and acceptable limits for “sterile” are required

→Monitoring of inks from the E.U. and imported inks are required

# Required Actions from the Forum

- Collecting information/ experience from different NEAs and stakeholders
- Discuss the collected information/experience and analyse the consistency between member states
- Develop guidance and harmonized standards for E.U. manufactures and import of ink from non. E.U. countries
  - Toxicological impurity analysis/ methodology (e.g. for heavy metals, aldehydes)
  - Microbiological safety (limits, analytical standards, sterilization procedures)
  - Labeling
- Funding of Research on the safety and metabolisms of pigments and inks in the body

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Thank you very much for your attention.

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