Proposal for regulatory rules on tattoo and PMU inks

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Contents

Summary

Being tattooed is of growing popularity, but no harmonised control is present in the EU on tattoo and PMU (Permanent Make-Up) inks. In 2003, the Council of Europe (CoE) adopted a non-binding Resolution on the safety of tattoos and PMU, recommending some chemical, labelling and hygienic requirements. These criteria were subsequently used by some European countries in their national legislation, thereby banning the use of certain chemicals in tattoos and PMU inks. The resolution was revised in 2008.

Joint Research Centre (JRC) has recently prepared a couple of reports on the safety of tattoo and PMU inks. They concluded that apart from the General Product Safety Directive (GPSD), there is not specific EU legislation on tattoos or PMU inks. Furthermore, they concluded that it is problematic that some chemicals used in tattoo and PMU inks are banned by EU regulation (such as restrictions of specific chemicals in specific products in Annex XVII of REACH or the Cosmetic Products Regulation) if in contact with skin, but they are currently allowed in tattoo inks because of no regulation in the area.

Today, only about 10 European countries have legislation concerning the chemical substances used in tattoo and PMU inks. Most of the legislation (if any) in European countries is based on the CoE Resolution from either 2003 or 2008. In October 2017, ECHA (European Chemicals Agency) therefore prepared a proposal for a restriction of hazardous substances in tattoos and PMU inks, which is based on the CoE Resolution from 2008 and the regulation on cosmetic products.

Purpose
The purpose of this project has been to develop a proposal for regulatory rules on tattoo and PMU inks for the chemical substances in these products. The proposal for regulatory rules will be based on the findings in the reports from JRC on tattoo and PMU inks as well as the CoE Resolution and the ECHA restriction proposal on tattoo and PMU inks. Furthermore, this project contains a discussion of the ECHA restriction proposal.

Description and discussion of relevant legislation and other information
Relevant legislation for tattoo and PMU inks was described and discussed. No specific legislation concerning chemical substances used in tattoo and PMU inks exists – other than the General Product Safety Directive. The GPSD does not contain any specific chemical requirements – only the general safety requirement of “products must be safe”, which also applies for chemical safety of the products. However, the GPSD only applies for the tattoo and PMU inks sold to the consumer.

In addition, only the general legislation concerning labelling and classification (CLP) of dangerous chemical substances as well as the general rules of registration, evaluation, authorisation and restrictions of chemicals in REACH applies. Finally, the biocidal product regulation also applies for tattoo and PMU inks, which means that only preservatives approved for the relevant product type must be used. Some of the restriction in Annex XVII of REACH also applies for tattoo inks, but they are general and not specially envisioned for tattoo inks.

The most used voluntary scheme today on tattoo and PMU inks is the CoE Resolution, which has been used as the basis for national legislation in some EU countries. Along with the regulation on cosmetic products, the CoE Resolution has also been used as the basis of the ECHA restriction proposal on tattoo and PMU inks.

Even though several different groups of chemical substances (CMR substances, skin sensitisers, colourants, preservatives, element impurities etc.) are restricted by the CoE Resolution, several new additions have been proposed by different Member States (e.g. new limit values and inclusion of more substances to be restricted).

In the newly published ECHA restriction proposal on tattoo and PMU inks, many of the critique points of the CoE Resolution are considered. The ECHA restriction proposal is hence more extensive and suggests restriction of more substances in tattoo and PMU inks, because it also uses the annexes of substances already restricted by the regulation on cosmetic products. However, one of the main critique points of the ECHA restriction proposal is that it is only substances with a harmonised classification that are restricted.

Screening of ingredients in tattoo and PMU inks
Based on the JRC reports and a previous study on colourants in tattoo inks and PMU, an overview of tattoo ink ingredients was prepared. For all ingredients, their harmonised classification as well as notified classification was looked up by use of the ECHA C&L Inventory and their classification was compared with a list of classifications defined as 'problematic classifications' in this report. The notified classification is the self-classified classifications listed by ECHA in the C&L Inventory. All classifications have been noted, even if only notified by one company.

The screening and review of the classifications of ingredients used in tattoo and PMU inks resulted in a list of 147 different colourants and 160 different other ingredients than colourants that are used in tattoo and/or PMU inks.

Based on the review, it was concluded that the most problematic ingredients in tattoo and PMU inks seem to be preservatives, colourants, buffering agents and solvents, and that it is necessary to go into details about these specific substances to be able to use these ingredients in acceptable concentrations. It was also concluded that for the 46 identified ingredients with problematic classification (using the definition used in this report), the ECHA proposal will only be able to restrict about 40% of these when only restricting substances with harmonised classifications. This means that the definition of problematic classification suggested in this report is stricter compared to the ECHA proposal.

Proposal for regulatory requirements for chemicals in tattoo and PMU inks
For this reason, a proposal for regulatory requirements for chemicals used in tattoo and PMU inks was suggested. The proposal prepared in this report was mainly based on the new ECHA restriction proposal, but a few changes were suggested:

- The restrictions based on classifications should not only apply for harmonised classifications, but also for the notified classifications, if 50% or more of the notifiers have notified the specific relevant classifications. Using this proposal, 46 substances of the 307 (147 colourants and 160 other ingredients) would be restricted in tattoo and PMU inks. In comparison, the ECHA proposal will exclude 19 of the examined substances used in tattoo and PMU inks.

- The limit value for substances with a classification as skin sensitising should be lowered.
- The restrictions based on classifications should also include substances that are acutely toxic to skin.
- Expansion of the negative list of substances to be restricted for use.
- Inclusion of a true positive list of substances to be approved for use in tattoo and PMU inks if certain concentration limits are complied with. The adoption of a substance on this positive list should only be carried out after a risk assessment, where the exposure pathway of tattoo and PMU inks (injection under the skin) has been performed.

Moreover, it was emphasised that it may be relevant (and necessary) to look more closely at the preservatives and perhaps set specific limit values for the approved preservatives (according to the regulation on biocidal products) based on risk assessments of the individual preservatives and based on the exposure pathway of injection under the skin. Similarly, solvents and buffering agents are a group of substances where specific acceptable limit values need to be set, as the generic limit values used may exclude a large part of this group of substances.

Finally, it is concluded that it will be necessary to introduce the proposed restrictions in this report into a new framework (i.e. not into REACH), as it will not be possible to use the REACH framework when introducing a true positive list as suggested in this report. Using a positive list would require an approval procedure as given in e.g. the cosmetics regulation for e.g. preservatives. Alternatively, the proposed restrictions could be incorporated in the legal framework for cosmetic products.

1 Introduction

1.1 Background

Today, 12% of the European population have a tattoo. Tattoo inks and PMU inks contain chemicals which stay in the body for life, but little is known about the long-term effects of these chemicals. However, adverse health effects like infections and allergies are increasingly reported (Piccinini et al, 2016a).

In 2003, the Council of Europe (CoE) adopted a non-binding Resolution (ResAP) on the safety of tattoos and PMU, recommending inter alia some chemical, labelling and hygienic requirements. These criteria were subsequently used by several European countries in their national legislation, thereby banning the use of certain chemicals in tattoos and PMU inks. The resolution was revised in 2008.

Joint Research Centre (JRC) has recently (in 2015 and 2016) prepared a couple of reports on the safety of tattoo and PMU inks (Piccinini et al., 2015a/2015b/2016a/ 2016b). The reports have been prepared on behalf of the Directorate General Justice and Consumers (DG JUST). The conclusions of these projects aim to provide the European Commission with the scientific evidences needed to decide if EU measures are necessary to ensure the safety of tattoo and PMU inks.

Two of the conclusions of the reports are:

- that apart from the general safety requirements by the General Product Safety Directive (GPSD), currently there is no specific EU legislation on tattoos or PMU products, and
- that some chemicals used in tattoo and PMU inks are banned by EU regulation (such as restrictions of specific chemicals in specific products in Annex XVII of REACH or the Cosmetic Product Regulation), if they come into contact with the skin, but currently they are allowed in tattoo inks because of no regulation on the area.

Due to the growing popularity of tattoos and the fact that no harmonised control is present in the EU on tattoo and PMU inks, ECHA was asked by the European Commission to assess the chemical-related risks associated with the inks, the need for action on EU level, and the relevant socio-economic impacts. This assessment resulted in a proposal for a restriction of hazardous substances in tattoos and permanent make-up, which was submitted by ECHA in October 2017.

1.2 Purpose

Therefore, the purpose of this study has been to develop a proposal for regulatory rules on tattoo and PMU inks for the chemical substances in these products. The proposal for regulatory rules will be based on the findings in the reports from JRC on tattoo and PMU inks as well as the CoE Resolution and the ECHA restriction proposal on tattoo and PMU inks.

1.3 Definitions

Tattoo inks are inks used to make permanent lifelong tattoos on the human body. Tattoo inks are applied by injecting the coloured inks into the dermis, i.e. the inner layer of skin beneath the epidermis (the outer layer of skin). **PMU** (Permanent Make-Up) is (semi)permanent tattoos used to resemble make-up (Piccinini et al., 2016a).

2 Project methodology used

This project has been carried out as a desk-top study and includes the following tasks:

1. Descriptions of existing legislation regarding chemical substances in tattoo and PMU inks.
2. Description of other relevant requirements for chemical substances in tattoo inks, i.e. non-binding requirements or national strategies on the area:
    a. Description of the Council of Europe's non-binding Resolution (ResAP) on the safety of tattoos and PMU.
    b. ECHA's proposal for a restriction concerning substances in tattoo inks and permanent make-up (ECHA, 2017a).
3. Description of the typical type of ingredients in tattoo and PMU inks as well as examples of the typically used ingredients in tattoo inks.
4. Review of the classifications of the substances used in tattoo and PMU inks.
5. Proposal for regulatory requirements for chemicals in tattoo and PMU inks.
6. Discussion, conclusions and recommendations.

3 Legislation

In this chapter, the existing legislation relevant for chemical substances in tattoo and PMU inks is described and reviewed. The following legislation is reviewed:

- General Product Safety Directive (GPSD)
- REACH Regulation (REACH)
- CLP Regulation (CLP)
- Biocidal Products Regulation (BPR)
- Cosmetic Products Regulation (CPR)

It should be noted that even though tattoo and PMU inks are not covered by the Cosmetic Products Regulation, this regulation is described anyway because it may be relevant to use this existing legislation in connection with the proposal for a regulatory requirement for tattoo and PMU inks. Furthermore, the Council of Europe Resolution on tattoo inks (described in chapter 4 "Other relevant information") is largely based on bans and restrictions referring to annexes in the Cosmetic Products Regulation.

3.1 General Product Safety Directive (GPSD)

The General Product Safety Directive (EU Directive no. 95, 2001) is intended to ensure product safety for EU consumer products not covered by specific other legislation. This is done by the general statement in article 3 of GPSD: "producers shall be obliged to place only safe products on the market".

In the GPSD, safe products are defined as "any product, which under normal or reasonably foreseeable conditions of use including duration… does not present any risk or only the minimum risks… considered to be acceptable and consistent with a high level of protection for the safety and health of persons…". The following points must be taken into account:

- the characteristics of the product, including its composition, packaging, instructions for assembly and, where applicable, for installation and maintenance;
- the presentation of the product, the labelling, any warnings and instructions for its use and disposal and any other indication or information regarding the product;
- the categories of consumers at risk when using the product, in particular children and the elderly.

Products are presumed safe:

1. If they follow specific Community provisions concerning safety of the product. This means that the General Product Safety Directive does only apply to risks or categories of risks not covered by the specific European product legislation. However, article 5 to 18 of the GPSD (concerning e.g. market surveillance from Member States, RAPEX notifications as well as producers' and distributors' obligation to inform consumers of risks, i.e. by use of appropriate warnings) still apply even though specific European legislation on the area applies.
   In the case of tattoo and PMU inks, no European legislation exists, which means that the GPS Directive applies in its entirety.

2. If they follow specific national legislation concerning safety of the product. In these cases, where specific national product legislation exists and is followed, conformity to the safety requirements of the General Product Safety Directive is presumed for the risks described in the national legislation.
   Seven EU member states have a specific national tattoo legislation in place based on the Council of Europe (CoE) non-binding Resolution (ResAP) on the safety of tattoos and PMU inks, and three other EU member states have prepared draft legislation based on CoE ResAP (ECHA, 2017a).

3. If they follow European standards, the references which have been published by the Commission in the Official Journal of the European Communities.
   This means that in the case where European standards for tattoo and PMU inks have been prepared upon request by the Commission and when references have been published in the Official Journal and the standards have been followed, conformity to the safety requirements of the General Product Safety Directive is presumed for the risks described in these national standards.

4. If they follow other European Standards.

5. If they follow relevant national standards (which do not transpose European standards).

6. If, in the absence of product specific legislation or relevant national standards, they follow:
   - Commission recommendations setting guidelines on product safety,
   - product safety codes of good practice in force for the sector concerned,
   - the state of art and technology
   - and reasonable consumer expectations concerning safety.

The presence of warnings does not exempt the product from compliance with the GPSD.

Furthermore, producers and distributors have the following obligations:

- They must provide consumers with the relevant information to enable them to assess the risks inherent in the products they supply.
- Provide the product or packaging with product identification (or batch identification), i.e. documentation necessary for tracing the origin of the products.
- Where appropriate, carry out simple testing of marketed products and if necessary keeping registers of products, complaints etc.
- Act with due care to help to ensure compliance with the applicable safety requirements, in particular by not supplying products that do not comply with the safety requirements, which they know or should have presumed, based on the information in their possession and as professionals.
- Immediately inform the competent authorities of the relevant Member States if a product they have placed on the market poses risks to the consumer that are incompatible with the general safety requirement.

It must be emphasised that in article 2 of the GPSD, a ‘product’ is defined as “any product — including in the context of providing a service — which is intended for consumers…”. This means that products used by professionals are not necessarily

covered by the GPSD – only products used (but not necessarily purchased) by the consumer.

3.1.1 Existing standards on tattoo and PMU inks

There are no existing European standards on tattoo and PMU inks according to the CEN search site[1]. Within the committee CEN/TC 435, a standard prEN 17169 with the title "Tattooing services – Safe practice and hygiene requirements" is under approval. This standard is, however, based on the title, assumed not to include chemical requirements for the substances used in tattoo and PMU inks, but mainly include requirements regarding safety and hygiene when carrying out the tattooing service.

3.1.2 Discussion

In the case of tattoo and PMU inks where no European legislation exists and where no European standards exist, the general statement "products must be safe" in the GPSD will apply – but only if the tattoo ink is sold to the consumer. In the case of national legislation or national standards, conformity to the safety requirements of the GPSD is presumed for the risks described in these national legislation and standards. This is the case for seven EU member states (Belgium, France, Germany, the Netherlands, Spain, Slovenia, and Sweden), where national legislation is in place for tattoo and PMU inks (ECHA, 2017a).

Tattoo and PMU inks are primarily used by professional tattooists, which means that consumers normally do not buy the actual tattoo ink or PMU ink, but buy a tattooing service from professional tattoo artists. However, it is possible for consumers to buy tattoo and PMU inks as well as disposable tattooing kits (needles)[2], in which case the GPSD will apply.

The GPSD does not contain any chemical requirements – only the general safety requirement of "safe products". This safety requirement is not described in detail, but it is defined as "it must not present any risk or only the minimum risks considered to be acceptable and consistent with a high level of protection for the safety and health of persons". This means that chemical risks are included as well, however, it is not well defined what is meant with "a high level of protection" or the "minimum risks considered to be acceptable". Furthermore, because of these very general statements and no specific chemical requirements, it is difficult for both producers and authorities to know when a chemical content in a product is "safe". From a producer's point of view, it would be easier to follow limit values or negative/positive lists of ingredients in tattoo and PMU inks.

The idea with the GPSD is that specific safety requirements should be elaborated in European standards. However, at the moment, no European standards are available for tattoo and PMU inks, as neither the Commission nor Member States have initiated this issue to the standard bodies.

According to the GPSD, products are also presumed safe if, in the absence of product specific legislation or relevant national standards, they follow (article 3 (3)):

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[1] European Committee for Standardization (https://standards.cen.eu/dyn/www/f?p=CENWEB:105::RESET::::)

[2] http://www.thetattooshop.co.uk/shop/Professional_Tattoo_Kit_0.html

- "Commission recommendations setting guidelines on product safety"
- "Product safety codes of good practice in force for the sector concerned"
- "The state of art and technology"

In 2008, the Council of Europe adopted a "Resolution on requirements and criteria for the safety of tattoos and permanent make-up" (CoE Resolution, 2008). The recommendations of the CoE Resolution are therefore relevant and the CoE Resolution is an important reference in the safety assessment of tattoo and PMU inks – especially for countries with no tattoo ink legislation in place. However, this resolution is non-binding and therefore it is not considered as legal status, and tattoo and PMU inks cannot be considered as safe according to the GPSD if they follow this CoE. Nevertheless, this resolution is considered as the reference for national legislation in those seven Member States which have legislation in place for tattoos. The CoE Resolution is described in more details in the next chapter.

3.2 REACH Regulation

Tattoo and PMU inks are chemical products and are therefore covered by the REACH Regulation (EU Regulation no. 1907/2006) on registration, evaluation, authorisation and restriction of chemicals. This means that all ingredients used in tattoo and PMU inks must be registered (by the respective deadlines) and thereby evaluated in connection with the registration (and with the respective evaluation requirements).

Furthermore, the restrictions of chemicals listed in Appendix XVII of REACH also apply. However, most of the restrictions do not apply to tattoo and PMU inks, but for other products such as toys, textiles, plastic products, paints etc. The restrictions in Appendix XVII which apply for tattoo and PMU inks are:

- Entries no.12 to 15 – restriction of the following chemicals in all mixtures in concentrations higher than 0.1%. The substances can be used in the production of dyes and are restricted because of their carcinogenic properties:
    - 2-napthylamine (and its salts)
    - Benzidine (and its salts)
    - 4-nitrobiphenyl
    - 4-aminobiphenyl xenylamine (and its salts)
- Entry no. 22 – PCP (pentachlorophenol), which formerly has been used as disinfectant and in anti-fouling paint.
- Entries no. 28 to 30 – substances that are carcinogenic (Carc 1A and 1B), mutagenic (Mut 1A and 1B) and reprotoxic (Repr. 1A and 1B) must not be present in mixtures supplied to the general public, when the concentrations are higher than the specific concentration limits listed for individual substances or the generic concentration limit (Mut. and Carc.: 0.1%; Repr.: 0.3%) according to the CLP Regulation.
- Entry no. 60 – acrylamide must not be present in mixtures in concentrations above 0.1%.

3.2.1 Discussion

According to the REACH Regulation, all ingredients used in tattoo and PMU inks must be registered in the REACH system. However, the latest registration deadline of 2018 has not been met yet, which means that all used ingredients in tattoo and PMU inks are not necessarily registered yet.

In most cases, Annex XVII of REACH, which contains different restrictions on chemicals, is not applicable for tattoo and PMU inks. The most relevant restriction seems to be the restriction on CMR substances in mixtures supplied to the general public. In general, the concentration limit is 0.1% for mutagenic and carcinogenic substances, but as high as 0.3 % for substances that are toxic to reproduction. However, if specific concentration limits exist for specific substances, these concentration limits apply instead.

Furthermore, this restriction in REACH Appendix XVII only covers mixture 'supplied to the general public'. In most cases, when people get a tattoo they will visit a tattoo saloon and get professionals to carry out the tattoo. In principle, this will mean that tattoo and PMU inks used by professionals are not covered by this REACH restriction and can in principle contain much higher amounts of CMR substances, as no specific legislation on tattoo and PMU inks exists at the moment. However, tattoo inks sold directly to the general public, e.g. on websites also selling tattooing kits, have to comply with this REACH restriction on CMR substances.

The REACH restrictions in Annex XVII (entry no. 43) contain a restriction on azo dyes that by reductive cleavage can release carcinogenic aromatic amines with a limit value of 30 ppm (0.003%). This restriction does, however, only apply for textile and leather articles. Currently, this means that consumers are protected from wearing clothing containing azo dyes, but may have the same azo dyes directly injected under the skin.

3.3 CLP Regulation

The CLP Regulation (EU Regulation no. 1272, 2008) on classification, labelling and packaging of substances and mixtures does not set chemical requirements for substances in tattoo and PMU inks, but describes the legal requirements concerning classification and labelling of chemical mixtures that contain dangerous chemical substances. This means that the CLP Regulation describes, how the tattoo and PMU inks should be classified and labelled depending on the content of dangerous chemical substances.

It is the responsibility of manufactures and importers of substances and chemical mixtures to classify, label and package their hazardous chemicals appropriately before placing them on the market. The CLP Regulation sets detailed criteria for the classification and labelling of the chemical substances and mixtures. Some of the elements in the CLP Regulation is described below, i.e.:

- Rules for classification of substances and mixtures
- Concentration thresholds for classification

The classification of individual substances is carried out by using specific data on the hazard of the individual substance. In Annex I of the CLP Regulation, the rules and principles for the classification are described. In general, the more severe hazards the more severe the resulting classification of the substance is. However, most chemical products are mixtures of different chemical substances. There are three ways to classify a mixture (ECHA, 2014; EU Regulation No. 1272, 2008):

1. Using data on hazards available on the mixture itself
2. Bridging principles
3. Classification based on hazards of the individual ingredients and their concentrations

Bridging principles can be used where relevant, reliable and adequate data are available on similar tested mixtures and the individual ingredients. The bridging principles are described in Annex I of the CLP Regulation. However, most often the classification of mixtures is carried out by knowledge on hazards of the individual ingredients and then using specific rules set for the classification of mixtures based on the classification of the individual substances in the mixture as described in Annex I of the CLP Regulation (ECHA, 2017d; ECHA, 2014; EU Regulation No. 1272, 2008).

At the classification of mixtures, there are the following relevant terms in use:

- Generic cut-off values
- Generic concentration limits
- Specific concentration limits

The generic cut-off value is the minimum concentration for a substance to be taken into account for classification purposes, where additivity rules apply, i.e. the concentration of different substances with the same classification can be 'added' by use of specific principles (EU Regulation No. 1272, 2008; ECHA, 2014). However, the concentration does not necessarily trigger a classification. The generic cut-off values are defined as listed in Table 1 below and are only used for acute toxicity, corrosion and skin/eye irritation. The generic cut-off values are also used for environmental hazards class, but these are not described in detail in this report, as it is the human hazard that is most relevant for tattoo and PMU inks (Annex I, Section 1.1.2.2, Table 1.1 in EU Regulation No. 1272, 2008).

Table 1: Generic cut-off values for concentrations to be taken into account for classification (EU Regulation No. 1272, 2008; ECHA, 2014)

Hazard class	Generic cut-off values to be taken into account
Acute toxicity - Category 1, 2 and 3 - Category 4	 0.1% 1%
Skin corrosion/skin irritation	1%[1]
Serious damage to eyes/eye irritation	1%[1]

[1] or below 1% where relevant

For hazards where the additivity rules do not apply, generic concentration limits are used. The generic concentration limits are limits assigned to a substance indicating a threshold at or above which the presence of that substance in a mixture leads to the classification of the mixture as hazardous. Generic concentration limits apply for all human health hazards except acute toxicity (and for the environmental classification concerning ozone layer, which is not described in detail in this report). The generic concentrations limits are listed in Table 2 below and are found in Annex I of the CLP Regulation (EU Regulation No. 1272, 2008; ECHA, 2014).

Table 2: Generic concentration limits for triggering a classification as hazardous (EU Regulation No. 1272, 2008; ECHA, 2014)

Ingredient classified as:	Concentration limit triggering classification of the mixture as:	
	Category 1, 1A or 1B	Category 2
Mut. / Carc. 1A and 1B	≥ 0.1%	
Mut. / Carc. 2		≥ 1%
Repr. 1A and 1B	≥ 0.3%	
Repr. 2		≥ 3%
STOT SE / RE 1	≥ 10%	1% ≤ conc. < 10%
STOT SE / RE 2		≥ 10%
Skin Sens. 1A	≥ 0.1%	
Skin Sens. 1 and 1B	≥ 1%	

Ingredient classified as:	Concentration limit triggering classification of the mixture as:	
	Category 1, 1A or 1B	**Category 2**
Skin Corr. 1A, 1B, 1C*	≥ 5%	1% ≤ conc. < 5%
Skin Irrit. 2*		≥ 10%
Eye effects 1*	≥ 3%	1% ≤ conc. < 3%
Eye effects 2*		≥ 10%

* It should be noted that the generic concentration limits for skin/eye irritation and eye damage and skin corrosion are more complex than listed above. Details can be found in Annex I of CLP.

Especially for sensitisers, it is stated in Annex I of the CLP Regulation that some substances that are classified as sensitisers may elicit an allergic response, when present in a mixture in quantities below the generic concentration limits, in individuals who are already sensitised to the substance or mixture. The generic concentration limits for elicitation are 10 times lower compared to the generic concentration limits for triggering classification as Skin Sens. This means that the generic concentration limit for elicitation of an allergic response in humans who are already sensitised is 0.01% for Skin Sens. 1A and 0.1% for Skin Sens. 1 and 1B.

The specific concentration limits are like generic concentration limits triggering a certain classification for the mixture when the specific concentration limit is exceeded for the substance in the mixture. The specific concentration limit is, however, specific for a single substance. Normally, the specific concentration limit is lower than the generic concentration limit and must be used instead of the generic concentration limit, if a specific concentration limit exists. The specific concentration limits are listed in Annex VI to the CLP (list of harmonised classifications). (EU Regulation No. 1272, 2008; ECHA, 2014).

3.3.1 Discussion

The CLP Regulation only sets requirements for how to classify the tattoo and PMU inks, and does not restrict any ingredients in the inks. It is, however, obvious that it is difficult to sell tattoo inks and PMU inks with problematic classification and labelling such as carcinogenic, mutagenic or skin sensitising.

The generic concentration limits are therefore relevant and mean that carcinogenic and mutagenic substances in principle can be present in the tattoo and PMU inks in concentrations below 0.1 and 1% for substances classified as Carc./Mut. 1 or Carc./Mut. 2 respectively, before the tattoo mixture must be classified as carcinogenic/mutagenic. For substances classified as reprotoxic, they can in principle be present in concentrations below 0.3 and 3% for Repr. 1 or Repr. 2 classified substances respectively, before the tattoo mixture must be classified as reprotoxic.

For skin sensitising substances, these substances can be present in the tattoo and PMU inks in concentrations below 0.1 and 1%, depending on the ingoing substances being classified as Skin Sens. 1A or Skin Sens. 1B/1 respectively, before the tattoo mixture must be classified as skin sensitising.

For skin corrosive/eye damaging and skin/eye irritating substances, the concentrations allowed before the entire tattoo mixture must be classified with such a classification are higher (1, 3, 5 or 10% depending on the specific situation/classification of the individual substances).

It should be noted that for the classification of the mixture, i.e. tattoo and PMU inks, the harmonised classification of the individual substances/ingredients is used. Only about 4,600 chemical substances have a harmonised classification. For all other chemical substances, it is the responsibility of the producers/importers to classify the individual chemical substances and the chemical mixtures. An important aspect is, however, that according to the REACH Regulation it is only a requirement to enclose information about the carcinogenic properties of substances if these are manufactured or imported in a tonnage above 1000 tonnes annually. This means that information about the carcinogenic effects of substances may not be available unless they are marketed in large amounts on the European market.

3.4 Biocidal Products Regulation

The Biocidal Products Regulation (BPR) no. (EU) 528/2012 (EU Regulation no. 528, 2012) entered into force on September 1, 2013, and replaced the old biocidal products directive. The principles of the old directive have been kept: All companies that make biocidal products available on the market must ensure that the products are authorised by the appropriate authority in an EU country or by ECHA. In the current transitional period, where all existing active substances are re-evaluated, biocidal products are exempted from the authorisation requirements if a decision on the active substance has not been taken. However, the biocidal products regulation has widened its scope as treated articles are now included in the legislation, whereas in the former biocidal products directive, only biocidal products were regulated.

Biocidal products are defined as:

- any substance or mixture, in the form in which it is supplied to the user, consisting of, containing or generating one or more active substances, with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action,
- any substance or mixture, generated from substances or mixtures which do not themselves fall under the first indent, to be used with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action (Art. 3(1)(a)).

Treated articles are defined as:

- any substance, mixture or article which has been treated with, or intentionally incorporates, one or more biocidal products (Art. 3(1)(a)).

This means that tattoo and PMU inks are considered as treated articles under the BPR, as the chemical inks themselves do not have the purpose of destroying harmful organisms, but are chemical products, which have been treated with biocidal products (preservatives) with the purpose of destroying any microbial growth in the inks.

Biocidal products require an authorisation, whereas treated articles only require:

1. labelling, but only in the cases where a claim of biocidal properties is made or where labelling is part of the active substance approval (Art. 58(3)),
2. that the active substance being used has been approved (or is under review) for that product type (PT) and use (Art. 58(2)).

The relevant product type (PT) for tattoo and PMU inks will be PT6, which is "preservatives for products during storage". The product type is defined as "Used for the preservation of manufactured products, other than foodstuffs, feeding stuffs, cosmetics or medicinal products or medical devices by the control of microbial deterioration to ensure their shelf life".

In principle, this means that it is only allowed to put tattoo and PMU products (inks) on the market, if the used preservatives (active substances/biocidal products) have been approved for this product type, i.e. PT6. A status of the approved active substances can be found in ECHAs database of biocidal active substances[3]. The latest update is from January 9, 2018 where the database contains information on 743 active substance-product type combinations for which approval has been sought. For PT6 "Preservatives for products during storage", 55 different active substances are listed of which 11 are approved, 3 are not approved, and the rest (41 active substances) are under review.

3.4.1 Discussion

The intention of the new Biocidal Products Regulation is that all active substances must be approved before use. In this approval phase, considerations regarding the human and environmental toxicity of the active substances will be taken into account. However, preservatives approved for PT6, i.e. preservatives for chemical products during storage, have most likely not undergone a risk assessment concerning the toxicological effects of injecting the tattoo inks into the human skin. Actually, the BPR guidelines volume III for "Human health"[4] mainly addresses skin contact, and not injection under the skin.

This means that even though the active substances used in tattoo and PMU inks have been approved as active substances for use for PT6 preservatives, they may not necessarily be considered as safe for humans in tattoos in the concentrations used. Actually, it is uncertain whether the BPR is applicable for tattoo and PMU inks injected under the skin, as this exposure route is not addressed in the BPR guidelines.

3.5 Cosmetic Products Regulation

Chemical substances in cosmetic products are regulated through the regulation on cosmetic products, EU Regulation no. 1223/2009 (EU, 2009a). The regulation on cosmetic products is described in detail below, as some aspects of the Cosmetic Products Regulation could be relevant for a future regulation on tattoo and PMU inks as well.

The regulation on cosmetic products contains several requirements regarding safety, content of chemical substances in cosmetic products and labelling of the products. Furthermore, the regulation on cosmetic products contains a number of limitations regarding different chemical substances, for instance, some substances are prohibited to use (annex II), it is only allowed to use certain colourants (annex IV), preservatives (annex V) and UV filters (annex VI), and finally certain chemical substances may only be used under certain conditions, e.g. in certain products (e.g. rinse-off products) or below specific concentrations (concentration limits) (annex III).

[3] https://echa.europa.eu/information-on-chemicals/biocidal-active-substances
[4] https://echa.europa.eu/guidance-documents/guidance-on-biocides-legislation

Below specific aspects of the Cosmetic Products Regulation are described in more details.

Safety assessment
A cosmetic product which is made available on the market in the EU must be safe for human health when it is used under normal or reasonably foreseeable conditions of use (article 3). To demonstrate that a cosmetic product is safe for human health, a safety assessment of the cosmetic product (article 10) must be performed. The safety assessment is described in a safety report.

Declaration of content
Cosmetic products must be labelled with a complete list of ingredients (article 19). Therefore, it is possible to see the used ingredients on the packaging of the product. In the declaration of contents, the ingredients must be stated by their INCI name ("International Nomenclature for Cosmetic Ingredients"). An INCI name may include several chemical substances. The list of INCI names is not a list of approved ingredients in cosmetic products (article 33). Ingredients must be listed in succession according to decreasing weight/content.

A special rule exists for declaration of colourants (CI numbers), where colourants which are not intended for hair colouring can be mentioned in any order after the other ingredients. For make-up products, which are marketed in many nuances, the used colourants can be stated in the declaration of contents with the words "may contain".

Colourants
Cosmetic products are only allowed to contain colourants included in annex IV "List of colorants allowed in cosmetic products" and if used according to the stipulated conditions (e.g. only for use in certain product types, for use on certain body parts or in a maximum allowed concentration) (article 14). Colourants (hair colourants) listed in annex III "List of substances which cosmetic products must not contain except subject to the restrictions laid down" may be used, but only under the specified conditions, i.e. in specific maximum concentrations and by including specific warnings.

Preservatives
Cosmetic products must only contain preservatives included in annex V "List of preservatives allowed in cosmetic products" and if used according to the stipulated conditions (such as only for use in certain product types, for use on certain body parts or in a maximum allowed concentration) (article 14). Preservatives listed in annex III "List of substances which cosmetic products must not contain except subject to the restrictions laid down" may be used, but only under the specified conditions and only if the substances are used for other purposes than a preservation purpose.

UV filters
Cosmetic products must only contain UV filters included in annex VI "List of UV filters allowed in cosmetic products" and if used according to the stipulated conditions (such as only for use in certain product types, for use on certain body parts or in a maximum allowed concentration) (article 14).

CMR substances
Cosmetic products must not contain substances which are classified as carcinogenic (Carc), mutagen (Mut) or toxic to reproduction (Repr) (so-called

CMR substances) with category 1A, 1B or 2 (article 15). The specific requirements are:

- The use in cosmetic products of substances classified as CMR 1A and 1B is prohibited. CMR 1A and 1B are as defined in the table of harmonised classification and labelling in the CLP Regulation 1272/2008. However, such substances may be used despite their classification as CMR 1 if all of the following conditions are fulfilled:
    - They comply with the food safety requirements (EU Regulation 178/2002).
    - There are no suitable alternative substances available (documented in an analysis of alternatives).
    - The application is made for a particular use of the product category with a known exposure.
    - They have been evaluated and found safe by the SCCS for use in cosmetic products, in particular in view of exposure to these products and taking into consideration the overall exposure from other sources and taking particular account of vulnerable population groups.
- The use in cosmetic products of substances classified as CMR 2 is prohibited. CMR 2 is as defined in the table of harmonised classification and labelling in the CLP Regulation 1272/2008. However, a substance classified as CMR 2 may be used, if:
    - The substance has been evaluated by the SCCS and found safe for use in cosmetic products.

It is specified for CMR 1A and 1B substances that the Commission shall amend the annexes to the Cosmetic Products Regulation within 15 months of the inclusion of the substance in the table of harmonised classification and labelling of the CLP Regulation. This implies that the ban of CMR 1A and 1B enters into force after the change of the annexes. However, it is not specified in the legislation when a change for a CMR 2 substance enters into force.

3.5.1 Discussion

The Cosmetic Products Regulation uses a mixture of negative lists (banned substances), positive lists (allowed substances – sometimes only when certain conditions like e.g. concentrations are met) and product safety assessments as tools to work against use of products that are unsafe for humans. Many of the same tools or even the same lists could be relevant for tattoo and PMU inks as well, as it seems relevant that restrictions concerning chemical products applied on skin should be valid for chemical products applied under the skin. Actually, the CoE Resolution as well as national legislation are based upon these rules set for cosmetic products.

These aspects will be discussed in more details in chapter 6 “Proposal regulatory requirements for chemicals in tattoo and PMU inks”.

3.6 Discussion

No specific legislation concerning chemical substances used in tattoo and PMU inks exist – other than the GPSD – and the GPSD only applies if the tattoo ink is used by the consumer. In addition, only the general legislation concerning labelling and classification (CLP) of dangerous chemical substances as well as the general rules of registration, evaluation, authorisation and restrictions of chemicals in

REACH applies. Finally, the biocidal product regulation also applies for tattoo and PMU inks, which means that only preservatives approved for the relevant product type are allowed to be used.

Some of the restrictions in Annex XVII of REACH also applies for tattoo inks, but they are general and not specially envisioned for tattoo inks. One of the general restrictions is a restriction on CMR substances in mixtures supplied to the general public. In most cases, when people get a tattoo they will visit a tattoo saloon and get professionals to carry out the tattoo. In principle, this will mean that tattoo and PMU inks used by professionals are not covered by this REACH restriction and can in principle contain much higher amounts of CMR substances, than the 0.1% (for CM substances) and 0.3% (for R substances) as defined in the REACH restriction.

A REACH restriction in Annex XVII (entry no. 43) contains a restriction on azo dyes that by reductive cleavage can release carcinogenic aromatic amines with a limit value of 30 ppm (0.003%). This restriction does, however, only apply for textile and leather articles, and not for tattoo inks. Currently, this means that consumers are protected from wearing clothing containing azo dyes, but may have the same azo dyes directly injected under the skin.

The GPSD does not contain any specific chemical requirements – only the general safety requirement of "products must be safe". This statement also includes chemical safety, but it is not well-defined what is meant with "a high level of protection" or the "minimum risks considered to be acceptable". Because of these very general statements and no specific chemical requirements, it is difficult for both producers and authorities to know when a chemical content in a product is "safe". From producers' and authorities' point of view, it would be easier to follow limit values or positive/negative lists of ingredients in tattoo and PMU inks.

The idea with the GPSD is that specific safety requirements should be elaborated in European standards based on a standardisation request by the Commission. However, at the moment, no standardisation request for tattoo and PMU inks has been forwarded to the European Standardisation Organisations.

According to the GPSD, products are also presumed safe if in the absence of product specific legislation or relevant national standards, they follow "Commission recommendations setting guidelines on product safety", "product safety codes of good practice in force for the sector concerned" or "the state of art and technology" (article 3 (3)). In 2008, the Council of Europe adopted a "Resolution on requirements and criteria for the safety of tattoos and permanent make-up" (CoE Resolution, 2008). The recommendations of the CoE Resolution are therefore relevant and the CoE Resolution is an important reference in the safety assessment of tattoo and PMU inks – especially for countries with no tattoo ink legislation in place. However, this resolution is non-binding and is therefore not considered as legal status, and tattoo and PMU inks cannot be considered as safe according to the GPSD if they follow this CoE. Seven EU member states have used this resolution as reference for their national legislation and three companies are on their way with similar national legislation based on this resolution. For these member states, where specific national legislation on tattoos exists, conformity to the safety requirements of the GPSD is presumed for the risks covered by this specific national legislation. However, article 5 to 18 of the GPSD (concerning e.g. market surveillance from Member States, RAPEX notifications as well as producers' and distributors' obligation to inform consumers of risks, i.e. by use of appropriate warnings) still apply. The CoE Resolution is described in more details in the next chapter.

4 Other relevant information

In this chapter, other relevant information for proposing regulatory requirements for tattoo and PMU inks is described and reviewed.

In the EU, the below countries have a specific national legislation or national strategy on tattoo inks concerning chemical requirements for tattoo and PMU inks (ECHA, 2017a; Piccinini et al., 2015a). Other countries may have legislation on hygiene aspects for tattooing, but no specific chemical requirements.

- Austria (draft legislation (in 2014) based on CoE Resolution 2008, but withdrawn as a result of an invention by the Commission)
- Belgium (legislation based on CoE Resolution 2003)
- Croatia (legislation based on additives as regulated by EU Regulation 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food)
- Czech Republic (only safe products must be marketed, otherwise no chemical requirements)
- Denmark (draft legislation (notified in 2013), but could not be implemented as a result of an invention by the Commission – hence today, no legislation, but recommendations based on CoE Resolution 2008)
- France (legislation based on CoE Resolution 2003)
- Germany (legislation based on CoE Resolution 2003)
- Italy (proposal for a legislation based on CoE Resolution 2008)
- Latvia (draft legislation based on CoE Resolution 2008)
- The Netherlands (legislation based on CoE Resolution 2003)
- Slovenia (legislation based on CoE Resolution 2008)
- Spain (legislation based on CoE Resolution 2008)
- Sweden (legislation based on CoE Resolution 2008)

The CoE Resolutions from both 2003 and 2008 are therefore relevant to review.

The legislation on tattoo inks in Croatia is according to Piccinini et al. (2015a) based on the EU Regulation 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food. Additives are only allowed to be used if produced following good manufacturing practice (GMP) (EU Regulation 2023/2006). This EU Regulation contains an annex with amongst other things detailed rules on good manufacturing practice (GMP) on printing inks. However, this regulation does not describe chemical requirements and is therefore not addressed further.

ECHA has reviewed the risk from certain substances in tattoo and PMU inks and concluded that a restriction proposal was needed. Thus, ECHA has, together with the competent authorities of Denmark, Italy and Norway, prepared a proposal at EU level regarding restriction of hazardous substances and tattoo and PMU inks. Germany has contributed to the development of the restriction dossier as well. This restriction proposal was published by ECHA on October 25, 2017 (ECHA, 2017a; ECHA, 2017b). This restriction proposal will be described and reviewed below.

For this reason, the following information is reviewed below:

- Council of Europe (CoE) non-binding Resolution (ResAP) on the safety of tattoos and PMU
- ECHA proposal for a restriction on substances in tattoo inks and PMU

4.1 CoE Resolution on safety of tattoos and PMU

The first Council of Europe Resolution on safety of tattoos and PMU was made in 2003 and was superseded by the newest CoE Resolution from 2008. The resolutions are proposals and recommendations for regulations as the Council of Europe is not part of the EU and cannot regulate. Currently, the EU members Belgium, France, Germany and the Netherlands have a specific national legislation on tattoo inks based on the CoE Resolution from 2003. Spain, Slovenia and Sweden have a national legislation based on the Resolution from 2008. Therefore, both resolutions are described in detail below.

4.1.1 CoE Resolution on safety of tattoos and PMU (2003)

The CoE Resolution on safety of tattoos and PMU from 2003 has listed the following specifications (CoE Resolution, 2003), which concern requirements for chemicals:

1. When applied and used as intended, tattoo and PMU products must not endanger the health or safety of persons or the environment. The manufacturer or person responsible for placing the product on the market should perform a risk evaluation based on recent toxicological data and knowledge.

2. Tattoo and PMU products must only be used if they comply with the following requirements:
    a. They do not contain or release aromatic amines listed in Table 1 of the Resolution (26 aromatic amines) under the conditions of appropriate test methods.
    b. They do not contain the substances listed in Table 2 of the Resolution (35 colourants). Table 2 of the Resolution is a non-exhaustive list of substances, which tattoo and PMU products should not contain, and it contains substances particularly with CMR and sensitising properties.
    c. They do not contain substances listed in Directive 76/768/EEC, Annex II. This requirement corresponds today to Annex II “List of substances prohibited in cosmetic products” in the existing EU Regulation 1223/2009 on cosmetic products.
    d. They do not contain substances specified in Directive 76/768/EEC, Annex IV, columns 2 to 4, i.e. it is only the colourants listed in column 1 (colourants allowed in all cosmetic products) that are permitted. This requirement corresponds today to Annex IV “List of colourants allowed in cosmetic products” with restrictions in column g in the existing EU Regulation 1223/2009 on cosmetic products (i.e. colourants which are not allowed in all cosmetic products).
    e. They do not contain CMR substances of category 1, 2 and 3 which are classified under Directive 67/548/EEC. This requirement corresponds today to CMR substances of category 1A, 1B and 2 in the existing CLP Regulation 1272/2008.
    f. They do not contain preservatives.

g. They are sterile and supplied in a container which maintains the sterility of the product until application.
h. They are supplied in a packaging size appropriate for single use on an individual consumer.

3. Furthermore, the CoE Resolution contains specific requirements concerning information on the packaging and public information for consumers. This is not described in further detail here.

4.1.2 CoE Resolution on safety of tattoos and PMU (2008)

The following changes were made in the Resolution from 2008, which superseded the 2003 Resolution:

- Aromatic amines: The wording was changed to concentrations that are technically avoidable according to good manufacturing procedures. Furthermore, the test methods are specified. One extra aromatic amine was added to Table 1 in the CoE Resolution (2008) document.
- Impurities: A new restriction is added:
  - Tattoo and PMU products must comply with maximum allowed concentrations of impurities listed in Table 3 of the Resolution and the minimum requirements for further organic impurities for colourants used in foodstuffs and cosmetic products as set out in Directive 95/45/EEC. This requirement corresponds today to the existing EU Regulation laying down specifications for food additives listed in Annex II and III to Regulation No. 1333/2008. Table 3 of the CoE Resolution (2008) is repeated in Table 3 below.
- Preservatives: The restriction of no use of preservatives has been changed to the following two restrictions for preservatives:
  - Preservatives should only be used to ensure the preservation of the product after opening and by no means as a correction of insufficient microbiologic purity in course of manufacture and of inadequate hygiene in tattooing and PMU practice.
  - Preservatives should only be used after a safety assessment and in the lowest effective concentration.
- Sterility: It has been added that the containers preferably should be in a packaging size appropriate for single use or their design should ensure that the contents will not be contaminated during the period of use.

Table 3: Maximum allowed concentrations of impurities in products for tattoos and PMU (equal to Table 1 in CoE Resolution, 2008)

Element or compound	Limit value
Arsenic (As)	2 ppm
Barium (Ba)	50 ppm
Cadmium (Cd)	0.2 ppm
Cobalt (Co)	25 ppm
Chromium (Cr VI)	0.2 ppm[1]
Copper (Cu) soluble[2]	25 ppm
Mercury (Hg)	0.2 ppm
Nickel (Ni)[3]	As low as technically achievable
Lead (Pb)	2 ppm
Selenium (Se)	2 ppm
Antimony (Sb)	2 ppm
Tin (Sn)	50 ppm
Zinc (Zn)	50 ppm
PAH	0.5 ppm
Benzene-a-pyrene (BaP)	5 ppb

[1] The presence of traces of chromium (VI) in products for tattoos and PMU should be mentioned on the package together with a warning (for example, “Contains chromium. Can cause allergic reactions.”).
[2] Soluble copper should be determined after extraction to an aqueous solution with pH 5.5.
[3] The presence of traces of nickel in products for tattoos and PMU should be mentioned on the package together with a warning (for example, “Contains nickel. Can cause allergic reactions.”).

4.1.3 Discussion of CoE Resolution on safety of tattoos and PMU

The CoE Resolutions on safety of tattoo and PMU inks restrict several unwanted toxic substances known to be present in tattoo and PMU inks. Especially the latest Resolution from 2008 lists several chemical requirements concerning ingredients used. Several of the chemical requirements listed are close to the Cosmetics Regulation (references are made to the Cosmetic Regulation), but some additional elements from the Cosmetics Regulation could have been restricted as well, such as:

- Annex V listing preservatives to be used and in which amounts. The CoE Resolution (2008), however, states that preservatives must only be used in the lowest effective concentration and that a safety assessment must be carried out.

Several EU Member States have made suggestions to expand the restrictions in the CoE Resolution (2008). These suggestions are listed in Piccinini et al., 2016b and include aspects such as:

- Add more aromatic amines to Table 1 of the CoE Resolution, i.e. aniline.
- Set specific limit values for the aromatic amines listed in Table 1 of the CoE Resolution.
- Add more colourants to Table 2 of the CoE Resolution, i.e. the non-exhaustive list of substances that should not be used in tattoo and PMU inks because of CMR and sensitising properties.
- Specify which types of PAHs that should be measured (Table 3 of the CoE Resolution), and perhaps set specific limit values for specific PAHs.
- Specify the limit value for nickel instead of the “as low as technically possible”.
- Lowering the limit value for the purities of certain elements (Table 3), i.e. for Co, Sb, As.
- Establish a positive list of preservatives to be used.
- Establish a positive list of colourants allowed to be used in tattoo and PMU inks.

All these proposed ‘extra’ restrictions to the CoE Resolution (2008) from some Member States suggest that even though the CoE Resolution sets many requirements for tattoo and PMU inks, the CoE Resolution is not perfect and needs to be expanded (include more restricted substances) and elaborated (specify certain limit values) to cover the restrictions wanted by these Member States.

4.2 ECHA restriction proposal

ECHA has reviewed the risk from certain substances in tattoo inks and PMU and concluded that a restriction proposal was needed. Together with the competent authorities of Denmark, Italy and Norway, ECHA has prepared a proposal to reduce the risks caused by hazardous substances contained in some tattoo inks. The aim of the proposal has not been to ban tattoo inks or tattooing, but to regulate

specific hazardous substances present in tattoo inks so they are safe for consumers (ECHA, 2017c). This restriction proposal was published by ECHA on October 25, 2017 (ECHA, 2017a; ECHA, 2017b).

The ECHA restriction proposal is built on existing European laws based on CoE Resolution 2003 or 2008. The requested scope of the proposal by the Commission was to include all substances listed in the CoE Resolution (2008) and potentially any additional substances with a harmonised classification as CMR category 1A or 1B or as skin sensitiser (ECHA, 2017a).

The conclusion of the Dossier Submitter's examination of the risk was that the use of certain threshold substances in tattoo and PMU ink mixtures is not adequately controlled. Therefore, an analysis was conducted to identify the most appropriate measure to address these risks (ECHA, 2017a).

The ECHA restriction proposal consists of two options – RO1 and RO2 (restriction option 1 and 2) which mainly differ in terms of the concentration limits proposed for the substances and how the links with the annexes of the Cosmetic Products Regulation are managed.

ECHA's main reason for proposing two options with different concentration limits has been that colourants are often of a low purity and therefore, a number of currently unknown impurities could potentially be contained in tattoo inks. Option RO1 therefore uses low limit values to be able to avoid impurities. Another reason is to decouple the restriction from future updates of Annex II and IV of the Cosmetic Product Regulation. Option RO2 therefore does not link to the Cosmetic Products Regulation directly, but includes the tables from the CP Regulation in the proposal.

Both restriction proposals restrict both tattoo and PMU inks:

- From being placed on the market if they contain any of the substances in scope of the restriction above the specified concentration limit.
- From being used if they contain any substances above the specified limit.

In addition, a labelling requirement is also proposed which includes to label the following information:

- ingredients that would not normally be required to be labelled under the CLP Regulation,
- that the product is intended for use as a tattoo ink,
- a reference number for the specific tattoo ink, and
- any relevant instructions for use.

Both restriction proposals take the following into account:

- If a substance is not permitted in cosmetic products, it should not be used in tattoo and PMU inks.
- Substances classified as CMR (category 1A and 1B) should not be used in tattoo and PMU inks.
- Substances with classification as skin sensitising, skin irritating or skin corrosive, or eye damaging or eye irritating should not be used in tattoo and PMU inks.

Both restriction proposals include a Table A, which is a (negative) list of substances only allowed in the maximum concentration listed. Table A also contains impurities for elements, primary aromatic amines and colourants that should not be used. However, both restriction proposals also include a Table B,

which is a list of specific colourants that are allowed to be used even though they are restricted in the CP Regulation (Annex II) for use in hair dyes. These colourants have been included in Table B because some colourants cannot be replaced and some classifications only apply for inhalation, which is not the relevant exposure route for tattoo inks.

No hygiene requirements are included in the proposal, as it is assumed that these requirements should be regulated at Member State level.

The two proposals from ECHA are listed in their entity below.

4.2.1 Restriction option 1 (RO1)

Restriction option 1 is cited below:

Restriction option 1 (RO1):

1. Tattoo inks shall not be placed on the market if they contain the following substances as specified below. In the event a substance is subject to more than one of the conditions in paragraphs 1.a) to 1.c), the stricter condition applies:
    a. Tattoo inks **shall not contain** the following substances, unless a concentration limit is specified under paragraph 2:
        i. Carcinogenic or mutagenic substances, category 1A, 1B and 2 excluding those substances classified only with the hazard statements H350i (May cause cancer by inhalation), H351i (Suspected of causing cancer by inhalation), H340i (May cause genetic defects via inhalation) and H341i (Suspected of causing genetic defects by inhalation).
        ii. Substances prohibited for use in cosmetic products as listed in Annex II of Regulation (EC) 1223/2009.
        iii. The following substances in Annex IV of Regulation (EC) 1223/2009 with the following conditions in column g of that Annex:
            - Rinse-off products
            - Not to be used in products applied on mucous membranes
            - Not to be used in eye products
    b. Tattoo inks shall not be placed on the market if they contain the following substances in concentrations greater than **0.1% w/w**, unless a concentration limit is specified under paragraph 2:
        i. Skin sensitising substances, category 1, 1A and 1B
        ii. Skin irritant or corrosive substances, category 1A, 1B, 1C and 2
        iii. Eye damaging and irritant substances, category 1 and 2
    c. Tattoo inks shall not be placed on the market if they contain substances toxic to reproduction:
        i. i. Category 1A and 1B in concentrations greater than **0.0014 % w/w**
        ii. ii. Category 2 in concentrations greater than **0.014% w/w**

2. Tattoo inks or permanent make-up shall not be placed on the market if they contain substances listed in Table A exceeding the specified concentration limits and polycyclic-aromatic hydrocarbons (PAH), classified as

carcinogenic or mutagenic categories 1A, 1B and 2 in individual concentrations exceeding **0.0005% w/w**[5].

3. By way of derogation, paragraph 1 does not apply to substances (colourants) listed in Table B (of the proposal).

4. Substances in Annex IV of Regulation (EC) 1223/2009 allowed in cosmetic products are also allowed in tattoo inks, subject to the conditions in columns h to i of that Annex, unless a lower concentration limit is specified in paragraphs 1 and 2.

5. Tattoo inks not meeting the requirements specified in paragraphs 1 to 4 shall not be used in tattoo and permanent make-up procedures.

6. The person responsible for the placing on the market of a tattoo ink shall ensure that the label provides, in addition to that required by Regulation (EC) No 1272/2008, the following information:
   a. The intended use of the mixture as a tattoo ink;
   b. A reference number to uniquely identify the batch;
   c. The name of all substances present in the tattoo ink that meet the criteria for classification for human health in accordance with Annex I of Regulation 1272/2008 but not covered by the current restriction proposal;
   d. The name of substances covered by the restriction proposal that are present in the ink at a lower concentration limit than the proposed one;
   e. Any relevant instructions for use.

   The labelling shall be clearly visible, easily legible and appropriately durable.
   The label shall be written in the official language(s) of the Member State(s) where the substance or 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 labelling shall be included on the instructions for use.
   The information on the label shall be made available to any person who will undergo the tattooing procedure before the procedure is undertaken.

7. Definitions for the purpose of this restriction entry
   a. Tattoo ink is a mixture consisting of colourants and auxiliary ingredients administered by intentional intradermal injection whereby a permanent skin marking or design (a “tattoo” or “permanent make-up”) is made.
   b. Tattoo or permanent make-up procedure is the intradermal injection of tattoo ink (or permanent make-up).

8. The restriction shall apply one year after its entry into force.

[5] In the ECHA proposal under RO1 and RO2 the PAH concentration limit is set at 0.0005% or equal to 5 ppm, whereas the concentration in table 11 of the ECHA proposal is set at 0.00005% or equal to 0.5 ppm as listed in the CoE Resolution (2008). Which limit value that is the correct is not known. However, the correct limit value is assumed to be 0.5 ppm, as they refer to REACH Annex XVII where the limit value of 0.5 ppm is used for toys.

4.2.2 Restriction option 2 (RO2)

Restriction option 2 is cited below:

Restriction option 2 (RO2):

1. Tattoo inks shall not be placed on the market if they contain the following substances **in concentrations greater than the relevant generic concentration limit** in Part 3 of Annex I of Regulation (EC) No 1272/2008, unless a specific concentration limit is set in Part 3 of Annex VI of Regulation (EC) No 1272/2008:
    a. Carcinogenic and mutagenic substances, category 1A, 1B and 2, excluding those substances classified only with the hazard statements H350i (May cause cancer by inhalation), H351i (Suspected of causing cancer by inhalation), H340i (May cause genetic defects via inhalation) and H341i (Suspected of causing genetic defects by inhalation)
    b. Substances toxic to reproduction, category 1A, 1B and 2
    c. Skin sensitising substances, category 1, 1A and 1B
    d. Skin irritant and corrosive substances, category 1A, 1B, 1C and 2
    e. Eye damaging and irritant substances, category 1 and 2

    These provisions shall apply unless the substances are included in paragraph 2. In the event a substance is subject to more than one of the conditions in paragraphs 1.a) to 1.e), the stricter condition applies.

2. Tattoo inks shall not be placed on the market if they contain the substances listed in Table A and polycyclic-aromatic hydrocarbons (PAH), classified as carcinogenic or mutagenic categories 1A, 1B and 2 in individual concentrations exceeding **0.0005% w/w**[6]

3. Unless already specified in paragraphs 1 or 2, tattoo inks shall not be placed on the market if they contain the substances in Table C and Table D, in concentrations exceeding **0.1% w/w**.

4. Unless already specified in paragraphs 1 to 3, tattoo inks shall not be placed on the market if they do not meet the conditions for the substances in Table E.

5. By way of derogation, paragraphs 1 to 4 do not apply to substances (colourants) listed in Table B.

6. Tattoo inks not meeting the requirements specified in paragraphs 1 to 5 shall not be used in tattoo and permanent make-up procedures.

7. The person responsible for the placing on the market of a tattoo ink shall ensure that the label provides, in addition to that required by Regulation (EC) No 1272/2008, the following information:
    a. The intended use of the mixture as a tattoo ink;
    b. A reference number to uniquely identify the batch;

[6] In the ECHA proposal under RO1 and RO2 the PAH concentration limit is set at 0.0005% or equal to 5 ppm, whereas the concentration in table 11 of the ECHA proposal is set at 0.00005% or equal to 0.5 ppm as listed in the CoE Resolution (2008). Which limit value that is the correct is not known. However, the correct limit value is assumed to be 0.5 ppm, as they refer to REACH Annex XVII where the limit value of 0.5 ppm is used for toys.

c. The name of all substances present in the tattoo ink that meet the criteria for classification for human health in accordance with Annex I of Regulation 1272/2008 but not covered by the current restriction proposal;
d. The name of substances covered by the restriction proposal that are present in the ink at a lower concentration limit than the proposed one;
e. Any relevant instructions for use.

The labelling shall be clearly visible, easily legible and appropriately durable.
The label shall be written in the official language(s) of the Member State(s) where the substance or 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 labelling shall be included on the instructions for use.
The information on the label shall be made available to any person who will undergo the tattooing procedure before the procedure is undertaken.

8. Definitions for the purpose of this restriction entry
    a. Tattoo ink is a mixture consisting of colourants and auxiliary ingredients administered by intentional intradermal injection whereby a permanent skin marking or design (a "tattoo" or "permanent make-up") is made.
    b. Tattoo or permanent make-up procedure is the intradermal injection of tattoo ink (or permanent make-up).

9. The restriction shall apply one year after its entry into force.

4.2.3 Discussion of ECHA restriction proposal on tattoo inks and PMU

4.2.3.1 Differences in RO1 and RO2 and comparison with CoE Resolution

The main differences in the two different ECHA restriction proposals RO1 and RO2 on tattoo inks and PMU are:

- Different set up of the requirements and thereby different referral to the Cosmetic Products (CP) Regulation
- Different concentration limits (limit values)

In RO1, the substances listed on Annex II and Annex IV of the CP Regulation are directly referred to as Annex II and Annex IV of the CP Regulation. This means that if new substances are added to Annex II and IV of the CP Regulation they would also automatically be restricted in tattoo inks and PMU.

In RO2, Annex II and IV have been enclosed as Table C, D and E respectively:

- where Table C corresponds to Annex II,
- table D corresponds to the substances in Annex IV that are proposed to be restricted because of their use restrictions in CP Regulation Annex IV,
- and table E corresponds to the substances in Annex IV, which are proposed to be allowed in tattoo inks with the conditions specified in Annex IV of the CP Regulation.

In general, there is no difference between RO1 and RO2 on this point as both proposals restrict the colourants from Annex IV of CP Regulation ("List of colourants allowed in cosmetic products"), where the following conditions are listed in column g (conditions):

- Rinse-off products
- Not to be used in products applied on mucous membranes
- Not to be used in eye products

However, if new substances are added to Annex II or Annex IV of the CP Regulation in the future, these changes would be included in RO1, but not in RO2 unless the tables (table C, D and E) were to be changed accordingly.

Furthermore, RO1 and RO2 differ significantly in concentration limits on certain areas. It is listed in the ECHA proposal that the main reason for proposing these two different options with different concentration limits has been that colourants are often of a low purity and therefore a number of currently unknown impurities could potentially be contained in tattoo inks.

In RO2, the generic concentration limits in the CLP Regulation are used, whereas other and stricter concentration limits are proposed in RO1. The differences in concentration limits are illustrated in Table 4 below.

Table 4: Differences in concentration limits set in RO1 and RO2

Type of substance	Concentration limit in RO1	Concentration limit in RO2
Carc./Mut.1A and 1B	Shall not contain*	0.1%
Carc./Mut. 2	Shall not contain*	1 %
Repr. 1A and 1B	0.0014%	0.3%
Repr. 2	0.014%	3%
Skin Sens. 1A	0.1%*	0.1%
Skin Sens. 1 and 1B	0.1%*	1%
Skin Corr. 1A, 1B, 1C	0.1%*	1, 3 or 5%
Skin Irrit. 2	0.1%*	10%
Eye Dam. 1	0.1%*	1, 3 or 5%
Eye Irrit. 2	0.1%*	10%

* Unless a specific concentration limit has been set in Table A

It should be highlighted that in RO2 it is mentioned that for substances where specific concentration limits are listed in Part 3 of Annex VI of the CLP Regulation, these specific concentration limits should be used instead of the generic (higher) concentration limits.

Furthermore, the ECHA proposal RO1 sets a limit value of CPR Annex II and Annex IV substances of “shall not contain” whereas the limit value in RO2 is 0.1% for these substances.

The ECHA proposal was developed based on existing legislation, i.e. the CoE Resolution (2008), which several countries have used for their national legislation. When comparing the CoE Resolution (2008) with the ECHA proposal, it can be seen that most of the restrictions from CoE Resolution are included in the ECHA proposal:

- Aromatic amines listed in table 1 of the CoE Resolution are included in table A of the ECHA proposal (except for two aromatic amines).
- Colourants listed in table 2 of the CoE Resolution are either included in table A of the ECHA proposal or are listed in Annex II of the CP Regulation (or table C of the ECHA proposal).
- Substances in Annex II and Annex IV of the CP Regulation are included in both schemes.
- CMR substances are restricted in both schemes.
- Impurities listed in table 3 of the CoE Resolution are listed in table A of the ECHA proposal, but for some of the elements, new limit values are

used in the ECHA proposal – some limit values are lower (As, Co, Pb), some are higher (Ba, Cu, Zn) and some are specified (Ni). For PAHs, these are now specifically restricted in the ECHA proposal (those classified as Carc./Mut.), and the limit value is higher (compared to CoE Resolution[7]).

The main differences between the ECHA proposal and the CoE Resolution (2008) are that:

- Preservatives in the CoE Resolution were restricted by "only to be used to ensure the preservation of the product after opening" and by "should only be used after a safety assessment and in the lowest possible concentration", whereas the preservatives now in the ECHA proposal are restricted by the general classification criteria (Skin Sens., Skin Irrit. etc.). Furthermore, the difference is that today the preservatives are automatically restricted by the BPR.
- New substances have been added to the specific list of restricted substances – table A in the ECHA proposal, compared to the CoE Resolution (2008):
    - Methanol
    - Aniline
    - p-toluidine/4-aminotoluene
    - 2,5-toluenediamine (PTD)
    - Sulphanilic acid/4-aminobenzenesulphonic acid
    - DEHP
    - DBP
    - Several new colourants (29 azo dyes) because they may decompose to primary aromatic amines.

4.2.3.2 Discussion

The main critique point for the ECHA proposal on tattoo inks and PMU is that only the substances in Part 3 of Annex VI to the CLP Regulation are restricted. Annex VI is the list of harmonised classifications for certain hazardous substances, and Part 3 is the table of the harmonised classifications. This means that the ECHA proposal only restricts a part of the about 4,600 substances that have a harmonised classification. Substances without a harmonised classification, but where the notifiers agree on the problematic classifications included in the ECHA proposal are not covered by the proposal. This is especially problematic for many skin sensitising substances (colourants and preservatives) which today are known as skin sensitisers, but do not yet have a harmonised classification as Skin Sens.

Furthermore, the problem with the RO2 proposal is that the generic concentration limits are used. This means that e.g. substances with a Repr. 2, Carc. 2 and Skin Sens. 1 classification are allowed in concentrations up to 3%, 1% and 1% respectively for each substance. The total concentration of problematic substances in tattoo inks and PMU can therefore be high for the RO2 proposal.

The RO1 proposal uses much lower limit values for ingredients with the problematic classifications – typically 0,1%, but for carcinogenic and mutagenic substances these are not allowed at all, and for reprotoxic substances the concentration limit is 0.0014 or 0.014% for Repr. 1 and Repr. 2, respectively.

[7] In the ECHA proposal under RO1 and RO2, the PAH concentration limit is set at 0.0005% or equal to 5 ppm, whereas the concentration in table 11 of the ECHA proposal is set at 0.00005% or equal to 0.5 ppm as listed in the CoE Resolution (2008). Which limit value that is the correct is not known. However, the correct limit value is assumed to be 0.5 ppm, as they refer to REACH Annex XVII where the limit value of 0.5 ppm is used for toys.

However, there may be a need for a practical enforcement limit value in the low ppm range for carcinogenic and mutagenic substances, as is set for reprotoxic substances. The very specific limit values of 0.0014% have been set for reprotoxic substances cat. 1 based on an exposure calculation carried out for a specific assumed tattoo size, specific amount of ink/cm^2 and a DNEL (Derived No Effect Level) of 0.001 mg/kg bw/day, which was the lowest identified DNEL value for reprotoxic cat. 1 substances. The DNEL value for reprotoxic cat. 2 substances was not assessed individually, but was set as a factor of 10 higher compared to cat. 1 substances (ECHA, 2017b – table 24).

In general, the limit values in RO1 seem adequately low; however, from a consumer safety point of view the limit value for sensitising substances may be too high, especially as the ingredients in tattoo inks and PMU are injected directly into the human body. Sensitising substances can be skin sensitising in much lower concentration than 0.1%. There is, however, no doubt that the RO1 ECHA proposal from a consumer's point of view is the best option of the two, as the limit values used in RO2 (the generic concentration limits from the CLP Regulation) will be too high.

It is, however, positive that restrictions have been made for different specific substances, which has been a critique point of the CoE Resolution, e.g.

- that the concentration limits for the impurities have been revised,
- that more azo dyes which could decompose to primary aromatic amines have been included,
- that aniline has been included in the negative list,
- that some phthalates have been included in the negative list,
- that it is specified which types of PAHs that should be measured (the PAHs classified as CMR).

Another critique point of the CoE Resolution has been to create a positive list of colourants to use. This has not been made in the ECHA proposal. A Table B exists which is a derogation from the general ban provisions. In both RO1 and RO2, the list of restrictions on classifications is exempted for the colourants listed in Table B, which contains 13 colourants.

Other critique points such as creating a positive list of preservatives to use have not been considered in the ECHA proposal.

It should be emphasised that this report does not go into details with the specific limit values and does not discuss, if these from a toxicological point of view are correct (in the correct order of magnitude).

5 Screening of ingredients

In this chapter, the typical use of ingredients in tattoo and PMU inks is described. This description is based on the JRC projects on tattoo and PMU inks, which have described the use of ingredients in detail. In these reports, the information on use of ingredients in tattoo and PMU inks is based on questionnaires to national authorities, tattooist associations and ink manufactures, as well as web and literature searches (Piccinini et al., 2016a).

Furthermore, the ingredients typically used in tattoo and PMU inks and their classification (harmonised and/or notified) will be discussed. For this purpose, a list of classifications that are considered as 'problematic' classifications for tattoo and PMU inks, which are injected into the human skin, is listed in section 5.2 "'Problematic' classifications for tattoo ingredients". In section 5.3, the classification of ingredients used in tattoo and PMU inks is discussed.

5.1 Description of typical types of ingredients

According to Piccinini et al. (2015b), tattoo and PMU inks are mixtures of insoluble pigments in a liquid made of binder(s) and solvent(s) that have been stabilised using additives. Furthermore, preservatives are often added to avoid microbiological contamination. The different groups of ingredients and their function are described in more details below (Piccinini et al., 2015b):

- **Colorants** are responsible for the ink colour and are major ingredients of tattoo and PMU inks and can reach a concentration of about 60% by weight, but the typical concentration is around 33%. Colorants are classified into two groups – pigments and dyes – based on their solubility properties.
    - **Pigments** are insoluble in the vehicle they are incorporated in. Pigments are the preferred choice for tattoo and PMUs because of their high photo stability and chemical resistance. Pigments can be inorganic and organic.
        - **Inorganic pigments:** Examples include iron oxides, titanium dioxide and chromium oxide green.
        - **Organic pigments:** Cover a wide range of colours divided into different chemical categories based on their structure, such as nitroso, nitro, monoazo, diazo, triazo, polyazo, azoic, stilbene, carotenoid, diphenylmethane, triarylmethane, xanthene, indamine, indophenol, azine, oxazine, thiazine, sulphur, lactone, aminoketone, hydroxyketone, anthraquinone, indigoid and phthalocyanine.
    - **Dyes** are soluble and have a fast biodegradability after application and are therefore generally not suitable for tattoo inks. In case they are used, they are used in PMUs and are used in combination with an insoluble base made of insoluble inorganic compounds.
- **Binding agents** are non-volatile compounds with a high molecular mass. Their function is to bind pigment particles to each other and to the tattooing needle to facilitate the injection of the tattoo and PMU ink in the skin.

- **Solvents** are used to solubilise and solvate the binder(s). Usually water is used as a solvent in tattoo and PMU inks, but also other solvents are used.
- **Fillers** can be used in tattoo and PMU inks to influence dispersability properties for re-dispersion of pigments after long-term storage. Fillers are usually inorganic substances such as barium sulphate or silica.
- **Additives** are used to modify certain characteristics of the inks. They are usually added in concentrations below 5% of weight. Additives used in tattoo and PMU inks are surfactants, humectants, thixotropic agents and preservatives.
    - **Surfactants** are used to adjust the surface tension and help with dispersion and stabilisation of pigments. Pigments tends to agglomerate, but surface-active ingredients help to reduce or avoid this tendency.
    - **Humectants** are used to hold and retain moisture, i.e. are used to slow the loss of moisture from the product during use. Typical humectants are glycerine, propylene glycol and sorbitol.
    - **Thixotropic agents**, such as silica, are used to prevent sedimentation of pigment dispersions during long-time storage. They increase the viscosity and thixotropy of the product.
    - **Preservatives** are added to prevent the growth of microbiological organisms in the inks. Growth of microorganisms is possible in the presence of water.

The typical composition of a tattoo ink is as follows (Piccinini et al., 2015b):

- About 33% are binders
    - e.g. polyethers, polyvinylpyrrolidone, block-copolymer, shellac, acrylic resins
- About 33% are pigments
    - e.g. inorganic and organic pigments, carbon black, barium sulphate
- About 33% are solvents
    - e.g. water, simple alcohols, polyols
- Maximum 5% are auxiliaries such as surfactants, humectants, thixotropic agents and preservatives

One important aspect for the pigments used in tattoo and PMU inks is, according to Piccinini et al. (2015b), that the pigments used in the formulation of tattoo and PMU inks are not produced for tattooing purposes, but are usually produced by the chemical industry for outdoor applications for products like textiles, paints for cars and plastics. The pigments are, however, used for tattoo and PMU inks because they show good light fastness properties, i.e. resistant to fading when exposed to light.

This means that the pigments do not undergo a risk assessment that considers their injection into the human body. Furthermore, the purity of the pigments is not very high (typically reported between 70 and 90%). Impurities such as chromium VI in chromium oxides, nickel, chromium, copper and cobalt in iron oxides, aromatic amines in azo-colourants, and PAHs in carbon black are therefore found.

5.2 ‘Problematic’ classifications for tattoo ingredients

Tattoo and PMU inks are injected directly into human skin. For this reason, it seems obvious that any substance that either is or is suspected to be carcinogenic, mutagenic or toxic to reproduction (CMR) as well as substances with effects on or via lactation should not be used in tattoo and PMU inks. For the same reason,

substances that are skin sensitising should be avoided in tattoo and PMU inks as well.

Other classifications that seem relevant to exclude from use in tattoo and PMU inks are substances that are classified as irritating or corrosive to skin. The ECHA restriction proposal on tattoo inks and PMU (ECHA, 2017a) chooses to exclude all irritating or corrosive substances to both skin and eyes. This is based on the assumption that substances with these classifications have intrinsic properties that will give at least the same, if not more severe effects when they are injected into the skin than applied on the skin. This assumption also applies to the eyes (ECHA, 2017b).

Furthermore, it seems relevant to exclude the use of substances in tattoo and PMU inks that are toxic or hazardous in contact with skin, i.e. substances with the hazard statements "H310 – Fatal in contact with skin", "H311 – Toxic in contact with skin", and "H312 – Harmful in contact with skin", corresponding to the following typical classifications:

- Acute Tox. 1 H310 – Fatal in contact with skin
- Acute Tox. 3 H311 – Toxic in contact with skin
- Acute Tox. 4 H312 – Harmful in contact with skin

Finally, it seems relevant to exclude the use of substances in tattoo and PMU inks that may cause damage to organs (STOT SE – Specific Target Organ Toxicity – Single Exposure, STOT RE – Specific Target Organ Toxicity – Repeated Exposure).

All in all, it is therefore suggested to look closer at the typical ingredients in tattoo and PMU inks which have the following classifications:

- CMR 1A, 1B and 2, corresponding to:
    - Carc. 1A/1B H350 – May cause cancer
    - Carc. 2 H351 – Suspected of causing cancer
    - Mut. 1A/1B H340 – May cause genetic defects
    - Mut. 2 H341 – Suspected of causing genetic defects
    - Repr. 1A/1B H360 – May damage fertility or the unborn child
    - Repr. 2 H361 – Suspected of damaging fertility or the unborn child
- Lact., corresponding to:
    - Lact. H362 – May cause harm to breast-fed children
- Skin Sens. 1A, 1B and 1, corresponding to:
    - Skin Sens. 1 H317 – May cause an allergic skin reaction
- Skin Corr./Eye Dam. 1A, 1B and 1C, corresponding to:
    - Skin Corr. 1A/1B H314 – Causes severe skin burns and eye damage
    - Eye Dam. 1 H318 – Causes serious eye damage
- Skin/Eye Irrit. 2, corresponding to:
    - Skin Irrit. 2 H315 – Causes skin irritation
    - Eye Irrit. 2 H319 – Causes serious eye irritation
- Acute Tox. in contact with skin:
    - Acute Tox. 1 H310 – Fatal in contact with skin
    - Acute Tox. 3 H311 – Toxic in contact with skin
    - Acute Tox. 4 H312 – Harmful in contact with skin
- Substances that may damage organs:
    - STOT SE 1 H370 – Causes damage to organs
    - STOT SE 2 H371 – May cause damage to organs

- STOT RE 1 H372 – Causes damage to organs through prolonged or repeated exposure
- STOT RE 2 H373 – May cause damage to organs through prolonged or repeated exposure

It is obvious that substances with one or more of these 'problematic' harmonised classifications (i.e. an agreement of an EU classification has been reached and the classification has been entered into Annex VI of the CLP Regulation) should be avoided in tattoo and PMU inks. If no harmonised classification exists, the producers must notify a self-classification to ECHA. This classification can be found in ECHA's C&L (Classification & Labelling) Inventory. However, different producers notify different self-classifications, which means that more than 30 different classifications may be available in the C&L Inventory for the same substance, and some classifications as for example 'Carc. 2' may be notified by only one or two companies out of perhaps the more than 2,000 companies that have notified a self-classification for the specific substance. The question is therefore, when to trust the self-classifications? Is a self-classification from one single company of 'Carc. 2' reliable, if the other 1,999 companies do not self-classify the substance in question as carcinogenic?

In this report, it is suggested to 'trust' the notified self-classification from the different producers, when 50% or more of the producers have notified the same self-classification to ECHA. This aspect is discussed in the next section below where the harmonised and notified classifications have been looked up in ECHA's C&L Inventory for the substances identified to be used in tattoo and PMU inks.

It must be emphasised that the use of the term 'problematic classifications' throughout this report refers to the problematic classifications as listed above, i.e. the problematic classifications as defined in this report. When referring to the '50% rule' throughout this report, this is defined as including the notified classifications as well, where 50% or more of the producers have notified the same self-classification to ECHA.

5.3 Ingredients used in tattoo and PMU inks and their classifications

The ingredients used in tattoo and PMU inks are described below and are based on the JRC project on tattoo and PMU inks (Piccinini et al., 2015b) as well as the review on colourants in consumer products carried out by Poulsen & Hundebøll (2016). The ingredients are dived into the following main categories:

- colourants
- binding agents
- solvents
- fillers
- surfactants
- humectants
- thixotropic agents
- preservatives
- and other additives/auxiliaries.

Some of the ingredients in tattoo and PMU inks may have multiple functions and will therefore be listed in more categories than one.

The classifications (harmonised and/or notified self-classifications) have been looked up for all ingredients listed (more than 300 different substances). The classifications and substances are not listed in this report, but are listed in an Excel sheet prepared in connection with this report.

5.3.1 Colourants

In a former project carried out for the Consumer Council at the Austrian Standards Institute, a review of colourants used in different consumer products – including tattoo and PMU inks – was carried out (Poulsen & Hundebøll, 2016). The information in this report was based on the JRC project on tattoo and PMU inks (Piccinini et al., 2015b) as well as other review projects on the subject (Danish and Swiss reviews).

Poulsen & Hundebøll (2016) identified in total 180 different colourants relevant for tattoo and PMU inks. However, about 30 of these colourants were listed because they are restricted/banned by the Council of Europe Resolution on tattoo inks (2008) and not because they were identified as being used in tattoo and PMU inks by other sources. The list of colourants identified in Poulsen & Hundebøll (2016) without the colourants restricted by the CoE Resolution (2008) and adjusted with a few new colourants according to Piccinini et al., 2015b has therefore been the starting point in this project. The resulting list is a list of total 147 different colourants that formerly have been identified for use in tattoo and/or PMU inks. In comparison, Piccinini et al. (2015b) identified 113 colourants for use in tattoo inks and 8 colourants only for use in PMU inks, i.e. a total of 121 colourants.

Of these 147 identified colourants in tattoo and PMU inks, most are azo-colourants (48%) and inorganic pigments (20%). Other colourants are anthraquinones (4%), aminoketones (4%), phthalocyanines (4%), xanthenes (4%) or natural colourants (4%).

Most of the colourants (99 of the 147) are used in both tattoo and PMU inks, 25 of the colourants are used in tattoo inks only, and 11 of the colourants are used only in PMU inks and not tattoo inks. For 5 of the colourants, no information on CAS number was identified, and for this reason the classifications have not been looked up for these colourants.

An overview of the classifications of the colourants used in tattoo and PMU inks can be found below in Table 5. Only the problematic classifications (as defined in section 5.2) found for the substances are listed in the table. If the sum of classifications does not add up with the total number of substances with the problematic classifications, it is due to the fact that some of the substances may have more than one of the problematic classifications. For the notified self-classifications, the number in brackets is the number of substances where 50% or more of the notifiers have notified the given self-classification.

Table 5: Overview of colourants in tattoo and PMU inks with problematic classifications

Problematic classification	Harmonised classification	Notified self-classification[1]
Carc. 1A, 1B, 2 H350 – May cause cancer H351 – Suspected of causing cancer	1	Annex III[3]: 24 7 (2) 5 (0)
Mut. 1A, 1B, 2 H340 – May cause genetic defects H341 – Suspected of causing genetic defects	1	Annex III[3]: 31 2 (0) 10 (0)
Repr. 1A, 1B, 2		Annex III[3]: 14

Problematic classification	Harmonised classification	Notified self-classification[1]
H360 – May damage fertility or the unborn child H361 – Suspected of damaging fertility or the unborn child	1	2 (0) 4 (0)
Lact. H362 – May cause harm to breast-fed children		1 (0)
Skin Sens. 1A, 1B, 2 H317 – May cause an allergic skin reaction	1	Annex III[3]: 21 26 (2)
Skin Corr./Eye Dam. 1A, 1B and 1C H314 – Causes severe skin burns and eye damage H318 – Causes serious eye damage	1	 5 (1) 17 (2)
Skin/Eye Irrit. 2 H315 – Causes skin irritation H319 – Causes serious eye irritation		 34 (2) 37 (4)
Acute Tox. 1, 3, 4 H310 – Fatal in contact with skin H311 – Toxic in contact with skin H312 – Harmful in contact with skin	1	 1 (0) 1 (0) 5 (0)
STOT SE/RE 1, 2 H370 – Causes damage to organs H371 – May cause damage to organs H372 – Causes damage to organs through prolonged or repeated exposure H373 – May cause damage to organs through prolonged or repeated exposure	1	 3 (0) 4 (0) 9 (0) 8 (0)
Total of 147 colourants with the classifications[2] - no CAS no. found for 5 of them	**1**	**63 (8)**

1. The number of substances with the given classification is listed. The number in brackets is the number of substances where 50% or more of the notifiers have notified the given self-classification.
2. If the sum of classifications does not add up with the total number of substances with the problematic classifications, it is because some of the substances may have more than one of the problematic classifications.
3. Annex III means that the substance is on ECHAs Annex III inventory, i.e. likely to meet the criteria of Annex III of the REACH Regulation (classified substances registered in quantities between 1 and 10 tonnes).

It can be seen from Table 5 that more than half of the colourants have one or more of the problematic notified classifications. However, only 1 colourant has a problematic harmonised classification and only 8 (of 63) colourants have notified one or more of the problematic classification (as defined in section 5.2) from 50% or more of the total notifying companies.

Of additional information, it can be added that one of the colourants is listed on the REACH Candidate list (as of 20.6.2016). This is the colourant with a problematic harmonised classification as e.g. CMR and Skin Sens.

Furthermore, 33 of the colourants are listed on the ECHA Annex III inventory. 15 of these 33 colourants are 'not classified' by notifiers today. ECHAs Annex III inventory means that they are likely to meet the criteria of Annex III to the REACH Regulation, i.e. substances with a classification that are registered in quantities between 1 and 10 tonnes. This ECHA Annex III inventory was produced by use of publicly available databases with experimental data and by using QSAR model results.

5.3.1.1 Colourants with problematic classifications

The 9 colourants with problematic either harmonised classification (1) or where 50% or more of the notifying companies have notified a problematic classification (as defined in section 5.2) are the following substances:

- Pigment Green 17 (CAS No. 1333-82-0) has a harmonised classification as Carc. 1A H350, Muta. 1B H340, Repr. 2 H361f, Skin Sens. 1 H317, Skin Corr. 1A H314, STOT RE 1 H372.
- Pigment Yellow 36 (CAS No. 37300-23-5) has a notified classification as Skin Sens. 1 H317 (68 companies out of 72 notify this classification).
- Acid Brown 14 (CAS No. 5850-16-8) has a notified classification as Skin Sens. 1 H317 (25 companies out of 39 notify this classification).
- Natural Red 4 (CAS No. 1260-17-9) has a notified classification as Skin Corr. 1A H314 and Eye Dam. 1 H318 (13 companies out of 23 notify these classifications).
- Basic Violet 10 (CAS No. 81-88-9) has a notified classification as Eye Dam. 1 H318 (1,319 companies out of 1,356 notify this classification).
- Pigment Violet 12 (CAS No. 81-64-1) has a notified classification as Skin Irrit. 2 H315 and Eye Irrit. 2 H319 (1,032 and 1,034 companies respectively out of 1,075 notify these classifications).
- Natural Orange 6 (CAS No. 83-72-7) has a notified classification as Skin Irrit. 2 H315 and Eye Irrit. 2 H319 (25 companies out of 28 notify these classifications).
- Basic Red 1 (CAS No. 989-38-8) has a notified classification as Eye Irrit. 2 H319 (63 companies out of 75 notify this classification).
- Pigment Yellow 154 (CAS No. 68134-22-5) has a notified classification as Eye Irrit. 2 H319 (355 companies out of 634 notify this classification).

These colourants are mainly used in both tattoo and PMU inks but in two cases only in tattoo inks. Some of the above colourants are also specifically mentioned in the ECHA restriction proposal because they do not have harmonised classifications that fall under the ECHA restriction proposal, but many of the notifiers have notified classifications, which makes them candidates for possible harmonised classifications under the CLP Regulation and within the scope of the ECHA restriction proposal (ECHA, 2017b). Furthermore, 1 colourant is listed in Annex II of the Cosmetic Products Regulation (CPR) and for this reason, it is specifically mentioned in the ECHA restriction proposal. However, no specific limit values are suggested for these colourants and they are therefore covered by the generic limit value, the specific relevant classifications (RO2) or 0.1% or lower depending on the classifications (RO1). These colourants are:

- Pigment Yellow 36 (CAS No. 37300-23-5) – notified classification
- Pigment Violet 12 (CAS No. 81-64-1) – notified classification
- Pigment Yellow 154 (CAS No. 68134-22-5) – notified classification
- Natural Orange 6 / Lawsone (CAS No. 83-72-7) – notified classification
- Basic Violet 10 (CAS No. 81-88-9) – restricted by Annex II of the CPR

Additionally, Basic Red 1 (CAS No. 989-38-8) is listed in the ECHA restriction proposal with a suggested limit value of 0.1% (for both RO1 and RO2).

5.3.1.2 Colourants restricted by other sources

The total list of colourants found to be used in tattoo and PMU inks by Piccinini et al. (2015b) and other sources listed in Poulsen & Hundebøll (2016) is as mentioned a list of 147 colourants. However, 27 of these colourants are either restricted by the CoE Resolution (2008) and/or restricted in some way in the cosmetic products (Cosmetic Products Regulation Annex II or IV (for Annex IV they are only allowed in some products e.g. rinse-off products)). These 27 colourants are:

- Colourants also listed above with a problematic classification:
    - Basic Violet 10 (CAS No. 81-88-9) – restricted by Annex II of the CPR and CoE Resolution (2008).

    - Basic Red 1 (CAS No. 989-38-8) – restricted by CoE Resolution (2008).
- Colourants not listed above with a problematic classification:
    - Pigment Blue 15 (CAS No. 147-14-8) – restricted by Annex II of the CPR, when used in hair dyes, but allowed according to Table B of the ECHA proposal.
    - Pigment Blue 17 (CAS No. 71799-04-7) – restricted by Annex IV of the CPR in other products than rinse-off products (only allowed in rinse-off products).
    - Pigment Blue 17 (CAS No. 153640-87-0) – restricted by Annex IV of the CPR in other products than rinse-off products (only allowed in rinse-off products).
    - Direct Blue 86 (CAS No. 1330-38-7) – restricted by Annex II of the CPR, when used in hair dyes and only allowed in rinse-off products according to Annex IV.
    - Acid Red 51 (CAS No. 16423-68-0) – restricted by Annex II of the CPR.
    - Solvent Red 1 (CAS No. 1229-55-6) – restricted by Annex II of the CPR, when used in hair dyes.
    - Pigment Red 3 (CAS No. 2425-85-6) – restricted by Annex IV of the CPR in other products than rinse-off products (only allowed in rinse-off products).
    - Pigment Red 4 (CAS No. 2814-77-9) – restricted by Annex II of the CPR, when used in hair dyes.
    - Pigment Red 5 (CAS No. 6410-41-9) – restricted by Annex II of the CPR, when used in hair dyes, but allowed according to Table B of the ECHA proposal.
    - Pigment Red 7 (CAS No. 6471-51-8) – restricted by Annex IV of the CPR in other products than rinse-off products (only allowed in rinse-off products).
    - Pigment Red 53 (CAS No. 2092-56-0) – restricted by Annex II of the CPR and by the CoE Resolution (2008).
    - Pigment Red 53:1 (CAS No. 5160-02-1) – restricted by Annex II of the CPR.
    - Pigment Red 63:1 (CAS No. 6417-83-0) – restricted by Annex II of the CPR, when used in hair dyes, but allowed according to Table B of the ECHA proposal.
    - Pigment Red 112 (CAS No. 6535-46-2) – restricted by Annex II of the CPR, when used in hair dyes and only allowed in rinse-off products according to Annex IV.
    - Pigment Red 122 (CAS No. 980-26-7) – restricted by Annex IV of the CPR in other products than rinse-off products (only allowed in rinse-off products).
    - Pigment Red 181 (CAS No. 2379-74-0) – restricted by Annex II of the CPR, when used in hair dyes, but allowed according to Table B of the ECHA proposal.
    - Pigment Orange 5 (CAS No. 3468-63-1) – restricted by Annex II of the CPR and by the CoE Resolution (2008).
    - Pigment Orange 43 (CAS No. 4424-06-0) – restricted by Annex IV of the CPR in other products than products applied on the mucous membrane.
    - Pigment Violet 19 (CAS No. 1047-16-1) – restricted by Annex II of the CPR, when used in hair dyes and only allowed in rinse-off products according to Annex IV.
    - Pigment Violet 23 (CAS No. 6358-30-1) – restricted by Annex II of the CPR, when used in hair dyes.

- Pigment Green 7 (CAS No. 1328-53-6) – restricted by Annex II of the CPR, when used in hair dyes, but allowed according to Table B of the ECHA proposal.
- Pigment Yellow 1 (CAS No. 2512-29-0) – restricted by Annex IV of the CPR in other products than products applied on the mucous membrane.
- Pigment Yellow 3 (CAS No. 6486-23-3) – restricted by Annex IV of the CPR in other products than products applied on the mucous membrane.
- Pigment Yellow 12 (CAS No. 6358-85-6) – restricted by Annex II of the CPR, when used in hair dyes.
- Pigment Yellow 83 (CAS No. 5567-15-7) – restricted by Annex IV of the CPR in other products than rinse-off products (only allowed in rinse-off products).

It should be noted that 13 of these 27 colourants have one or more problematic notified classifications, but only 2 of them have notified problematic classification where 50% or more of the notifiers have notified the problematic classifications. The colourants with the problematic classifications are not the colourants which are allowed to be used according to Table B of the ECHA proposal.

5.3.1.3 Colourants with no information on classification

For some colourants, no information was available concerning their classification, i.e. they were not identified in the ECHA C&L Inventory. This could indicate that their use is limited, but according to Piccinini et al. (2015b) they are still recorded to be used in tattoo and PMU inks.

In all, 27 colourants were not found in the ECHA C&L Inventory, i.e. no classification was available. However, about half of these colourants are allowed to be used according to either EN 71-7 (toys) or Annex IV of the CP Regulation (approved to be used without any restrictions, such as only for use in rinse-off products). For the rest (17) of the colourants, no information is available except that 6 of them are listed in the Annex III inventory of REACH with suspected carcinogenic and/or skin sensitising effects. These 17 colourants are:

- Cinnarbar (HgS) (CAS No. 23333-45-1)
- Direct Red 53 (CAS No. 6375-58-2)
- Natural Red 22 (CAS No. 98225-55-9)
- Natural Red 23 (CAS No. 6771-96-6)
- Pigment Red 7 (CAS No. 6471-51-8) – but listed in Table A of the ECHA proposal
- Pigment Red 60 (CAS No. 1325-16-2)
- Pigment Red 53 (CAS No. 2092-56-0)
- Pigment Red 210 (CAS No. 61932-63-6) – but listed in Table A of the ECHA proposal
- Pigment Red 222 (CAS No. 71872-63-4)
- Pigment Red 257 (CAS No. 117989-29-4)
- Pigment Orange 22 (CAS No. 6358-48-1)
- Pigment Orange 74 (CAS No. 85776-14-3) – but listed in Table A of the ECHA proposal
- Pigment Yellow 155 (CAS No. 77465-46-4)
- Pigment Violet 37 (CAS No. 57971-98-9)
- Pigment Blue 17 (CAS No. 71799-04-7)
- Pigment Blue 17 (CAS No. 153640-87-0)
- Pigment Black 6 and 7 (CAS No. 98615-67-9)

As illustrated above, 3 of the 17 colourants are, however, added to Table A of the ECHA proposal, i.e. they are not allowed to be used in concentrations above 0.1% irrespective of their classifications.

5.3.2 Binding agents

According to Piccinini et al. (2015b), the binding agents typically used are polyethers, polyvinylpyrrolidone, block copolymer and shellac.

Piccinini et al. (2015b) has identified 15 different binding agents (i.e. with a binding function according to the CosIng database (database on cosmetic ingredients) and with different CAS numbers. These binding agents are typically used in both tattoo and PMU inks. Only a few of the binding agents are listed to be used in tattoo inks only and not in PMU inks. For 6 of the 15 binding agents, no information on CAS number was found, and for this reason the classifications have not been looked up for these binding agents.

An overview of the classifications of the binding agents used in tattoo and PMU inks can be found below in Table 6. Only the problematic classifications (as defined in section 5.2) found for the substances are listed in the table. If the sum of classifications does not add up with the total number of substances with the problematic classifications, it is due to the fact that some of the substances may have more than one of the problematic classifications. For the notified self-classifications, the number in brackets is the number of substances where 50% or more of the notifiers have notified the given self-classification.

Table 6: Overview of binding agents in tattoo and PMU inks with problematic classifications

Problematic classification	Harmonised classification	Notified self-classification[1]
Carc. 1A, 1B, 2 H350 – May cause cancer H351 – Suspected of causing cancer		1 (0)
Mut. 1A, 1B, 2 H340 – May cause genetic defects H341 – Suspected of causing genetic defects		
Repr. 1A, 1B, 2 H360 – May damage fertility or the unborn child H361 – Suspected of damaging fertility or the unborn child		Annex III[3]: 2 1 (0)
Lact. H362 – May cause harm to breast-fed children		
Skin Sens. 1A, 1B, 2 H317 – May cause an allergic skin reaction	1	2 (1)
Skin Corr./Eye Dam. 1A, 1B and 1C H314 – Causes severe skin burns and eye damage H318 – Causes serious eye damage		1 (0)
Skin/Eye Irrit. 2 H315 – Causes skin irritation H319 – Causes serious eye irritation		6 (0) 8 (0)
Acute Tox. 1, 3, 4 H310 – Fatal in contact with skin H311 – Toxic in contact with skin H312 – Harmful in contact with skin		1 (0) 2 (0)
STOT SE/RE 1, 2 H370 – Causes damage to organs H371 – May cause damage to organs H372 – Causes damage to organs through prolonged or repeated exposure		1 (0)

Problematic classification	Harmonised classification	Notified self-classification[1]
H373 – May cause damage to organs through prolonged or repeated exposure		
Total of 15 binding agents with the classifications[2] - no CAS no. found for 6 of them	**1**	**9 (1)**

1. The number of substances with the given classification is listed. The number in brackets is the number of substances where 50% or more of the notifiers have notified the given self-classification.
2. If the sum of classifications does not add up with the total number of substances with the problematic classifications, it is because some of the substances may have more than one of the problematic classifications.
3. Annex III means that the substance is on ECHAs Annex III inventory, i.e. likely to meet the criteria of Annex III of the REACH Regulation (classified substances registered in quantities between 1 and 10 tonnes).

It can be seen from Table 6 that all of the 9 identified binding agents with CAS numbers available have notified at least one of the problematic classifications. However, in most cases, only a few of the notifiers (well below 50%) have notified the problematic classification in question, compared to the total number of notifiers. Only for the one binding agent with a harmonised classification as skin sensitising, all (100%) of the notifiers agree with the harmonised classification.

Of additional information, it can be added that none of the binding agents is listed on the REACH Candidate list (as of 7.7.2017). However, 2 of the binding agents are listed on the ECHA Annex III inventory, i.e. they are likely to meet the criteria of Annex III to the REACH Regulation, i.e. substances with a classification that are registered in quantities between 1 and 10 tonnes. This ECHA Annex III inventory was produced by use of publicly available databases with experimental data and by use of QSAR model results.

5.3.2.1 Binding agents with problematic classifications

The one binding agent with problematic classification (as defined in section 5.2) is the following substance. The binding agent has a harmonised classification as Skin Sens. 1 H317.

- Rosin (CAS No. 8050-09-7)

Rosin is according to Piccinini et al. (2015b) used in both tattoo and PMU inks. Rosin is mentioned in the ECHA restriction proposal, but not listed with a specific limit value and is therefore covered by the generic limit value for skin sensitising substances, i.e. 1% in RO2 or 0.1% in RO1.

5.3.3 Solvents

Usually water is used as a solvent in tattoo and PMU inks, but other solvents are also used (Piccinini et al., 2015b). Alcohols such as ethanol and isopropyl alcohol can be used to modify the drying properties and viscosity of the inks, but too high concentration will give skin irritation. Glycerine can be added as humectant and helps increasing viscosity. Propylene glycol can be added as humectant and to increase dispersability.

Piccinini et al. (2015b) has identified 16 different solvents (i.e. with a solvent function according to the CosIng database (database on cosmetic ingredients) and with different CAS numbers. These solvents are typically used in both tattoo and PMU inks. Only a few of the solvents are listed to be used in tattoo inks only and not in PMU inks. CAS numbers were identified for all solvents.

An overview of the classifications for the solvents used in tattoo and PMU inks can be found below in Table 7. Only the problematic classifications (as defined in section 5.2) found for the substances are listed in the table. If the sum of classifications does not add up with the total number of substances with the problematic classifications, it is because some of the substances may have more than one of the problematic classifications. For the notified self-classifications, the number in brackets is the number of substances where 50% or more of the notifiers have notified the given self-classification.

Table 7: Overview of solvents in tattoo and PMU inks with problematic classifications

Problematic classification	**Harmonised classification**	**Notified self-classification[1]**
Carc. 1A, 1B, 2 H350 – May cause cancer H351 – Suspected of causing cancer		Annex III[3]: 1 2 (0) 2 (0)
Mut. 1A, 1B, 2 H340 – May cause genetic defects H341 – Suspected of causing genetic defects		Annex III[3]: 1 2 (0) 1 (0)
Repr. 1A, 1B, 2 H360 – May damage fertility or the unborn child H361 – Suspected of damaging fertility or the unborn child	1	Annex III[3]: 3 3 (1) 2 (0)
Lact. H362 – May cause harm to breast-fed children		
Skin Sens. 1A, 1B, 2 H317 – May cause an allergic skin reaction		Annex III[3]: 2 1 (0)
Skin Corr./Eye Dam. 1A, 1B and 1C H314 – Causes severe skin burns and eye damage H318 – Causes serious eye damage		 3 (0) 1 (0)
Skin/Eye Irrit. 2 H315 – Causes skin irritation H319 – Causes serious eye irritation	 2	 7 (1) 10 (3)
Acute Tox. 1, 3, 4 H310 – Fatal in contact with skin H311 – Toxic in contact with skin H312 – Harmful in contact with skin	 1	 1 (1) 3 (0)
STOT SE/RE 1, 2 H370 – Causes damage to organs H371 – May cause damage to organs H372 – Causes damage to organs through prolonged or repeated exposure H373 – May cause damage to organs through prolonged or repeated exposure	 1	 3 (1) 4 (0) 3 (0) 1 (0)
Total of 16 solvents with the classifications[2] **- no CAS no. found for 0 of them**	**4**	**15 (5)**

1. The number of substances with the given classification is listed. The number in brackets is the number of substances where 50% or more of the notifiers have notified the given self-classification.
2. If the sum of classifications does not add up with the total number of substances with the problematic classifications, it is because some of the substances may have more than one of the problematic classifications.
3. Annex III means that the substance is on ECHAs Annex III inventory, i.e. likely to meet the criteria of Annex III of the REACH Regulation (classified substances registered in quantities between 1 and 10 tonnes).

It can be seen from Table 7 that 15 of the 16 identified solvents have notified at least one of the problematic classifications. However, in some of the cases, only a few of the notifiers (well below 50%) have notified the problematic classification in question, compared to the total number of notifiers. Four of the solvents have a

harmonised classification containing one or two of the problematic classifications (Repr. 1B H360, Eye Irrit. 2 H319, Acute Tox. 3 H311 or STOT SE 1 H370). These harmonised classifications have also been notified by almost all of the notifiers.

Of additional information, it can be added that one of the solvents (DBP – dibutyl phthalate) is listed on the REACH Candidate list (as of 7.7.2017). Furthermore, 5 of the solvents are listed on the ECHA Annex III inventory, with suspected CMR effects or suspected skin sensitising effects. The ECHA Annex III inventory means that these substances are likely to meet the criteria of Annex III to the REACH Regulation, i.e. substances with a classification that are registered in quantities between 1 and 10 tonnes. This ECHA Annex III inventory was produced by use of publicly available databases with experimental data and by use of QSAR model results.

5.3.3.1 Solvents with problematic classifications

The solvents with problematic classification (as defined in section 5.2) are the following substances:

- Dibutyl phthalate (CAS No. 84-74-2) has a harmonised classification as Repr. 1B H360 and all 964 companies notify this classification as well.
- Methanol (CAS No. 67-56-1) has a harmonised classification as Acute Tox. 3 H311 and STOT SE 1 H370. Almost all companies (5,272 out of 5,278) notify these classifications as well.
- Isopropyl alcohol (CAS No. 67-63-0) has a harmonised classification of Eye Irrit. 2 H319 (and 6,089 companies out of 6,093 also notify this classification).
- Methyl ethyl keton / butanone (CAS No. 78-93-3) has a harmonised classification of Eye Irrit. 2 H319 (and 3,063 companies out of 3,065 also notify this classification).
- 7-Diethylamino-4-methylcoumarin (CAS No. 91-44-1) with a notified classification of Eye Irrit. 2 H319 (288 companies out of 470 notify this classification).

Of these substances, only 7-diethylamino-4-methylcoumarin and dibutyl phthalate is used in tattoo inks, and not in PMU inks according to Piccinini et al. (2015b).

Dibutyl phthalate and methanol are listed in supplementary table A in the ECHA restriction proposal, which is a table of substances proposed not to be allowed in tattoo inks and PMU above the listed limit values. Dibutyl phthalate is listed with a limit value of 0.009% and methanol with a limit value of 10.9%. The other 3 solvents with problematic classifications are not listed in the ECHA restriction proposal with specific limit values and are therefore covered by the generic limit value for eye irritating substances of 10% for RO2 or 0.1% for RO1. As solvents are often used in high concentrations (around 30% according to Piccinini et al. (2015b)), these solvents would not be allowed to be used when the ECHA proposal enters into force.

5.3.4 Fillers

Fillers are usually inorganic substances such as barium sulphate or silica according to Piccinini et al. (2015b). Other fillers have not been identified for use in tattoo or PMU inks according to Piccinini et al. (2015b). Silica is only used in tattoo inks, where barium sulphate may be used in both tattoo and PMU inks (Piccinini et al., 2015b).

None of these two listed fillers has a harmonised classification and none of the fillers has a notified self-classification in the ECHA C&L Inventory. Barium sulphate has been registered within REACH and is according to the registration dossier not classified.

5.3.5 Surfactants

Surfactants are used in tattoo and PMU inks to adjust surface tension thereby promote dispersion and stabilisation of pigments. Piccinini et al. (2015b) identified 9 different surfactants (with a function as surfactants according to the CosIng database (database on cosmetic ingredients)), which are used in both tattoo and PMU inks.

An overview of the classifications for these surfactants used in tattoo and PMU inks can be found below in Table 8. Only the problematic classifications (as defined in section 5.2) found for the substances are listed in the table. If the sum of classifications does not add up with the total number of substances with the problematic classifications, it is because some of the substances may have more than one of the problematic classifications. For the notified self-classifications, the number in brackets is the number of substances where 50% or more of the notifiers have notified the given self-classification.

Table 8: Overview of surfactants in tattoo and PMU inks with problematic classifications

Problematic classification	**Harmonised classification**	**Notified self-classification[1]**
Carc. 1A, 1B, 2 H350 – May cause cancer H351 – Suspected of causing cancer		
Mut. 1A, 1B, 2 H340 – May cause genetic defects H341 – Suspected of causing genetic defects		
Repr. 1A, 1B, 2 H360 – May damage fertility or the unborn child H361 – Suspected of damaging fertility or the unborn child		Annex III[3]: 2
Lact. H362 – May cause harm to breast-fed children		
Skin Sens. 1A, 1B, 2 H317 – May cause an allergic skin reaction		2 (0)
Skin Corr./Eye Dam. 1A, 1B and 1C H314 – Causes severe skin burns and eye damage H318 – Causes serious eye damage		1 (0) 2 (2)
Skin/Eye Irrit. 2 H315 – Causes skin irritation H319 – Causes serious eye irritation		6 (1) 8 (1)
Acute Tox. 1, 3, 4 H310 – Fatal in contact with skin H311 – Toxic in contact with skin H312 – Harmful in contact with skin		1 (0)
STOT SE/RE 1, 2 H370 – Causes damage to organs H371 – May cause damage to organs H372 – Causes damage to organs through prolonged or repeated exposure H373 – May cause damage to organs through prolonged or repeated exposure		1 (0)
Total of 9 surfactants with the classifications[2] - no CAS no. found for 0 of them	**0**	**9 (3)**

1. The number of substances with the given classification is listed. The number in brackets is the number of substances where 50% or more of the notifiers have notified the given self-classification.
2. If the sum of classifications does not add up with the total number of substances with the problematic classifications, it is because some of the substances may have more than one of the problematic classifications.
3. Annex III means that the substance is on ECHAs Annex III inventory, i.e. likely to meet the criteria of Annex III of the REACH Regulation (classified substances registered in quantities between 1 and 10 tonnes).

It can be seen from Table 8 that all the identified surfactants have notified at least one of the problematic classifications. However, in most cases, only a few of the notifiers (well below 50%) have notified the problematic classification in question, compared to the total number of notifiers. None of the surfactants has a harmonised classification.

Of additional information, it can be added that none of the surfactants is listed on the REACH Candidate list (as of 7.7.2017). However, 2 of the surfactants are listed on the ECHA Annex III inventory, with suspected CMR effects (suspected reprotoxic effects). The ECHA Annex III inventory means that these substances are likely to meet the criteria of Annex III to the REACH Regulation (based on QSAR model results), i.e. substances with a classification that are registered in quantities between 1 and 10 tonnes.

5.3.5.1 Surfactants with problematic classifications

The surfactants with problematic classification (as defined in section 5.2) are the following substances:

- PEG Isooctyl phenyl ether CH (CAS No. 9002-93-1[8]) with a notified classification as Eye Dam. 1 H318 (188 companies out of 333) and Skin Irrit. 2 H315 (187 companies out of 333 notify this classification).
- Disodium cocoyl glutamate (CAS No. 68187-30-4) with a notified classification of Eye Irrit. 2 H319 (111 companies out of 112 notify this classification).
- C9-11 Pareth-6 (CAS No. 68439-46-3) with a notified classification of Eye Dam. 1 H318 (2,166 companies out of 2,210 notify this classification).

Of these substances, all are used in both tattoo and PMU inks according to Piccinini et al. (2015b). None of these 3 surfactants with problematic classifications is listed in the ECHA restriction proposal with specific limit values and is therefore covered by the generic limit value for eye damaging as well as eye and skin irritating substances of 1-10% for RO2 depending on the classification and 0.1% for RO1.

5.3.6 Humectants

Humectants are auxiliaries used to hold and retain moisture in a mixture. Four of the 10 humectants used in tattoo and PMU inks also have a function as solvents. Nine of the 10 humectants identified are used in both tattoo and PMU inks.

An overview of the classifications for these humectants used in tattoo and PMU inks can be found below in Table 9. Only the problematic classifications (as defined in section 5.2) found for the substances are listed in the table. If the sum of classifications does not add up with the total number of substances with the

[8] It should be noted that the CAS No. was not listed in Piccinini et al. (2015b). The classifications listed are therefore found for the most common CAS No. listed for this substance when performing an internet search.

problematic classifications, it is because some of the substances may have more than one of the problematic classifications. For the notified self-classifications, the number in brackets is the number of substances where 50% or more of the notifiers have notified the given self-classification.

Table 9: Overview of humectants in tattoo and PMU inks with problematic classifications

Problematic classification	Harmonised classification	Notified self-classification[1]
Carc. 1A, 1B, 2 H350 – May cause cancer H351 – Suspected of causing cancer		 1 (0)
Mut. 1A, 1B, 2 H340 – May cause genetic defects H341 – Suspected of causing genetic defects		
Repr. 1A, 1B, 2 H360 – May damage fertility or the unborn child H361 – Suspected of damaging fertility or the unborn child		
Lact. H362 – May cause harm to breast-fed children		
Skin Sens. 1A, 1B, 2 H317 – May cause an allergic skin reaction		Annex III[3]: 2 1 (0)
Skin Corr./Eye Dam. 1A, 1B and 1C H314 – Causes severe skin burns and eye damage H318 – Causes serious eye damage		 2 (0) 2 (0)
Skin/Eye Irrit. 2 H315 – Causes skin irritation H319 – Causes serious eye irritation		 5 (1) 7 (1)
Acute Tox. 1, 3, 4 H310 – Fatal in contact with skin H311 – Toxic in contact with skin H312 – Harmful in contact with skin		
STOT SE/RE 1, 2 H370 – Causes damage to organs H371 – May cause damage to organs H372 – Causes damage to organs through prolonged or repeated exposure H373 – May cause damage to organs through prolonged or repeated exposure		 2 (0) 2 (0)
Total of 10 humectants with the classifications[2] - no CAS no. found for 0 of them	**0**	**7 (2)**

1. The number of substances with the given classification is listed. The number in brackets is the number of substances where 50% or more of the notifiers have notified the given self-classification.
2. If the sum of classifications does not add up with the total number of substances with the problematic classifications, it is because some of the substances may have more than one of the problematic classifications.
3. Annex III means that the substance is on ECHAs Annex III inventory, i.e. likely to meet the criteria of Annex III of the REACH Regulation (classified substances registered in quantities between 1 and 10 tonnes).

It can be seen from Table 9 that 7 of the 10 identified humectants have notified at least one of the problematic classifications. However, in most of the cases, only a few of the notifiers (well below 50%) have notified the problematic classification in question, compared to the total number of notifiers. None of the humectants has a harmonised classification.

Of additional information, it can be added that none of the humectants is listed on the REACH Candidate list (as of 7.7.2017). However, 2 of the humectants are listed on the ECHA Annex III inventory, with suspected skin sensitising effects.

The ECHA Annex III inventory means that these substances are likely to meet the criteria of Annex III to the REACH Regulation based on QSAR model results, i.e. substances with a classification that are registered in quantities between 1 and 10 tonnes.

5.3.6.1 Humectants with problematic classifications

The humectants with problematic classification (as defined in section 5.2) are the following substances:

- Lactic acid (CAS No. 50-21-5) with a notified classification as Skin Irrit. 2 H315 (1,604 companies out of 1,741 notify this classification).
- Caprylil glycol (1,3-octadienol) (CAS No. 1117-86-8) with a notified classification as Eye Irrit. 2 H319 (239 companies out of 344 notify this classification).

Of these substances, both are used in tattoo and PMU inks according to Piccinini et al. (2015b). None of these 2 humectants with problematic classifications is listed in the ECHA restriction proposal with specific limit values and is therefore covered by the generic limit value for eye and skin irritating substances of 10% for RO2 or 0.1% for RO1.

5.3.7 Thixotropic agents

A thixotropic agent typically used in tattoo inks is silica. Other thixotropic agents have not been identified for use in tattoo or PMU inks according to Piccinini et al. (2015b). Silica is only used in tattoo inks and not PMU inks. Thixotropic agents are used to inhibit the sedimentation of pigment dispersions during long term storage (Piccinini et al., 2015b). Silica has also the function as a filler (see above).

Silica does neither have a harmonised classification nor a notified self-classification in the ECHA C&L Inventory. Silica has not been registered within REACH so no additional information can be found here.

5.3.8 Preservatives

Preservatives are used to ensure the preservation of the tattoo and PMU ink product after opening and may be used in concentrations ranging from 0.0003 to 1.5%. The preservatives most often used are benzoisothiazolinone (BIT) and methylisothiazolinone (MI). In all, 50 different preservatives have been identified for use in tattoo. 20 of the 50 preservatives are not used in PMU inks (Piccinini et al., 2015b).

For 2 of the 50 preservatives, no information on CAS number was found and for this reason the classifications have not been looked up for these preservatives.

An overview of the classifications of the preservatives used in tattoo and PMU inks can be found below in Table 10. Only the problematic classifications (as defined in section 5.2) found for the substances are listed in the table. If the sum of classifications does not add up with the total number of substances with the problematic classifications, it is due to the fact that some of the substances may have more than one of the problematic classifications. For the notified self-classifications, the number in brackets is the number of substances where 50% or more of the notifiers have notified the given self-classification.

Table 10: Overview of preservatives in tattoo and PMU inks with problematic classifications

Problematic classification	Harmonised classification	Notified self-classification[1]
Carc. 1A, 1B, 2	Proposal: 1	
H350 – May cause cancer	1	2 (0)
H351 – Suspected of causing cancer	1	8 (3)
Mut. 1A, 1B, 2		
H340 – May cause genetic defects		2 (1)
H341 – Suspected of causing genetic defects	3	5 (2)
Repr. 1A, 1B, 2		
H360 – May damage fertility or the unborn child	1	3 (2)
H361 – Suspected of damaging fertility or the unborn child		5 (0)
Lact.		
H362 – May cause harm to breast-fed children		
Skin Sens. 1A, 1B, 2		
H317 – May cause an allergic skin reaction	9	25 (13)
Skin Corr./Eye Dam. 1A, 1B and 1C		
H314 – Causes severe skin burns and eye damage	5	11 (7)
H318 – Causes serious eye damage	5	23 (9)
Skin/Eye Irrit. 2		
H315 – Causes skin irritation	7	28 (14)
H319 – Causes serious eye irritation	5	29 (11)
Acute Tox. 1, 3, 4		
H310 – Fatal in contact with skin	RAC: 1	6 (1)
H311 – Toxic in contact with skin	3	8 (6)
H312 – Harmful in contact with skin	1	8 (3)
STOT SE/RE 1, 2		
H370 – Causes damage to organs		5 (0)
H371 – May cause damage to organs		3 (0)
H372 – Causes damage to organs through prolonged or repeated exposure	3	7 (1)
H373 – May cause damage to organs through prolonged or repeated exposure	1	7 (1)
Total of 50 preservatives with the classifications[2] - no CAS no. found for 2 of them	**19**	**41 (33)**

1. The number of substances with the given classification is listed. The number in brackets is the number of substances where 50% or more of the notifiers have notified the given self-classification.
2. If the sum of classifications does not add up with the total number of substances with the problematic classifications, it is because some of the substances may have more than one of the problematic classifications.

In Table 10, the following is listed in the column for harmonised classification:

- 'Proposal: 1' under Carc. – this means that one preservative (melamine) has a proposal for a harmonised classification as Carc. The same preservative has a notified classification as Carc. 2 H351 by 4 notifiers out of a total of 635 notifications.
- 'RAC: 1' under Acute Tox. 2 H310 – this means that for one preservative (Kathon – the mixture of MI and CMI), RAC has concluded that this preservative should be classified as Acute Tox. 2 H310.

It can be seen from Table 10 that the majority (41 out of 50) of the preservatives has notified at least one of the problematic classifications (as defined in section 5.2), and it is 33 out of 50 preservatives where 50% or more of the notifiers have notified at least one of the problematic classifications. Actually, 19 of 50 preservatives have a harmonised classification with at least one of the problematic classifications. In total 34 preservatives have either a problematic harmonised classification or a problematic notified classification where 50% or more of the notifiers have notified at least one of the problematic classifications.

Of additional information, it can be added that the preservative sodium borate is listed on the REACH Candidate list (as of 7.7.2017). Furthermore, 17 of the preservatives are listed on the ECHA Annex III inventory with suspected CMR effects. Five of these 17 preservatives are preservatives with no problematic classifications, which are listed in ECHA Annex III Inventory with suspected CMR effects (based on QSAR model results). These 5 preservatives are:

- Dibenzofuran (CAS No. 132-64-9) – suspected carcinogen and mutagen
- Fluoren-9-one (CAS No. 486-25-9) – suspected carcinogen, mutagen and toxic for reproduction
- Dehydroacetic acid (CAS No. 520-45-6) – suspected carcinogen and skin sensitiser
- Dehydroacetic acid (CAS No. 771-03-9) – suspected carcinogen and skin sensitiser
- 2,4-dichlorobenzyl alcohol (CAS No. 1777-82-8) – suspected toxic for reproduction

5.3.8.1 Preservatives and the Biocidal Products Regulation

As described in section 3.4 “Biocidal Products Regulation”, tattoo and PMU inks are considered as treated articles under the BPR, as they are chemical products which have been treated with biocidal products (preservatives) with the purpose of destroying any microbial growth in the inks. For treated articles, it is required that the active substance being used has been approved (or is under review) for the product type, which here is PT6 “preservatives for products during storage”.

In principle, this means that it is only allowed to put tattoo and PMU products (inks) on the market, if the used preservatives (active substances/biocidal products) have been approved for this product type PT6. The 50 preservatives which according to Piccinini et al. (2015b) have been or are in use in tattoo and PMU inks have therefore been looked up in ECHAs database of Biocidal Active Substances[9]. However, it must be emphasised that the data on preservatives used in tattoo and PMU inks may be before the BPR entered into force.

The result is that

- 5 of the 50 preservatives used in tattoo and PMU inks according to Piccinini et al. (2015b) are approved for PT6 according to ECHAs database on biocidal active substances.
- 8 of the 50 preservatives are under review for use for PT6.
- And for 35 of 50 preservatives, no approval has been sought for PT6 for the listed preservative and these are therefore not allowed to be used in tattoo and PMU inks today.
- The last 2 of the 50 preservatives have not been included in the search as no CAS no. was given for these preservatives.

This clearly illustrates that according to BPR, only a few of the former used preservatives can be used in tattoo and PMU inks today – assuming that the authorisation under BPR is relevant for tattoo and PMU inks (the risk associated with skin injection does not seem to be evaluated for BPR authorisation). This aspect is, however, not discussed in detail in this report but a subject which needs elaboration.

Actually, 12 of the 13 preservatives that are either approved or under approval under the BPR have problematic classifications where 50% or more of the

[9] https://echa.europa.eu/information-on-chemicals/biocidal-active-substances

notifying companies have notified one or more problematic classifications. These are discussed below.

In the ECHA proposal on tattoo and PMU inks, it is noted that preservatives are under the scope of BPR and therefore not further examined in the ECHA proposal. It is, however, noted that certain preservatives may be restricted for use in tattoo and PMU inks due to their harmonised classification (ECHA, 2017a). This will be valid for 7 of the 13 preservatives that are either approved or under approval, when only looking at their harmonised classification (see Table 11 below).

5.3.8.2 Preservatives with problematic classifications

The 34 preservatives with problematic classification (as defined in section 5.2) are the substances listed in Table 11 below. Of these 33 preservatives, 14 of them are only used in tattoo inks and not in PMU inks according to Piccinini et al. (2015b).

It should be noted that the 5 substances with problematic Annex III classifications are not included in the list. It has been noted in the table if the preservatives are approved, under review or not approved according to ECHAs database on biocidal active substances. This has been marked with green shading for the 12 preservatives, which have been either approved or are under review for PT6 under BPR, but still have one or more harmonised or notified problematic classifications.

For the notified problematic classifications, it has been noted in the table how many of the total notifying companies that have notified the given problematic classifications.

It should be emphasised that this category of substances are not assessed nor discussed in the ECHA restriction proposal on tattoo inks because preservatives in tattoo inks are under the scope of the biocides regulation. Therefore, no specific limit values are set for preservatives. It is only noted in the restriction proposal that certain preservatives may be restricted for use in tattoo inks due to their harmonised classification, e.g. formaldehyde, triclosan, phenoxyethanol etc. (ECHA, 2017a).

Table 11: The 34 preservatives in tattoo and PMU inks with problematic classifications as defined in this report. Green shadings are preservatives that are either approved or under approval (BPR).

Name	CAS No.	Problematic classification	Status BPR	Other remarks
Formaldehyde	50-00-0	**Harmonised:** Carc. 1B H350 Muta. 2 H341 Skin Sens. 1 H317 Acute Tox. 3 H311 Skin Corr. 1 H314 **Notified:** Eye Dam. 1 H318	No approval has been sought for PT6 (BPR)	
Polyaminopropyl biguanide	32289-58-0	**Harmonised:** Carc. 2 H351 Skin Sens. H317 Eye Dam. 1 H318 STOT RE 1 H372 **Notified:** No other	No approval has been sought for PT6 (BPR), but other CAS numbers are under review	

Name	CAS No.	Problematic classification	Status BPR	Other remarks
Polyaminopropyl biguanide	133029-32-0	**Harmonised:** None **Notified:** Carc 2 H351	No approval has been sought for PT6 (BPR)	Notified by 1 of 2
Melamine	108-78-1	**Harmonised:** None **Notified:** None	No approval has been sought for PT6 (BPR)	Proposal for harmonised classification as carcinogenic
Glyoxal	107-22-2	**Harmonised:** Muta. 2 H341 Skin Sens. H317 Eye Irrit. 2 H319 Skin Irrit. H315 **Notified:** No other	No approval has been sought for PT6 (BPR)	
Phenol	108-95-2	**Harmonised:** Muta. 2 H341 Acute Tox. 3 H311 Skin Corr. 1B H314 STOT RE 2 H373 **Notified:** No other	No approval has been sought for PT6 (BPR)	Restricted in cosmetic products (Annex II)
Sodium borat	1330-43-4	**Harmonised:** Repr. 1B H360 **Notified:** No other	No approval has been sought for PT6 (BPR)	
Sodium borat	1303-96-4	**Harmonised:** None **Notified:** Repr. 1B H360	No approval has been sought for PT6 (BPR)	Notified by 1499 of 1533
Hexachlorobutadiene	87-68-3	**Harmonised:** None **Notified:** Skin Sens. 1 H317 Skin Irrit. 2 H315 Acute Tox. 4 H312	No approval has been sought for PT6 (BPR)	Notified by 33 of 46 40 of 46 36 of 46
4-Chloro-3,5-dimethylphenol (Chloroxylenol)	88-04-0	**Harmonised:** Skin Sens. 1 H317 Skin Irrit. 2 H315 Eye Irrit. 2 H319 **Notified:** No other	No approval has been sought for PT6 (BPR)	
Hexamethylenetetramine (methenamine)	100-97-0	**Harmonised:** Skin Sens. 1 H317 **Notified:** No other	No approval has been sought for PT6 (BPR)	
BIT – Benzoisothiazolinone	2634-33-5	**Harmonised:** Skin Sens. 1 H317 Skin Irrit. 2 H315 Eye Dam. 1 H318 **Notified:** No other	Under review for PT6 (BPR)	

Name	CAS No.	Problematic classification	Status BPR	Other remarks
MI – Methylisothiazolinone (2-methyl-4-isothiazolinone)	2682-20-4	**Harmonised:** None **Notified:** Skin Sens. 1 H317 Skin Corr. 1B H314 Acute Tox. 3 H311	Under review for PT6 (BPR)	Notified by 1537 of 1599 1536 of 1599 954 of 1599
MCI - Methylchloroisothiazolinone (5-chloro-2-methyl-2H-isothiazol-3-one)	26172-55-4	**Harmonised:** None **Notified:** Skin Sens. 1 H317 Skin Corr. 1B H314 Eye Dam. 1 H318	Under review for PT6 (BPR)	Notified by 1564 of 1611 1585 of 1611 962 of 1611
OIT – Octylisothiazolinone (2-octyl-2H-isothiazol-3-one)	26530-20-1	**Harmonised:** Skin Sens. 1 H317 Skin Corr. 1B H314 Acute Tox. 3 H311 **Notified:** No other	Under review for PT6 (BPR)	
MCI/MI mixture – 5-Chloro-2methyl-2Hisothiazol-3-one/2-Methyl-2H-isothiazol-3one mixture (Kathon)	55965-84-9	**Harmonised:** None **Notified:** Skin Sens. 1 H317 Skin Corr. 1B H314	Approved for PT 6 (PBR)	RAC: Acute Tox. 2 H310 Notified by 376 of 376 376 of 376
Methyldibromo glutaronitrile	35691-65-7	**Harmonised:** None **Notified:** Skin Sens. H317 Eye Dam. 1 H318 Skin Irrit. 2 H315	Approved for PT 6 (PBR)	Notified by 653 of 1045 854 of 1045 769 of 1045
Iodopropynyl butylcarbamate	55406-53-6	**Harmonised:** Skin Sens. 1 H317 Eye Dam. 1 H318 STOT RE 1 H372 **Notified:** No other	Approved for PT 6 (PBR)	
Glutaral	111-30-8	**Harmonised:** Skin Sens. 1 H317 **Notified:** No other	Approved for PT 6 (PBR)	
Thymol	89-83-8	**Harmonised:** None **Notified:** Skin Corr. 1B H314	No approval has been sought for PT6 (BPR)	Notified by 1241 of 1241
Hydroymethyl aminoethanol	65184-12-5	**Harmonised:** None **Notified:** Skin Corr. 1B H314	No approval has been sought for PT6 (BPR)	Notified by 23 of 24
2-Bromo-2-nitropropane-1,3-diol (Bronopol)	52-51-7	**Harmonised:** Eye Dam. 1 H318 Skin Irrit. 2 H315 Acute Tox. 4 H312 **Notified:** No other	Under review for PT6 (BPR)	

Name	CAS No.	Problematic classification	Status BPR	Other remarks
Chlorhexidine	55-56-1	**Harmonised:** None **Notified:** Eye Dam. 1 H318 Skin Irrit. 2 H315	No approval has been sought for PT6 (BPR)	Notified by 37 of 65 57 of 65
Benzoic acid	65-85-0	**Harmonised:** Eye Dam. 1 H318 Skin Irrit. 2 H315 STOT RE 1 H372 **Notified:** No other	No approval has been sought for PT6 (BPR)	
Salisylic acid	69-72-7	**Harmonised:** None **Notified:** Eye Dam. 1 H318 Eye Irrit. 2 H319	No approval has been sought for PT6 (BPR)	Notified by 1374 of 2671 1338 of 2671 Restricted in cosmetic products – limit value is 2% (Annex III)
o-Phenylphenol (biphenyl-2-ol)	90-43-7	**Harmonised:** Skin Irrit. 2 H315 Eye Irrit. 2 H319 **Notified:** No other	Approved for PT 6 (PBR)	
2-Amino-2-methylpropanol	124-68-5	**Harmonised:** Skin Irrit. 2 H315 Eye Irrit. 2 H319 **Notified:** No other	No approval has been sought for PT6 (BPR)	
Phenoxyethanol	122-99-6	**Harmonised:** Eye Irrit. 2 H319 **Notified:** No other	Under review for PT6 (BPR)	
Propylparaben	94-13-3	**Harmonised:** None **Notified:** Skin Irrit. 2 H315 Eye Irrit. 2 H319	No approval has been sought for PT6 (BPR)	Notified by 1048 of 1682 1122 of 1682
Butylparaben	94-26-8	**Harmonised:** **Notified:** Skin Irrit. 2 H315 Eye Irrit. 2 H319	No approval has been sought for PT6 (BPR)	Notified by 387 of 727 388 of 727
Methylparaben	99-76-3	**Harmonised:** None **Notified:** Skin Irrit. 2 H315 Eye Irrit. 2 H319	No approval has been sought for PT6 (BPR)	Notified by 1063 of 1997 1070 of 1997

Name	CAS No.	Problematic classification	Status BPR	Other remarks
Isopropylparaben	4191-73-5	**Harmonised:** None **Notified:** Eye Irrit. 2 H319	No approval has been sought for PT6 (BPR)	Notified by 51 of 65 Restricted in cosmetic products (Annex II)
Sorbic acid	110-44-1	**Harmonised:** None **Notified:** Skin Irrit. 2 H315 Eye Irrit. 2 H319	Under review for PT6 (BPR)	Notified by 1091 of 1291 1237 of 1291
Triclosan Irgasan	9012-63-9	**Harmonised:** None **Notified:** Acute Tox. 1 H310	No approval has been sought for PT6 (BPR)	Notified by 23 of 23

Preservatives with green shading have been either approved or are under review for PT6 under BPR.

All in all, Table 11 illustrate that many (34 of the 50) preservatives have problematic classifications (as defined in section 5.2) as either the harmonised classification or as the notified classification (with 50% or more of the notifiers notifying the problematic classifications). Furthermore, only 13 of the 50 preservatives used in tattoo inks according to Piccinini et al. (2015b) are approved or are under review for PT6 under the BPR – and most of these (12 out of 13 preservatives) have one or more harmonised or notified problematic classifications.

It is only the preservative DMDM hydantoin (CAS No. 6440-58-0) where the preservative is under review for PT6 under the BPR and where 50% or more of the notifiers have not notified problematic classifications. DMDM hydantoin has a notified classification of Skin Irrit. 2 H315, Skin Sens. 1 H317, Eye Irrit. 2 H319, Acute Tox. 3 H311, Muta. 2 H341 and Carc. 2 H351, but only 75, 66, 64, 3, 3 and 3 companies respectively out of a total of 426 notifiers have notified these classification, i.e. well below 50%.

It should be noted that the above listed use of preservatives in tattoo and PMU inks is based on Piccinini et al. (2015b), who has based their information on older reports or own investigations in the years before 2015. This means that the use of preservatives is before the new BPR entered into force. Today, according to BPR, it will only be legal to use the 13 preservatives for which an approval has been sought or an approval has been granted. It is, however, problematic that 7 of the 13 preservatives, for which approval has been sought, have one or more of the problematic harmonised classifications – and 12 of the 13 preservatives have one or more of the problematic notified classification (where more than 50% of the notifiers have notified this classification).

On the other hand, it should be emphasised that these problematic classifications (as defined in section 5.2) are for the preservatives in pure form and preservatives are often used in low concentrations. For some preservatives, their use may therefore be in concentrations which will not result in a problematic classification of the tattoo and PMU mixture, according to the generic concentration limits of CLP. They will, however, contribute to the total percentage of ingredients with the problematic concentrations. In the ECHA proposal, a generic concentration limit

value of 1-10% is used depending on the classification listed for the preservatives for RO2 and 0.1% for RO1.

5.3.9 Other additives/auxiliaries

The function is listed if available (identified) for the other additives. The other additives/auxiliaries are divided into sub-categories according to their function as listed in the CosIng database (database on Cosmetic Ingredients), such as:

- emulsion stabilising substances (improves emulsion stability and shelf-life)
- substances used for masking/perfuming (reducing the odour)
- substances used for buffering (stabilising the pH value)
- and the rest, i.e. substances with no known function or substances with functions as skin conditioning or emollients, i.e. substances that keep the skin in good conditioning or soften/smooth the skin.

5.3.9.1 Emulsion stabilising substances

Emulsion stabilisers are auxiliaries used to help the process of emulsification and they improve emulsion stability and shelf-life. Four of the 11 emulsion stabilisers used in tattoo and PMU inks also have a function as binders. All emulsion stabilisers are used in both tattoo and PMU inks.

An overview of the classifications for these emulsion stabilisers used in tattoo and PMU inks can be found below in Table 12. Only the problematic classifications (as defined in section 5.2) found for the substances are listed in the table. If the sum of classifications does not add up with the total number of substances with the problematic classifications, it is because some of the substances may have more than one of the problematic classifications. For the notified self-classifications, the number in brackets is the number of substances where 50% or more of the notifiers have notified the given self-classification.

Table 12: Overview of emulsion stabilisers in tattoo and PMU inks with problematic classifications

Problematic classification	Harmonised classification	Notified self-classification[1]
Carc. 1A, 1B, 2 H350 – May cause cancer H351 – Suspected of causing cancer		 1 (0) 1 (0)
Mut. 1A, 1B, 2 H340 – May cause genetic defects H341 – Suspected of causing genetic defects		 1 (0)
Repr. 1A, 1B, 2 H360 – May damage fertility or the unborn child H361 – Suspected of damaging fertility or the unborn child		Annex III[3]: 1
Lact. H362 – May cause harm to breast-fed children		
Skin Sens. 1A, 1B, 2 H317 – May cause an allergic skin reaction		 2 (0)
Skin Corr./Eye Dam. 1A, 1B and 1C H314 – Causes severe skin burns and eye damage H318 – Causes serious eye damage		 2 (0)
Skin/Eye Irrit. 2 H315 – Causes skin irritation H319 – Causes serious eye irritation		 4 (0) 5 (0)
Acute Tox. 1, 3, 4 H310 – Fatal in contact with skin H311 – Toxic in contact with skin		

Problematic classification	Harmonised classification	Notified self-classification[1]
H312 – Harmful in contact with skin		1 (0)
STOT SE/RE 1, 2 H370 – Causes damage to organs H371 – May cause damage to organs H372 – Causes damage to organs through prolonged or repeated exposure H373 – May cause damage to organs through prolonged or repeated exposure		 1 (0) 1 (0)
Total of 11 emulsion stabilisers with the classifications[2] **- no CAS no. found for 0 of them**	**0**	**6 (0)**

1. The number of substances with the given classification is listed. The number in brackets is the number of substances where 50% or more of the notifiers have notified the given self-classification.
2. If the sum of classifications does not add up with the total number of substances with the problematic classifications, it is because some of the substances may have more than one of the problematic classifications.
3. Annex III means that the substance is on ECHAs Annex III inventory, i.e. likely to meet the criteria of Annex III of the REACH Regulation (classified substances registered in quantities between 1 and 10 tonnes).

It can be seen from Table 12, that 7 of the 11 identified emulsion stabilisers have notified at least one of the problematic classifications (as defined in section 5.2). However, in all the cases, only a few of the notifiers (well below 50%) have notified the problematic classification in question, compared to the total number of notifiers. None of the emulsion stabilisers has a harmonised classification. Hence, there are no emulsion stabilisers with problematic classifications notified by the majority of the notifiers.

It can be added that none of the emulsion stabilisers is listed on the REACH Candidate list (as of 7.7.2017). However, one of the emulsion stabilisers is listed on the ECHA Annex III inventory, as suspected toxic for reproduction. The ECHA Annex III inventory means that these substances are likely to meet the criteria of Annex III to the REACH Regulation based on QSAR model results, i.e. substances with a classification that are registered in quantities between 1 and 10 tonnes.

5.3.9.2 Substances used for buffering

Substances used for buffering are auxiliaries used to stabilise the pH value of the mixture. All 7 substances identified to be used for buffering are used in both tattoo and PMU inks.

An overview of the classifications for these buffering substances used in tattoo and PMU inks can be found below in Table 13. Only the problematic classifications (as defined in section 5.2) found for the substances are listed in the table. If the sum of classifications does not add up with the total number of substances with the problematic classifications, it is because some of the substances may have more than one of the problematic classifications. For the notified self-classifications, the number in brackets is the number of substances where 50% or more of the notifiers have notified the given self-classification.

Table 13: Overview of substances used for buffering in tattoo and PMU inks with problematic classifications

Problematic classification	Harmonised classification	Notified self-classification[1]
Carc. 1A, 1B, 2 H350 – May cause cancer H351 – Suspected of causing cancer		Annex III[3]: 1

Problematic classification	Harmonised classification	Notified self-classification[1]
Mut. 1A, 1B, 2 H340 – May cause genetic defects H341 – Suspected of causing genetic defects		
Repr. 1A, 1B, 2 H360 – May damage fertility or the unborn child H361 – Suspected of damaging fertility or the unborn child		1 (0)
Lact. H362 – May cause harm to breast-fed children		
Skin Sens. 1A, 1B, 2 H317 – May cause an allergic skin reaction		
Skin Corr./Eye Dam. 1A, 1B and 1C H314 – Causes severe skin burns and eye damage H318 – Causes serious eye damage	3	6 (3) 7 (0)
Skin/Eye Irrit. 2 H315 – Causes skin irritation H319 – Causes serious eye irritation	Proposal: 2 Proposal: 2	5 (1) 6 (3)
Acute Tox. 1, 3, 4 H310 – Fatal in contact with skin H311 – Toxic in contact with skin H312 – Harmful in contact with skin		1 (0) 1 (0)
STOT SE/RE 1, 2 H370 – Causes damage to organs H371 – May cause damage to organs H372 – Causes damage to organs through prolonged or repeated exposure H373 – May cause damage to organs through prolonged or repeated exposure		1 (0) 1 (0)
Total of 7 buffering substances with the classifications[2] **- no CAS no. found for 0 of them**	**3 (proposal: 2)**	**7 (7)**

1. The number of substances with the given classification is listed. The number in brackets is the number of substances where 50% or more of the notifiers have notified the given self-classification.
2. If the sum of classifications does not add up with the total number of substances with the problematic classifications, it is because some of the substances may have more than one of the problematic classifications.
3. Annex III means that the substance is on ECHAs Annex III inventory, i.e. likely to meet the criteria of Annex III of the REACH Regulation (classified substances registered in quantities between 1 and 10 tonnes).

It can be seen from Table 13 that 7 of the 7 identified substances used for buffering have notified at least one of the problematic classifications (as defined in section 5.2), and in all 7 cases it is 50% or more of the notifiers which have notified the problematic classification in question, compared to the total number of notifiers. Three of the substances used for buffering have a harmonised classification, and further two substances have a proposal for a harmonised classification with one or more of the problematic classifications.

It can be added that none of the substances used for buffering is listed on the REACH Candidate list (as of 7.7.2017). However, one of the substances is listed on the ECHA Annex III inventory, as a suspected carcinogen. The ECHA Annex III inventory means that these substances are likely to meet the criteria of Annex III to the REACH Regulation based on QSAR model results, i.e. substances with a classification that are registered in quantities between 1 and 10 tonnes.

Substances used for buffering with problematic classifications
The substances used for buffering with problematic classification (as defined in section 5.2) are the following substances:

- Lactic acid (CAS No. 50-21-5) with a notified classification as Skin Irrit. 2 H315 (1,604 companies out of 1,741 notify this classification).
- Citric acid (CAS No. 77-92-9) with a notified classification as Eye Irrit. 2 H319 (2,612 companies out of 3,223 notify this classification). Moreover, a classification as Skin Irrit. 2 H315 and Eye Irrit. 2 H319 has been proposed.
- Citric acid (CAS No. 5949-29-1) with a notified classification as Eye Irrit. 2 H319 (2,612 companies out of 3,223 notify this classification). Moreover, a classification as Skin Irrit. 2 H315 and Eye Irrit. 2 H319 has been proposed.
- Aminomethyl propanediol (CAS No. 115-69-5) with a notified classification as Skin Irrit. 2 H315 and Eye Irrit. 2 H319 (178 and 151 companies respectively out of 178 notify these classifications).
- Sodium hydroxide (CAS No. 1310-73-2) with a harmonised classification as Skin Corr. 1A H314.
- Hydrocloric acid (CAS No. 7647-01-0) with a harmonised classification as Skin Corr. 1A H314.
- Ammonia (CAS No. 7664-41-7) with a harmonised classification as Skin Corr. 1A H314.

Of these substances, all are used in tattoo and PMU inks according to Piccinini et al. (2015b). None of these 7 buffering substances with problematic classifications is listed in the ECHA restriction proposal with specific limit values and is therefore covered by the generic limit value for eye and skin irritating or skin corrosive substances of 1-10% for RO2 and 0.1% for RO1.

5.3.9.3 Other additives/auxiliaries
A list of 44 substances identified for use in tattoo and PMU inks is stated as "other additives/auxiliaries". These are substances with either no known function (20 substances), skin conditioning properties (21), emollient properties (soften the skin) (12), opacifying properties (reduce transparency) (3) and other properties. The ingredients may be listed with more than one function. Impurities found in tattoo and PMU inks are not included here.

10 of the other auxiliaries identified are only used in tattoo inks and not in PMU inks. The rest of the other auxiliaries identified is used in both tattoo and PMU inks.

An overview of the classifications for these auxiliaries used in tattoo and PMU inks can be found below in Table 14. Only the problematic classifications (as defined in section 5.2) found for the substances are listed in the table. If the sum of classifications does not add up with the total number of substances with the problematic classifications, it is because some of the substances may have more than one of the problematic classifications. For the notified self-classifications, the number in brackets is the number of substances where 50% or more of the notifiers have notified the given self-classification.

Table 14: Overview of other auxiliaries in tattoo and PMU inks with problematic classifications

Problematic classification	**Harmonised classification**	**Notified self-classification[1]**
Carc. 1A, 1B, 2		
H350 – May cause cancer		1 (0)
H351 – Suspected of causing cancer	1	4 (3)

Problematic classification	Harmonised classification	Notified self-classification[1]
Mut. 1A, 1B, 2 H340 – May cause genetic defects H341 – Suspected of causing genetic defects		 2 (2)
Repr. 1A, 1B, 2 H360 – May damage fertility or the unborn child H361 – Suspected of damaging fertility or the unborn child		Annex III[3]: 2
Lact. H362 – May cause harm to breast-fed children		
Skin Sens. 1A, 1B, 2 H317 – May cause an allergic skin reaction		Annex III[3]: 4 6 (2)
Skin Corr./Eye Dam. 1A, 1B and 1C H314 – Causes severe skin burns and eye damage H318 – Causes serious eye damage	 2	 1 (0) 8 (5)
Skin/Eye Irrit. 2 H315 – Causes skin irritation H319 – Causes serious eye irritation		Annex III[3]: 1 11 (6) 18 (3)
Acute Tox. 1, 3, 4 H310 – Fatal in contact with skin H311 – Toxic in contact with skin H312 – Harmful in contact with skin	 1	 2 (1)
STOT SE/RE 1, 2 H370 – Causes damage to organs H371 – May cause damage to organs H372 – Causes damage to organs through prolonged or repeated exposure H373 – May cause damage to organs through prolonged or repeated exposure	 1	 1 (0) 1 (0) 1 (0) 5 (1)
Total of 44 other auxiliaries with the classifications[2] **- no CAS no. found for 0 of them**	**2**	**19 (9)**

1. The number of substances with the given classification is listed. The number in brackets is the number of substances where 50% or more of the notifiers have notified the given self-classification.
2. If the sum of classifications does not add up with the total number of substances with the problematic classifications, it is because some of the substances may have more than one of the problematic classifications.
3. Annex III means that the substance is on ECHAs Annex III inventory, i.e. likely to meet the criteria of Annex III of the REACH Regulation (classified substances registered in quantities between 1 and 10 tonnes).

It can be seen from Table 14 that 19 of the 44 identified other auxiliaries have notified at least one of the problematic classifications. However, in most of the cases, it is only a few of the notifiers (well below 50%) which have notified the problematic classification in question, compared to the total number of notifiers. Two of the other auxiliaries have a harmonised classification.

Of additional information, it can be added that none of the other auxiliaries is listed on the REACH Candidate list (as of 7.7.2017). However, 4 of the other auxiliaries are listed on the ECHA Annex III inventory with suspected skin sensitising effects or suspected toxic for reproduction. The ECHA Annex III inventory means that these substances are likely to meet the criteria of Annex III to the REACH Regulation based on QSAR model results, i.e. substances with a classification that are registered in quantities between 1 and 10 tonnes.

Other auxiliaries with problematic classifications
The other auxiliaries with problematic classification (as defined in section 5.2) are the following substances:

- N-vinyl-2-pyrrolidone (CAS No. 88-12-0) with a harmonised classification as Carc. 2 H351, Eye Dam. 1 H318, Acute Tox. 4 H312 and STOT RE 2 H373.
- Tetramethyl decynediol (Surfonyl®104, TMDD) (CAS No. 126-86-3) with a notified classification as Eye Dam. 1 H318 (807 companies out of 1,558 notify this classification).
- Menthol (CAS No. 2216-51-5) with a notified classification as Skin Irrit. 2 H315 (1,159 companies out of 1,200 notify this classification).
- beta-Naphthol ethoxylate (CAS No. 35545-57-4) with a notified classification as Skin Irrit. 2 H315 and Eye Irrit. 2 H319 (1 company out of 1 notifies this classification).
- Nonylphenol, branched, ethoxylated, phosphate (CAS No. 68412-53-3) with a notified classification as Skin Irrit. 2 H315 and Eye Dam. 1 H318 (530 and 551 companies respectively out of 584 notify these classifications).
- Ethylhexyl glycerine (CAS No. 70445-33-9) with a harmonised classification of Eye Dam. 1 H318.
- Rosa Centifolia extract (CAS No. 84604-12-6) with a notified classification as Skin Irrit. 2 H315, Skin Sens. H317, Eye Irrit. 2 H319, Muta. 2 H341 and Carc. 2 H351 (112, 124, 115, 112 and 114 companies respectively out of 154 notify these classifications).
- Rosa damascena extract (CAS No. 90106-38-0) with a notified classification as Skin Irrit. 2 H315, Skin Sens. 1 H317, Eye Dam. 1 H318, Muta. 2 H341 and Carc. 2 H351 (1,035, 1,033, 1,028, 1,020 and 1,022 companies respectively out of 1069 notify these classifications).
- Octoxynol, iso-Octylphenolethoxylate (CAS No. 92046-34-9) with a notified classification as Skin Irrit. 2 H315 and Eye Irrit. 2 H319 (59 companies out of 59 notify these two classifications).

Of these substances, most are used in both tattoo and PMU inks according to Piccinini et al. (2015b). It is noted in the ECHA restriction proposal that N-vinyl-2-pyrrolidone is restricted in cosmetic products (Annex II). None of these 9 other auxiliaries with problematic classifications is listed in the ECHA restriction proposal with specific limit values and is therefore covered by the generic limit value for the specific relevant classifications, i.e. 1-10% for RO2 and 0.1% for RO1.

5.4 Discussion of ingredients in tattoo and PMU inks

Based on the harmonised or notified classifications of different ingredients in tattoo and PMU inks, different problematic ingredients with problematic classifications (as defined in section 5.2) have been identified. The review of the classifications of ingredients used in tattoo and PMU inks resulted in the following:

- 147 different colourants have been identified for use in tattoo and/or PMU inks (for 5 colourants no CAS numbers were identified).
- 160 different other ingredients than colourants have been identified for use in tattoo and PMU inks (for 17 of these ingredients no CAS numbers were identified).

Of these ingredients identified (with CAS numbers available) for use in tattoo and PMU inks, the following numbers of ingredients were identified where the

substances were classified with one or more of the problematic classifications listed in section 5.2. The problematic classifications were either found in a harmonised classification of the ingredients or by the notified classifications where at least 50% of the notifiers had notified the given classification:

- 9 colourants (and further 17 colourants were restricted by either the CoE Resolution or the CP Regulation)
- 1 binding agent
- 5 solvents
- 0 filler
- 3 surfactants
- 2 humectants
- 0 thixotropic agent
- 34 preservatives – but only 13 of these would be allowed to be used today according to BPR (are either approved or under approval – for the rest no approval has been sought for PT6 (BPR))
- 6 buffering agents (as one also has a function as humectant)
- 9 other ingredients

From this overview, it can be concluded that the most problematic ingredients in tattoo and PMU inks seem to be preservatives, colourants, buffering agents, solvents and other types of ingredients. In Table 15 below, the total list of ingredients in tattoo and PMU inks with problematic ingredients is stated (only the preservatives allowed to be used today are included in the table).

Table 15: Overview of all ingredients in tattoo and PMU inks with problematic classifications as defined in this report

Name	Function	CAS No.	Problematic classification	Notifications	Restricted by ECHA proposal
Pigment Green 17	Colourant	1333-82-0	**Harmonised:** Skin Corr. 1A H314 Skin Sens. 1 H317 Muta. 1B H340 Carc. 1A H350 Repr. 2 H361f STOT RE 1 H372 **Notified:** No other		Yes
Pigment Yellow 36	Colourant	37300-23-5	**Harmonised:** None **Notified:** Skin Sens. 1 H317	Notified by 68 of 72	No
Acid Brown 14	Colourant	5850-16-8	**Harmonised:** None **Notified:** Skin Sens. 1 H317	Notified by 25 of 39	No
Natural Red 4	Colourant	1260-17-9	**Harmonised:** None **Notified:** Skin Corr. 1A H314 Eye Dam. 1 H318	Notified by 13 of 23 13 of 23	No
Basic Violet 10	Colourant	81-88-9	**Harmonised:** None **Notified:** Eye Dam. 1 H318	Notified by 1319 of 1356	Yes (by inclusion in CPR Annex II)
Pigment Violet 12	Colourant	81-64-1	**Harmonised:** None **Notified:** Skin Irrit. 2 H315 Eye Irrit. 2 H319	Notified by 1032 of 1075 1034 of 1075	No

Name	Function	CAS No.	Problematic classification	Notifications	Restricted by ECHA proposal
Natural Orange 6	Colourant	83-72-7	**Harmonised:** None **Notified:** Skin Irrit. 2 H315 Eye Irrit. 2 H319	Notified by 25 of 28 25 of 28	No
Basic Red 1	Colourant	989-38-8	**Harmonised:** None **Notified:** Eye Irrit. 2 H319	Notified by 63 of 75	Yes In table A of ECHA proposal and restricted by CoE (2008)
Pigment Yellow 154	Colourant	68134-22-5	**Harmonised:** None **Notified:** Eye Irrit. 2 H319	Notified by 355 of 634	No
Rosin	Binding agent	8050-09-7	**Harmonised:** Skin Sens. 1 H317 **Notified:** No other		Yes
Dibutyl phthalate	Solvent	84-74-2	**Harmonised:** Repr. 1B H360 **Notified:** No other		Yes In Table A of ECHA proposal and restricted by CPR Annex II
Methanol	Solvent	67-56-1	**Harmonised:** Acute Tox. 3 H311 STOT SE 1 H370 **Notified:** No other		Yes In Table A of ECHA proposal and restricted by CPR Annex III
Isopropyl alcohol	Solvent	67-63-0	**Harmonised:** None **Notified:** Eye Irrit. 2 H319	Notified by 6089 of 6093	No
Methyl ethyl keton / butanone	Solvent	78-93-3	**Harmonised:** None **Notified:** Eye Irrit. 2 H319	Notified by 3063 of 3065	No
7-Diethylamino-4-methylcoumarin	Solvent	91-44-1	**Harmonised:** None **Notified:** Eye Irrit. 2 H319	Notified by 288 of 470	No
PEG Isooctyl phenyl ether CH	Surfactant	9002-93-1	**Harmonised:** None **Notified:** Eye Dam. 1 H318 Skin Irrit. 2 H315	Notified by 188 of 333 187 of 333	No
Disodium cocoyl glutamate	Surfactant	68187-30-4	**Harmonised:** None **Notified:** Eye Irrit. 2 H319	Notified by 111 of 112	No
C9-11 Pareth-6	Surfactant	68439-46-3	**Harmonised:** None **Notified:** Eye Dam. 1 H318	Notified by 2166 of 2210	No
Lactic acid	Humectant Buffering	50-21-5	**Harmonised:** None **Notified:** Skin Irrit. 2 H315	Notified by 1604 of 1741	No

Name	Function	CAS No.	Problematic classification	Notifications	Restricted by ECHA proposal
Caprylil glycol	Humectant	1117-86-8	**Harmonised:** None **Notified:** Eye Irrit. 2 H319	Notified by 239 of 344	No
BIT – Benzoisothiazolinone	Preservative	2634-33-5	**Harmonised:** Skin Sens. 1 H317 Skin Irrit. 2 H315 Eye Dam. 1 H318 **Notified:** No other		Yes
MI – Methylisothiazolinone (2-methyl-4-isothiazolinone)	Preservative	2682-20-4	**Harmonised:** None **Notified:** Skin Sens. 1 H317 Skin Corr. 1B H314 Acute Tox. 3 H311	Notified by 1537 of 1599 1536 of 1599 954 of 1599	No (but restricted by CPR Annex V)
MCI - Methylchloroisothiazolinone (5-chloro-2-methyl-2H-isothiazol-3-one)	Preservative	26172-55-4	**Harmonised:** None **Notified:** Skin Sens. 1 H317 Skin Corr. 1B H314 Eye Dam. 1 H318	Notified by 1564 of 1611 1585 of 1611 962 of 1611	No (but restricted by CPR Annex V)
OIT – Octylisothiazolinone (2-octyl-2H-isothiazol-3-one)	Preservative	26530-20-1	**Harmonised:** Skin Sens. 1 H317 Skin Corr. 1B H314 Acute Tox. 3 H311. **Notified:** No other		Yes
MCI/MI mixture – 5-Chloro-2methyl-2Hisothiazol-3-one/2-Methyl-2H-isothiazol-3one mixture (Kathon)	Preservative	55965-84-9	**Harmonised:** None **Notified:** Skin Sens. 1 H317 Skin Corr. 1B H314	RAC: Acute Tox. 2 H310 Notified by 376 of 376 376 of 376	No (but restricted by CPR Annex V)
Methyldibromo glutaronitrile	Preservative	35691-65-7	**Harmonised:** None **Notified:** Skin Sens. H317 Eye Dam. 1 H318 Skin Irrit. 2 H315	Notified by 653 of 1045 854 of 1045 769 of 1045	No
Iodopropynyl butylcarbamate	Preservative	55406-53-6	**Harmonised:** Skin Sens. 1 H317 Eye Dam. 1 H318 STOT RE 1 H372 **Notified:** No other		Yes and restricted by CPR Annex V
Glutaral	Preservative	111-30-8	**Harmonised:** Skin Sens. 1 H317 **Notified:** No other		Yes and restricted by CPR Annex V
2-Bromo-2-nitropropane-1,3-diol (Bronopol)	Preservative	52-51-7	**Harmonised:** Eye Dam. 1 H318 Skin Irrit. 2 H315 Acute Tox. 4 H312 **Notified:** No other		Yes and restricted by CPR Annex V

Name	Function	CAS No.	Problematic classification	Notifications	Restricted by ECHA proposal
o-Phenylphenol (biphenyl-2-ol)	Preservative	90-43-7	**Harmonised:** Skin Irrit. 2 H315 Eye Irrit. 2 H319 **Notified:** No other		Yes and restricted by CPR Annex V
Phenoxyethanol	Preservative	122-99-6	**Harmonised:** Eye Irrit. 2 H319 **Notified:** No other		Yes and restricted by CPR Annex V
Sorbic acid	Preservative	110-44-1	**Harmonised:** None **Notified:** Skin Irrit. 2 H315 Eye Irrit. 2 H319	Notified by 1091 of 1291 1237 of 1291	No (but restricted by CPR Annex V)
Citric acid	Buffering	77-92-9 and 5949-29-1	**Harmonised:** None Proposal for Skin Irrit. 2 H315 Eye Irrit. 2 H319 **Notified:** Eye Irrit. 2 H319	Notified by 2612 of 3223	No
Aminomethyl propanediol	Buffering	115-69-5	**Harmonised:** None **Notified:** Skin Irrit. 2 H315 Eye Irrit. 2 H319	Notified by 178 of 178 151 of178	No
Sodium hydroxide	Buffering	1310-73-2	**Harmonised:** Skin Corr. 1A H314 **Notified:** No other		Yes and restricted by CPR Annex III
Hydrocloric acid	Buffering	7647-01-0	**Harmonised:** Skin Corr. 1A H314 **Notified:** No other		Yes
Ammonia	Buffering	7664-41-7	**Harmonised:** Skin Corr. 1A H314 **Notified:** No other		Yes and restricted by CPR Annex III
N-vinyl-2-pyrrolidone	Other (unknown)	88-12-0	**Harmonised:** Carc. 2 H351 Eye Dam. 1 H318 Acute Tox. 4 H312 STOT RE 2 H373 **Notified:** No other		Yes and restricted by CPR Annex II
Tetramethyl decynediol (Surfonyl®104, TMDD)	Other (unknown)	126-86-3	**Harmonised:** None **Notified:** Eye Dam. 1 H318	Notified by 807 of 1558	No
beta-Naphthol ethoxylate	Other (unknown)	35545-57-4	**Harmonised:** None **Notified:** Skin Irrit. 2 H315 Eye Irrit. 2 H319	Notified by 1 of 1 1 of 1	No
Nonylphenol, branched, ethoxylated, phosphate	Other (unknown)	68412-53-3	**Harmonised:** None **Notified:** Skin Irrit. 2 H315 Eye Dam. 1 H318	Notified by 530 of 584 551 of 584	No

Name	Function	CAS No.	Problematic classification	Notifications	Restricted by ECHA proposal
Octoxynol, iso-Octylphenolethoxylate	Other (unknown)	92046-34-9	**Harmonised:** None **Notified:** Skin Irrit. 2 H315 Eye Irrit.. 2 H319	 Notified by 59 of 59 59 of 59	No
Menthol	Denaturant Masking Refreshing Soothing	2216-51-5	**Harmonised:** None **Notified:** Skin Irrit. 2 H315	 Notified by 1159 of 1200	No
Ethylhexyl glycerine	Skin conditioning	70445-33-9	**Harmonised:** Eye Dam. 1 H318 **Notified:** No other	 Notified by	Yes
Rosa Centifolia extract	Skin conditioning	84604-12-6	**Harmonised:** None **Notified:** Skin Irrit. 2 H315 Skin Sens. H317 Eye Irrit. 2 H319 Muta. 2 H341 Carc. 2 H351	 Notified by 112 of 154 124 of 154 115 of 154 112 of 154 114 of 154	No
Rosa damascena extract	Masking Tonic	90106-38-0	**Harmonised:** None **Notified:** Skin Irrit. 2 H315 Skin Sens. 1 H317 Eye Dam. 1 H318 Muta. 2 H341 Carc. 2 H351	 Notified by 1035 of 1069 1033 of 1069 1028 of 1069 1020 of 1069 1022 of 1069	No

This overview of ingredients used in tattoo and PMU inks and their classification shows that a total of 46 ingredients (47 different CAS numbers) has one or more problematic harmonised or notified classifications. Of these 46 ingredients:

- 19 ingredients would be restricted by the new ECHA proposal because the substances have either one of the restricted harmonised classification or because the substances are listed on Annex II of the CP Regulation or in table A of the ECHA proposal.
- 3 ingredients would not be restricted by the new ECHA proposal because they have no harmonised classification. However, they are restricted by e.g. the CP Regulation Annex V (limit value on preservatives). Furthermore, 50% or more of the notifiers have notified one or more of the problematic classifications.
- 24 ingredients would not be restricted by the new ECHA proposal because they have no harmonised classification, but 50% or more of the notifiers have notified one or more of the problematic classifications.

This means that the ECHA proposal will not be able to restrict all ingredients (19 out of 46) with relevant problematic classifications (as defined in section 5.2), which have been identified in this review as the ECHA proposal is based on harmonised classifications and not the notified classifications. Harmonised classifications only exist for a fraction of the chemical substances on the market today (for a total of 4,600 substances). According to the review carried out on identified ingredients in tattoo and PMU inks and their classifications, the ECHA

proposal will only be able to restrict about 40% of the identified ingredients with problematic classifications.

From the review carried out in this report, it can be concluded that the most critical groups of ingredients in tattoo and PMU inks are:

- Preservatives where 12 of 13 approved (or under approval) preservatives under BPR will be restricted by the proposal suggested in this report (using the '50% rule' for notified classifications). When using the criteria in the ECHA proposal RO1, 7 out of 13 preservatives would be restricted.
- Solvents where 5 out of 15 solvents will be restricted by the proposal suggested in this report. When using the criteria in the ECHA proposal RO1, 4 out of 15 solvents would be restricted.
- Buffering agents where 7 out of 7 substances will be restricted by the proposal suggested in this report. When using the criteria in the ECHA proposal RO1 and assuming that the 2 existing proposals for a harmonised classification will enter into force, 5 out of 7 buffering agents would be restricted.

These types of ingredients are 'critical' because they are essential for the tattoo or PMU ink recipe, but all or a large part of the used substances in these groups will be excluded for use when using the regulatory proposal suggested in this report as well as the ECHA RO1 proposal. Of course, this does not mean that a regulatory proposal for restricting problematic substances in tattoo and PMU inks should not be made. It, however, illustrates that specific criteria may be needed (or may even be necessary) for these groups of substances, i.e. specific limit values should be set for the specific preservatives, solvents and buffering agents used in tattoo and PMU inks by use of toxicological data available and perhaps existing opinions for these substances regarding their use in cosmetic products.

Preservatives are not necessarily used in high concentrations or in concentrations above 0.1%, but the exclusion of almost all (proposal in this report using the '50% rule') or more than half (the ECHA proposal) of the preservatives warrants that specific limit values should be set for this group of substances. Actually, it may be necessary for the preservatives to establish a positive list of preservatives that can be used and in which concentrations, as the authorisation of preservatives under BPR not necessarily considers the correct exposure pathway for tattoo and PMU inks. The authorisation under BPR focuses on intake, inhalation and exposure on skin, and the risks associated with skin injection do not seem to be evaluated. This aspect is, however, not discussed in detail in this report but is a subject that needs elaboration.

Solvents are used in high concentrations (around 30%) which means that the solvents with the problematic classifications (as defined in section 5.2) will be excluded for use in tattoo inks entirely. Especially, as one of the most often used solvents, isopropyl alcohol (according to Piccinini et al. (2015b)), will be excluded, it would be a good idea to look more closely at the solvents used and set specific concentration limits for these substances based on specific toxicological information for these substances and not based on a generic concentration limit.

Finally, the group buffering agents will be excluded for use due to their irritating or corrosive properties. Buffering agents are often an acid or a base which is used to neutralise the pH value of the mixture and thereby even neutralising the irritating or corrosive properties of other ingredients in the mixture. All acids or bases will naturally be classified as skin/eye irritating or corrosive. However, as their purpose is to neutralise the pH value of the tattoo mixture, it may be relevant (and

necessary) to look at this group of substances and set specific limit values for these substances instead of relying on a generic concentration limit.

6 Proposal regulatory requirements for chemicals in tattoo and PMU inks

As discussed in section 4.2.3 “Discussion of ECHA restriction proposal on tattoo inks and PMU” and section 5.4 “Discussion of ingredients in tattoo and PMU inks”, the ECHA restriction proposal does not restrict all the ingredients which have been identified as problematic ingredients in this review report. It is therefore suggested that the ECHA restriction proposal should be expanded to cover other aspects as well. These aspects are discussed below and suggestions are made for a proposal for regulatory requirements for different chemical ingredients in tattoo and PMU inks. The aspects discussed are the following:

- General requirements concerning classification
- General requirements concerning impurities and break down products
- Specific requirements for specific substances
- Framework of the legislation

6.1 General requirements

6.1.1 General requirements concerning classification

In Table 16 below, an overview of the problematic classifications used in this review report compared to the classifications restricted in the ECHA proposal is presented.

Table 16: Comparison of classifications restricted in the ECHA proposal and classifications discussed in this review report

Type of classification	Problematic classifications as defined in this report	Classifications restricted in the ECHA proposal
CMR effects	Carc. 1A/1B H350 Carc. 2 H351 Muta. 1A/1B H340 Muta. 2 H341 Repr. 1A/1B H360 Repr. 2 H361	Carc. 1A/1B H350 Carc. 2 H351 Muta. 1A/1B H340 Muta. 2 H341 Repr. 1A/1B H360 Repr. 2 H361
Lactating effects	Lact. H362	-
Skin sensitisation	Skin Sens. 1A/1B/1 H317	Skin Sens. 1A/1B/1 H317
Skin corrosion/irritation	Skin Corr. 1A/1B/1C H314 Skin Irrit. 2 H315	Skin Corr. 1A/1B/1C H314 Skin Irrit. 2 H315
Eye damage/irritation	Eye Dam. 1 H318 Eye Irrit. 2 H319	Eye Dam. 1 H318 Eye Irrit. 2 H319
Acute toxicity in contact with skin	Acute Tox. 1 H310 Acute Tox. 3 H311 Acute Tox. 4 H312	-
Specific target organ toxicity	STOT SE 1 H370 STOT SE 2 H371 STOT RE 1 H372 STOT RE 2 H373	-

The review of the classification of used ingredients in tattoo and PMU inks carried out in this project illustrates that:

- The ECHA proposal will restrict 19 of the 147 colourants and 160 other ingredients reviewed in this project, i.e. a total of 19 of 307 ingredients or 6.2%.
- The proposal in this review of using the classification where 50% of the notifiers have notified the problematic classification will restrict 46 of 307 ingredients or 15%.

The review carried out in this project therefore illustrates that the ECHA proposal only will restrict about 40% of the ingredients compared to the proposal suggested in this report. This is due to the fact that the ECHA proposal only restricts substances where the listed classifications have been harmonised. This approach is clearly not adequate because it is only a fraction of the chemical substances on the market which have a harmonised classification. Therefore, it is suggested to include substances where 50% or more of the notifiers have notified the problematic classifications (as defined in section 5.2). It is of course debatable if such approach is usable in practise and if 50% is the correct number. Below e.g. 10% will clearly be too low and include a lot of substances where only a couple of the notifiers have e.g. notified a Carc. 2 classification. A lower percentage will therefore include several more substances. A higher percentage of e.g. 75% of the notifiers will of course make the classification more trustworthy, but in this report 50% of the notifiers have been used as the point of intersection as it seems reasonable to believe in the classification when the majority of the notifiers has notified the classification. This aspect is, however, not discussed further in this report.

6.1.1.1 CMR

Regarding the CMR effects, the ECHA proposal suggests limiting all substances with a harmonised classification as CMR 1A, 1B or 2. However, the two restriction options RO1 and RO2 set different limit values for these substances as illustrated in Table 4. RO1 defines a 'no content' of carcinogenic and mutagenic substances in all categories and uses low limit values of 0.0014% and 0.014% for Repr. 1A/1B and Repr. 2 substances, respectively. For RO2, the generic concentration limit values in the CLP Regulation are used, i.e. 0.1% and 1% for Carc./Mut. 1 and Carc./Mut. 2 respectively, and 0.3% and 3% for Repr. 1 and Repr. 2, respectively.

The proposed concentration limit values for RO2 seem way too high, especially taking into account that the concentration limits suggested are for each individual substance in the tattoo and PMU inks. In a worst-case scenario, more substances with CMR classification could be used and thereby resulting in a high concentration of CMR substances in the product. However, in such a case, the tattoo and PMU ink must be classified as CMR and thereby hopefully not possible to sell. It is therefore suggested to follow the 'non-use' as proposed in the ECHA RO1 proposal for CMR substances. Alternatively, a low limit value of e.g. 0.001 and 0.01% could be suggested for CMR 1 and 2. It has, however, not been the purpose of this project to review the used limit values from a toxicological point of view. The limit values in RO1 seem adequately low although it must be taken into account that the tattoo and PMU inks are directly injected into the human body and are produced to stay in the human body for decades.

Similarly to the ECHA proposal, it seems reasonable to exclude the substances which are only carcinogenic or mutagenic through inhalation.

The restrictions proposed are therefore:

Tattoo inks shall not be placed on the market if they contain the following substances with either the harmonised or notified classifications as specified below. For the notified classifications, it is, however, only the classifications where 50% or more of the notifiers have notified the listed classifications, which are relevant.

1. Tattoo inks shall not contain the following substances, unless a specific concentration limit is specified for individual substances (in this restriction proposal):
    - Carcinogenic or mutagenic substances, category 1A, 1B and 2 excluding those substances classified only with the hazard statements H350i (May cause cancer by inhalation), H351i (Suspected of causing cancer by inhalation), H340i (May cause genetic defects via inhalation) and H341i (Suspected of causing genetic defects by inhalation).

2. Tattoo inks shall not contain the following substances, unless a specific concentration limit is specified (in this restriction proposal):
    - Repr. category 1A and 1B in concentrations greater than 0.0014 % w/w
    - Repr. category 2 in concentrations greater than 0.014% w/w

6.1.1.2 Lactating effects

In this review project, it was suggested also to include the classification Lact. H362, i.e. substances that may cause harm to breast-fed children. However, the review performed in this report illustrated that this is not a classification that seems relevant for ingredients in tattoo and PMU inks. Actually, only one of the ingredients is classified with Lact. H362 and for this colourant, it is only 1 out of a total of 612 notifiers that have notified this classification, and hence well below 50% of the notifiers.

When looking at ECHA's C&L Inventory, only about 650 substances out of 135,000 substances in the database have the notified classification Lact. H362 and only 25 substances with a harmonised classification as lactating. It is therefore suggested not to include this classification in the proposal for regulatory requirements for tattoo inks and PMU inks. If in the future, it will be necessary to restrict substances with this effect (if no other classifications automatically (e.g. reprotoxic) eliminate these substances), a substance specific restriction can be made (put on a negative list).

6.1.1.3 Skin sensitisers

The review of classifications for ingredients used in tattoo and PMU inks carried out in this report illustrates that 13 ingredients would be restricted by a Skin Sens. classification, also if including the notified classifications and using the '50% rule' – and only looking at the preservatives, which are actually allowed to be used today according to the BPR. Numerous other preservatives (formerly used in tattoo and PMU inks) have a notified classification as skin sensitising, but these are not included in the above number as they would not be allowed to be used today because of the BPR.

Regarding the skin sensitising effects, the ECHA proposal suggests limiting all substances with a harmonised classification as Skin Sens. 1. However, the two restriction options RO1 and RO2 set different limit values for these substances as illustrated in Table 4. RO1 uses a limit value of 0.1% and RO2 a limit value of 0.1% for Skin Sens. 1A and a limit value of 1% for Skin Sens. 1 and 1B.

The proposed concentration limit values for RO2 seem too high, especially taking into account that the concentration limits suggested are for each individual substance in the tattoo and PMU inks. Furthermore, most classifications identified

were Skin Sens. 1 classifications, i.e. resulting in a limit value of 1%. Several skin sensitisers are resulting in effects in concentrations way below 1% and in some cases also way below 0.1%. It may therefore be necessary to use lower limit values here or set individual limit values for specific substances.

In Annex I of the CLP Regulation, it is stated that for some substances which are classified as sensitisers, they may elicit an allergic response when present in a mixture in quantities below the generic concentration limits in individuals who are already sensitised to the substance or mixture. In the CLP Regulation, they state that the generic concentration limit for elicitation is 10 times lower compared to the generic concentration limits for triggering classification as Skin Sens. Hence, the generic concentration limit for elicitation of an allergic response in humans who are already sensitised is 0.01% for Skin Sens. 1A and 0.1% for Skin Sens. 1 and 1B. Furthermore, an SCCS opinion on the skin sensitising effects of fragrances in cosmetic products concludes that a general limit value of 100 ppm (0.01%) should be used in general for skin sensitising fragrances unless substance specific data are available (SCCS No. 1459, 2012). For this reason, it is suggested to lower the limit value for substances classified skin sensitising to 0.01%.

The restrictions proposed are therefore:

Tattoo inks shall not be placed on the market if they contain the following substances with either the harmonised or notified classifications as specified below. For the notified classifications, it is, however, only the classifications where 50% or more of the notifiers have notified the listed classifications, that are relevant.

3. Tattoo inks shall not contain the following substances unless a specific concentration limit is specified for individual substances (in this restriction proposal):
    - Skin sensitising substances, category 1, 1A and 1B in concentrations greater than 0.01%

6.1.1.4 Skin or eye irritating or damaging

The review of classifications for ingredients used in tattoo and PMU inks carried out in this report illustrates that 15 and 14 ingredients would be restricted by either a Skin Irrit. 2 or an Eye Irrit. 2 classification respectively, if also including the notified classifications where 50% or more of the notifiers have notified the classification – and only looking at the preservatives, which are actually allowed to be used today according to the BPR. The more severe Skin Corr. 1 or Eye Damage 1 classification was found for 5 and 14 ingredients respectively in total. The group of substances resulting in most skin/eye irritation or skin/eye corrosion/damage classifications is the preservatives.

It should be noted that 21 ingredients would be restricted by use of the harmonised classification as skin or eye irritating or damaging (not including the preservatives not allowed according to the BPR), whereas 48 ingredients would be restricted by use of the notified classifications (the '50% rule') as well.

Regarding the skin and eye irritating/damaging, the ECHA proposal suggests limiting all substances with a harmonised classification as Skin Corr., Eye Dam., Skin Irrit. and Eye Irrit. However, the two restriction options RO1 and RO2 set different limit values for these substances as illustrated in Table 4. RO1 uses a limit value of 0.1% for all these substances, whereas RO2 uses a limit value of 1, 3 or 5% for Skin Corr. or Eye Dam. substances, depending on the situation, and 10% for the skin and eye irritation substances (Skin Irrit. 2 and Eye Irrit. 2).

The proposed limit values in RO2 seem too high especially taking into account that the concentration limits suggested are for each individual substance in the tattoo and PMU inks. For this reason, it is suggested to use the limit value as presented in RO1, i.e. a limit value of 0.1% for all such substances. Many preservatives are classified with these types of skin/eye irritating/damaging classifications. However, these preservatives are often used in low concentration (can be below 0.1%) and it is suggested to prepare a true positive list (if necessary) of preservatives with a specification of the limit value acceptable (from a toxicological perspective including the exposure route under the skin) if it is necessary to use preservatives in higher concentrations.

The restrictions proposed are therefore:

Tattoo inks shall not be placed on the market if they contain the following substances with either the harmonised or notified classifications as specified below. For the notified classifications, it is, however, only the classifications where 50% or more of the notifiers have notified the listed classifications, that are relevant.

4. Tattoo inks shall not contain the following substances, unless a specific concentration limit is specified for individual substances (in this restriction proposal):
    - Skin irritant or corrosive substances, category 1A, 1B, 1C, and 2 in concentrations greater than 0.1%
    - Eye damaging and irritant substances, category 1 and 2 in concentrations greater than 0.1%

6.1.1.5 Toxic in contact with skin

In this review project, it was suggested also to include the classification concerning toxicity in contact with skin, i.e. Acute Tox. 1 H310, Acute Tox. 3 H311 and Acute Tox. 4 H312. However, the review performed in this report illustrated that this is not a classification that will exclude that many substances in tattoo and PMU inks, simply because not than many ingredients have these classifications.

The review of classifications for ingredients used in tattoo and PMU inks carried out in this report illustrates that 0, 3 and 2 ingredients would be restricted by either an Acute Tox. 1 H310, Acute Tox. 3 H311 or Acute Tox. 4 H312 classification respectively, if also including the notified classifications where 50% or more of the notifiers have notified the classification – and only looking at the preservatives, which are actually allowed to be used today according to the BPR. However, these 5 ingredients may be excluded by other classifications as well (bronopol (Skin Irrit./Eye Dam.), methylchloroisothiazolinone (Skin Sens./Eye Dam./Skin Corr.), octylisothiazolinone (Skin Sens./Skin Corr.), and n-vinyl-2-pyrrolidone (Carc)). One ingredient, methanol will not be excluded by other classification (except for the STOT SE H370 classification suggested in this report), but in the ECHA proposal methanol is one of the substances specifically listed in the negative list Annex A with a limit value of 10.9%.

It is therefore debatable whether this group of classification is relevant to include in a restriction proposal or not. However, it has been a choice in this report to include it in the proposal with a limit value of 0.1%, which is also the generic cut-off value for acute toxicity (except Acute Tox. 4, which is 1%).

The restrictions proposed are therefore:

Tattoo inks shall not be placed on the market if they contain the following substances with either the harmonised or notified classifications as specified below. For the notified classifications, it is, however, only the classifications where 50% or more of the notifiers have notified the listed classifications, which are relevant.

5. Tattoo inks shall not contain the following substances, unless a specific concentration limit is specified for individual substances (in this restriction proposal):
    - Substances that are acutely toxic to skin, i.e. Acute Tox. 1 H310, Acute Tox. 3 H311 and Acute Tox. 4 H312 in concentrations greater than 0.1%

6.1.1.6 Specific target organ toxicity

In this review project, it was suggested also to include the classification concerning specific target organ toxicity, i.e. STOT SE 1 H370, STOT SE 2 H371, STOT RE 1 H372 and STOT RE 2 H373. However, the review performed in this report illustrated that this is not a classification that will exclude that many substances in tattoo and PMU inks, simply because not than many ingredients have these classifications.

The review of classifications for ingredients used in tattoo and PMU inks carried out in this report illustrates that 1 ingredient (methanol) has a STOT SE H370 classification and 1 ingredient (n-vinyl-2-pyrrolidone) has a STOT RE 2 H373 classification, when including the notified classifications where 50% or more of the notifiers have notified the classification – and only looking at the preservatives, which are actually allowed to be used today according to the BPR. For both substances, the STOT classification is also a harmonised classification. One of the ingredients (n-vinyl-2-pyrrolidone) may be excluded by other classifications as well (Carc), whereas methanol will not be excluded by other classifications (except for Acute Tox. 3 H311 which is also proposed to be a classification that is restricted in this report). However, methanol is in the ECHA proposal one of the substances which are specifically listed in the negative list Annex A with a limit value of 10.9%.

It is therefore debatable whether this group of classification is relevant to include in a restriction proposal or not. It has been a choice in this report to exclude it from the proposal to simplify the proposal as much as possible.

6.1.2 General requirements concerning impurities and break down products

It is a well-known fact that tattoo and PMU inks can contain impurities; in fact, the purity of tattoo and PMU inks is on average around 70-90% (Piccinini et al., 2015b). Therefore, both the CoE Resolution (2008) and the ECHA proposal also include negative lists of different impurities and break down products with specific limit values that are not allowed to be exceeded.

6.1.2.1 Heavy metals

The CoE Resolution (2008) and the ECHA proposal restrict the same 15 heavy metals, but the limit values are different, as discussed earlier. However, in the ECHA proposal, a toxicological review has been performed concerning the new limit values proposed. It has not been the purpose of this report to review these limit values, and for this reason it is therefore suggested to include the limit values as proposed in Table A of the ECHA proposal.

The restrictions proposed are therefore:

Tattoo inks shall not be placed on the market if they contain substances listed in Table A exceeding the specified concentration limits.

6.1.2.2 PAH

The CoE Resolution (2008) restricted PAHs with a total limit value of 0.5 ppm. However, it was not specified exactly which types of PAHs that should be measured and this was subject to interpretation. The ECHA proposal only restricts the PAHs classified as CM and with a limit value of 5 or 0.5 ppm (an error in the proposal)[10]. This proposal by ECHA (i.e. PAHs classified as Carc. or Mut.) will at least restrict the 8 PAHs which are restricted in articles made of plastics and rubber according to REAHC Annex XVII entry no. 50:

- Benzo[a]pyren (BaP) CAS-nr. 50-32-8
- Benzo[e]pyren (BeP) CAS-nr. 192-97-2
- Benzo[a]anthracen (BaA) CAS-nr. 56-55-3
- Chrysen (CHR) CAS-nr. 218-01-9
- Benzo[b]fluoranthen (BbFA) CAS-nr. 205-99-2
- Benzo[j]fluoranthen (BjFA) CAS-nr. 205-82-3
- Benzo[k]fluoranthen (BkFA) CAS-nr. 207-08-9
- Dibenzo[a,h]anthracen (DBAhA) CAS-nr. 53-70-3

Furthermore, the PAH naphthalene is also classified as carcinogenic and will fall under this restriction. In the ECHA proposal, it is noted that entry 50 in REACH Annex XVII is currently being reviewed and any changes to this limit should be reflected in the restriction.

In this project, it is decided to use the same restriction as suggested by the ECHA proposal, but to use the limit value of 0.5 ppm (which is believed to be the intention with the proposal, but written wrong in the proposal). Furthermore, it is suggested that it is not only PAHs with a harmonised classification as Carc. or Mut., but also the notified classifications of Carc. and Mut. if 50% or more of the notifiers have notified such a classification. This will make it in line with the other restrictions in this proposal.

The restrictions proposed are therefore:

Tattoo inks shall not be placed on the market if they contain the following substances with either the harmonised or notified classifications as specified below. For the notified classifications, it is, however, only the classifications where 50% or more of the notifiers have notified the listed classifications, that are relevant.

6. Tattoo inks shall not contain the following substances, unless a specific concentration limit is specified for individual substances (in this restriction proposal):
    - Polycyclic-aromatic hydrocarbons (PAHs) classified as carcinogenic or mutagenic categories 1A, 1B and 2 in individual concentrations greater than 0.00005%

[10] In the ECHA proposal under RO1 and RO2, the PAH concentration limit is set at 0.0005% or equal to 5 ppm whereas the concentration in table 11 of the ECHA proposal is set at 0.00005% or equal to 0.5 ppm as listed in the CoE Resolution (2008). Which limit value that is the correct is unknown. However, the correct limit value is assumed to be 0.5 ppm, as they refer to REACH Annex XVII where the limit value of 0.5 ppm is used for toys.

6.1.2.3 Release of aromatic amines

In both the CoE Resolution (2008) and the ECHA proposal, specific aromatic amines are restricted. The CoE Resolution does not set a specific limit value ('must not contain'), but a limit value of 5 ppm for each aromatic amine is used in the ECHA proposal where the aromatic amines are listed in Table A.

It is suggested to use the proposal as proposed by ECHA, i.e:

> Tattoo inks shall not be placed on the market if they contain substances listed in Table A exceeding the specified concentration limits.

6.2 Specific requirements for specific substances

Besides the more general requirements, it will also be necessary to set specific requirements for specific substances because some substances may be more toxic than the general limit values used account for. On the other hand, it may be necessary to allow some substances in higher concentrations than the general limit values set. For example, for preservatives and buffering agents where almost all used substances have problematic classifications (using the '50% rule' and the definition as listed section 5.2). This can be done by use of negative lists and positive lists. Furthermore, it may simply be an advantage to use negative and/or positive lists in the legislation, as this will allow for specific changes to specific substances if new information should be available in the future (which was not available at the time of preparing the legislation).

In the ECHA proposal, the following is proposed by use of Table A and Table B:

- Table A is a negative list of substances which are not allowed in tattoo and PMU inks above the listed concentrations. Table A contains the following types of substances:
  - Element impurities
  - Aromatic amines
  - Colourants
  - Specific substances, such as DEHP, DBP, methanol, aniline and a few other substances
- Table B is a derogation list of colourants which are allowed to be used even though they are restricted in cosmetic products (CP Regulation Annex II) for use in hair dyes.

In chapter 5 "Screening of ingredients", it was illustrated that the most problematic substances were found for preservatives, colourants, solvents and buffering agents. Preservatives fall under the BPR. However, it is uncertain whether injection under the skin is covered as an exposure pathway in the authorisation of the substances under BPR. This aspect is not discussed in detail in this report but is a subject that needs elaboration. Perhaps the BPR needs clarification on this point.

In this report, it is illustrated that most of the preservatives approved according to the BPR have classifications that will exclude them for use in tattoo and PMU inks in concentrations above 0.1%. Therefore, it may be necessary to look more closely at the acceptable levels of preservatives and prepare specific requirements for this group of substances. Similarly, colourants are an important group of substances for tattoo and PMU inks, where specific requirements are also justified (and also carried out in the ECHA proposal).

For solvents which also are a large part of the tattoo and PMU inks, it may also be necessary to set specific limit values for specific used solvents. Ethanol is one

solvent, which will not be excluded by the restricted classifications in this proposal, but isopropyl alcohol is. However, this is not discussed in detail here, but could be a future aspect to examine.

Buffering agents may not be used in that high concentrations, but because of their purpose in the mixture – to neutralise the pH value - they will all have irritating or corrosive properties and classifications, and will thereby be excluded from use in concentrations above 0.1%. It may therefore be necessary to set specific limit values for this group of substances.

In this report, specific requirements are proposed for colourants, preservatives and buffering agents.

6.2.1 Specific requirements for colourants

This review has identified 147 colourants for use in tattoo and PMU inks. Of these 147 colourants[11]:

- 5 colourants were not identified by CAS number and therefore they have not been assessed further.
- 9 colourants were identified with problematic classifications (as defined in section 5.2) – and will therefore be excluded when using the general classification restrictions. However, it should be noted that they are only excluded if using the rule of '50% or more of the notifiers have notified the classification', as these colourants (except for one) have no harmonised classification. In the ECHA proposal, some of these 9 colourants are listed in the negative list (Table A), but not all.
- 25 colourants are restricted by e.g. CoE Resolution or in Annex II of the CPR or is e.g. only allowed in rinse-off products according to Annex IV of the CPR. These 25 colourants were not restricted by the problematic classifications, as they have no harmonised problematic classifications or no problematic classifications where 50% or more of the notifiers have notified such a classification. All these colourants are, however, excluded for use because of the restriction in the ECHA proposal concerning the negative list (Table A) or Annex II or Annex IV in the CP Regulation.
- 37 colourants were neither restricted nor approved for use in other schemes such as toys or food. For most of these colourants, they are 'not classified' according to most notifiers and no classification exists (cannot be found in the ECHA C&L Inventory (for 14 colourants)).
- 83 colourants are approved to be used by one or several different schemes, i.e. they are on different positive lists such as EN 71-7 (for toys), Swiss Confederation on food contact materials, EU Regulation 1333/2008 on food additives or on Annex IV of the CP Regulation without any limits of their use.

According to this overview, it therefore seems correct to combine the general restrictions by problematic classifications with both a negative list for unwanted colourants in tattoo and PMU inks and also a positive list of colourants, as has been done for Table A (negative list) in the ECHA proposal.

Table A of the ECHA proposal mainly contains colourants as restricted by the CoE Resolution as well as 29 new colourants (azo dyes) that may release aromatic amines. In addition to the colourants in Table A, the ECHA proposal also restricts the colourants listed in Annex II of the CP Regulation and the colourants with

[11] Please notice that some overlap exists between the different groups listed.

limited use in Annex IV of the CP Regulation (i.e. colourants only allowed to be used in rinse-off products etc.). Colourants in Table A are restricted in a concentration of 0.1% in general, but this could of course be changed if new information is available.

It could be discussed whether the colourants listed in Table B according to the ECHA proposal should be allowed to be used in tattoo inks and PMU. Some of them are listed in Annex II of the CP Regulation (when used in hair dyes), but they have been allowed in the ECHA proposal mainly because some colourants cannot be replaced and some classifications only apply for inhalation, which is not the relevant exposure route for tattoo inks. These colourants have, however, not been examined further in this project.

The review performed in this report illustrates that a large group of colourants seems to be acceptable to use in tattoo and PMU inks, as these have been approved to be used (are on a positive list) in connection with legislation such as toys or food. However, even though they are accepted to be used in food does not necessarily mean that they are acceptable for skin injection. It is therefore suggested to make an assessment of these substances and then if the risk assessment turns out positive, to add these colourants to a true positive list (e.g. a new Table C) of the ECHA proposal.

The review in this report, however, also illustrates that for some colourants, no information is available. It is therefore suggested that until such colourants have been examined more closely, these should be added to Table A of the ECHA proposal. As listed in 5.3.1 “Colourants”, 3 of 17 colourants with no classifications are already listed in Table A of the ECHA proposal.

It is proposed to follow the restrictions for colourants as listed in the ECHA proposal RO1, but to add more colourants in both Table A and to a new Table C.

The restrictions proposed are therefore:

Tattoo inks shall not contain the following substances, unless a specific concentration limit is specified for individual substances (in this restriction proposal):

- Substances prohibited for use in cosmetic products as listed in Annex II of Regulation 1223/2009.
- Substances listed in Annex IV of Regulation 1223/2009 with the following conditions in column g of that Annex:
    - Rinse-off products
    - Not to be used in products applied on the mucous membrane
    - Not be used in eye products

Tattoo inks shall not be placed on the market if they contain substances listed in Table A exceeding the specified concentration limits *(and Table A of the ECHA proposal should be expanded to include colourants with no information available concerning classification).*

The above restrictions do not apply to the substances listed in Table B.

The above restrictions do not apply to the substances listed in Table C (*Table C does not exist in the ECHA proposal and is a positive list that should be made for colourants acceptable for use as e.g. food colourants if in a risk assessment, they are acceptable to inject under the skin).*

6.2.2 Specific requirements for preservatives

Preservatives fall under the BPR, which means that it is only allowed to use the preservatives that are approved or are under approval for the relevant product type. However, as stated earlier, it is uncertain whether injection under the skin is covered as an exposure pathway in the authorisation of the substances under BPR. This aspect is not discussed in detail in this report, but is a subject that needs elaboration and the BPR may need clarification on this point.

In this report, it is illustrated that most of the preservatives approved according to the BPR have classifications that will exclude them for use in tattoo and PMU inks in concentrations above 0.1%, which was the limit value proposed. Therefore, it may be necessary to look more closely at the acceptable levels of preservatives and prepare specific requirements for the preservatives, e.g. by use of a positive list.

It is suggested to look closely at the opinions and risk assessments carried out in connection with the CP Regulation, but also to take into consideration that the preservatives are not rinsed-off, but actually injected directly into the skin. The limit values used in the CP Regulation may therefore be too high for use for tattoo and PMU inks. This should be a future examination point of a proposal on tattoo and PMU inks.

However, for now it is decided to use the general requirement concerning classifications (as described above) for the preservatives, but a positive list of preservatives with specific limit values based on a risk assessment should be carried out in the future. Therefore, no additional requirement is proposed for the preservatives at the moment, except for the fact that preservatives should be added to the positive list in the future.

The restrictions proposed are therefore:

The above restrictions do not apply to the substances listed in Table C (*Table C does not exist in the ECHA proposal and is a positive list that should be made for preservatives acceptable for use in specific concentrations (limit values) as determined by a risk assessment, which accounts for the products being injected under the skin).*

6.2.3 Specific requirements for buffering agents

As illustrated in the review in this report (section 5.3.9.2 “Substances used for buffering”), all buffering agents (7 out of 7) will be restricted by the general classification criteria proposed in this report and almost all (5 out of 7) would be restricted by the ECHA RO1 proposal. However, these buffering agents are only classified with skin and/or eye irritating and/or corrosive classifications because the buffering agents are acids or bases, which are used to neutralise the pH value of the final mixture.

A general classification criterion for skin/eye irritating/corrosive properties may therefore not be relevant for this group of substances. This could be avoided by setting a general criterion that buffering agents used for neutralising the pH value could be excluded from the general criteria for irritating/corrosive classification, if the buffering agents have no other of the problematic classifications (as defined in section 5.2). This may, however, be tricky to define, and may be handled better by setting specific limit values for the buffering agents in a positive list. Where to set the specific limit values for the used buffering agents has, however, not been carried out in this report, but should be a future discussion point.

The restrictions proposed are therefore:

The above restrictions do not apply to the substances listed in Table C (*Table C does not exist in the ECHA proposal and is a positive list that should be made for buffering agents acceptable for use in specific concentrations (limit values) as determined by a risk assessment, which accounts for the products being injected under the skin).*

6.3 Framework of the legislation

The ECHA proposal for a restriction of substances in tattoo inks and PMU is a restriction proposal prepared for the REACH system, i.e. the restriction is supposed to be a new entry in Annex XVII of REACH "Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles".

Normally, Annex XVII of REACH only includes restrictions, however, the ECHA proposal has also included a derogation list (Table B), as all the listed restrictions concerning classifications and Annex II and IV of the CP Regulation do not apply for the substances (colourants) listed in Table B.

It is not possible within the REACH framework to introduce a true positive list, as suggested in this report by introducing a new Table C, as use of a positive list would need an approval procedure as given in e.g. the cosmetics regulation for e.g. preservatives. Therefore, it seems more straightforward to prepare a new framework for substances used in tattoo and PMU inks, which will make it clearer and easier to include both negative and positive lists. As discussed above (and also illustrated by the ECHA proposal), this seems to be the best way to account for the different groups of substances used in tattoo and PMU inks, as well as lack of toxicological information for specific substances or group of substances.

However, preparing a new framework, i.e. a new piece of legislation on EU level for tattoo and PMU inks alone is expected to take longer time than including a restriction in an existing EU framework such as REACH. Another option could be to incorporate the restrictions in tattoo and PMU inks in the legal framework for cosmetic products.

7 Suggested regulatory requirements for chemicals in tattoo and PMU inks

This chapter presents the total list of requirements as suggested in chapter 6 "Proposal regulatory requirements for chemicals in tattoo and PMU inks". The proposal for requirements for chemical substances in tattoo and PMU inks is mainly based on the ECHA proposal RO1, but with certain additions and differences. The differences from ECHA proposal RO1 are marked in bold.

One major difference from the suggestion in this report to the ECHA proposal is the suggestion of a true positive list of preservatives, colourants, buffering agents and other substances for which a risk assessment has been carried out and where the correct exposure pathway (injected under the skin) is taken into account. It is not possible within the REACH framework to introduce a true positive list, as suggested in this report by introducing a new Table C, as use of a positive list would need an approval procedure as given in e.g. the cosmetics regulation for e.g. preservatives. Therefore, a new framework is needed or the suggested restrictions for tattoo and PMU inks could be incorporated in the legal framework for cosmetic products.

Tattoo inks shall not be placed on the market if they contain the following substances with either the harmonised **or notified classifications** as specified below. **For the notified classifications, it is, however, only the classifications where 50% or more of the notifiers have notified the listed classifications, that are relevant.**

1. Tattoo inks shall not contain the following substances, unless a specific concentration limit is specified for individual substances (in this restriction proposal):
    - Carcinogenic or mutagenic substances, category 1A, 1B and 2 excluding those substances classified only with the hazard statements H350i (May cause cancer by inhalation), H351i (Suspected of causing cancer by inhalation), H340i (May cause genetic defects via inhalation) and H341i (Suspected of causing genetic defects by inhalation).

2. Tattoo inks shall not contain the following substances, unless a specific concentration limit is specified for individual substances (in this restriction proposal):
    - Repr. category 1A and 1B in concentrations greater than 0.0014 % w/w
    - Repr. category 2 in concentrations greater than 0.014% w/w

3. Tattoo inks shall not contain the following substances, unless a specific concentration limit is specified for individual substances (in this restriction proposal):
    - Skin sensitising substances, category 1, 1A and 1B in concentrations greater than **0.01%**

4. Tattoo inks shall not contain the following substances, unless a specific concentration limit is specified for individual substances (in this restriction proposal):
    - Skin irritant or corrosive substances, category 1A, 1B, 1C, and 2 in concentrations greater than 0.1%
    - Eye damaging and irritant substances, category 1 and 2 in concentrations greater than 0.1%

5. Tattoo inks shall not contain the following substances, unless a specific concentration limit is specified for individual substances (in this restriction proposal):
    - **Substances that are acutely toxic to skin, i.e. Acute Tox. 1 H310, Acute Tox. 3 H311 and Acute Tox. 4 H312 in concentrations greater than 0.1%**

6. Tattoo inks shall not contain the following substances, unless a specific concentration limit is specified for individual substances (in this restriction proposal):
    - Polycyclic-aromatic hydrocarbons (PAHs) classified as carcinogenic or mutagenic categories 1A, 1B and 2 in individual concentrations greater than 0.00005%

Tattoo inks shall not contain the following substances, unless a specific concentration limit is specified for individual substances (in this restriction proposal):

- Substances prohibited for use in cosmetic products as listed in Annex II of Regulation 1223/2009.
- Substances listed in Annex IV of Regulation 1223/2009 with the following conditions in column g of that Annex:
    - Rinse-off products
    - Not to be used in products applied on the mucous membrane
    - Not be used in eye products

Tattoo inks shall not be placed on the market if they contain substances listed in Table A exceeding the specified concentration limits ***(and Table A of the ECHA proposal should be expanded to include colourants with no information available concerning classification)*.**

The above restrictions do not apply to the substances listed in Table B.

The above restrictions do not apply to the substances listed in Table C (*Table C does not exist in the ECHA proposal, but is a positive list that should be made for e.g. the substances listed below, if the substances in a risk assessment are accepted to be injected under the skin in the specific listed concentrations:*

- ***colourants acceptable for use as e.g. food colourants***
- ***preservatives acceptable for use in specific concentrations (limit values)***
- ***buffering agents acceptable for use in specific concentrations (limit values)).***

8 Discussion and recommendations

In this report, a proposal for regulatory requirements for chemical substances used in tattoo and PMU inks has been prepared. The proposal is mainly based on the ECHA proposal (RO1) for restrictions of substances in tattoo and PMU inks. However, changes have been proposed to both the limit values used, the negative list (Table A), the derogation list (Table B) used, suggestion of introducing a true positive list, as well as changes to the overall use of only restricting harmonised classifications. Based on the review performed in this report, certain areas, however, need a more thorough examination before including it in a legislation on tattoo and PMU inks. These areas are discussed below and are:

- Preparation of a true positive list for preservatives and allowed limit values
- Preparation of a negative and positive list for colourants
- Preparation of a positive list for buffering agents
- More detailed examination concerning solvents
- Introduction of a new framework than REACH

Preservatives fall under the BPR, which means that it is only allowed to use the preservatives that are approved or are under approval for the relevant product type. However, it is uncertain whether injection under the skin is covered as an exposure pathway in the authorisation of the substances under BPR. This aspect is not discussed in detail in this report, but is a subject that needs elaboration and maybe a clarification in BPR (or BPR guidelines) is needed on this point.

In the ECHA proposal, specific restrictions concerning preservatives (and specific limit values for preservatives) have not been discussed as it is stated that the BPR automatically will restrict the use of preservatives. Two issues are, however, of importance for the preservatives. The first issue is, as mentioned above, that it is uncertain whether the actual use of preservatives in tattoo and PMU inks (i.e. injection under the skin) is covered in the authorisation of the substances under BPR. The second issue is that a large part of the preservatives will be excluded by the ECHA proposal and the proposal in this report of using the ‘50% rule’. The review performed in this report illustrates that 12 of 13 of the approved preservatives (or the preservatives under approval) will be excluded for use in concentrations above 0.1% by the general classification criteria set in the proposal in this report, when using the ‘50% rule’ for the notified classifications. When only using the harmonised classifications, 7 out of 13 preservatives will be excluded by the ECHA RO1 proposal (for use in concentrations below 0.1%).

For this reason, it will be relevant to look more closely at the acceptable levels of preservatives and prepare specific requirements for the preservatives. It will be relevant to use the information already available in the CP Regulation (specific limit values set for preservatives) as well as the scientific opinions available on the preservatives. It is, however, necessary to take into consideration that the preservatives are not rinsed-off, but injected directly into the skin. The limit values used in the CP Regulation may therefore be too high for use for tattoo and PMU inks and should therefore be examined more closely in a risk assessment concerning the use in tattoo and PMU inks. These considerations (a specific risk assessment for a product injected under the skin) on preservatives should result in a

true positive list (Table C) of preservatives allowed to be used irrespective of their classification.

Additionally, it could be discussed in more details which solution is the best way to handle the use of **colourants** with no (or little) information available concerning classification. The review prepared in this report illustrates that for a part of the colourants used, according to Piccinini et al. (2015b), information regarding their toxicity (and classification) is missing. This could imply that they are not used to the same extend to day but they were listed in use when the Piccinini report was prepared. Colourants with no (or little) information should not be used in tattoo and PMU inks as these will stay in the human body for years. In the proposal prepared in this report, these substances are put on the negative list (Table A), but another way to ensure use of only acceptable colourants could be to establish a positive list of colourants which are only allowed to be used. The colourants on the positive list could be colourants approved for food, food contact materials and toys, as well as colourants with known and a low toxicity. However, the exposure pathway of injection under the skin needs to be taken into consideration in a risk assessment.

Moreover, the review performed in this report illustrates that the general limit values for the restricted problematic classifications (as defined in section 5.2) will exclude the use of all (7 out of 7) **buffering agents** by use of the proposal in this report and almost all (5 out of 7) by the ECHA proposal RO1 in concentrations above 0.1%. As the buffering agents are used to neutralise the pH value of the final tattoo mixture and as the buffering agents are only classified with skin and/or eye irritating and/or corrosive classifications, because the buffering agents are acids or bases, the general classification criterion for skin/eye irritating/corrosive properties may therefore not be relevant for this group of substances. Therefore, it is relevant (and may be necessary) to set specific limit values for the used buffering agents based on specific toxicological information for the specific substances. This should be a future discussion point before adopting regulatory requirements for chemical substances in tattoo and PMU inks.

Furthermore, the review performed in this report illustrates that the general restriction concerning classification will exclude one of the often-used **solvents** such as isopropyl alcohol whereas another often-used solvent ethanol will not be excluded. Solvents are a large part of the recipe of tattoo and PMU inks and are usually used in concentrations of about 33% (Piccinini et al., 2015b). It should therefore be examined in further details which solvents that are used most often and if these will be excluded via the general classification criteria. The review by Piccinini et al. (2015b) lists some solvents, but it is not evident which solvents that are used most often – except that ethanol and isopropyl alcohol are often used. For some solvents, it may be relevant to review them individually from a toxicological point of view and perhaps include them in Table A with a larger limit value than the general limit value used for the relevant classifications.

Finally, it will be necessary to introduce the proposed restrictions in this report into a **new framework** as it will not be possible to use the REACH framework when using a true positive list (Table C) as suggested in this report. Using a positive list would need an approval procedure as given in e.g. the cosmetics regulation for e.g. preservatives. Alternatively, the proposed restrictions could be incorporated in the legal framework for cosmetic products.

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