

# Screening of preservatives in tattoos and liquid toys



Study commissioned by:  
The Consumer Council at the Austrian Standards Institute  
and funded by  
the Austrian Ministry of Labour, Social Affairs and Consumer Protection

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***Final report***  
**24 FEBRUARY 2015**



# Contents

CONTENTS	1
1 INTRODUCTION	3
2 PURPOSE OF THIS STUDY	4
3 SCREENING FOR USE OF PRESERVATIVES	5
3.1 METHODOLOGY USED	5
4 RESULT OF THE SCREENING	6
4.1 PRESERVATIVES IDENTIFIED IN TATTOO INKS	6
4.1.1 <i>Pigments, Preservatives and Impurities in Tattoo Inks (U. Hauri, 2012)</i>	9
4.1.2 <i>Chemical Substances in Tattoo Ink (Jacobsen et al., 2012)</i>	9
4.1.3 <i>Dermatologic Complications with Body Art: Tattoos, Piercings and Permanent Make-Up (Cuyper, 2009)</i>	9
4.1.4 <i>Tattoo Inks Carrier Chemistry (About Education, Chemistry 2014)</i>	9
4.1.5 <i>Eternal Ink Material Safety Data Sheet (2015)</i>	9
4.1.6 <i>FDA Will Review Toxic Tattoo Chemicals (OCA, 2008)</i>	10
4.1.7 <i>Rising Concern over Cosmetic Tattoos (Ortiz, 2011)</i>	10
4.1.8 <i>Thimerosal: Current Sources of Contact in Brazil (NICB, 2014)</i>	10
4.1.9 <i>Thimerosal (Thiomersal – Thimersol, 2008)</i>	10
4.2 PRESERVATIVES IDENTIFIED IN LIQUID TOYS	10
5 DISCUSSION	17
5.1 DISCUSSION	17
5.2 RECOMMENDATIONS	20
6 REFERENCES	21



# 1 Introduction

The current regulatory framework in the European Union to protect consumers from chemicals contained in consumer articles has been found insufficient in previous review studies commissioned by The Consumer Council at the Austrian Standards Institute (ASI) and funded by the Austrian Ministry of Labour, Social Affairs and Consumer Protection. These studies are:

- Chemical requirements for consumer products - Proposals for regulatory measures to improve chemical safety for consumers (Poulsen et al., 2010)
- Chemical requirements for consumer products – Part II (Poulsen & Strandesen, 2011)
- Chemical requirements for consumer products – Part II (Strandesen & Poulsen, 2012)
- Chemical requirements for toys (Poulsen, 2013)
- Chemical requirements for child use and care articles (Poulsen, 2014)
- Chemical requirements for other articles – a screening (Poulsen et al., 2014)

The conclusions from the previous studies indicate that in general there is a lack of chemical requirements for many different types of consumer products. In some areas (especially toys and food contact materials (but mainly for plastics)), several chemical requirements do exist, but even here risk assessments indicate that these requirements ought to be strengthened in order to protect especially children from hazardous chemicals.

This present study will look at preservatives used in tattoo inks and liquid toys.

## 2 Purpose of this study

Preservatives are used in a variety of different consumer products, e.g. tattoo inks, liquid toys and cosmetics. Preservatives may be necessary in products containing water in order to extend the shelf life of the products. Some preservatives have been identified as having problematic properties such as being skin sensitising or suspected endocrine disruptors. Humans can be exposed to preservatives orally, dermally or by inhalation, but the dermal route seems to be the main route of exposure for the examples of consumer products containing preservatives listed above.

Some preservatives are regulated in different legislation, e.g. a positive list of preservatives with allowed maximum concentration exists for cosmetics. However, the use of preservatives is not regulated in all type of consumer products (e.g. for tattoos). Thus, it is relevant to identify the current uses and types of preservatives used on the European market to assess the potential exposure of preservatives to humans.

The purpose of this project is to perform a screening of

- Preservatives used in tattoo inks
- Preservatives used in liquid toys

For the identified preservatives, the following activities will hereafter be carried out

- Looking up the CLP classification for the identified preservatives
- Comparison of the use of preservatives to the positive list of preservatives for cosmetics

The main focus for this smaller study will, however, be on tattoo inks as at the beginning of 2014 FORCE Technology finished a project for the Danish EPA concerning the use of preservatives in liquid toys. The findings of this report will be summarised shortly in this report.

# 3 Screening for use of preservatives

This chapter describes how the screening has been carried out and the result of the screening.

## 3.1 Methodology used

The screening has been carried out by use of the following elements:

- Performing a literature search on the use of preservatives in tattoo inks and liquid toys.
- Examples of hazardous chemicals found in the tattoo inks and liquid toys have been listed.

The examples of hazardous chemicals found in the selected consumer product category have been identified by use of following sources:

- Survey on chemicals in consumer products, Danish EPA ([www.mst.dk](http://www.mst.dk)<sup>1</sup>).
- Material Safety Data Sheets (MSDS) for tattoo inks.
- A general Google search on the specific product category.

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<sup>1</sup> <http://eng.mst.dk/topics/chemicals/consumers-consumer-products/>

## 4 Result of the screening

### 4.1 Preservatives identified in tattoo inks

A literature search for preservatives found in tattoo inks resulted in the following examples (see Table 1), which are described in more details in the text below.

Table 1: Preservatives found in tattoo inks

Preservative	CAS No.	Classification <sup>1</sup>	Allowed in cosmetics <sup>2</sup>	Comment	Reference
Formaldehyde <sup>3</sup>	50-00-0	<b>Acute Tox. 3, H301 Acute Tox. 3, H311 Skin Corr. 1B, H314 Skin Sens. 1, H317 Acute Tox. 3, H331 Muta. 2, H341 Carc. 1B, H350</b>	Yes  0.2%	Found in 13% of the 416 inks in a Swiss survey (2008-2012) in a concentration of 0.004 to 0.23%.	Hauri, 2012
Bronopol (2-bromo-2-nitropropane-1,3-diol)	52-51-7	<b>Acute Tox. 4, H302 Acute Tox. 4, H312 Skin Irrit. 2, H315 Eye Dam. 1, H318 STOT SE 3, H335 Aquatic Acute 1, H400</b>	Yes  0.1%	Found in 0.2% of the 416 inks in a Swiss survey (2008-2012) in a concentration of 0.02%.	Hauri, 2012
Thimerosal	54-64-8	Acute Tox. 2, H300 Acute Tox. 1, H310 Acute Tox. 2, H330 STOT RE 2, H373 Aquatic Acute 1, H400 Aquatic chronic 1, H410	Yes, but only for eye pro- ducts  0.007% (Hg)	“One of the chemicals known to be used in tattoo ink is thimerosal, also called thiomersal, an organic compound made with mercury. Thimerosal is commonly included in tattoo inks, vaccines, antivenins, and eye and ear products as a preservative. Due in part to toxic effects of the mercury, thimerosal is very effective in killing off fungal and bacterial growth”.	OCA, 2008
				The article concerns the use of thimerosal in Brazil. It is mentioned that thimerosal is used as a preservative in tattoo inks, but this area is not investigated in the article, due to lack of information on product labels.	NCBI, 2014
				Thimerosal is used as a preservative in tattoo inks.	Thimerosal, 2008
Chlorhexidine	55-56-1	Skin Irrit. 2, H315 Eye Irrit. 2, H319 Resp. Sens. 1, H334 STOT SE 3, H335 Aquatic Acute 1, H400 Aquatic Chronic 1, H410	Yes  0.3%	Found in 0.2% of the 416 inks in a Swiss survey (2008-2012) in a concentration of 0.02%.	Hauri, 2012



Preservative	CAS No.	Classification <sup>1</sup>	Allowed in cosmetics <sup>2</sup>	Comment	Reference
Ethanol  <i>It is, however, expected that ethanol mainly is used for its properties as a solvent.</i>	64-17-5	<b>Flam. Liq. 2</b>	Yes, but not as a preservative	Ethanol is mentioned as one of the safest and most common ingredients in liquid tattoo ink.	About education, chemistry, 2014
				Under section 2: Ingredient information, it is stated: "Our products are primarily composed of organic pigment, distilled water, witch hazel, alcohol, and not considered to be an hazardous substance".	Eternal Ink MSDS, 2015
				"In addition to pigment, tattoo inks contain diluents and preservatives, such as glycerin or ethanol, which facilitate the dyeing process in the skin."	Ortiz, 2011
Benzoic acid	65-85-0	<b>Skin Irrit. 2, H315 Eye Dam. 1, H318 STOT RE 1, H372</b>	Yes  0.5% for leave on prod.	Found in 4% of the 416 inks in a Swiss survey (2008-2012) in a concentration of 0.004 to 0.07%.	Hauri, 2012
				"Because organic material and water are subject to bacterial and fungal contamination, preservatives like benzoic acid are often added to the tattooing/PMU products."	Cuyper, 2009
				Benzoic acid is one of the dominating preservatives in the German survey on tattoo inks (6.7% of 148 tested products showed a content of preservatives)	Jacobsen, 2012
Salicylic acid	69-72-7	Acute Tox. 4, H302 Acute Tox. 4, H312 Eye Irrit. 2, H319	Yes  0.5%	Found in 0.5% of the 416 inks in a Swiss survey (2008-2012) in a concentration of 0.02 to 0.02%.	Hauri, 2012
4-chloro-3,5-dimethylphenol/ chloroxylenol	88-04-0	<b>Acute Tox. 4, H302 Skin Irrit. 2, H315 Skin Sens. 1, H317 Eye Irrit. 2, H319</b>	Yes  0.5%	Found in 0.2% of the 416 inks in a Swiss survey (2008-2012) in a concentration of 0.25%.	Hauri, 2012
o-Phenylphenol	90-43-7	<b>Skin Irrit. 2, H315 Eye Irrit. 2, H319 STOT SE 3, H335 Aquatic Acute 1, H400</b>	Yes  0.2% as phenol	Found in 0.2% of the 416 inks in a Swiss survey (2008-2012) in a concentration of 0.06%.	Hauri, 2012
Propyl paraben	94-13-3	Skin Irrit. 2, H315 Eye Irrit. 2, H319 STOT SE 3, H335	Yes 0.4% (0.8% in total)	Found in 0.2% of the 416 inks in a Swiss survey (2008-2012) in a concentration of 0.01%.	Hauri, 2012
Methyl paraben	99-76-3	Skin Irrit. 2, H315 Eye Irrit. 2, H319 STOT SE 3, H335	Yes  0.4% (0.8% in total)	Found in 0.5% of the 416 inks in a Swiss survey (2008-2012) in a concentration of 0.04 to 0.06%.	Hauri, 2012
Glyoxal	107-22-2	<b>Skin Irrit. 2, H315 Skin Sens. 1, H317 Eye Irrit. 2, H319 Acute Tox. 4, H332 Muta. 2, H341</b>	No	Found in 1.2% of the 416 inks in a Swiss survey (2008-2012) in a concentration of 0.01 to 0.02%.	Hauri, 2012

Preservative	CAS No.	Classification <sup>1</sup>	Allowed in cosmetics <sup>2</sup>	Comment	Reference
Phenol	108-95-2	<b>Acute Tox. 3, H301</b> <b>Acute Tox. 3, H311</b> <b>Skin Corr. 1B, H314</b> <b>Acute Tox. 3, H331</b> <b>Muta. 2, H341</b> <b>STOT RE 2, H373</b>	No	Found in 3% of the 416 inks in a Swiss survey (2008-2012) in a concentration of 0.004 to 0.43%.	Hauri, 2012
Sorbic acid (hexa-2,4-dienoic acid)	110-44-1	Skin Irrit. 2, H315 Eye Irrit. 2, H319	Yes 0.6%	Found in 0.1% of the 416 inks in a Swiss survey (2008-2012) in a concentration of 0.01%.	Hauri, 2012
Ethyl paraben	120-47-8	Asp. Tox. 1, H304 Skin Irrit. 2, H315 Skin Sens. 1, H317 Eye Irrit. 2, H319	Yes 0.4% (0.8% in total)	Found in 0.2% of the 416 inks in a Swiss survey (2008-2012) in a concentration of 0.02%.	Hauri, 2012
Phenoxyethanol	122-99-6	<b>Acute Tox. 4, H302</b> <b>Eye Irrit. 2, H319</b>	Yes 1.0%	Found in 1.2% of the 416 inks in a Swiss survey (2008-2012) in a concentration of 0.06 to 1.49%.	Hauri, 2012
Benzisothiazolone (BIT) (1,2-benzisothiazolin-3-one)	2634-33-5	<b>Acute Tox. 4, H302</b> <b>Skin Irrit. 2, H315</b> <b>Skin Sens. 1, H317</b> <b>Eye Dam. 1, H318</b> <b>Aquatic Acute 1, H400</b>	No	Found in 12% of the 416 inks in a Swiss survey (2008-2012) in a concentration of 0.4 mg/kg to 245 mg/kg.	Hauri, 2012
				Benzisothiazolone (BIT) is one of the dominating preservatives in the German survey on tattoo inks (6.7% of 148 tested products showed a content of preservatives)	Jacobsen, 2012
Methylisothiazolinone (MI)	2682-20-4	Acute Tox. 3, H301 Acute Tox. 3, H311 Skin Corr. 1B, H314 Skin Sens. 1, H317 Eye Dam. 1, H318 STOT SE 3, H335 Aquatic Acute 1, H400	Yes 0.01%	Methylisothiazolinone (MI) is one of the dominating preservatives in the German survey on tattoo inks (6.7% of 148 tested substances showed a content of preservatives)	Jacobsen, 2012
Octylisothiazolinone (OIT) (2-octyl-2H-isothiazol-3-one)	26530-20-1	<b>Acute Tox. 4, H302</b> <b>Acute Tox. 3, H311</b> <b>Skin Corr. 1B, H314</b> <b>Skin Sens. 1, H317</b> <b>Acute Tox. 3, H331</b> <b>Aquatic Acute 1, H400</b> <b>Aquatic Chronic 1, H410</b>	No	Found in 4% of the 416 inks in a Swiss survey (2008-2012) in a concentration of 40 mg/kg to 450 mg/kg.	Hauri, 2012
				Octylisothiazolinone (OIT) is one of the dominating preservatives in the German survey on tattoo inks (6.7% of 148 tested products showed a content of preservatives)	Jacobsen, 2012
Methylisothiazolinone (MI) / Methylchlorisothiazolinone (MIC)  The mixture is named Kathon	55965-84-9 2682-20-4/ 26172-55-4	<b>Acute Tox. 3, H301</b> <b>Acute Tox. 3, H311</b> <b>Skin Corr. 1B, H314</b> <b>Skin Sens. 1, H317</b> <b>Acute Tox. 3, H331</b> <b>Aquatic Acute 1, H400</b> <b>Aquatic Chronic 1, H410</b>	Yes, in rinse-off prod. <sup>4</sup>  0.0015 %	Found in 4% of the 416 inks in a Swiss survey (2008-2012) in a concentration of 0.5 mg/kg to 82 mg/kg.	Hauri, 2012

1: Harmonised classification is marked in bold and with grey background. If no harmonised classification exists, the notified classification given by most notifiers according to ECHA C&L Inventory is listed.

2: "Allowed in cosmetics" refers to if the preservatives are listed in Annex V "List of preservatives allowed in cosmetic products" (Regulation No. 1223, 2009). All preservatives in this Annex V are only allowed under certain conditions e.g. under a certain maximum concentration in ready for use preparation. The maximum concentration is listed in the table.

3: Formaldehyde has been reclassified and the classification is applicable as of 1<sup>st</sup> April 2015 (Regulation No. 605, 2014).

4: According to EU Regulation No. 1003/2014, the use of Kathon in cosmetic products as of 16 July 2015 is only allowed in rinse-off products. Before this date, the use of Kathon in products is allowed in all types of cosmetic products.

#### 4.1.1 Pigments, Preservatives and Impurities in Tattoo Inks (U. Hauri, 2012)

The State Laboratory of Basel City under the Official food authority of Basel-City carried out a study of tattoo inks in the period of 2008 – 2012. Chemical analyses were carried out on 416 tattoo inks from 73 brands. Many different chemical substances were analysed and preservatives were among one of the focus areas of the study. 18 different preservatives were identified in the study. Of these 15 were allowed in cosmetics (with certain restrictions like maximum concentrations or specific uses) and three were not. The dominating preservatives were formaldehyde, benzisothiazolone (BIT), methylisothiazolinone (MI)/methylchlorisothiazolinone (MIC) (this mixture is also named Kathon), benzoic acid and octylisothiazolinone (OIT). It should be noted that as of 16 July 2015 Kathon is no longer allowed to be used in leave-on cosmetic products (Regulation No. 1003, 2014).

#### 4.1.2 Chemical Substances in Tattoo Ink (Jacobsen et al., 2012)

The Danish EPA has made a report on chemical substances in tattoo ink. This study mainly focuses on the colourants used, but they also describe different surveys on tattoo inks. They refer to a German study from 2009, carried out by Bundeministerium für Ernährung, Landwirtschaft und Verbraucherschutz. The study investigates the metal content and preservative content in 148 commercial tattoo inks. In 6.7% of the samples, preservatives were used. The dominating preservatives were benzoic acid, benzoisothiazolone (BIT), methylisothiazoline (MI) and octylthiazolone (OIT).

#### 4.1.3 Dermatologic Complications with Body Art: Tattoos, Piercings and Permanent Make-Up (Cuyper, 2009)

This e-book is about dermatological complications with body art. Under the section regarding preservatives the chemical component benzoic acid is mentioned as one of the commonly used preservatives in tattoo inks.

#### 4.1.4 Tattoo Inks Carrier Chemistry (About Education, Chemistry 2014)

An educational webpage writes an entry on the subject “Tattoo Inks carrier chemistry” with focus on liquid tattoo ink. Ethanol is mentioned as one of the safest and most common ingredients in liquid tattoo ink. However, the use of ethanol is mainly described as a carrier of the pigment, and not as a preservative. It is, however, well-known that ethanol has antimicrobial properties and is also listed with this function (antimicrobial) in the CosIng database (the European Commission database with information on cosmetic substances and ingredients<sup>2</sup>). It is, however, expected that primarily, ethanol is not used with preserving properties.

#### 4.1.5 Eternal Ink Material Safety Data Sheet (2015)

Eternal Ink is a tattoo ink producer. On the Eternal Ink Material Safety Data Sheet under section 2: Ingredient information is stated: “Our products are

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<sup>2</sup> <http://ec.europa.eu/consumers/cosmetics/cosing/index.cfm?fuseaction=search.simple>

primarily composed of organic pigment, distilled water, witch hazel, alcohol, and not considered to be a hazardous substance”.

#### 4.1.6 FDA Will Review Toxic Tattoo Chemicals (OCA, 2008)

This article describes that FDA has launched an investigation that will look into the chemicals contained in tattoo and permanent make-up inks, as well as their potential health effects. In this article, a preservative, used in tattoo ink called thimerosal or thiomersal, is mentioned. Thimerosal is an organic compound that contains mercury. The preservative is commonly included in tattoo inks and other products as a preservative. Because of the toxic effects of mercury, thimerosal is very effective in killing fungal and bacterial growth.

#### 4.1.7 Rising Concern over Cosmetic Tattoos (Ortiz, 2011)

This article is written to raise awareness of the danger of cosmetic tattoos. Ethanol is described as a commonly used diluent and preservative in tattoo inks.

#### 4.1.8 Thimerosal: Current Sources of Contact in Brazil (NICB, 2014)

The article describes the use of thimerosal in Brazil. It is mentioned that thimerosal is used as a preservative in contact lenses, vaccines and in tattoo inks, but the area of tattoo inks is not investigated in the article, due to lack of information on product labels.

#### 4.1.9 Thimerosal (Thiomersal – Thimersol, 2008)

This is an informative page about the preservative thiomersal. Thiomersal is a compound that most often contains 49% mercury by weight and it is used as an antiseptic and antifungal agent in various products as well as in tattoo inks.

## 4.2 Preservatives identified in liquid toys

In 2012 and 2013, FORCE Technology carried out a survey for the Danish EPA on the use of preservatives in toys (i.e. liquid toys such as modelling clay, finger paints, slime, soap bubbles etc.). This project consisted of a literature survey to identify the use of preservatives in liquid toys, contact to the toy industry in Denmark, and a chemical analysis of selected liquid toys on the Danish market.

It is not expected that the use of preservatives in toys has changed much during the last two years. For this reason, the results of the Danish EPA survey are summarised in the tables below. Table 2 is a list of the preservatives identified in the survey of the different product types of liquid toys.

Table 2: Identified preservatives for the different product types (liquid toys).  
Reference: Poulsen & Nelsen., 2014.

Product type	Preservative	Highest concentration
<b>Modelling clay</b>	2- phenoxyethanol Parabens (ethyl-, propyl- and butyl-) Dichlorbenzyl alcohol Benzyl alcohol Sodium benzoate Potassium sorbate	0.0045% 0.0020% 0.0025% 0.0025% 0.3% 0.3%
<b>Hobby paint</b>	Formaldehyde Kathon (MI/MCI) 1,2-benzisothiazol-3(2H)-one (BIT) 2-phenylethanol Benzyl benzoate Bronopol Sodium benzoate	0.087% < 0.0015% 0.0045% 0.0035% 0.0015% Approx. 0.04% <b>No information</b>
<b>Finger paint</b>	2-phenoxyethanol 2-amino-2-methylpropanol 1,2-benzisothiazol-3(2H)-one MCI MI Kathon (a mixture of the two above) Bronopol Denatonium benzoate Parabens (which ones are not stated) Diazolidinylureum Dichlorbenzyl alcohol Free formaldehyde	Approx. 0.89% Approx. 0.098% Approx. 0.00018% 0.0031% 0.0095% 0.0095% <b>No information</b> <b>No information</b> <b>No information</b> <b>No information</b> <b>No information</b> 0.069%
<b>Window paint/ Glass paint</b>	Kathon Bronopol	< 0.0015% Approx. 0.04%
<b>Face paint and make-up</b>	2-phenoxyethanol Sodium benzoate Polymaniopropyl biguanide Parabens (methyl-, ethyl-, propyl-, butyl- and isobutyl-) DMDM Hydantoin Potassium sorbate Iodopropynyl butylcarbamate (IPBC)	<b>No information</b> <b>No information</b> <b>No information</b> <b>No information</b> <b>No information</b> <b>No information</b> <b>No information</b>
<b>Glue</b>	2-methyl-2H-isothiazol-3-on (MI) Kathon (MI/MCI) 2-phenoxyethanol Sodium hydroxymethyl glycinate Parabens (methyl-, ethyl-, propyl-, butyl- and isobutyl-) Formaldehyde	0.00885% 0.0000813% 0.8% 0.5% Approx. 0.4% 0.00034%
<b>Slime</b>	Methylparaben Ethylparaben Parabens (propyl- and butyl-) Sodium benzoate Preventol D7 (is a mixture of isothiazolinones) 2-phenoxyethanol	0.002% 0.002% <b>No information</b> 0.002% 0.0025% <b>No information</b>
<b>Soap bubbles</b>	Methylisothiazolinon (MI) DMDM Hydantoin 2-phenoxyethanol Free formaldehyde Parabens (methyl-, ethyl-, propyl- and butyl-)	<b>No information</b> 0.3034% 0.6896% 0.0025% 0.001%

In the study for the Danish EPA, chemical analyses were carried out in order to determine the use of preservatives in 11 liquid toys. Eight different preservatives were identified in the 11 analysed liquid toys. The preservatives

identified are listed in Table 3 below and no new preservatives were identified, i.e. all the identified preservatives were also found in the literature survey (Table 2).

It should be noted that the formaldehyde measured in the 11 liquid toys (in Table 3) is free formaldehyde, which comes from release of formaldehyde from preservatives that can release formaldehyde (so-called formaldehyde releasers such as DMDM hydantoin, bronopol, BIT, etc.).

Table 3: Preservatives identified by chemical analysis in 11 liquid toys (Poulsen & Nielsen, 2014)

Preservative	Lowest value measured (mg/kg)	Highest value measured (mg/kg)	Identified in number of products out of 11
Methylparaben	845	1965	3
Ethylparaben	3745	3785	1
Propylparaben	965	985	1
Formaldehyde	3.5	1220	11
2-phenoxyethanol	4060	11.300	2
Sodium benzoate	450	4050	2
Bronopol	305	1000	2
Potassium sorbate	2240	2250	1

The information in Table 2 and Table 3 has been aggregated in a table (Table 4) with all 25 identified preservatives in liquid toys, containing information on classification and if the preservative is allowed in cosmetics – in line with Table 1 for preservatives in tattoos. The references listed in Table 4 refer to the references cited in the Danish EPA survey (Poulsen & Nielsen, 2014).

In the report from the Danish EPA on preservatives in toys (Poulsen & Nielsen, 2014), a risk assessment was carried out for the parabens, 2-phenoxyethanol, formaldehyde and bronopol. The risk assessment concluded that it is not likely that the used concentrations of these preservatives in liquid toys will constitute a risk for children even if playing with several different kinds of liquid toys. The report, however, points to the fact that many of the assessed preservatives are also used in cosmetic products and in this case, the exposure to these preservatives in cosmetic products should be added as well in order to determine the total risk. However, these calculations were not carried out in the project.

Table 4: Preservatives found in liquid toys (according to Poulsen &amp; Nielsen, 2014)

Preservative	CAS No.	Classification <sup>1</sup>	Allowed in cosmetics <sup>2</sup>	Comment	Reference
Formaldehyde <sup>3</sup>	50-00-0	<b>Acute Tox. 3, H301</b> <b>Acute Tox. 3, H311</b> <b>Skin Corr. 1B, H314</b> <b>Skin Sens. 1, H317</b> <b>Acute Tox. 3, H331</b> <b>Muta. 2, H341</b> <b>Carc. 1B, H350</b>	Yes	Content of 0.087% formaldehyde in hobby paint and 0.0025% formaldehyde in soap bubbles.	Reported by the industry in Poulsen & Nielsen, 2014
			0.2%		
			Yes	Measured in all 11 liquid toys by chemical analysis in concentrations of 0.00035 – 0.122 %.	Poulsen & Nielsen, 2014
			0.2%	Content of 0.004 - 0.069% found in finger paints – a Dutch survey.	Voetsel & Autoriteit, 2010
				Content of 0.00021 – 0.00034% found in two hobby glue products.	Nilsson & Jensen, 2003
Bronopol (2-bromo-2-nitropropane-1,3-diol)	52-51-7	<b>Acute Tox. 4, H302</b> <b>Acute Tox. 4, H312</b> <b>Skin Irrit. 2, H315</b> <b>Eye Dam. 1, H318</b> <b>STOT SE 3, H335</b> <b>Aquatic Acute 1, H400</b>	Yes	Content of approx. 0.04% in hobby paint and glass paint.	Reported by the industry. in Poulsen & Nielsen, 2014
			0.2%	Measured in 2 of 11 liquid toys by chemical analysis in concentrations of 0.0305 – 0.100 %.	Poulsen & Nielsen, 2014
				Identified – but no information about the content.	Voetsel & Autoriteit, 2010
2-phenylethanol	60-12-8	Acute Tox. 4, H302 Eye Irrit. 2, H319	No	Used in concentrations of 0.0035% in hobby paint.	Reported by the industry in Poulsen & Nielsen, 2014
Propyl paraben	94-13-3	Skin Irrit. 2, H315 Eye Irrit. 2, H319 STOT SE 3, H335	Yes 0.4% (0.8% in total)	Used in concentrations of 0.0020% in modelling clay, approx. 0.4% in glue and in 0.001% in soap bubbles. Used in finger paint and slime.	Reported by the industry in Poulsen & Nielsen, 2014
				Used in slimy toys.	Svendsen et al., 2006
				Used in face paint and make-up for children.	Forbrugerkemi, 2011
				Measured in concentrations of 0.0985% in 1 of 11 liquid toy products.	Poulsen & Nielsen, 2014
Butyl paraben	94-26-8	Skin Irrit. 2, H315 Eye Irrit. 2, H319 STOT SE 3, H335	Yes 0.4% (0.8% in total)	Used in concentrations of 0.0020% in modelling clay, approx. 0.4% in glue, and in 0.001% in soap bubbles. Used in finger paint and slime.	Reported by the industry in Poulsen & Nielsen, 2014
				Used in slimy toys.	Svendsen et al., 2006
				Used in face paint and make-up for children.	Forbrugerkemi, 2011
Methyl paraben	99-76-3	Skin Irrit. 2, H315 Eye Irrit. 2, H319 STOT SE 3, H335	Yes 0.4% (0.8% in total)	Used in concentrations of approx. 0.04% in glue, in 0.001% in soap bubbles, and in 0.002% in slime. Used in finger paint.	Reported by the industry in Poulsen & Nielsen, 2014
				Used in face paint and make-up for children.	Forbrugerkemi, 2011

Preservative	CAS No.	Classification <sup>1</sup>	Allowed in cosmetics <sup>2</sup>	Comment	Reference
				Measured in concentrations of 0.0845 – 0.1965% in 3 of 11 liquid toy products.	Poulsen & Nielsen, 2014
Benzyl alcohol	100-51-6	<b>Acute Tox. 4, H302 Acute Tox. 4, H332</b>	Yes 1.0%	Used in concentrations of 0.0025% in modelling clay.	Reported by the industry in Poulsen & Nielsen, 2014
Ethyl paraben	120-47-8	Asp. Tox. 1, H304 Skin Irrit. 2, H315 Skin Sens. 1, H317 Eye Irrit. 2, H319	Yes 0.4% (0.8% in total)	Used in concentrations of approx. 0.04% in glue, in 0.001% in soap bubbles, and in 0.002% in slime. Used in finger paint.	Reported by the industry in Poulsen & Nielsen, 2014
				Used in slimy toys.	Svendsen et al., 2006
				Used in face paint and make-up for children.	Forbrugerkemi, 2011
				Measured in concentrations of 0.3785% in 1 of 11 liquid toy products.	Poulsen & Nielsen, 2014
Benzyl benzoate	120-51-4	<b>Acute Tox. 4, H302 Aquatic Chronic 2, H411</b>	No	Used in concentrations of 0.0015% in hobby paint.	Reported by the industry in Poulsen & Nielsen, 2014
Phenoxyethanol	122-99-6	<b>Acute Tox. 4, H302 Eye Irrit. 2, H319</b>	Yes 1.0%	Used in concentrations of 0.0045% in modelling clay, approx. 0.89% in finger paint, 0.8% in glue, and 0.6896% in soap bubbles. Used in face paint and make-up, and slime products.	Reported by the industry in Poulsen & Nielsen, 2014
				Used in slimy toys.	Svendsen et al., 2006
				Used in face paint and make-up for children.	Forbrugerkemi, 2011
				Measured in concentrations of 0.406 to 1.13% in 2 of the liquid toy products.	Poulsen & Nielsen, 2014
2-amino-2-methylpropanol	124-68-5	<b>Skin Irrit. 2, H315 Eye Irrit. 2, H319 Aquatic Chronic 3, H412</b>	No	Used in concentrations of approx. 0.098% in finger paints.	Reported by the industry in Poulsen & Nielsen, 2014
Sodium benzoate	532-32-1	<b>Not classified or Eye Irrit. 2, H319</b>	Yes 0.5% for leave on prod.	Used in concentrations of 0.3% in modelling clay, and 0.002% in slime. Used in hobby paint, face paint, and make-up, but no information on concentrations.	Reported by the industry in Poulsen & Nielsen, 2014
				Used in face paint and make-up for children.	Forbrugerkemi, 2011
				Measured in concentrations of 0.045 to 0.405% in 2 of the liquid toy products.	Poulsen & Nielsen, 2014
Dichlorbenzyl alcohol (2,4-dichlorobenzyl alcohol)	1777-82-8	<b>Aquatic Chronic 3, H412</b>	Yes 0.15%	Used in concentrations of 0.0025% in modelling clay. Used in finger paint.	Reported by the industry in Poulsen & Nielsen, 2014



Preservative	CAS No.	Classification <sup>1</sup>	Allowed in cosmetics <sup>2</sup>	Comment	Reference
Benzisothiazolone (BIT) (1,2-benzisothiazolin-3-one)	2634-33-5	<b>Acute Tox. 4, H302 Skin Irrit. 2, H315 Skin Sens. 1, H317 Eye Dam. 1, H318 Aquatic Acute 1, H400</b>	No	Used in concentrations of approx. 0.00018% in finger paint and of 0.0045% in hobby paint.	Reported by the industry in Poulsen & Nielsen, 2014
Methylisothiazolinone (MI)	2682-20-4	Acute Tox. 3, H301 Acute Tox. 3, H311 Skin Corr. 1B, H314 Skin Sens. 1, H317 Eye Dam. 1, H318 STOT SE 3, H335 Aquatic Acute 1, H400	Yes  0.01%	Used in concentrations of 0.0095% in finger paint and 0.00885% in glue. Used in soap bubbles (no information about concentration).	Reported by the industry in Poulsen & Nielsen, 2014.
				Used in concentrations of 0.0151% in finger paint.	Voedsel & Autoriteit, 2010.
Denatonium benzoate	3734-33-6	Acute Tox. 4, H302 Acute Tox. 4, H332 Aquatic Chronic 3, H412	No	Used in finger paint, but no information about concentration used.	Reported by the industry in Poulsen & Nielsen, 2014
Isobutylparaben	4247-02-3	Eye Dam. 1, H318	Yes 0.4% (0.8% in total)	Used in concentrations of approx. 0.4% in glue.	Reported by the industry in Poulsen & Nielsen, 2014
				Used in face paint and make-up for children.	Forbrugerkemi, 2011
DMDM Hydantoin	6440-58-0	Acute Tox. 4, H302	Yes  0.6%	Used in concentrations of 0.3034% in soap bubbles.	Reported by the industry in Poulsen & Nielsen, 2014
				Used in face paint and make-up for children.	Forbrugerkemi, 2011
Potassium sorbate	24634-61-5	Skin Irrit. 2, H315 Eye Irrit. 2, H319	Yes  0.6%	Used in concentrations of 0.3% in modelling clay. Used in face paint and make-up, but no information about concentrations.	Reported by the industry in Poulsen & Nielsen, 2014
				Used in face paint and make-up for children.	Forbrugerkemi, 2011
				Measured in a concentration of 0.225% in one liquid toy product.	Poulsen & Nielsen, 2014
Methylchloroisothiazolinone (MIC)	26172-55-4	Acute Tox. 3, H301 Acute Tox. 3, H311 Skin Corr. 1B, H314 Skin Sens. 1, H317 Eye Dam. 1, H318 STOT SE 3, H335 Aquatic Acute 1, H400	Yes  But only as Kathon 0.0015 %	Used in concentrations of 0.0031% in finger paint.	Reported by the industry in Poulsen & Nielsen, 2014
				Used in concentrations of 0.0014% in glass paint.	Mikkelsen et al., 2004
Polyaminopropyl biguanide	28757-47-3	<b>Acute Tox. 4, H302 Skin Sens. 1B, H317 Eye Dam. 1, H318 Carc. 2, H351 STOT RE 1, H372 Aquatic Acute 1, H400 Aquatic Chronic 1, H410</b>	Yes  0.3%	Used in face paint and make-up, but no information regarding used concentrations.	Reported by the industry in Poulsen & Nielsen, 2014
Iodopropynyl butylcarbamate (IPBC)	55406-53-6	<b>Acute Tox. 4, H302 Skin Sens. 1, H317 Eye Dam. 1, H318 Acute Tox. 3, H331 STOT RE 1, H372</b>	Yes  0.01% in leave on	Used in face paint and make-up, but no information regarding used concentrations.	Reported by the industry in Poulsen & Nielsen, 2014

Preservative	CAS No.	Classification <sup>1</sup>	Allowed in cosmetics <sup>2</sup>	Comment	Reference
		<b>Aquatic Acute 1, H400</b> <b>Aquatic Chronic 1, H410</b>	prod.	Used in face paint and make-up for children.	Forbrugerkemi, 2011
Methylisothiazolinone (MI) / Methylchlorisothiazolinone (MIC)  The mixture is named Kathon	55965-84-9  2682-20-4/ 26172-55-4	<b>Acute Tox. 3, H301</b> <b>Acute Tox. 3, H311</b> <b>Skin Corr. 1B, H314</b> <b>Skin Sens. 1, H317</b> <b>Acute Tox. 3, H331</b> <b>Aquatic Acute 1, H400</b> <b>Aquatic Chronic 1, H410</b>	Yes, in rinse-off prod. <sup>4</sup>  0.0015 %	Used in concentrations of < 0.0015% in hobby paint and glass paint, 0.0095% in finger paint, 0.0000813% in glue and 0.0025% in slime.	Reported by the industry in Poulsen & Nielsen, 2014
Sodium hydroxymethylamino acetate	70161-44-3	Acute Tox. 4, H302 Eye Irrit. 2, H319	Yes  0.5%	Used in glue in concentrations of 0.5%.	Reported by the industry in Poulsen & Nielsen, 2014
Diazolidinyl urea	78491-02-8	Skin Sens. 1, H317	Yes  0.5%	Used in finger paints, but no information regarding the concentration used.	Reported by the industry in Poulsen & Nielsen, 2014

1: Harmonised classification is marked in bold and with grey background. If no harmonised classification exists, the notified classification given by most notifiers according to ECHA C&L Inventory is listed.

2: "Allowed in cosmetics" refers to if the preservatives are listed in Annex V "List of preservatives allowed in cosmetic products" (Regulation No. 1223, 2009). All preservatives on this Annex V are only allowed under certain conditions e.g. under a certain maximum concentration in ready for use preparation. The maximum concentration is listed in the table.

3: Formaldehyde has been reclassified and the classification is applicable as of 1<sup>st</sup> April 2015 (Regulation No. 605, 2014).

4: According to EU Regulation No. 1003/2014 the use of Kathon in cosmetic products as of 16 July 2015 is only allowed in rinse-off products. Before this date, the use of Kathon products is allowed all types of cosmetic products.

# 5 Discussion

## 5.1 Discussion

The survey illustrates that many of the same preservatives are used in both tattoo inks and liquid toys. In all, 20 different preservatives (different CAS numbers) were identified for use in tattoo inks (Table 1) and 25 different preservatives were identified for use in liquid toys (Table 4), such as modelling clay, finger paint, glass paint, slime, soap bubbles, glue, face paint and make-up for children.

There is some overlap between the preservatives identified for use in tattoo inks and liquid toys. The preservatives that are used in both product areas are:

- Formaldehyde
- Bronopol
- Propyl paraben
- Methyl paraben
- Ethyl paraben
- Phenoxyethanol
- Benzisothiazolinone (BIT)
- Methylisothiazolinone (MI)
- Kathon – the mixture of MI/MIC

In Table 1 and Table 4, it is indicated whether or not the preservatives are allowed to be used in cosmetic products. Most of the identified preservatives are allowed in cosmetic products. However, it should be noted that as of 16 July 2015 Kathon is no longer allowed to be used in leave-on cosmetic products, but it will only be allowed in rinse-off products because of its skin sensitisation potential (Regulation No. 1003, 2014).

For tattoo inks, five of the 20 preservatives are not allowed in cosmetic products; these are:

- Glyoxal
- Phenol
- Benzisothiazolinone (BIT)
- Octylisothiazolinone (OIT)
- Ethanol
  - Ethanol is not allowed in cosmetic products as a preservative, but is allowed to be used as a solvent. It is expected that the use of ethanol is due to its solvent properties.

For tattoo inks, two other preservatives have other restrictions concerning their uses:

- Thimerosal - is allowed in cosmetic products, but only for eye products. Thimerosal was found in tattoo inks which are not used around the eyes.
- Kathon – is allowed in cosmetic products, but only in rinse-off products (as of 16 July 2015).

For liquid toys, five of the 25 preservatives are not allowed in cosmetic products; these are:

- 2-phenylethanol
- Benzyl benzoate
- 2-amino-2-methylpropanol
- Benzisothiazolinone (BIT)
- Denatonium benzoate

Furthermore, the preservative Kathon has other restrictions concerning its use:

- Kathon – is allowed in cosmetic products, but only in rinse-off products (as of 16 July 2015).

The harmonised or notified classification (ECHA C&L Inventory) has been looked up and listed in Table 1 and Table 4 for all identified preservatives. Preservatives with classifications of concern (i.e. CMR properties or sensitising properties) are listed in the table below. Furthermore, thimerosal has been included in Table 5 below, as thimerosal is classified with Acute Tox. 1, H310 “Fatal in contact with skin”.

Table 5: Identified preservatives in tattoo inks and liquid toys with classifications of concern

Preservative	CAS No.	Classification <sup>1</sup>	Allowed in cosmetics <sup>2</sup>	Used in
Formaldehyde <sup>3</sup>	50-00-0	<b>Acute Tox. 3, H301</b> <b>Acute Tox. 3, H311</b> <b>Skin Corr. 1B, H314</b> <b>Skin Sens. 1, H317</b> <b>Acute Tox. 3, H331</b> <b>Muta. 2, H341</b> <b>Carc. 1B, H350</b>	Yes  0.2%	Tattoo inks Liquid toys
Thimerosal	54-64-8	Acute Tox. 2, H300 Acute Tox. 1, H310 Acute Tox. 2, H330 STOT RE 2, H373 Aquatic Acute 1, H400 Aquatic chronic 1, H410	Yes, but only for eye products  0.007% (Hg)	Tattoo inks
Chlorhexidine	55-56-1	Skin Irrit. 2, H315 Eye Irrit. 2, H319 Resp. Sens. 1, H334 STOT SE 3, H335 Aquatic Acute 1, H400 Aquatic Chronic 1, H410	Yes  0.3%	Tattoo inks
4-chloro-3,5-dimethylphenol	88-04-0	<b>Acute Tox. 4, H302</b> <b>Skin Irrit. 2, H315</b> <b>Skin Sens. 1, H317</b> <b>Eye Irrit. 2, H319</b>	Yes  0.5%	Tattoo inks
Glyoxal	107-22-2	<b>Skin Irrit. 2, H315</b> <b>Skin Sens. 1, H317</b> <b>Eye Irrit. 2, H319</b> <b>Acute Tox. 4, H332</b> <b>Muta. 2, H341</b>	No	Tattoo inks
Phenol	108-95-2	<b>Acute Tox. 3, H301</b> <b>Acute Tox. 3, H311</b> <b>Skin Corr. 1B, H314</b> <b>Acute Tox. 3, H331</b> <b>Muta. 2, H341</b> <b>STOT RE 2, H373</b>	No	Tattoo inks
Ethyl paraben	120-47-8	Asp. Tox. 1, H304 Skin Irrit. 2, H315 Skin Sens. 1, H317 Eye Irrit. 2, H319	Yes  0.4% (0.8% in total)	Tattoo inks Liquid toys

Preservative	CAS No.	Classification <sup>1</sup>	Allowed in cosmetics <sup>2</sup>	Used in
Benzisothiazolone (BIT) (1,2-benzisothiazolin-3-one)	2634-33-5	<b>Acute Tox. 4, H302</b> <b>Skin Irrit. 2, H315</b> <b>Skin Sens. 1, H317</b> <b>Eye Dam. 1, H318</b> <b>Aquatic Acute 1, H400</b>	No	Tattoo inks Liquid toys
Methylisothiazolinone (MI)	2682-20-4	Acute Tox. 3, H301 Acute Tox. 3, H311 Skin Corr. 1B, H314 Skin Sens. 1, H317 Eye Dam. 1, H318 STOT SE 3, H335 Aquatic Acute 1, H400	Yes  0.01%	Tattoo inks Liquid toys
Octylisothiazolinone (OIT) (2-octyl-2H-isothiazol-3-one)	26530-20-1	<b>Acute Tox. 4, H302</b> <b>Acute Tox. 3, H311</b> <b>Skin Corr. 1B, H314</b> <b>Skin Sens. 1, H317</b> <b>Acute Tox. 3, H331</b> <b>Aquatic Acute 1, H400</b> <b>Aquatic Chronic 1, H410</b>	No	Tattoo inks
Methylchloroisothiazolinone (MIC)	26172-55-4	Acute Tox. 3, H301 Acute Tox. 3, H311 Skin Corr. 1B, H314 Skin Sens. 1, H317 Eye Dam. 1, H318 STOT SE 3, H335 Aquatic Acute 1, H400	Yes  But only as Kathon 0.0015%	Liquid toys
Polyaminopropyl biguanide	28757-47-3	<b>Acute Tox. 4, H302</b> <b>Skin Sens. 1B, H317</b> <b>Eye Dam. 1, H318</b> <b>Carc. 2, H351</b> <b>STOT RE 1, H372</b> <b>Aquatic Acute 1, H400</b> <b>Aquatic Chronic 1, H410</b>	Yes  0.3%	Liquid toys
Iodopropynyl butylcarbamate (IPBC)	55406-53-6	<b>Acute Tox. 4, H302</b> <b>Skin Sens. 1, H317</b> <b>Eye Dam. 1, H318</b> <b>Acute Tox. 3, H331</b> <b>STOT RE 1, H372</b> <b>Aquatic Acute 1, H400</b> <b>Aquatic Chronic 1, H410</b>	Yes  0.01% in leave on prod.	Liquid toys
Methylisothiazolinone (MI) / Methylchlorisothiazolinone (MIC)  The mixture is named Kathon	55965-84-9  2682-20-4/ 26172-55-4	<b>Acute Tox. 3, H301</b> <b>Acute Tox. 3, H311</b> <b>Skin Corr. 1B, H314</b> <b>Skin Sens. 1, H317</b> <b>Acute Tox. 3, H331</b> <b>Aquatic Acute 1, H400</b> <b>Aquatic Chronic 1, H410</b>	Yes, in rinse-off prod. <sup>4</sup>  0.0015%	Tattoo inks Liquid toys
Diazolidinyl urea	78491-02-8	Skin Sens. 1, H317	Yes  0.5%	Liquid toys

1: Harmonised classification is marked in bold and with grey background. If no harmonised classification exists, the notified classification given by most notifiers according to ECHA C&L Inventory is listed.

2: "Allowed in cosmetics" refers to if the preservatives are listed in Annex V "List of preservatives allowed in cosmetic products" (Regulation No. 1223, 2009). All preservatives in this Annex V is only allowed under certain conditions e.g. under a certain maximum concentration in ready for use preparation. The maximum concentration is listed in the table.

3: Formaldehyde has been reclassified and the classification is applicable as of 1<sup>st</sup> April 2015 (Regulation No. 605, 2014).

4: According to EU Regulation No. 1003/2014 as of 16 July 2015, the use of Kathon in cosmetic products is only allowed in rinse-off products. Before this date, the use of Kathon products is allowed in all types of cosmetic products.

Table 5 illustrates that three of the preservatives identified for use in either tattoo inks or liquid toys or both have CMR properties (formaldehyde, phenol and polyaminopropyl biguanide). The rest of the listed preservatives in Table

5 has sensitising properties, and thimerosal has been included in Table 5, as thimerosal is classified with Acute Tox. 1, H310 “Fatal in contact with skin”.

It is of course problematic that preservatives classified with CMR properties are used in these types of products. The new Toy Directive does regulate the use of CMR substances in toys – however, the problem is that the allowed concentrations are not necessarily prohibitive for their use as preservatives like these are used in low concentrations in the toy products.

Furthermore, it is of concern that so many of the preservatives used are classified with sensitising properties, especially because the investigated products (tattoo inks and liquid toys) are used directly in or on the skin. The preservative Kathon has recently (as of 16 July 2015) been restricted for use in leave-on cosmetic products due to its sensitising properties (Regulation No. 1003, 2014).

Finally, it is of concern that a preservative like thimerosal that is classified with Acute Tox. 1, H310 “Fatal in contact with skin” is used in tattoo inks. Thimerosal contains mercury which is toxic. However, thimerosal has not been identified in tattoo inks in the large Swiss study, but mainly via American or Brazilian webpages.

The used concentration should of course be taken into account when assessing the risk (which is not a part of this study). The concentrations identified for the preservatives illustrate that preservatives are used in low concentrations, usually well below 1%. Use of phenoxyethanol may be the exception where concentrations of up to 1.49% have been measured in tattoo inks.

Besides the above listed preservatives of concern (Table 5), other preservatives are also discussed in the scientific community as being problematic with regard to their health aspects, e.g. parabens with endocrine disrupting effects which are not reflected in the classifications of the substances.

## 5.2 Recommendations

This survey of preservatives used in tattoo inks and liquid toys illustrates that it may be of relevance to investigate the following aspects further:

- Does the use of preservatives with CMR properties constitute a risk for the consumer in the concentrations used?
- Does the use of preservatives with sensitising properties constitute a risk for the consumer?
- Should preservatives with CMR and/or sensitising properties be used in consumer products? Can they be substituted by other preservatives? Is it possible to establish acceptable concentrations?
- Should a positive list of preservatives be prepared for tattoo inks and liquid toys as well in line with the cosmetics regulation?

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