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Survey and occurrence of PPD, PTD and other allergenic hair dye substances in hair dyes

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Survey and occurrence of PPD, PTD and other allergenic hair dye substances in hair dyes

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Preface

This project has been carried out by the following FORCE Technology staff members:

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- Erik Bjarnov and Susann Geschke, chemical analysis
- Maria Strandesen, quality assurance

The project has been supervised by Louise Fredsbo Karlsson, Lærke Ambo Nielsen and Bettina Ørsnes Andersen from the Danish Environmental Protection Agency.

The project is completed in the period June 2011 to November 2012. The products mentioned in this report have been purchased, found on the internet or obtained from producers/distributors during the period of July 2011 to November 2011.

The purpose was to map the Danish market of hair dye products for both private use and professional use (at hairdressers).

The hair dye substances were identified, and their allergenic properties listed. 30 products were selected for chemical analysis, measuring the content of certain hair dye substances. Furthermore, a short description of the possible health hazards of selected hair dye substances was given.

Summary and conclusions

In this survey the Danish market for hair dyes was investigated. It was estimated that the Danish market contains at least 4,000 different hair dye products counting all the colours and tones. 365 of these were included in the survey and their declared content of hair dye substances was investigated. A small number of hair dye products were analyzed for the quantitative content of selected hair dye substances.

A database was formed with all the ingredients listed along with several other information about the products (type of hair dye, for professional or private use and so on).

The purpose of the survey was to gather information about the hair dye products on the Danish market especially with focus on the occurrence of PPD, PTD and their salts and derivatives as well as other hair dye substances with extreme, strong or moderate sensitizing potential. It was investigated whether permanent hair dyes without PPD, PTD and salts and derivatives exist – and in general if hair dye products without extreme, strong or moderate sensitizers are available on the market. The ultimate purpose of this was to investigate if it is possible to give any advice on the choice of hair dye product to consumers who wish to minimize their risk of hair dye allergy. Focus was exclusively on hair dye substances and no other ingredients in the hair dyes were addressed in this survey.

It was attempted to include hair dyes so they represent the Danish market the best possible way with the exception that products from the so-called “green saloons” were over represented. The reason for this was that there had been a discussion whether these products might have less sensitizing properties than the classic oxidative hair dyes and therefore it was desirable to explore this group of products in the survey.

The survey showed that the professional market for hair dyes is larger than the private market, therefore 206 professional hair dyes and 159 hair dyes from the private market were included in the survey. Furthermore the survey showed that permanent hair dyes represent the majority of the Danish market compared to semi-permanent and direct dyes. 77% of the hair dyes investigated were permanent hair dyes, 22% were semi-permanent and only 1% were direct dyes.

With regard to the occurrence of PPD, PTD and their salts and derivatives the survey showed that both within the group of permanent and the group of semi-permanent hair dyes products without PPD, PTD and salts and derivatives were found. In total 24% of the investigated products did not contain PPD, PTD or their salts and derivatives.

Of the permanent hair dyes investigated 18 % did not contain PPD, PTD or their salts and derivatives, whereas the number was 41% for the semi-permanent hair dyes and 100% for the direct dyes which are based on CI colours. Products without PPD, PTD and salts and derivatives were mainly found on the professional market for hair dyes. 30% of all the investigated

professional hair dyes did not contain PPD and PTD and salts and derivatives, whereas the number was 16% for the private hair dyes investigated in this survey. However products in the survey from the professional market were not entirely representative for the market, as the green saloons were over represented.

Quantitative chemical analysis was performed for a selection of the hair dyes. Due to the small number of products analyzed, a solid conclusion cannot be made on this basis. The results from the chemical analysis indicate that:

- Dark colours had a higher concentration of the analyzed hair dye substances including PTD compared to the lighter colours.
- In this survey no pattern was seen regarding concentration of different hair dye substances in permanent hair dyes versus semi-permanent hair dyes.

With regard to the occurrence of extreme, strong or moderate sensitizers in hair dyes it was found that 40 products (11%) of the investigated permanent and semi-permanent hair dyes did not contain these hair dye substances. The main part of these products was for the professional market and 26 of the 40 products were claimed to be permanent hair dye products. The group of 40 products was further investigated, and it was found that a main portion of these products are non-oxidative hair dyes whose function is based on different principles than the classical oxidative hair dyes. Some of them were plant based henna products. It was not within the scope of this project to investigate the efficacy of hair dyes with regard to durability (permanent/semi permanent) or coverage of original hair colour.

When going through the abovementioned group of hair dye products, 12 hair dye substances without extreme, strong or moderate sensitizing potential were found in these products. A summary of possible other health hazards were made based on mainly SCCS opinions and a few references from the open scientific literature. For most of these substances, SCCS opinions exist.

Of the 12 substances, 7 were evaluated as safe by the SCCS, 1 was not safe and for the remaining 4 further data was needed. The European Commission has reported that 3 of those 4 substances are either currently under assessment or will be assessed as soon as new data are submitted. For the remaining one substance industry has not submitted any data and it is for the time being not clear whether they intend to submit a dossier. The substance that was concluded not to be safe is also being re-evaluated as industry is submitting additional data. It is therefore expected that a final conclusion regarding the 5 of the 12 substances will be made within the following years, and this will ultimately lead to a final conclusion regarding the group of hair dye products with either no or only weak sensitizing potential.

However, the fact that several hair dye substances with apparently no or only weak sensitizing potential exist might in general point to a potential for the development of new hair dye products with less risk of hair dye allergy for the consumer.

Analyzing the distribution of the 7 abovementioned hair dye substances in further details shows that in this survey two hair dye products contain only one or more of those 7 hair dye substances. Those products are red, permanent hair dyes for professional use only.

In conclusion: If one chooses to exclude extreme, strong and moderate skin sensitizing hair dye substances 44 of the 365 products in this survey are available and if one furthermore excludes hair dye substances which has not been assessed as safe by the SCCS only 2 of the 365 products in this survey is available. On the other hand – if one chooses to exclude only extreme and strong skin sensitizing hair dye substances a number of products exist and can be found on the market by avoiding hair dye products with the warning text and symbol which is required on the label from November 2012. These labelling requirements are mandatory for oxidative and some non oxidative hair dye products containing hair dye substances with either extreme or strong sensitizing potential.

When discussing skin sensitization and hair dyes it must be emphasized that even if a number of negative animal tests exists, a full guarantee against skin sensitization can never be given. Furthermore the products in this survey have only been evaluated in regard to their content of hair dye substances, and they may contain other substances such as perfume, which in some cases can cause skin sensitization.

1 Introduction

1.1 INTRODUCTION

1.1.1 Use pattern and adverse skin reactions from hair dyes

In 2003 the Danish National Allergy Research Centre performed an interview-based survey of the Danish adult population and their possible allergic reactions to hair dyes. 4000 adults were interviewed about their hair dyeing habits. The study showed that 18.4% of the men and 74.9% of the women had dyed their hair once or more at some point of their life (Søsted et al., 2005). This means that just above 2 million people in Denmark in 2003 at some point in their life had dyed their hair. The median age for the first hair dyeing was 16 years, but the range was between 1 and 80 years.

Adverse skin reactions to hair dyes compatible with an allergic reaction were reported in 5.3% of the individuals who had ever used hair dye. This means that above 100,000 persons in Denmark had experienced an adverse skin reaction to hair dyes - possibly allergy, possibly irritation. Of these, only 15.6% had been in contact with healthcare services after the hair dye reaction (Søsted et al., 2005).

Another more recent survey of younger women showed that 66.9% of the 1,277 young women (average age of 17.5 years) had dyed their hair within the last year. They had on average dyed their hair 3.7 times within the last year. 10% of the women had experienced adverse skin reactions like erythema, flaking and itching in connection with the hair dye, and 2.9% had experienced oedema of the face in connection with the hair dye (Bregnhøj A. et al., 2011).

1.1.2 Skin allergy from hair dyes

About 100 different hair dye substances can be used for the composition of a hair dye. Several of these are considered to be sensitizers. PPD (p-phenylenediamine) has been used for the dyeing of hair for many years and is known to be an extreme sensitizer (SCCP/0989/2006). Toluene-2,5-diamine (PTD) is another extreme sensitizer among the hair dye substances (SCCP/1084/2007).

A recent Swedish survey showed that PPD was found in 19 of 122 (16%) oxidative hair dye products on the Swedish market and PTD in 49 products (40%). Other sensitizers like resorcinol and m-aminophenol were found in more of the products, 100 (82%) and 83 (68%) of the 122 products respectively (Yazar *et al.*, 2009).

British scientists have carried out an investigation that shows that 7.2% of a group of people using a hair dye (containing PPD in a concentration of 0.5%) for five minutes once a week for six months were sensitized within a period of six months. In another group of people using a permanent hair dye (containing PPD in a concentration of 1.5%) once a month but for 30-40

minutes each time, 1.3% were sensitized after six months (National Allergy Research Centre, 2011). PPD is allowed in concentrations up to 2% in the mixed hair dye (Council Directive 76/768/EEC).

Research has shown that persons who are sensitized to PPD will react to PPD in hair dyes already at very low concentrations. 10% will experience an allergic reaction if the content of PPD is 0.0038% or more (Søsted, 2007).

1.1.3 Yearly sale of hair dyes

Statistics from Statistics Denmark are not specific enough to show the exact number of hair dye products sold per year in Denmark. The product category "Preparations for use on the hair, excluding shampoos, hair lacquers, hair water and preparations for permanent waving or straightening" contains hair dyes, but also products like conditioners, hair treatment products etc. In 2010 the sale in this product category was 219.2 million DKK. Assuming this number is only hair dyes, and assuming that a hair dye product has an average price of 120 DKK, this would mean that 1.8 million of such products were sold in Denmark in 2010. This number is most likely overestimated, but nevertheless reveals that the hair dye market in Denmark is extensive.

1.2 PURPOSE OF THIS PROJECT

The purpose of the project was to:

- Investigate the occurrence of PPD and PTD and their salts and derivatives in hair dyes on the Danish market.
- Examine the occurrence of other common hair dye substances which are extreme or strong sensitizers in hair dyes that do not contain either PPD or PTD and their salts and derivatives.
- Investigate if the quantitative content of PPD, PTD and their salts and derivatives, as well as other sensitizing hair dye substances varies across different colours of the hair dyes.
- Examine if there is a correlation between the type of hair dye (permanent, semi-permanent etc.) and the content of PPD, PTD and other sensitizing hair dye substances.
- Investigate the market for products which do not contain hair dye substances with moderate, strong or extreme allergy potency – and investigate whether these hair dye substances might cause other concerns in regards to consumer health.

2 Definitions/abbreviations

2.1 HAIR DYE/HAIR DYE PRODUCT

A hair dye is in this project defined as a product which is sold with the purpose of dyeing hair on the scalp. Hair dyes can be sold for private use or for professional use.

Private hair dyes are in this project defined as products which can be purchased by any consumer in retail or on the internet.

Professional products are defined as products marketed only to hairdressers or sold at internet shops that give an impression that the products are only for the professional market. Professional products are usually not directly available for the consumer. The only way the consumer can purchase the hair dye is in combination with the service of performing the actual hair dyeing process at the hairdresser, or at a few web shops.

Some overlap between the two groups was seen in this survey.

2.2 HAIR DYE BRAND

A hair dye brand is in this report defined as a specific series of hair dye products with the same overall name, e.g. “L’Oréal Casting Creme Gloss” or “Schwarzkopf Essential Color”. Each hair dye brand therefore consists of a series of different hair dye products with different colours.

A specific producer (e.g. L’Oréal or Henkel) has several different hair dye brands (see Table 4-1).

2.3 HAIR DYE SUBSTANCE

A hair dye product typically contains a mixture of different hair dye substances together with other ingredients. Hair dye substances are defined in the EU’s CosIng database¹ as ingredients with the function “hair dyeing”. In total 208 different ingredients are found in the CosIng database with the function “hair dyeing”.

2.4 CATEGORIES OF HAIR DYES

According to The Association of Danish Cosmetics and Detergent Industries (SPT, 2010), the industry divides the different hair dyes into three different categories according to the expected durability of the colour:

¹ CosIng is the European Commission database with information on cosmetic substances and ingredients

- Level 3/group III: Permanent hair dye. A two-component oxidative product which has to be mixed before use. After using a permanent hair dye, the hair is in theory totally coloured until it grows out.
- Level 2/group II: Semi-permanent hair dye that lasts for about 24 shampoos. This hair dye is also a two-component oxidative product. However, the oxidizing effect is less than for the permanent hair dye and the colour does not cover the natural colour totally.
- Level 1/group I: Direct dye. When using this dye, the colour will be washed out after about 8 to 12 shampoos. The product is non-oxidative and has only one component. It is only possible to change the hair colour slightly and it will not cover grey hair.

The classic permanent and semi permanent hair dye is an oxidative hair dye. This means that the final colour will develop in the hair by oxidation of the hair dye substances. The oxidation process is typically mediated by the hydrogen peroxide in the mixing fluid.

Some companies use both the terms semi-permanent and demi-permanent hair dyes. It seems that the term demi-permanent hair dyes is in between permanent and semi-permanent. It was, however, very few producers that used the term “demi-permanent” hair dyes. For this reason demi-permanent and semi-permanent hair dyes are treated as one group in this project.

Non-oxidative hair dyes that are marketed as having a durability which is either permanent or semi-permanent also exist on the market. These products are in most cases one component, which means they are not supposed to be mixed before use, and the colour of the product is the colour that will appear in the hair when dyeing it.

Hair dyes to be sprayed on the hair – called “spray hair dyes” or “party hair dyes” - are a different kind of hair dyes compared to the other above mentioned hair dyes, as they do not last for long. Typically they only last for one or a few shampoos. This type of hair dyes is therefore not a part of this survey.

For this reason the following types of hair dyes are used in this project:

1. Permanent hair dyes (oxidative and non-oxidative).
2. Semi-permanent hair dyes, which cover also the few demi-permanent hair dyes found in this survey (oxidative and non-oxidative).
3. Direct dyes.

2.5 HAIR DYE COLOUR AND TONE

Most hair dye producers use a numbering system for the colour and tone of their hair dyes. The exact hair dye colour is therefore defined with both a colour (e.g. brown, red, blond) and a tone which is the darkness or brightness of the colour and usually defined by a number from 1 to 12 (where 1 usually represents the darkest colour and 12 represents the lightest colour).

In this project the colour/tone combination will however be referred to merely as “colour” since the tone is not consistently stated on the packages. Therefore the “colour” in this project is the combination of colour and tone, unless otherwise stated.

2.6 INCI NAME AND COSING

INCI is an abbreviation for "International Nomenclature Cosmetic Ingredients" and is a common nomenclature to apply for cosmetic ingredients. According to the EU Council Directive 76/768/EEC relating to cosmetic products, the ingredients of the cosmetic products have to be stated on the container with their INCI name. An INCI name can cover several different chemical substances, for instance in cases of botanical extracts.

CosIng is a database which contains all the INCI names. It is not a list of approved ingredients in cosmetics but a list indicating the ingredients that are or have been used. If an INCI name for an ingredient is not available, the chemical name of the ingredient is to be used and the company marketing the product has to apply for an INCI name for the substance.

3 Legislation

In the EU the Cosmetics Directive (76/768/EEC) applies for all member states. In Denmark this has been implemented into the Cosmetics Statutory Order (Stat. Ord. 422, 2006).

In 2009, the EU adopted a new regulation on cosmetic products (EC No. 1223/2009). However, this regulation does not apply before 11 July 2013, with the exception of a few articles. All the hair dyes in this project were on the market in the summer of 2011 and therefore they are regulated under the Statutory order.

In this chapter focus will be on selected aspects of the regulation which are relevant for hair dye products.

3.1 THE COSMETICS STATUTORY ORDER

Cosmetic products are regulated in the Danish Cosmetics Statutory Order. The statutory order implements the European provisions in the cosmetics area and includes a number of provisions about the content of chemical substances in cosmetics as well as labelling of the products.

According to § 10 of the Cosmetics Statutory Order, cosmetic products that are marketed in the EU must not be harmful to human health when they are used under normal conditions or under conditions which reasonably can be foreseen. A number of restrictions for different ingredients in cosmetic products are listed, i.e. only certain preservatives are allowed.

3.1.1 Labelling of cosmetic products

Cosmetic products have to be labelled with the following information in Danish on the actual product and on the packaging (Stat. Ord. 422, 2006):

- Company name and address of the manufacturer who is responsible for the marketing in the EU (§ 19).
- Content in weight or volume (if more than 5 g or more than 5 ml (§ 20)).
- Durability date (if the shelf life is below 30 months (§ 21)).
- Particular precautions to be observed in use, especially those listed in the annexes (§ 22).
- The number of the production batch or the reference specification so that date and place of production can be identified (§ 23).
- The function of the cosmetic product (unless it appears from its presentation (§ 24)).
- A list of the ingredients of the product arranged in order after descending weight at that time the ingredients are added to the cosmetic product (§ 25). The list of ingredients (stated by their INCI name) only has to be stated on the packaging, not necessarily on the product itself.

3.1.2 List of ingredients

The following rules apply for the list of ingredients of cosmetic products (Stat. Ord. 422, 2006, § 25):

- Impurities are not considered to be constituents.
- Perfume or aromatic compositions and their raw materials shall be referred to by the term “perfume” or “aroma”. According to appendix 3 of the statutory order, 26 fragrances have to be stated with their INCI name in the list of ingredients irrespective of their function in the products when the concentration is higher than 0.001% in products which are not to be rinsed off and 0.01% in products which are to be rinsed off.
- Ingredients in a concentration less than 1% can be mentioned in any order after the ingredients with a concentration higher than 1%.
- The ingredients are stated by their usual name according to the common nomenclature (INCI name) for cosmetic ingredients.
- For small cosmetic products or packaging of such a form that in practice makes it impossible to state the list of ingredients clearly enough on the product, the ingredients must be stated on an enclosed notice, label, strip or card which is fastened to the cosmetics product. If it is impossible to fasten a message or similar to the products (for instance, if they are too small) the list of ingredients must be stated in a notice close to the products.
- For decorative cosmetics, i.e. products such as lipstick, eye shadow, rouge, mascara etc., that are marketed in different colours, it is allowed to list all the colours used in the list of ingredients, as long as the wording “can contain” or the symbol “+/-“ is added. However, it should be noted that hair dye is not considered to be a part of decorative cosmetics (according to § 5).

3.1.3 Restrictions in use of chemical substances in cosmetics

The Cosmetics Statutory Order (Stat. Ord. 422, 2006) lists a number of restrictions on the use of cosmetics products. Examples of such restrictions are:

- A list of ingredients that are not allowed in cosmetics products
- A list of ingredients that are only allowed under special conditions (for instance, at a maximum concentration)
- Three lists of ingredients that are only allowed within a special group (hair dye substances, preservatives and U.V. absorbers).

3.1.4 Safety

Cosmetic products marketed within the EU must not cause damage to human health when used under normal conditions or under normal foreseeable conditions of use. An assessment of the safety of the cosmetic product must always be available to the relevant national authority on the address that is listed on the container of the cosmetic product (production site/company address). This safety assessment must take the following aspects into account: The general toxicological profile of the ingredients, the chemical structure of the ingredients, the conditions under which the product is used, the exposure conditions (degree and route of exposure, area of body where the cosmetic

product is used) and the intended user group (children/adults). A special safety assessment must be carried out if the cosmetic products are intended for use by children under the age of three (Stat. Ord. 422, 2006, §33).

3.1.5 Warning labels

Today, hair dyes which contain certain sensitizing hair dye substances like PPD and PTD must be labelled with mandatory directions for use as well as a warning on the product.



A hair dye containing for example PPD must be labelled with the symbol shown above and the warning: “Can cause an allergic reaction. Contains phenylenediamines. Do not use to dye eyelashes or eyebrows”.

New rules about mandatory warning labels for hair dye products have been adopted in 2010 (Stat. Ord. No. 426, 2010). These rules apply for products that are marketed after 1. November 2011 and they apply to all products after 1. November 2012. This means that none of these rules applied for the products that were purchased in this project during the summer of 2011.

The new mandatory warning labels that should be stated on hair dyes are:

“Hair colorants can cause severe allergic reactions.

Read and follow instructions.

This product is not intended for use on persons under the age of 16.

Temporary ‘black henna’ tattoos may increase your risk of allergy.

Do not colour your hair if:

- you have a rash on your face or sensitive, irritated and damaged scalp,
- you have ever experienced any reaction after colouring your hair,
- you have experienced a reaction to a temporary ‘black henna’ tattoo in the past”.

The warning symbol shown above must be labelled as well.

4 Survey

The main purposes of this project were to examine the occurrence of the hair dye substances PPD and PTD (and their salts and derivatives) in hair dye products on the Danish market and thereby answer among other things the question whether permanent hair dyes without PPD or PTD (and their salts and derivatives) exist on the market. Both hair dyes for private use (found in retail) and hair dyes for professional use (used by hairdressers) were investigated.

The starting point of this project was to collect about 300 hair dye products, as it was expected that with such a number of products we would be able to – with some certainty – comment on how large a percentage of hair dye products on the Danish market that contains PPD and PTD (and their salts and derivatives).

Information about the hair dye products was entered into an Access database as the multiple information about the cosmetic ingredients, product type (permanent, semi-permanent, direct dye), hair dye colour (black, brown etc.) and so on is much easier to handle in a database, especially with such a large number of products.

Below is described how information about the products was obtained and how the database of the products was constructed. Finally, the results of the survey and various extractions from the database are presented.

4.1 SURVEY OF HAIR DYES ON THE DANISH MARKET

The survey of the hair dye products on the Danish market was carried out in the period of July 2011 to November 2011. The following sources were used during the survey:

- Internet search
- Contact to the hair dye product industry (producers/distributors/retailers)
- Systematic collection of hair dye products in retail shops, at hairdressers and via purchase on the internet.

A database of 365 hair dye products was developed.

4.1.1 Initial survey of hair dyes via the internet

A comprehensive search was performed on the internet in order to map the available brands of hair dye products on the Danish market. The search was performed by using different search words like “hair dyes” etc. Furthermore, lists of producers and distributors in the business were used in order to track down different hair dye products.

This internet search combined with information obtained from the hair dye industry gave an overview of hair dye products used on the Danish market. The result can be found in Table 4-1 below.

As the market for hair dye products was extensive, it was not possible to include all different hair dye products or hair dye brands in the database in this survey. The choice was to focus on the hair dye brands which were most used (according to information from industry, retailers and hairdressers). Furthermore, it was not possible to buy hair dye products from all the different brands, as we were not allowed to buy hair dye products intended for the professional market only.

Hair dye products that are part of the database are marked with a grey background in the second column. As the internet search performed in this survey was probably not complete, the total number is underestimated. This survey shows that at least 514 different hair dye products were available on the private market and that at least 3,152 hair dye products were available on the professional market. An educated guess is therefore that the Danish market for hair dye products consisted of more than 4,000 different hair dye products for both the private and the professional market.

TABLE 4-1: RESULT OF THE INTERNET SEARCH FOR HAIR DYE PRODUCTS. THE NUMBER OF PRODUCTS FOUND THROUGH WEBPAGES IS LISTED IF AVAILABLE.

Producer/distributor	Hair dye brand	Link to internet shop or producer	No. of products
<i>Products for private use</i>			
	Colora Henna Creme – økologiske	http://redgel.dk/okologiske-harfarver.html	11
BettyBeauty	Betty Color for the hair down there	www.phure.dk	2
Börlind Company	Puravera Sanfte Creme-Coloration	www.helsam.dk	15
Combe International	Just for MEN	www.shampooshoppen.dk	6
Dansk Helios	Santé Naturkosmetik - 100% Herbal Hair Color	www.sante-naturkosmetik.dk www.solstraalen-helsekost.dk	9
Garnier	Garnier Naturligt resultat	www.nemlig.com	6
	Garnier Natural Color	www.matas.dk	19
	Garnier Nutrisse Cream		
	Garnier Nutrisse Truly Blonde		
	Garnier Nutrisse Ultra Color		
Gentle Beauty	Herbatint permanent herbal haircolor	www.livfuld.dk	30
Herb	Tints of Nature	http://tintsofnature.dk	24
NJD Cosmetics	Henné Color	www.ren-velvaereshop.dk	8
Hardford	Jane Hellen Mood Hair Color	www.shopping4net.dk	20
Henkel	Schwarzkopf Blonde	www.henkel.dk	6
	Schwarzkopf Essential Color	www.shopping4net.dk	16
	Schwarzkopf Brilliance	www.matas.dk	9
	Schwarzkopf Live Color XXL	www.citibeautysalon.com	9
	Schwarzkopf Men Perfect		3
	Schwarzkopf Natural & Easy		16
	Schwarzkopf Soyance Silk		9
	Schwarzkopf Country Colours		10
	Schwarzkopf Poly Color Toning-shampoo		11
	Syoss Color		16
	Poly Palette		8
KPSS Danmark	Goldwell Colorance	www.houseofhair.dk	16
Logona Naturkosmetik	Logona	www.ren-velvaereshop.dk	7
L'Oréal	L'Oréal Recital Preference	www.matas.dk	17
	L'Oréal Excellence Creme	www.loreal.dk	15

Producer/distributor	Hair dye brand	Link to internet shop or producer	No. of products
	L'Oréal Casting Crème Gloss L'Oréal Casting Glossy Blonds L'Oréal Casting Sublime Mouse L'Oréal Perfect Blonde L'Oréal Preference L'Oréal Touch on Highlights	www.citibeautysalon.com	16 4 12 1 14 Min. 1
Naturigin	Naturigin Organic Based	www.naturigin.com	19
Proctor & Gamble	Wella Color Fresh Wella Color Touch	http://www.billigvoks.dk www.farvedelins.dk www.nicehair.dk	16 18
Rømer Naturprodukt	Henna crème farver	www.helsam.dk	6
Sanotint	Sanotint Classic Sanotint Light Sanotint Skyllfarver	http://www.netspiren.dk http://www.netspiren.dk http://www.ren-velvaereshop.dk/	28 9 8
Unicare Nordic	Henna Henna plus	http://www.ren-velvaereshop.dk www.helsam.dk	13 31
Total			514
Products for professional use			
Bella vista (Henkel)	Schwarzkopf Igora Royal Schwarzkopf Igora Vibrance Schwarzkopf Igora Botanic Schwarzkopf Igora Color 10 Schwarzkopf Igora Color Gloss Schwarzkopf Igora Duality Schwarzkopf Essensity Schwarzkopf Blond me Fix Color	www.bella-vista.dk	4 2 6 1 10 7 1 2 13
	Berrywell farver	www.jyskfrisoerlager.dk	36
La Biosthetique	La Biosthetique Colour Tint & Tone Advanced	http://www.labiosthetique.com	81
Cameo	Cameo color	www.all4hair.nu	109
Castelfranco Veneto	Inebrya Cremea Colorante	www.bd-store.dk	97
Colomer Denmark	Revlon Professional Revlonissimo Creme Gel Revlon Professional Revlonissimo Super Blonde Revlon Professional Revlonissimo Cromatisc Revlon Professional Revlonissimo High Coverage Revlon Revlonissimo NMT Creme gel Alterna Haircare	www.revlonprofessional.com www.alternahaircare.com www.beauty.cos	84 9 4 21 No info. 1
Cosmobell (EWC Aps)	Easi Water Color	www.cosmobell.dk www.easiwatercolour.com	41
Coss	Alfaparf Kemon	www.coss.dk	No info. No info.
DanHair	Farouk CHI Blonde Blonde CHI Chromashine Conditioning Demi-Permanent Bold Color Exhibit A CHI Infra High Lift Cream Color CHI Infra Environmental NO Lift Cream Color Exhibit A CHI Ionic Permanent Shine Hair Color BioSilk - Liquid Gel Color BioSilk - BioGlitz Color 2100 BioSilk - Powder Lighteners	www.faraouk.com	2 8 9 10 95 70 71 4

Producer/distributor	Hair dye brand	Link to internet shop or producer	No. of products
	BioSilk - Permanent Hair Color SunGlitz - Cream Lighteners SunGlitz - Powder Lighteners SunGlitz - Ultraglitz Lightener		30 8 7 4
Davines	Mask Mask Light L'Art Decolor	www.davines.com	8 1 6
Design Frisørerne	Framcolor 2001 Framcolor ADD Framcolor Deposit Framcolor Eclectic	www.design-frisor.dk	90 10 5 32
DK Hair	Emsibeth Cromakey farver Thermal Color	www.dkhair.dk	96 51
Fair Incorporated	Life Color Plus	www.fair-incorp.dk	90
G&G Denmark	Paul Mitchell The Color Paul Mitchell PM Shines	www.paulmitchell.dk	No info. No info.
Gado Italia	Remedy Crema Colorante	www.jyskfrisoerlager.dk	60
Gloria Cosmetics	Henne Color Henne Maïa Light Mountain Natural Light Mountain color of the Gray	www.gloria-cosmetics.dk	11 4 11 6
Hairmix	Organic Color System RUSK deep shine	www.hairmix.dk	64 70
Hairtech	Keune Tinta	www.keune.com	No info. No info.
HH Simonsen (Joico)	JOICO® Vero K-PAK Colour, JOICO® K-PAK Chrome Palco	www.hhsimonsen.dk	Min. 1 Min. 1 No info.
ICON Hairspa	SENS PUR Hair Color Pact	www.iconhairspa.dk	61 64 9
Id Hair	Miscela IdHair Hair Paint IdHair ColourID Henna		No info. Min. 5 Min. 5 Min. 5
Kadus	Kadus Fervidol Kadus Selecta Premium	www.all4hair.nu www.all4hair.nu	39 122
KPSS Danmark	Goldwell Top chic Goldwell Elumen Goldwell Colorance Acid Color Goldwell Colorance Depot Goldwell Oxycur Platin Highlights Goldwell Oxycur Platin	www.all4hair.nu www.goldwell.dk www.all4hair.nu	135 38 No info. 89 No info. No info.
Logona Naturkosmetik	Logona Herbal Hair		9
L'Oréal	L'Oréal Professional Majirel L'Oréal Majiblond Ultra L'Oréal Majirouge L'Oréal Majicontrast L'Oréal Professional Majirouge Mix+ L'Oréal Professional Richesse de Diacolor L'Oréal Professional Hi Richesse L'Oréal Inoa L'Oréal Lou Color L'Oréal Color Supreme	www.lorealprofessional.dk www.all4hair.nu	125 9 3 8 3 55 27 72 59 25
Matrix	Matrix Wonder Brown Permanent Haircolor Matrix SOCOLOR Beauty Permanent Cream Haircolor	www.matrix.com	No info. Min. 5

Producer/distributor	Hair dye brand	Link to internet shop or producer	No. of products
	Matrix Color Sync Seamless Crème Demi-Color Matrix Prizm.PLUS Semi-Permanent Hypershine Conditioning Color Gloss Matrix Colourgraphics 2		Min. 4 No info. No info.
	Mousse skum farver	www.jyskfrisoerlager.dk	4
Postquam	Postquam Color Mousse		Min. 2
Proctor & Gamble	Wella Professionals Color Fresh Wella Professionals Color Touch Wella Colour Touch Plus Wella Professionals Koleston Perfect Wella Professionals Koleston Pure naturals Wella Simply Colours Kadus Professional	www.all4hair.nu	25 68 15 129 Min. 1 No info. 108
Professional by farma	Fantasia Color	www.fnb.dk	110
	Pure Color	www.madamhair.dk www.hair.dk	42
Rokkedal	z.one concept	www.z-one.it	No info.
Redken	Redken Color Fusion	www.redken.dk	Min. 2
Renbow International	Professional Crazy Color	www.jyskfrisoerlager.dk	24
Rolland Laboratories	HColor Oway O-Way		Min. 3 Min. 4
Sebastian Colourshine	Sebastian Cellophanes Sebastian Colourshine Laminates Cellophanes		Min. 1 Min. 2
Stargazer	Crazy Haircolor	www.jyskfrisoerlager.dk	26
	Trinity	www.all4hair.nu	89
	Økologisk Colora Henna pulverfarver Økologisk Colora Henna Cremefarver	www.jyskfrisoerlager.dk	35 22
Total			3152

4.1.1.1 Different uses of hair dyes

This initial survey showed that hair dyes can be used for different purposes:

- Traditional hair dye products for the hair on women's and men's scalps. Special hair dye products were found for men – however, this was a small market.
- Hair dye products with the purpose of dyeing the pubic hair of women – however, this was a small market.
- Hair dye products with the purpose of dyeing the beard of men.
- Hair dye products with the purpose of dyeing eye lashes and brows.

The main part of the hair dye products included in the database was hair dye products marketed towards women. The same products could of course be used by men, but from the general presentation of the products they seemed to be marketed mostly for women. A few hair dye products marketed especially for men were included in the database as well. Similar a few hair

dye products (two products) with the purpose of dyeing the pubic hair of women were (unintentionally) included in the database².

4.1.2 Contact to the hair dye industry

Following the internet search for hair dye products the following types of organisations were contacted:

- Trade organisations (producers, hairdressers)
- Producers and distributors of hair dye products
- Retail industry
- Hairdressers

4.1.2.1 Contact to trade organisations

SPT

The Association of Danish Cosmetics and Detergent Industries (SPT) was contacted and the purpose of this project was presented. SPT informed that the group of permanent and semi-permanent hair dye products was by far the largest group of hair dye products on the market. SPT informed that the group of direct dyes only covered a smaller part of the total market³. Our survey confirmed this picture: the permanent hair dyes were the largest group, semi-permanent hair dyes the second largest group, and the group of direct hair dyes only covered a small part of the market. However, since our survey includes both permanent and semi-permanent non oxidative hair dyes in contrast to the definitions available from SPT the results were not directly comparable.

According to SPT about 65% of the hair dyeing market consists of hair dye products for professional use, and the rest (35%) is for private use. This information only covers information from the members of SPT, and is based on an estimation of market shares from each of their members⁴. The result of the internet search (Table 4-1) showed that the professional market was the largest.

SPT sent out an email to their members asking to participate in this project by sending lists of ingredients on their hair dyes to the project group.

SPT had the following members that marketed hair dye products in Denmark:

- L'Oréal Danmark
- Dansk Helios (Santé)
- Henkel Danmark (Schwarzkopf)
- Proctor & Gamble (Wella)
- Unicare Nordic (Henna)
- Bella Vista
- Biosthetique
- Colomer Denmark
- Cosmobell Danmark

² For technical reasons these products were not removed from the database. They were, however, only two products out of 365 products and did not influence the results or the extracts from the database significantly. These two products (for dyeing of pubic hair) were both permanent hair dyes with a content of either PPD or PTD sulfate.

³ Personal communication with Anne-Dorthe Mathiesen, SPT, 12.7.2011.

⁴ Personal communication with Anne-Dorthe Mathiesen, SPT, 12.7.2011.

- Coss
- HairMix A/S
- IDHair
- KPSS Danmark (Goldwell)
- SalonSupport

The email from SPT was followed by personal contact from the project group to a selection of the above companies. This gave the result that the following companies contributed with information to this project – either by sending lists of ingredients of selected hair dyes or other information:

- Bella Vista
- Biosthetique
- Dansk Helios
- Hair Mix
- Henkel
- IDHair
- KPSS Danmark
- L'Oréal Danmark
- Proctor & Gamble Danmark ApS

As this survey could not cover all available hair dye products on the market, the participating companies were asked to give information about the lists of ingredients for a selection of their products only. The hair dyes were selected by use of the following methods:

1. Selecting products with the highest sales volume: The producers/retailers were asked to provide lists of ingredients for their best selling products, but in some cases this information was confidential.
2. Selecting products randomly covering the entire spectre of hair dye products (from black to light blond): The products were selected randomly either by the companies themselves or by the project group, if they were not able to give information about their best selling hair dye products. The hair dye products were, however, selected so they would cover the entire spectre of hair dye products from black to light blond.

The contact to producers and distributors of hair dye products also confirmed that the group of permanent and semi-permanent hair dye products is by far the largest group of hair dye products on the market. The group of direct dyes only covers a smaller part of the total market.

Some producers and distributors of hair dye products gave the information that typically the most used hair dye products lay within the range of 5 (dark brown) to 9 (light blond). The numbering system typically ranged from 1 (black) and 12 (very light blond/white).

Hairdressers

Furthermore, the trade organisation for Danish hairdresser employers (Dansk Frisørmesterforening, DF) was contacted in order to identify which hair dye products were the most common products on the professional hairdressers market.

4.1.2.2 *Contact to producers and distributors of hair dye products*

Not all producers of hair dyes were members of SPT, therefore other selected producers or distributors were contacted as well. The following companies contributed with information to this project – either by sending lists of ingredients or other information:

- DanHair
- Gado Italia
- M. Maegaard ApS
- Postquam Cosmetics
- Qhair (Rene Kordon)

More companies were contacted, but were not willing to participate with information to the project.

4.1.2.3 *Retail industry*

COOP Denmark (a large supermarket chain in Denmark) was contacted in order to learn about the best selling hair dye products for private use. COOP Denmark was chosen as they had a total market share of 37% in Denmark⁵. COOP informed about the top-10 of the best selling hair dye products in their stores. The names are confidential, but all top-10 hair dye products have been a part of this survey and were included in the database of the 365 hair dye products.

Information about the top-10 best selling hair dye products confirmed the information from the contacted producers that brown and blond colours were the best selling hair dyes. All ten products in the top-10 list from COOP were either brown or blond.

Furthermore, COOP delivered a top-10 of the most selling hair dye brands. This information is confidential as well. However, selected hair dye products from all top-10 brands have been included in this survey and were therefore a part of the database of the 365 hair dye products. Not every single hair dye product of the top-10 brands was included in the database, but a large part of them (i.e. about 40-50%) – and the top selling products were included as mentioned above. The selected hair dye products from the top-10 brands were chosen randomly, divided evenly between the different hair dye colours.

4.1.2.4 *Hairdressers and hairdresser schools*

In order to learn about the most used brands and most used hair dye colours, a small selection of different hairdresser saloons as well as hairdresser schools were contacted.

In total 27 different hairdressers/hairdressers schools were contacted – 24 hairdressers and 3 hairdresser schools. They were asked the following questions:

- Which hair dye brand are you using in your saloon?
- Which hair dye colours are you using the most?
- Is it possible to obtain some of your empty hair dye packaging? (With the purpose of noting the list of ingredients in the database).

The hairdressers were selected in the area of Greater Copenhagen and North Zealand. However, five of the selected hairdressers were so-called Green Saloons. This means that the products from those saloons are over

⁵ Personal communication with Malene Teller Blume, COOP Danmark, 7.7.2011.

represented in the database as the relative number of the green saloons versus other saloons is not in proportion to the actual relative number of green versus other saloons.

A few hairdressers were very helpful and delivered several empty packages. These hair dye products were entered into the database.

This limited survey at selected hairdressers showed that the following brands of professional hair dyes were used (Table 4-2). The total adds up to more than 24, as some hairdressers were using more than one hair dye brand.

TABLE 4-2 HAIR DYE PRODUCTS USED BY PROFESSIONAL HAIRDRESSERS IN THEIR SALOONS

Hair dye brand	Producer	No. of hairdressers using the brand
Matrix SOCOLOR.beauty	L'Oréal	1
Inoa	L'Oréal	4
Richesse	L'Oréal	1
Majirel	L'Oréal	1
Majirouge	L'Oréal	1
<i>Not further specified</i>	L'Oréal	2
HColor	DanHair	1
Chi-colors	DanHair	1
O Way	DanHair	1
Wella Professionals Koleston Perfect	Wella	3
Wella Simply Colors	Wella	1
Wella Colour Touch	Wella	1
<i>Not further specified</i>	Wella	1
<i>Not further specified</i>	Goldwell	1
Topchic	Goldwell	2
Elumen	Goldwell	7
Schwarzkopf professional <i>(not further specified)</i>	Schwarzkopf	1
Henna	IDHair Company	1
Logona	Logona	1

As described, three selected hairdresser schools in Denmark were contacted in order to learn which hair dye brands they were using in their saloons. The brands they used were the following:

- Hair Company
- Coss
- NYCE (New York Cosmetics)
- L'Oréal Majirouge
- Goldwell Elumen

This limited survey showed that professional hairdressers mostly used hair dye products from the following producers:

- L'Oréal (especially the brand named Inoa)
- Goldwell (especially the brand named Elumen)
- Wella
- DanHair

Afterwards these producers were contacted in order to request information about the lists of ingredients of selected products. Some hairdressers gave information about which specific hair dye colours they used the most. This information was used when the producers were contacted, meaning that lists of ingredients were requested for the most used hair dye colours.

As L'Oréal and Goldwell products according to the survey were used the most by hairdressers, these hair dye products were therefore represented by a larger number of hair dye products in the database (i.e. more hair dye colours were included in the database from these producers).

4.1.2.5 Green Saloons

From June 2008 the concept known as "Green Saloons" started in Denmark. Green Saloons is a concept that has been introduced by Danish Hairdresser and Cosmetician Federation (Dansk Frisør og Kosmetiker Forbund), Energy Service Denmark (Energitjenesten) and Copenhagen Green Business (Københavns Grønne Erhverv)⁶.

The following six requirements are mandatory for the Green Saloons:

1. The Saloon has knowledge about chemistry and health, among other things by at least a three-day course.
2. No products in the saloon must contain specific chosen substances from the following Prohibited List⁷:
 - 1-naphthol
 - Substances with "aminophenol" in their chemical name
 - Formaldehyde and formaldehyde releasers
 - Thioglycolic acid and thioglycolate
 - 4-amino-2-hydroxytoluene
 - 4-amino-3-nitrophenol
 - Methylisothiazolinone and methylchlorisothiazolinone
 - Substances with "paraben" in their chemical name
 - Substances with "p-phenylenediamin" (PPD) in their chemical name
 - Substances with "resorcinol" in their chemical name
 - Substances with "toluene-2,5-diamine" (PTD) in their name
3. The saloon pays special attention towards allergy and hypersensitivity.
4. Brightening of the hair is only allowed in stripes or without contact with the scalp.
5. Cleaning of the saloon must be carried out by using eco-labelled cleaning products.
6. If the saloon serves coffee/tea etc. the products must be organic.

This means that products sold in Green Saloons must be free from the following hair dye substances:

- PPD (salts and derivatives)
- PTD (salts and derivatives)
- Resorcinol and other resorcinol compounds (e.g. 2-methylresorcinol and 4-chlororesorcinol)
- Aminophenols (e.g. m-aminophenol, p-aminophenol, o-aminophenol⁸, 2-methyl-5-hydroxyethylaminophenol, p-methylaminophenol sulphate, p-aminophenol sulphate, m-aminophenol sulphate, 3-nitro-p-hydroxyethylaminophenol)

⁶ <http://www.energitjenesten.dk/hvem-star-bag-gron-salon.html>

⁷ All substances on the "Prohibited List" are listed. See this link for details: http://www.energitjenesten.dk/images/erhverv/gron_salon/gron_salon_forbudtliste_jan11.pdf

⁸ o-aminophenol is from January 3 2012 no longer allowed in cosmetic products. However, all hair dyes included in this survey were purchased before this date, and the content of o-aminophenol was therefore allowed.

- 4-amino-2-hydroxytoluene
- 4-amino-3-nitrophenol

A positive list and a negative list of products have been made for the Green Saloons. These lists also contain a number of hair dye products. On the positive list, the following hair dye products can be found:

- Farouk (Danhair) – CHI Infra High Lift Cream Color
- Gloria Cosmetics – Henne Maïa, Naturel
- Goldwell – Elumen
- Henna Plus – Colour Powder Super Red
- ID Hair – Miscela Cognac
- Logona (Pureshop) – Color Creme
- Logona (Pureshop) – Herbal Hair Color
- Phitoflos (Cutrin) – Henna colours
- Santé (Dansk Helios) – 100% Herbal Hair Color

A selection of these hair dye products mentioned on the positive list for the Green Saloons had therefore also been a part of the survey and is included in the database.

4.1.3 Strategy for selecting hair dyes to be included in the survey

On the basis of the contact to industry and internet search for hair dye products, the following strategy for selection of hair dye products to be included in the survey was decided:

1. Only products *available in Denmark*, i.e. products on the Danish retail market or products which could be purchased on Danish websites were included in the survey.
2. The number of *private and professional products should be distributed relatively evenly* – or with a slight overweight to professional products, as the survey showed that the professional market was larger than the private market. This means that about 150 private products and about 150 professional products should be included in the database, as the goal was to have a database of 300 products in all.
3. The number of *permanent/semi-permanent contra direct dyes* should be distributed as close to the distribution found on the Danish market as possible.
4. A part of the selected hair dye products should be hair dye products that were either on the positive list or negative list for *Green Saloons*. Likewise a part of the hair dye products should be hair dye products marketed as “green”, “organic”, “mild” etc. However, this group should represent the actual market shares.
5. The hair dye products should be selected from different producers. However, producers with a large amount of products on the market should have more products represented in the database in order to represent the actual market.
6. Different hair dye colours should be selected. However, if possible the distribution between colours should illustrate the actual use, i.e. bluish/purple colours were only represented in small amounts in order to make sure that all colours were represented in the database.

4.1.4 Collection of hair dyes in retail shops and via the internet

First, a selection of the received lists of ingredients – either from the producers or from selected hairdressers - was entered into the database. Based on an overview of this information (i.e. distribution of colours, product type and product category), the rest of the products were either purchased at retail shops, via the internet or at hairdressers.

During the survey it turned out that it was difficult to purchase professional hair dye products. Lists of ingredients for a number of professional hair dye products were obtained from the about 10 producers/distributors of professional hair dye products that participated with information to this project. A few professional hair dye products were bought in a few internet shops. However, some internet shops would not sell professional hair dye products to non-hairdressers. The rest of the professional hair dye products were therefore either received as empty packages from different hairdressers and a few products were bought from hair saloons.

For this reason, some of the professional hair dye brands might be overrepresented in the database, as it was not possible to find/buy professional hair dye products from the many other brands listed in Table 4-1. On the other hand, the professional hair dye brands which were largely represented in the database were also used by many hairdressers according to our survey. For this reason, the database was expanded to cover 365 products in all, thereby ensuring a more equal distribution of hair dye brands (according to market shares) in the database.

4.2 DATABASE OF THE INVESTIGATED HAIR DYES

During this project, a database in Microsoft Access 2003 was developed containing a total of 365 hair dye products available on the Danish market. The purpose of the database was to create an overview of the products and their content of hair dye substances (and other ingredients) in a relatively simple way. Furthermore, it was possible by use of the database to sort the information and to extract specific information of the entered data.

The database was built on a product overview where the information listed below was recorded for each product.

- Various information about the product
 - Product name
 - Product type (private/retail product or professional/hairdresser product)
 - Product category (permanent hair dye, semi-permanent hair dye, direct dyes)
 - Colour of the hair dye
 - The hair dye colour number (if any)
 - Necessary contact time in order for the dye to work properly
 - Source of information (whether the products were purchased or list of ingredients received in another way, where the product was purchased and when)
 - Name of the producer or distributor
 - Batch number (only for products bought)

- Container descriptions
- Substances as listed on the list of ingredients
 - INCI name
 - The total number of ingredients in the product. It was noted for each entry in the database, which ingredients that were part of e.g. the dye mixture and the possible fixation fluid.
 - The ranking order of the ingredients (e.g. water was listed as the first ingredient)
 - Both list of ingredients for the dye itself (dye mixture) and the fixation fluid used to mix with the dye mixture was entered into the database, if the hair dye product contained a fixation fluid.

A fixation fluid is primarily found for hair dye products on the private market, where the hair dye product is sold as a dyeing kit. Professional hair dye products are typically sold as hair dye mixture and fixation fluid individually. In many cases the fixation fluid is therefore not included for the professional products.

In the following, a more detailed description with information about the registrations in the database of each of the above points is presented.

4.2.1 Ingredients contained in the products

The ingredients in a cosmetic product shall be stated in order after descending weight. However, ingredients in a concentration less than 1% can be mentioned in any order after the other ingredients. The order in which the ingredients are mentioned on the container is therefore an indication of the quantity of the different constituents in the product. However, this cannot be used to compare concentrations in different hair dye products.

For each product, information was entered into the database about the ingredients of the cosmetic products but also in which order (ranking) the ingredients are listed on the product. Thus, the ranking is an indication of the relative concentration of the ingredients in the products.

4.2.2 Hair dye colour categories

Many different hair dye colours exist (see chapter 2 “Definitions/abbreviations”), especially for hair dye products for professional use. In order to group the hair dye products in as few colours as possible the following overall hair dye colours were used:

- Black (including blue-black, purple-black etc.)
- Brown/dark brown (including violet/brown etc.)
- Brown – chestnut
- Brown – mahogany
- Light brown – light chestnut
- Red (including reddish brown/auburn/chestnut/copper and orange/red)
- Dark blond
- Light blond

- Blond/grey – ash blonde
- Blue
- Purple/violet
- Green
- Orange/yellow

In some cases it was difficult to use one of these few hair dye colour categories for specific hair dye products, e.g. if the hair dye was blue-black or if the hair dye was called “mahogany chestnut”. In these cases it was of course a subjective judgement of the hair colour, and the hair dye products were put in the category that described the hair colour in the most suitable way.

4.2.3 Container description

A short description of the look of the container was entered into the database in order to be able to locate the purchased products more quickly (besides using the identification number). An example could be: *“Beige cardboard packaging with black text and a picture of the hair dye colour”*.

4.2.4 Other comments

In the database, there was space to note possible comments about the product in question. The noted comments were for instance the following:

- Information about possible spelling mistakes in the INCI names of the list of ingredients as well as a note with an assumption of the INCI names which should have been stated.
- Information about ingredients only listed as “may contain”.

4.2.5 Contact time

The necessary contact time in order for the dye to work properly was entered into the database. The contact time was primarily available for the hair dye products that were purchased.

4.3 RESULTS OF THE SURVEY

In the following, the data material which could be extracted from the database of the 365 hair dye products is presented.

A total of 365 different hair dye products were included in the survey. The products were purchased or information was provided about the products either from producers/distributors or by collecting used hair dye products from hairdressers.

For 141 of these hair dye products information about the fixation fluid was entered as well.

The survey was conducted in the period of July 2011 to November 2011.

4.3.1 Product name and importers/producers

The product name and the name of the importers and/or producers were listed in the database in two separate fields. However, intentionally, all specific product names and the names of the importers and producers were kept out of this report.

The brands included in the database as well as the importers/producers behind the different brands included in the database can be found in Table 4-1, where the included products are marked with bold and with a grey background in the second column.

4.3.2 Product type

The 365 hair dye products included in the database were distributed as follows:

- 159 hair dye products are for private use
- 206 hair dye products are for professional use (hairdressers)

The goal of having a database with minimum 150 hair dye products for private use and minimum 150 products for professional use was therefore met.

As previously mentioned, the professional hair dye market was larger than the market for private hair dyes. Therefore an overweight of professional hair dye products were chosen.

4.3.3 Product category

The 365 hair dye products included in the database were distributed as follows on the different product categories (permanent hair dye, semi-permanent hair dye and direct dyes).

TABLE 4-3 OVERVIEW OF DISTRIBUTION BETWEEN PRODUCT TYPE AND PRODUCT CATEGORY FOR THE 365 HAIR DYE PRODUCTS IN THE DATABASE

	Private products		Professional products		Sum	
Permanent hair dyes	130	82%	152	74%	282	77%
Semi-permanent hair dyes	27	17%	52	25%	79	22%
Direct dyes	2	1%	2	1%	4	1%
Sum	159	100%	206	100%	365	100%

This illustrates that the largest market was permanent hair dyes.

4.3.4 Hair dye colour

The 365 hair dye products included in the database were distributed as follows on the different hair dye colours.

TABLE 4-4 OVERVIEW OF DISTRIBUTION BETWEEN THE COLOURS OF THE 365 HAIR DYE PRODUCTS IN THE DATABASE

	Private products	Professional products	Sum	
Black	21	9	30	8%
Brown/dark brown	26	29	55	15%
Brown - chestnut	13	10	23	6%
Brown - mahogany	6	7	13	4%
Light brown/chestnut	17	32	49	13%
Dark blonde	12	29	41	11%
Blond/ash blonde	10	18	28	8%
Light blonde	35	32	67	18%
Red	15	28	43	12%
Blue	1	2	3	1%
Green	0	2	2	1%
Violet/purple	1	4	5	1%
Orange/yellow	2	4	6	2%
Sum	159	206	365	100%

4.3.5 How was the information obtained?

As described earlier, the following methods were used to gather the lists of ingredients for the 365 different hair dye products:

- Products were purchased in retail (supermarkets, perfumeries etc.)
- Products were purchased from internet shops
- Products were purchased from hairdressers
- Lists of ingredients were obtained from different producers/distributors of hair dye products in Denmark
- Lists of ingredients were found on internet web shops
- Empty packages of hair dye products were collected from various hairdressers in the Copenhagen area.

The information about the ingredients in hair dye products was therefore obtained by a mixture of physically having the hair dye products and using electronically information. Only 20% of the hair dye products were actually purchased (either in retail or mostly via the internet). The 80% of the products that were not purchased covered

- 36 products (10%) which were part of an investigation carried out by the Danish Chemicals Inspection in 2011
- 73 products (20%) which were received as empty packaging from several different hairdressers.

4.3.6 Contact time

Information about the contact time was only available for 142 hair dye products (products bought or where empty packages were obtained). The contact time is the period of time the hair dye product needs to work in the hair before rinsing – according to the respective user instructions on the products. The variation in the contact time is listed below in Table 4-5.

The average contact time was about the same for all product categories and product types, i.e. about 25 to 35 minutes.

TABLE 4-5 OVERVIEW OF THE CONTACT TIME STATED ON THE DIFFERENT HAIR DYE PRODUCTS

	Private products		Professional products	
	Minutes	No. of products	Minutes	No. of products
Permanent	5	2	5-30	2
	10-45	2	20	1
	15	2	20-35	4
	15-30	1	25-30	7
	20	8	30	5
	25	4	30-40	1
	20-30	3	30-45	15
	30	19	35-45	1
	25-45	1	35	1
	45	1	40	6
	30-90	1		
	30-120	4		
	60-120	1		
	Average: 32 minutes		Average: 33 minutes	
Semi-permanent	10-25	3	5-20	4
	20	3	10-15	3
	45	2	15-20	6
			20	3
			minutes	3
			15-30	3
			20-25	3
			30-45	1
			30-90	7
			60-120	
Average: 25 minutes		Average: 36 minutes		
Direct dyes	No information	Minutes	Products	
		Spread into the hair and leave in until next hair wash	2	

The contact time does not seem to vary across the different hair dye colours either. In Table 4-6 the contact time is listed for all permanent hair dyes only for the different hair dye colours.

TABLE 4-6 OVERVIEW OF THE CONTACT TIME FOR PERMANENT HAIR DYES

	Minutes	No. of products	Average contact time in minutes
Black	30-45	1	38
	35	1	
	40	2	
Brown/dark brown	25-30	1	34
	30	1	
	30-45	2	
	40	1	
Brown - chestnut	No information		
Brown - mahogany	20-35	1	32
	30-45	1	
Light brown/chestnut	5-30	1	29
	25-30	2	
	30	1	
	30-45	1	
	40	1	
Dark blonde	5-30	1	29
	20	1	
	20-35	1	
	25-30	2	
	30	1	
	30-40	1	
	30-45	1	
40	1		
Blond/ash blonde	20-35	1	29
	25-35	1	
Light blonde	25-30	1	36
	30-45	6	
Red	30	2	35
	30-45	4	
Blue	20-35	1	28
Green	No information		
Violet/purple	No information		
Orange/yellow	No information		

4.3.7 Ingredients in the hair dyes

The database of the 365 different hair dye products showed that a total of 570 different ingredients were used in these products including the hair dye substances. This number, however, covered both the actual dye mixture, but also the possible fixation fluid which was entered for a total of 141 hair dye products. The 570 different ingredients were ingredients with many different functions, i.e. solvents, viscosity controllers, preservatives, perfumes etc. besides from the actual hair dye substances.

In the dye mixtures 541 different ingredients were used. The similar number for the fixation fluid was only 80.

4.3.8 Hair dye substances contained in the products

In total 110 different hair dye substances were used in the 365 different hair dye products. Of these

- 95 were marked with the function “hair dyeing” according to the EU CosIng database⁹.
- 15 were marked with the function “cosmetic colorant” according to the EU CosIng database, i.e. Colour Index substances.
- 1 was marked with both functions “hair dyeing” and “cosmetic colorant” according to the EU CosIng database¹⁰.

In 2006 the SCCS (The Scientific Committee on Consumer Safety) published “Memorandum on Hair Dye Substances and their Skin Sensitizing Properties”. In this memorandum SCCS classified 46 hair dye substances according to their skin sensitizing properties. The hair dye substances were given the following classifications, based on a specific set of criteria mentioned in the memorandum (page 6 in SCCP Memorandum, 2006):

- Extreme sensitizers
- Strong sensitizers
- Moderate sensitizers
- Not classifiable (with R43/H317)

Of the 46 hair dye substances 10 of these substances were categorised as extreme sensitizers, 13 as strong sensitizers and 4 as moderate skin sensitizers, all fulfilling the EU criteria for classification as skin sensitizer (R43/H317). SCCS concluded in the memorandum that “hair dye substances which fulfil the criteria for classification as R43 (“May cause sensitization by skin contact”), may not be safe for consumers. This is particularly so for hair dye substances categorised as extreme and strong skin sensitizers.” (SCCP Memorandum, 2006).

The 95 hair dye substances found in the products in this survey are listed with their sensitizing potential in Table 4-7.

The sensitizing potential was listed by the use of the categories defined by SCCS when possible. The term “Not classifiable” is used by SCCS in cases where data points to a *weak* sensitizing potential or *no* sensitizing potential. In cases where an SCCS opinion did not exist, or the SCCS opinion concludes that a skin sensitizing potential cannot be excluded (typically because of poor quality of data, lack of data or inconclusive data) the sensitizing potential was based on QSAR predication (Søsted *et al.*, 2004). If a QSAR prediction did not exist in these cases, the substance was categorized “No/inadequate data” (this category was used for eight of the hair dye substances).

This gave the following categories: "Extreme", "Strong", "Moderate", "Not classifiable" or "No/inadequate data".

Finally some of the substances were found to be prohibited, i.e. are restricted according to Annex II of the Cosmetics Directive (“List of substances which must not form part of the composition of cosmetic products”), and were therefore assigned the category “Not relevant (substance prohibited)”. Eight of the total 95 hair dye substances were prohibited, and these were found in 5 different hair dye products.

⁹ <http://ec.europa.eu/consumers/cosmetics/cosing/>

¹⁰ This one substance is therefore included both in the number of substances listed with the function “Hair dyeing” and the function “Cosmetic colorant”.

This gives the following overview of the content of hair dye substances in the 365 hair dye products and their sensitising potential. Only substances marked with the function “hair dyeing” are included in the table. However, when operating with this definition of the term hair dye substances, the result was that 20 out of the 365 products in total did not contain any actual hair dye substances. This aspect is further described in section 4.3.9 “Products without hair dye substances”.

TABLE 4-7 OVERVIEW OF THE 95 USED HAIR DYE SUBSTANCES IN THE 365 HAIR DYE PRODUCTS AND THEIR SENSITIZING POTENTIAL. THE LIST IS SORTED WITH THE MOST FREQUENTLY USED HAIR DYE SUBSTANCE LISTED FIRST.

INCI Name	CAS No.	In no. of products	Restriction	Sensitizing potential	Reference
RESORCINOL	108-46-3	218	III/22	Strong	SCCS/1270/09
M-AMINOPHENOL	591-27-5	193	III/217	Strong	SCCP Memorandum, 2006
2-METHYLRESORCINOL	608-25-3	143	III/245	Moderate	SCCP/1206/08
P-AMINOPHENOL	123-30-8	132		Strong	SCCS/1409/11
TOLUENE-2,5-DIAMINE SULFATE	615-50-9	131	III/9a	Extreme	SCCS/1390/10
4-AMINO-2-HYDROXYTOLUENE	2835-95-2	111	III/243	Strong	SCCP Memorandum, 2006
4-CHLORORESORCINOL	95-88-5	84	No restriction	Moderate	SCCS/1224/09, rev. of 12.07.10
P-PHENYLENEDIAMINE	106-50-3	81	III/8a	Extreme	SCCP Memorandum, 2006
TOLUENE-2,5-DIAMINE	95-70-5	80	III/9a	Extreme	SCCS/1390/10
2,4-DIAMINOPHENOXYETHANOL HCl	66422-95-5	72	III/244	Moderate	SCCS/1367/10
2-AMINO-4-HYDROXYETHYLAMINOANISOLE SULFATE	83763-48-8	72	III/248	Not classifiable	SCCS/1250/09/Søsted et al., 2004
2-AMINO-3-HYDROXYPYRIDINE	16867-03-1	50	No restriction	Not classifiable	SCCP/1126/07
2-METHYL-5-HYDROXYETHYLAMINOPHENOL	55302-96-0	40	III/232	Not classifiable	SCCP Memorandum, 2006
2-AMINO-6-CHLORO-4-NITROPHENOL	6358-09-4	37	III/252	Strong	SCCP Memorandum, 2006
1-NAPHTHOL	90-15-3	30	III/16	Strong	SCCP/1123/07
4-AMINO-M-CRESOL	2835-99-6	26	III/246	Strong	SCCP Memorandum, 2006
N,N-BIS(2-HYDROXYETHYL)-P-PHENYLENEDIAMINE SULFATE	54381-16-7 / 57524-61-5 / 58262-44-5	24	III/8	Strong	SCCP Memorandum, 2006
HC YELLOW NO. 2	4926-55-0	23	No restriction	Strong/moderate	SCCS/1309/10/Søsted et al., 2004
ACID VIOLET 43	4430-18-6	23	IV/1	Not classifiable	SCCP Memorandum, 2006
ACID ORANGE 7	633-96-5	23	IV/1	Not classifiable	SCCS/1382/10
6-HYDROXYINDOLE	2380-86-1	22	No restriction	Extreme	SCCP Memorandum, 2006
LAWSONIA INERMIS EXTRACT	84988-66-9	21	No restriction	Not classifiable	SCCP Memorandum, 2006
HC RED NO. 3	2871-01-4	21	No restriction	Extreme	SCCS/1293/10
HC YELLOW NO. 10	109023-83-8	15	III/197	Not classifiable	SCCP/1080/07
1,5-NAPHTHALENEDIOL	83-56-7	14	III/241	Moderate	SCCS/1365/10
PHENYL METHYL PYRAZOLONE	89-25-8	13	III/230	Strong	SCCP Memorandum, 2006
O-AMINOPHENOL*	95-55-6	13	II/1372	Strong/moderate	SCCS/1291/10/Søsted et al., 2004
P-METHYLAMINOPHENOL SULFATE	55-55-0	12	III/223	Moderate	SCCP Memorandum, 2006

INCI Name	CAS No.	In no. of products	Restriction	Sensitizing potential	Reference
HYDROXYETHYL-2-NITRO-P-TOLUIDINE	100418-33-5	11	III/2/10	Strong/moderate	SCCS/1387/10/Søsted et al., 2004
1-HYDROXYETHYL 4,5-DIAMINO PYRAZOLE SULFATE	155601-30-2	10	No restriction	Extreme	SCCS/1449/11
ACID RED 52	3520-42-1	10	III/193	Not classifiable	SCCP/1115/07
2,4-DIAMINOPHENOXYETHANOL SULFATE	70643-20-8	10	III/244	Moderate	SCCS/1367/10
BASIC YELLOW 87	68259-00-7	9	No restriction	Not classifiable	SCCS/1333/10
2,5,6-TRIAMINO-4-PYRIMIDINOL SULFATE	39267-74-8 / 35011-47-3 / 1603-02-7	9	No restriction	No/inadequate data	SCCP/1122/07/not included in Søsted et al., 2004
4-HYDROXYPROPYLAMINO-3-NITROPHENOL	92952-81-3	9	III/205	Not classifiable	SCCP/1082/07
HYDROXYBENZOMORPHOLINE	26021-57-8	9	III/234	Not classifiable	SCCP Memorandum, 2006
HC YELLOW NO. 4	52551-67-4 / 59820-43-8	9	No restriction	Strong/moderate	SCCS/1230/09/Søsted et al., 2004
SODIUM PICRAMATE	831-52-7	8	No restriction	Moderate	SCCS/1227/10
6-METHOXY-2-METHYLAMINO-3-AMINOPYRIDINE HCl	90817-34-8 / 83732-72-3 (2HCl)	8	III/203	Moderate	SCCP/1121/07
2,7-NAPHTHALENEDIOL	582-17-2	8	III/216	Moderate	SCCS/1366/10
BASIC ORANGE 31	97404-02-9	8	No restriction	Moderate	SCCS/1447/11
N-PHENYL-P-PHENYLENEDIAMINE SULFATE	4698-29-7	7	III/8	Extreme	SCCP Memorandum, 2006
5-AMINO-6-CHLORO-O-CRESOL	84540-50-1	7	No restriction	Strong/moderate	SCCS/1225/09 Revision of 07 January 2011/Søsted et al., 2004
BASIC RED 51	77061-58-6	7	No restriction	Not classifiable	SCCS/1436/11
ACID BLACK 1	1064-48-8	7	IV/1	Moderate	SCCS/1226/09
HC BLUE NO. 12	132885-85-9 / 104516-93-0	6	III/225	Moderate	SCCP/1135/07
N-PHENYL-P-PHENYLENEDIAMINE	101-54-2	6	III/8	Extreme	SCCP/0991/06
BASIC BROWN 16	26381-41-9	6	No restriction	Moderate	SCCP/1165/08
BASIC VIOLET 2	3248-91-7	5	IV/1	Not classifiable	SCCS/1340/10 Revision of 13-14 December 2011/Søsted et al., 2004
ACID RED 33	3567-66-6	5	III/194	Not classifiable	SCCP/1102/07
BASIC BROWN 17	68391-32-2	5	No restriction	Strong/moderate	SCCS/1448/11/Søsted et al., 2004
ACID YELLOW 23	1934-21-0	4	III/189	Strong/moderate	SCCNFP/0786/04/Søsted et al., 2004
HYDROXYETHYL-3,4-METHYLENEDIOXYANILINE HCl	94158-14-2	4	III/249	Strong	SCCS/1269/09
1,3-BIS-(2,4-DIAMINOPHENOXY)PROPANE HCl	74918-21-1	4	III/202	Moderate	SCCP/1098/07
BASIC RED 76	68391-30-0	4	No restriction	Not classifiable	SCCS/1385/10 Revision of 21 June 2011/Søsted et al., 2004
BASIC VIOLET 16	6359-45-1	3	No restriction	No/inadequate data	No opinion/not included in Søsted et al., 2004

INCI Name	CAS No.	In no. of products	Restriction	Sensitizing potential	Reference
HC YELLOW NO. 13	10442-83-8	3	No restriction	No/inadequate data	SCCS/1322/10 Revision of 22 March 2011/not included in Søsted et al., 2004
2-HYDROXYETHYL PICRAMIC ACID	99610-72-7	3	III/222	Not classifiable	SCCP/1208/08
2-CHLORO-P-PHENYLENEDIAMINE SULFATE	6219-71-2 / 61702-44-1	3	III/8	Strong/moderate	No opinion/Søsted et al., 2004
HYDROXYPROPYL BIS(N-HYDROXYETHYL-P-PHENYLENEDIAMINE) HCl	128729-28-2	3	III/242	Strong	SCCP/1051/06
BASIC YELLOW 57	68391-31-1	3	No restriction	Not classifiable	SCCS/1231/09 Revision of 12 July 2010/Søsted et al., 2004
ACID GREEN 25	4403-90-1	3	IV/1	Not classifiable	SCCP Memorandum, 2006
2,6-DIAMINOPYRIDINE SULFATE	146997-97-9	3	No restriction	No/inadequate data	No opinion/not included in Søsted et al., 2004
N,N'-BIS(2-HYDROXYETHYL)-2-NITRO-P-PHENYLENEDIAMINE	84041-77-0	3	III/8	Not classifiable	SCCS/1228/09 Revision of 12 July 2010
P-AMINOPHENOL SULFATE	63084-98-0	3	No restriction	Strong	P-aminophenol is strong according to opinion SCCS/1409/11 and Søsted et al., 2004. No data on the sulphate
BASIC BLUE 99	68123-13-7	3	No restriction	Strong/moderate	SCCS/1437/11/Søsted et al., 2004
P-PHENYLENEDIAMINE SULFATE	16245-77-5	3	III/8a	Extreme	SCCP/0989/06
M-AMINOPHENOL SULFATE	68239-81-6	3	III/217	Strong	m-aminophenol is strong according to SCCP Memorandum, 2006 and Søsted et al., 2004. No data on the sulphate
HC BLUE NO. 2	33229-34-4	2	III/199	Strong/moderate	SCCP/1035/06/Søsted et al., 2004
4-AMINO-3-NITROPHENOL	610-81-1	2	III/215	Extreme	SCCP/1207/08
LAWSONE	83-72-7	2	No restriction	Strong	SCCP Memorandum, 2006
PIGMENT BLUE 15:1	147-14-8	2	II/1367	Not classifiable	Substance is prohibited (Søsted et al., 2004; 2008/88/EC)
2,3-DIAMINODIHYDROPYRAZOLOPYRAZOLONE DIMETHOSULFONATE	857035-95-1	2	No restriction	No/inadequate data	No opinion/not included in Søsted et al., 2004
3-NITRO-P-HYDROXYETHYLAMINOPHENOL	65235-31-6	2	III/250	Extreme	SCCP/1036/06
TETRAAMINOPYRIMIDINE SULFATE	5392-28-9	2	No restriction	No/inadequate data	SCCP/1118/07/not included in Søsted et al., 2004
ACID BLUE 9	3844-45-9	2	III/190	Not classifiable	SCCP Memorandum, 2006
BASIC RED 2	477-73-6	2	II/1322	Not relevant (substance prohibited)	Substance prohibited
ACID YELLOW 3	95193-83-2	2	IV/1	Not classifiable	SCCNFP/0789/04
ACID RED 92	18472-87-2	2	No restriction	Not classifiable	SCCS/1428/11 Revision of 26-27 June 2012
HC RED NO. 11	95576-92-4	2	III/50	No/inadequate data	SCCS/1406/11/not included in Søsted et al., 2004

INCI Name	CAS No.	In no. of products	Restriction	Sensitizing potential	Reference
ACID RED 18	2611-82-7	2	III/192	Not classifiable	SCCP Memorandum, 2006
BASIC RED 46	12221-69-1	2	II/1259	Not relevant (substance prohibited)	Substance prohibited
6-AMINO-M-CRESOL	2835-98-5	2	No restriction	Strong/moderate	No opinion/Søsted et al., 2004
HC RED NO. 10	95576-89-9	2	III/50	No/inadequate data	SCCS/1406/11/not included in Søsted et al., 2004
HYDROXYETHYL-P-PHENYLENEDIAMINE SULFATE	93841-25-9	1	III/256	Strong	SCCS/1310/10 Revision of 12 July 2010
CURRY RED	25956-17-6	1	III/191	Not classifiable	SCCP Memorandum, 2006
DISPERSE VIOLET 1	128-95-0	1	No restriction	Moderate	SCCS/1232/09 Revision of 16 September 2010
HC BLUE NO. 16	502453-61-4	1	No restriction	No/inadequate data	No opinion/not included in Søsted et al., 2004
BASIC VIOLET 1	8004-87-3	1	II/388	Not relevant (substance prohibited)	Substance prohibited
HC YELLOW NO. 5	56932-44-6	1	II/1285 (DELISTED)	Not relevant (substance prohibited)	Substance prohibited
ACID YELLOW 1	846-70-8	1	IV/1	Extreme	SCCP/1160/08
BASIC GREEN 4	569-64-2	1	II/1188	Not relevant (substance prohibited)	Substance prohibited
PIGMENT VIOLET 23	6358-30-1	1	II/1360	Not relevant (substance prohibited)	Substance prohibited
BASIC RED 22	12221-52-2	1	II/1292	Not relevant (substance prohibited)	Substance prohibited
BASIC YELLOW 28	54060-92-3	1	II/1272	Not relevant (substance prohibited)	Substance prohibited

*o-aminophenol is from January 3 2012 no longer allowed in cosmetic products. However, all hair dye products included in this survey were purchased before this date, and the content of o-aminophenol was therefore allowed.

Comparison with other surveys

As mentioned in the introduction a recent Swedish survey investigated 122 oxidative hair dye products on the Swedish market. This survey showed that PPD was found in 19 of the 122 products (16%) and PTD in 49 of the 122 products (40%). Other allergenic hair dye substances like resorcinol and m-aminophenol were found in more of the products, 100 (82%) and 83 (68%) of the 122 products respectively (Yazar *et al.*, 2009). In this survey on the Danish market PPD and PTD (and their salts and derivatives) were in comparison found in larger percentages of the investigated products, 28% and 58% respectively. Resorcinol and m-aminophenol were, however, found in a lower percentage of the investigated products, 60% and 53% respectively.

4.3.8.1 PPD and PTD in hair dye products

PPD and its salts (reference number 8a in Annex III Part 1) are allowed after mixing under oxidative conditions in a maximum concentration of 2% calculated as a free base when applied to the hair (Commission Directive 2009/130/EC). According to EU Council Directive 76/768/EEC relating to cosmetic products N-substituted derivatives of PPD and their salts (reference

number 8 in Annex III Part 1) are allowed in a maximum concentration of 6% calculated as a free base, which means that the maximum allowable concentration after mixing is 3%.

PTD and its salts (reference number 9a in Annex III Part 1) are allowed after mixing under oxidative conditions in a maximum concentration of 4% calculated as a free base when applied to hair (Commission Directive 2009/130/EC). According to EU Council Directive 76/768/EEC relating to cosmetic products methylphenylenediamines, their N-substituted derivatives and their salts (reference number 9 in Annex III Part 1) are allowed in a maximum concentration of 10% calculated as a free base, which means that the maximum allowable concentration after mixing is 5%.

Some of the contacted companies gave general information about the content of PPD and PTD in their hair dye products. The following information was received:

- Two of the large players on the market use PTD or PTD sulfate in almost all of their hair dye products (about 90%). PPD is not used in any products from these two producers.
- A smaller company uses PTD in all their hair dye products (for the professional market). A salt of PPD is used only in two colours.

Table 4-7 shows that PPD was used in 81 of the 365 hair dye products. PTD and PTD sulfate were used in 80 and 131 hair dye products respectively.

However, salts of PPD and PTD were also used. The PPD (reference number 8 and 8a) and PTD (reference number 9 and 9a) ingredients that were used in the 365 hair dye products are listed in Table 4-8 and Table 4-9 below. In total 99 hair dye products contained one or more PPD ingredients and 211 products contained PTD or PTD sulfate. Of these 94% and 88% were permanent hair dyes respectively, i.e. the majority of the hair dye products with PPD or PTD and its salts or derivatives were permanent hair dyes. The rest was semi-permanent hair dyes.

Four of the PPD derived hair dye substances were in this project initially classified as having no restriction and therefore not belonging to the N-substituted PPD derivatives or salts of PPD. Therefore these four were not included in the term used in this report “PPD and their salts and derivatives”. However two of these are in fact restricted by the generic entry III/8. The two are:

- 2-chloro-p-phenylenediamine sulfate (CAS 6219-71-2 / 61702-44-1) – found in 3 products and only used in combination with PPD sulfate.
- N,N'-bis(2-hydroxyethyl)-2-nitro-p-phenylenediamine (CAS 84041-77-0) – found in 3 products and *not* used in combination with any PPD or PTD salts or derivatives.

The two other PPD derivatives which were not classified as belonging to the group of PPD and their salts and derivatives are:

- Hydroxyethyl-p-phenylenediamine sulfate (CAS 93841-25-9) – found in 1 product and used in combination with PTD sulfate.
- Hydroxypropyl bis(N-hydroxyethyl-p-phenylenediamine) HCl (CAS 128729-28-2) – found in 3 products and used in combination with a PPD compound (N,N-bis(2-hydroxyethyl)-p-phenylenediamine sulfate) and/or in combination with PTD or PTD sulfate.

TABLE 4-8 PPD AND SOME OF ITS DERIVATES FOUND IN THE HAIR DYE PRODUCTS

PPD ingredients	CAS no.	Ref. no. in Directive	In no. of products	Remarks	Sensitizing potential
P-PHENYLENEDIAMINE (PPD)	106-50-3	8a	81		Extreme
P-PHENYLENEDIAMINE SULFATE	16245-77-5	8a	3	Is in all cases used together with 2-chloro-p-phenylenediamine sulfate in semi-permanent hair dyes.	Extreme
N,N-BIS(2-HYDROXYETHYL)-P-PHENYLENEDIAMINE SULFATE	54381-16-7 / 57524-61-5 / 58262-44-5	8	24	Is in many cases used alone, but also together with PPD in several products, and also with other PPD compounds.	Strong
N-PHENYL-P-PHENYLENEDIAMINE	101-54-2	8	6	Is in all cases used together with PPD.	Extreme
N-PHENYL-P-PHENYLENEDIAMINE SULFATE	4698-29-7	8	7	Is in most cases found together with PPD, but is used alone in two products.	Extreme
<i>Covers in total – number of hair dye products:</i>			99		

PTD only has one derivative, which is the PTD sulfate. No other derivatives were used. PTD and PTD sulfate were not used in combination in any of the products investigated in this survey. Both PTD ingredients were used in both permanent and semi-permanent hair dye products.

TABLE 4-9 PTD AND PTD SULFATE FOUND IN THE 365 PRODUCTS

PTD ingredients	Cas No.	Ref. no. in Directive	In no. of products	Sensitizing potential
TOLUENE-2,5-DIAMINE	95-70-5	9a	80	Extreme
TOLUENE-2,5-DIAMINE SULFATE	615-50-9	9a	131	Extreme
<i>Covers in total – no. of hair dye products:</i>			211	

4.3.8.2 Products containing both PPD and PTD (or their salts and derivatives)

35 of the 365 products contained both PPD and PTD (or their salts or their derivatives). However, for some of the products either PPD or PTD (or their salts or their derivatives) were listed as “may contain” in the ingredients list, which is not in accordance with the Cosmetic Directive (as hair dye substances are not allowed to be listed as “may contain”).

4.3.8.3 Concentrations of PPD and PTD in different colours

According to an earlier survey (before lowering the limit of the allowed concentration of PPD in hair dye products), PPD could be found in concentrations between 0.2% and up to 3.75% (Abdelraheem, 2010). It was not stated directly, but the percentages seemed to cover the actual dye mixture and not the mixed finished hair dyeing preparation.

For some of the hair dye products information about the approximate concentration of PPD and PTD was provided by the producers. These

percentages covered the actual dye mixture and not the mixed finished hair dyeing preparation.

In four products the concentration of PPD was listed to be less than 0.2% (smallest content listed) and less than 0.7% (highest content listed). There were too few products with this information to make an assessment of the connection between content of PPD and the hair dye colour.

However, for PTD information about the approximate concentration for 41 products were provided by the producers. The concentrations are listed as presented in the table below. The percentages are given in concentration ranges as the exact concentration is confidential. According to the cosmetic product legislation PTD and its salts (reference number 9a in Annex III Part 1) are allowed after mixing under oxidative conditions in a maximum concentration of 4% calculated as a free base when applied to hair (Commission Directive 2009/130/EC). The percentages listed below are the concentrations for the dye mixture itself, and not for the mixed finished hair dyeing preparation. This means that a concentration of 5% in the dye mixture still could be under the limit value of 4% in the mixed finished hair dye preparation.

TABLE 4-10 APPROXIMATE CONCENTRATION OF PTD IN THE PRODUCTS

Concentration of PTD	Hair dye colour
< 0.1 %	All 3 products are light blond
0.1 – 1 %	3 products are dark brown 4 products are dark blond 3 products are red 6 products are light blond 2 products are light chestnut
1 – 5 %	5 products are black 8 products are dark brown 2 products are chestnut brown 2 products are mahogany brown 1 product is light chestnut 1 product is dark blond 1 product is red

The information in Table 4-10 indicates that the concentration of PTD seems to rise as the colour of the hair dye products darkens.

In the two tables below the products with either PPD (and its derivatives and salts) or PTD (and PTD sulfate) and their colour are listed.

TABLE 4-11 HAIR DYE COLOUR OF PRODUCTS CONTAINING PPD
(AND ITS SALTS AND DERIVATIVES)

Hair dye colour	No. of products		Percentage*
Blonde/ash blonde	9	11%	32%
Blue	1	1%	33%
Brown - chestnut	3	4%	13%
Brown - mahogany	3	4%	23%
Brown/dark brown	21	25%	38%
Green	1	1%	50%
Light blonde	15	18%	22%
Light brown/chestnut	12	14%	24%
Dark blonde	12	14%	29%
Orange/yellow	1	1%	17%
Red	6	7%	14%
Black	14	17%	47%
Violet/purple	1	1%	20%
Sum of products	99	100%	

* This column shows the percentage of the hair dye products with this specific colour that contains PPD (and its salts and derivatives) compared to the total number of hair dye products with this colour.

TABLE 4-12 HAIR DYE COLOUR OF PRODUCTS CONTAINING PTD (AND ITS SALTS)

Hair dye colour	No. of products		Percentage*
Blonde/ash blonde	20	9%	71%
Blue	1	0%	33%
Brown - chestnut	11	5%	48%
Brown - mahogany	7	3%	54%
Brown/dark brown	38	18%	69%
Green	1	0%	50%
Light blonde	36	17%	54%
Light brown/chestnut	30	14%	61%
Dark blonde	29	14%	71%
Orange/yellow	0	0%	0%
Red	19	9%	44%
Black	19	9%	63%
Violet/purple	0	0%	0%
Sum of products	211	100%	

* This column shows the percentage of the hair dye products with this specific colour that contains PTB (or PTB sulfate) compared to the total number of hair dye products with this colour.

These two tables above do not show any clear trend. About 50 or 60 % of the hair dye products contained PTB whether the hair dye was black, dark brown or light blonde. As the number of products across the different hair dye colours was very different, it is therefore not possible to conclude whether PPD and/or PTB was used more frequently in one colour compared to another.

However, as illustrated in Table 4-10 above, the concentration of PTB in the darker colours seemed to be higher compared to the lighter colours.

4.3.9 Products without hair dye substances

Of the 365 hair dye products included in this survey 20 products did not contain any hair dye substances, i.e. hair dye substances with the function “hair dyeing” according to CosIng. These 20 products can be described as follows:

- Product category:
 - 4 products are direct dyes based on CI colours, 2 products are semi-permanent products and 14 products are permanent products.
- Product type:
 - 5 products are professional hair dye products and 15 are hair dye products from the private market.
- Colour:
 - 12 products have the colour “light blond”¹¹ meaning that a different kind of chemistry may be used (bleaching with e.g. persulfate compounds). One of the “light blond” hair dyes was a direct dye.
 - 2 products have the colour “black”
 - 2 products have the colour “dark blond”
 - 1 product has the colour “red”
 - 1 product has the colour “dark brown”
 - 1 product has the colour “light brown”
 - 1 product has the colour “ash blond”

These 20 products without hair dye substances were investigated further:

- 4 products were direct dyes and did therefore not contain substances with the function “hair dye”, but contained CI colours instead.
- 11 of the remaining 16 permanent or semi-permanent products had the colour “light blond” where a different kind of chemistry might be used (bleaching with e.g. persulfate compounds).
 - 7 products did not contain persulfate compounds or other bleaching compounds according to CosIng. Neither did they contain any CI colours or hair dye substances.
 - 4 products did contain persulfate compounds, which means that they were bleaching products and cannot be regarded as hair dyes.
- Of the 5 remaining of the 16 permanent or semi-permanent products, the following could be found:
 - 4 products contained the ingredient “Lawsonia inermis cera”, which in the CosIng database was marked with the function “hair conditioning” and *not* “hair dyeing” even though the ingredient had the same CAS No. as “Lawsonia inermis extract”. These products must therefore be regarded as hair dyes even though according to the definitions in the CosIng database they did not contain any hair dye substances.
 - 1 product contained the ingredient “Indigofera tinctoria”, which in the CosIng database was marked with the function “masking” and “tonic” and *not* “hair dyeing” even though a SCCFNP Opinion existed stating that the ingredient was used with hair dyeing purposes in hair dyes. This product must therefore be regarded as a hair dye even though according to

¹¹ In this survey 67 products were light blond hair dyes.

the definitions in the CosIng database it did not contain hair dye substances.

It can therefore be concluded that only 4 of the 20 products that did not contain hair dyes were actually not hair dyes – they must be regarded as bleaching products. However, 7 other light blonde products did not contain any colours, and for this reason it was decided to exclude the 11 light blonde products from the tables presented from section 4.3.10.7 .

4.3.10 Sensitizing hair dye substances contained in the products

PPD and PTD (and their salts and derivatives) are hair dye substances that are classified as extreme sensitizers (or strong for one PPD derivative). It was therefore interesting to investigate the following:

- How many of the hair dye products did not contain either PPD or PTD?
- Did permanent hair dye products without PPD and PTD exist?
- Did hair dye products without PPD and/or PTD exist on the private market?
- Did hair dye products without PPD and PTD exist in all colours?

However, as shown in Table 4-7, a number of the other used hair dye substances also had extreme, strong or a moderate sensitizing potential. It was therefore also relevant to examine:

- Which hair dye substances were used instead of PPD and PTD, and was the sensitizing potential known for these hair dye substances?
- How many of the examined products did not contain any hair dye substances with extreme, strong or moderate sensitizing potential?
 - Further investigation of the abovementioned products; did these contain hair dye substances which had other concerning properties in regard to human health? And what categories of products could be found in this group (permanent/semi-permanent, private/professional etc.)

These questions were answered on the basis of the database that was prepared with the 365 hair dye products.

4.3.10.1 How many of the hair dyes did not contain either PPD or PTD?

Extracts from the database showed that 89 hair dye products did not contain PPD or PTD or any of the PPD or PTD salts or derivatives. However, when only including the PPD and PTD salts and derivatives (i.e. the reference numbers 8, 8a, 9 and 9a in Annex III Part I of the Directive), the total number of products was 86 (as three products contained one of the four listed p-phenylenediamine compounds listed in section 4.3.8.1 “PPD and PTD in hair dye products”). This corresponds to 24% of the hair dye products did not contain neither PPD nor PTD and their salts and derivatives.

4.3.10.2 Do permanent hair dyes without PPD and PTD exist?

Of these 89 hair dye products extracts from the database showed that

- 53 hair dye products were permanent hair dye products (18% of all the investigated permanent hair dye products are without PPD or PTD and their salts and their derivatives)
- 32 hair dye products were semi-permanent hair dye products (41% of all the investigated semi-permanent hair dye products were without PPD or PTD and their salts and derivatives)

- 4 hair dye products were dye rinsing product/direct dyes (100% of all the investigated direct dyes are without PPD or PTD and their salts and derivatives)

TABLE 4-13 DISTRIBUTION OF HAIR DYE PRODUCTS WITHOUT PPD OR PTD AND THEIR SALTS AND DERIVATIVES

Type of hair dye	Private products		Professional products		Total	
Permanent	21	23.6%	32	36.0%	53	59.6%
Semi-permanent	4	4.5%	28	31.5%	32	36.0%
Direct dyes	2	2.2%	2	2.2%	4	4.4%
Total	27	30.3%	62	69.7%	89	100%

4.3.10.3 Do private hair dyes without PPD and/or PTD exist?

Of these 89 hair dye products extracts from the database showed that

- 62 hair dye products were professional hair dye products (30% of all the investigated professional hair dye products are without PPD or PTD and their salts and derivatives)
- 27 hair dye products were hair dye products on the private market (16% of all the investigated hair dye products on the private market were without PPD or PTD and their salts and derivatives)

This means that it was possible to find private hair dye products without PPD or PTD and their salts and derivatives. Of the 27 hair dye products on the private market without PPD or PTD and their salts and derivatives, 21 were permanent hair dye products.

4.3.10.4 Do hair dye products without PPD and PTD exist in all colours?

The table below shows the number of products that existed in the different colours for the 89 hair dye products that did not contain either PPD or PTD and their salts and derivatives.

TABLE 4-14 COLOURS OF HAIR DYE PRODUCTS NOT CONTAINING PPD OR PTD (AND SALTS AND DERIVATIVES)

Hair dye colour	No. of products		Percentage*
Blonde/ash blonde	3	3%	11%
Blue	1	1%	33%
Brown - chestnut	9	10%	39%
Brown - mahogany	3	3%	23%
Brown/dark brown	7	8%	13%
Green	1	1%	50%
Light blonde	20	22%	30%
Light brown/chestnut	11	12%	22%
Dark blonde	3	3%	7%
Orange/yellow	5	6%	83%
Red	19	21%	42%
Black	3	3%	10%
Violet/purple	4	4%	80%
Sum of products	89	100%	

* This column shows the percentage of the hair dye products with this specific colour that contains PPD or PTD (or their salts and derivatives) compared to the total number of hair dye products with this colour.

The table shows that it was possible to find hair dye products in any of the colours without PPD or PTD (and their salts and derivatives).

4.3.10.5 Which hair dye substances were used instead of PPD and PTD?

The table below shows the hair dye substances that were used instead of PPD and PTD (and their salts and derivatives). The table shows the 56 different hair dye substances that were used in 89 hair dye products that did not contain PPD or PTD or any of their salts and derivatives. When comparing to Table 4-7 “Overview of the 95 used hair dye substances in the 365 hair dye products” it can hence be concluded that some of the hair dye substances were only used in combination with PPD or PTD salts or derivatives – at least for the products investigated in this survey.

The table shows that Acid Orange 7, Acid Violet 43 and Lawsonia Inermis Extract (also known as henna) were the three most often used hair dye substances. The table shows that the five most frequently used hair dye substances in hair dye products that did not contain either PPD or PTD (and their salts and derivatives) were either non-sensitizers or a weak sensitizer. Extreme and strong sensitizers did exist in this group of hair dye products too, but only in a few products.

TABLE 4-15 HAIR DYE SUBSTANCES USED IN HAIR DYE PRODUCTS WITHOUT PPD OR PTD OR ANY OF THEIR SALTS AND DERIVATIVES

INCI Name	CAS No.	In no. of products	Restriction	Sensitizing potential	References
ACID ORANGE 7	633-96-5	23	IV/1	Not classifiable	SCCS/1382/10
ACID VIOLET 43	4430-18-6	23	IV/1	Not classifiable	SCCP Memorandum, 2006
LAWSONIA INERMIS EXTRACT	84988-66-9	19	No restriction	Not classifiable	SCCP Memorandum, 2006
HC YELLOW NO. 10	109023-83-8	15	III/197	Not classifiable	SCCP/1080/07
ACID RED 52	3520-42-1	10	III/193	Not classifiable	SCCP/1115/07
ACID BLACK 1	1064-48-8	7	IV/1	Moderate	SCCS/1226/09
BASIC BROWN 16	26381-41-9	6	No restriction	Moderate	SCCP/1165/08
HYDROXYETHYL-2-NITRO-P-TOLUIDINE	100418-33-5	6	III 2/10	Strong/moderate	SCCS/1387/10/Søsted et al., 2004
ACID RED 33	3567-66-6	5	III/194	Not classifiable	SCCP/1102/07
BASIC BROWN 17	68391-32-2	5	No restriction	Strong/moderate	SCCS/1448/11/Søsted et al., 2004
HC BLUE NO. 12	132885-85-9 / 104516-93-0	5	III/225	Moderate	SCCP/1135/07
ACID YELLOW 23	1934-21-0	4	III/189	Strong/moderate	SCCNFP/0786/04/Søsted et al., 2004
BASIC ORANGE 31	97404-02-9	4	No restriction	Moderate	SCCS/1447/11
4-AMINO-2-HYDROXYTOLUENE	2835-95-2	4	III/243	Strong	SCCP Memorandum, 2006
BASIC YELLOW 87	68259-00-7	4	No restriction	Not classifiable	SCCS/1333/10
BASIC RED 76	68391-30-0	4	No restriction	Not classifiable	SCCS/1385/10 Revision of 21 June 2011/Søsted et al., 2004
HC YELLOW NO. 2	4926-55-0	4	No restriction	Strong/moderate	SCCS/1309/10/Søsted et al., 2004
BASIC VIOLET 2	3248-91-7	3	IV/1	Not classifiable	SCCS/1340/10 Revision of 13-14 December 2011/Søsted et al., 2004

INCI Name	CAS No.	In no. of products	Restriction	Sensitizing potential	References
2-AMINO-6-CHLORO-4-NITROPHENOL	6358-09-4	3	III/252	Strong	SCCP Memorandum, 2006
BASIC BLUE 99	68123-13-7	3	No restriction	Strong/moderate	SCCS/1437/11/Søsted et al., 2004
2-HYDROXYETHYL PICRAMIC ACID	99610-72-7	3	III/222	Not classifiable	SCCP/1208/08
BASIC RED 51	77061-58-6	3	No restriction	Not classifiable	SCCS/1436/11
BASIC VIOLET 16	6359-45-1	3	No restriction	No/inadequate data	No opinion/not included in Søsted et al., 2004
BASIC YELLOW 57	68391-31-1	3	No restriction	Not classifiable	SCCS/1231/09 Revision of 12 July 2010/Søsted et al., 2004
P-AMINOPHENOL	123-30-8	3		Strong	SCCS/1409/11
N,N'-BIS(2-HYDROXYETHYL)-2-NITRO-P-PHENYLENEDIAMINE	84041-77-0	3	III/8	Not classifiable	SCCS/1228/09 Revision of 12 July 2010
ACID GREEN 25	4403-90-1	3	IV/1	Not classifiable	SCCP Memorandum, 2006
4-HYDROXYPROPYLAMINO-3-NITROPHENOL	92952-81-3	3	III/205	Not classifiable	SCCP/1082/07
ACID RED 18	2611-82-7	2	III/192	Not classifiable	SCCP Memorandum, 2006
ACID RED 92	18472-87-2	2	No restriction	Not classifiable	SCCS/1428/11 Revision of 26-27 June 2012
ACID YELLOW 3	95193-83-2	2	IV/1	Not classifiable	SCCNFP/0789/04
ACID BLUE 9	3844-45-9	2	III/190	Not classifiable	SCCP Memorandum, 2006
2-METHYL-5-HYDROXYETHYLAMINOPHENOL	55302-96-0	2	III/232	Not classifiable	SCCP Memorandum, 2006
HC RED NO. 11	95576-92-4	2	III/50	No/inadequate data	SCCS/1406/11/not included in Søsted et al., 2004
PIGMENT BLUE 15:1	147-14-8	2	II/1367	Not classifiable	Substance is prohibited (Søsted et al., 2004; 2008/88/EC)
LAWSONE	83-72-7	2	No restriction	Strong	SCCP Memorandum, 2006
HC YELLOW NO. 13	10442-83-8	2	No restriction	No/inadequate data	SCCS/1322/10 Revision of 22 March 2011/Not included in Søsted et al., 2004
HC RED NO. 10	95576-89-9	2	III/50	No/inadequate data	SCCS/1406/11/not included in Søsted et al., 2004
BASIC RED 2	477-73-6	2	II/1322	Not relevant (substance prohibited)	Substance prohibited
SODIUM PICRAMATE	831-52-7	2	No restriction	Moderate	SCCS/1227/10
BASIC RED 46	12221-69-1	2	II/1259	Not relevant (substance prohibited)	Substance prohibited
2,3-DIAMINODIHYDROPYRAZOLO PYRAZOLONE DIMETHOSULFONATE	857035-95-1	1	No restriction	No/inadequate data	No opinion/not included in Søsted et al., 2004
RESORCINOL	108-46-3	1	III/22	Strong	SCCS/1270/09
PIGMENT VIOLET 23	6358-30-1	1	II/1360	Not relevant (substance prohibited)	Substance prohibited
1-HYDROXYETHYL 4,5-DIAMINO PYRAZOLE SULFATE	155601-30-2	1	No restriction	Extreme	SCCS/1449/11

INCI Name	CAS No.	In no. of products	Restriction	Sensitizing potential	References
3-NITRO-P-HYDROXYETHYLAMINOPHENOL	65235-31-6	1	III/250	Extreme	SCCP/1036/06
M-AMINOPHENOL	591-27-5	1	III/217	Strong	SCCP Memorandum, 2006
4-AMINO-3-NITROPHENOL	610-81-1	1	III/215	Extreme	SCCP/1207/08
4-AMINO-M-CRESOL	2835-99-6	1	III/246	Strong	SCCP Memorandum, 2006
6-HYDROXYINDOLE	2380-86-1	1	No restriction	Extreme	SCCP Memorandum, 2006
BASIC RED 22	12221-52-2	1	II/1292	Not relevant (substance prohibited)	Substance prohibited
BASIC GREEN 4	569-64-2	1	II/1188	Not relevant (substance prohibited)	Substance prohibited
ACID YELLOW 1	846-70-8	1	IV/1	Extreme	SCCP/1160/08
HC BLUE NO. 16	502453-61-4	1	No restriction	No/inadequate data	No opinion/not included in Søsted et al., 2004
DISPERSE VIOLET 1	128-95-0	1	No restriction	Moderate	SCCS/1232/09 Revision of 16 September 2010
CURRY RED	25956-17-6	1	III/191	Not classifiable	SCCP Memorandum, 2006
BASIC YELLOW 28	54060-92-3	1	II/1272	Not relevant (substance prohibited)	Substance prohibited
BASIC VIOLET 1	8004-87-3	1	II/388	Not relevant (substance prohibited)	Substance prohibited
5-AMINO-6-CHLORO-O-CRESOL	84540-50-1	1	No restriction	Strong/moderate	SCCS/1225/09 Revision of 07 January 2011/Søsted et al., 2004

4.3.10.6 Which hair dye substances were used instead of PPD and PTD in permanent hair dye products?

As described in section 4.3.8.1 “PPD and PTD in hair dye products” the majority of the hair dye products with PPD or PTD and its salts or derivatives were permanent hair dyes – 94% and 88% respectively. For this reason the hair dye substances used in permanent hair dyes were investigated.

Table 4-16 below shows the hair dye substances that were used instead of PPD and PTD (and their salts and derivatives) in *permanent* hair dyes. 35 different hair dye substances were used in these 52 *permanent* hair dyes that did not contain PPD or PTD or any of their salts and derivatives.

Approximately the same picture is shown in this table Table 4-16 compared to Table 4-15. Acid Orange 7 and Acid Violet 43 are the two most often used hair dye substances. The five most frequently used hair dye substances used in permanent hair dyes that do not contain either PPD or PTD (and their salts and derivatives) are either non-sensitizers or a weak sensitizer. Extreme and strong sensitizers do exist in this group of hair dye products too, but only in a few products.

TABLE 4-16 HAIR DYE SUBSTANCES IN PERMANENT HAIR DYES WITHOUT PPD OR PTD OR ANY OF THEIR SALTS AND DERIVATIVES

INCI Name	CAS No.	In no. of products	Restriction	Sensitizing potential	References
ACID ORANGE 7	633-96-5	18	IV/1	Not classifiable	SCCS/1382/10
ACID VIOLET 43	4430-18-6	17	IV/1	Not classifiable	SCCP Memorandum, 2006
HC YELLOW NO. 10	109023-83-8	15	III/197	Not classifiable	SCCP/1080/07
ACID RED 52	3520-42-1	8	III/193	Not classifiable	SCCP/1115/07
LAWSONIA INERMIS EXTRACT	84988-66-9	8	No restriction	Not classifiable	SCCP Memorandum, 2006
ACID RED 33	3567-66-6	5	III/194	Not classifiable	SCCP/1102/07
ACID BLACK 1	1064-48-8	5	IV/1	Moderate	SCCS/1226/09
4-AMINO-2-HYDROXYTOLUENE	2835-95-2	4	III/243	Strong	SCCP Memorandum, 2006
P-AMINOPHENOL	123-30-8	3		Strong	SCCS/1409/11
BASIC BROWN 17	68391-32-2	2	No restriction	Strong/moderate	SCCS/1448/11/Søsted et al., 2004
LAWSONE	83-72-7	2	No restriction	Strong	SCCP Memorandum, 2006
BASIC BROWN 16	26381-41-9	2	No restriction	Moderate	SCCP/1165/08
PIGMENT BLUE 15:1	147-14-8	2	II/1367	Not classifiable	Substance is prohibited (Søsted et al., 2004; 2008/88/EC)
2-METHYL-5-HYDROXYETHYLAMINOPHENOL	55302-96-0	2	III/232	Not classifiable	SCCP Memorandum, 2006
BASIC RED 46	12221-69-1	2	II/1259	Not relevant (substance prohibited)	Substance prohibited
BASIC RED 2	477-73-6	2	II/1322	Not relevant (substance prohibited)	Substance prohibited
6-HYDROXYINDOLE	2380-86-1	1	No restriction	Extreme	SCCP Memorandum, 2006
2-HYDROXYETHYL PICRAMIC ACID	99610-72-7	1	III/222	Not classifiable	SCCP/1208/08
4-HYDROXYPROPYLAMINO-3-NITROPHENOL	92952-81-3	1	III/205	Not classifiable	SCCP/1082/07
4-AMINO-M-CRESOL	2835-99-6	1	III/246	Strong	SCCP Memorandum, 2006
2,3-DIAMINODIHYDROPYRAZOLO PYRAZOLONE DIMETHOSULFONATE	857035-95-1	1	No restriction	No/inadequate data	No opinion/not included in Søsted et al., 2004
5-AMINO-6-CHLORO-O-CRESOL	84540-50-1	1	No restriction	Strong/moderate	SCCS/1225/09 Revision of 07 January 2011/Søsted et al., 2004
SODIUM PICRAMATE	831-52-7	1	No restriction	Moderate	SCCS/1227/10
RESORCINOL	108-46-3	1	III/22	Strong	SCCS/1270/09
PIGMENT VIOLET 23	6358-30-1	1	II/1360	Not relevant (substance prohibited)	Substance prohibited
M-AMINOPHENOL	591-27-5	1	III/217	Strong	SCCP Memorandum,

INCI Name	CAS No.	In no. of products	Restriction	Sensitizing potential	References
					2006
BASIC YELLOW 57	68391-31-1	1	No restriction	Not classifiable	SCCS/1231/09 Revision of 12 July 2010/Søsted et al., 2004
ACID YELLOW 1	846-70-8	1	IV/1	Extreme	SCCP/1160/08
BASIC RED 76	68391-30-0	1	No restriction	Not classifiable	SCCS/1385/10 Revision of 21 June 2011/Søsted et al., 2004
BASIC RED 51	77061-58-6	1	No restriction	Not classifiable	SCCS/1436/11
BASIC RED 22	12221-52-2	1	II/1292	Not relevant (substance prohibited)	Substance prohibited
BASIC ORANGE 31	97404-02-9	1	No restriction	Moderate	SCCS/1447/11
1-HYDROXYETHYL 4,5-DIAMINO PYRAZOLE SULFATE	155601-30-2	1	No restriction	Extreme	SCCS/1449/11
BASIC BLUE 99	68123-13-7	1	No restriction	Strong/moderate	SCCS/1437/11/Søsted et al., 2004
BASIC YELLOW 87	68259-00-7	1	No restriction	Not classifiable	SCCS/1333/10

4.3.10.7 How many of the examined products did not contain sensitizing hair dye substances?

By use of the database and the sensitizing potential listed for the different hair dye substances, it was examined how many of the products included in this survey that *did not contain* any sensitizing hair dye substances. The results are presented in the table below.

As mentioned earlier 5 products were found to contain one or more hair dye substances that are prohibited according to Annex II of the Cosmetics Directive (“List of substances which must not form part of the composition of cosmetic products”). These 5 products were therefore not included in the tables below.

As mentioned earlier it was decided to exclude 11 products from the tables below, as they cannot be considered as hair dyes (they do not contain hair dye substances). In all 16 products were therefore not included in the tables below, which therefore illustrate how many hair dye products out of a total of 349 investigated products that did not contain sensitizing hair dye substances.

According to Table 4-7 some of the hair dye substances have a sensitizing potential that falls into two different categories (the cases where QSAR information is used and the sensitizing potential “strong/moderate” is given). Therefore the numbers for “strong” and “moderate” are given as one single number (in both Table 4-17 and Table 4-19).

TABLE 4-17 NUMBER OF PRODUCTS (OUT OF A TOTAL OF 349) *WITHOUT* HAIR DYE SUBSTANCES WITH A SPECIFIC SENSITIZING POTENTIAL.

	Extreme	Strong	Moderate	Not classifiable	No data/ inadequate data
Number of products without hair dye substances with the listed sensitizing potential(s)	70	47		147	325
	44				
	11				

Table 4-17 illustrates that 70 out of 349 investigated products in this survey did not contain hair dye substances with an extreme sensitizing potential. If the consumers want to avoid hair dye products with extreme, strong and moderate sensitizing hair dye substances, they should use one of the 44 hair dye products (out of the 349 investigated products).

However, it is important to notice that for 9 of the 95 different hair dye substances no data on their sensitizing potential was found, not even QSAR data. If these substances do in fact have a sensitizing potential, the number of hair dye products without sensitizing hair dye substances will of course be lower (in both Table 4-17 and Table 4-19). However in the group of the 44 products without extreme, strong or moderate hair dye substances only one single hair dye substance has no/inadequate data concerning sensitization. This hair dye substance is found in 2 products (semi-permanent), so all in all the lack of data for sensitization does not affect the final result significantly.

The 44 hair dye products that did not contain any hair dye substances with an extreme, strong or moderate sensitizing potential can be divided into the following types of hair dye products:

- 9 products did not contain any hair dye substances according to definitions in CosIng. 4 of these are direct dyes based on CI colours. 5 are based on e.g. a lawsonia inermis extract that is not listed with the function “hair dye” according to CosIng.
- 30 products are products that could be or were bought at hairdressers that are part of the concept “Green Saloons” (see section 4.1.2.5 “Green Saloons”).
- 5 products are products that are found at either other hairdressers or at different internet shops.

The 44 hair dye products are furthermore described by their product category, type and hair colour in the table below.

TABLE 4-18 CATEGORISATION OF THE 44 HAIR DYE PRODUCTS WITHOUT EXTREME, STRONG OR MODERATE SENSITIZERS

<i>44 hair dye products without extreme, strong or moderate sensitizers</i>		
Product category	Product type	Hair colour
26 permanent	35 professional 9 private	2 black
14 semi-permanent		6 dark brown
4 direct dyes		7 brown chestnut
		2 brown mahogany
		8 light chestnut
		2 dark blonde
		1 orange/yellow
		1 violet
		10 red
		2 ash blonde
		3 light blonde

Table 4-19 illustrates the same aspect. However, this time the numbers are for permanent hair dyes only, i.e. excluding any semi-permanent or direct dyes (and the four permanent hair dyes with one or more of the prohibited hair dye substances and the permanent light blonde hair dyes containing no hair dye substances or CI colours).

TABLE 4-19 NUMBER OF PERMANENT HAIR DYES (OUT OF A TOTAL OF 268) WITHOUT HAIR DYE SUBSTANCES WITH A SPECIFIC SENSITIZING POTENTIAL

	Extreme	Strong	Moderate	Not classifiable	No data/ inadequate data
Number of products without hair dye substances with the listed sensitizing potential(s)	38	28		107	258
	26				
	4				

Table 4-19 illustrates that it was possible to find permanent hair dyes on the Danish market without any sensitizing substances. This means that 26 of the permanent hair dye products (about 9% of the permanent hair dye products) on the Danish market investigated in this survey did not contain hair dye substances with an extreme, strong or moderate sensitizing potential.

5 Products/substances selected for analysis

This section describes the strategy used for selecting products for chemical analysis.

5.1 STRATEGY FOR SELECTING PRODUCTS FOR ANALYSIS

Based on the survey presented in the previous chapter, it was decided in cooperation with the Danish EPA to focus on two aspects when analyzing hair dye products for the content of specific hair dye substances. The two focus areas were:

1. Investigating the quantitative PPD/PTD content in different colours for both permanent and semi-permanent hair dyes.
2. Investigating the concentration of other extremely or strongly sensitizing hair dye substances (in hair dye products with and without PPD respectively).

30 hair dye products in total were selected for chemical analysis of specific hair dye substances. Of the 30 hair dye products 15 were from the private and 15 from the professional market.

5.1.1 Focus area 1 – PTD concentration in different colours

It was decided to select 12 products for the chemical analysis of hair dye substances for focus area 1. The following criteria were used:

- 4 different brands of hair dye products were chosen, i.e. 3 products from each of the 4 brands were chosen. The hair dye brands or specific hair dye products that are used the most or are most popular (according to the survey) were chosen.
- 9 products were permanent hair dyes (i.e. all three products from 3 brands).
- 3 products were semi-permanent hair dyes (i.e. all three products from one brand).
- Each set of 3 products (from the same brands) was selected in the range from dark to bright; i.e. one black or dark brown hair dye, one brown hair dye and one blond or light blond hair dye.
- 2 x 3 products were private hair dye products and 2 x 3 products were professional products.
- The products were selected, so they also contained the hair dye substances that were investigated in focus area 2.

Originally the purpose of this analysis was to investigate how concentrations of both PPD and PTD vary over different colours within a brand. This was changed during the project because of the following reasons:

- Focus was on the most used hair dye brands – and these contained PTD (about 60% of the products contained PTD or PTD sulfate whereas 30% contained PPD or its salts or derivatives).

- It was not possible to buy all the investigated products (especially the professional products) for the chemical analysis, as these are not available on the consumer market. Therefore these products could not be chosen for chemical analysis, unless the producer volunteered to send products for the investigation.
- Not all brands of hair dyes contained three products distributed from dark to the more light colours which all contained PPD. Therefore it was not possible to compare concentrations of PPD from lighter to darker colours.

The products from this focus area were analyzed for the content of:

- PTD and PTD sulfate.
- The other selected hair dye substances (see below).

5.1.2 Focus area 2 – concentration of other sensitizing hair dye substances

For focus area 2 it was decided to select 18 products in total for the chemical analysis of selected hair dye substances. The hair dye products were selected on the basis of the declaration of contents.

The hair dye substances in focus for the chemical analysis were selected using the following criteria:

1. They are used in permanent hair dyes.
2. They are used in several hair dyes (most frequent hair dye substances) – according to Table 4-7.
3. They are either extreme or strong sensitizers.
4. It is possible to perform the chemical analysis with the selected method.

Focus area 2 was split into two different focus areas:

- 2.1 Investigation of the concentration of extremely or strongly sensitizing hair dye substances in hair dye products that did not contain either PPD or PTD or their salts and derivatives.
- 2.2 Investigation of the concentration of the same extremely or strongly sensitizing hair dye substances in hair dye products that did contain either PPD or PTD or their salts and derivatives.

The purpose of this was to compare the concentrations of these extremely or strongly sensitizing hair dye substances in the two groups of hair dyes.

5.1.2.1 Focus area 2.1

Initially, it was investigated, how many products with extremely or strongly sensitizing hair dye substances that *did not contain* either PPD or PTD (and their salt and derivatives). The information in the database showed that 17 products contained extremely or strongly sensitizing hair dye substances and did not at the same time contain neither PPD and/nor PTD (and their salts and derivatives).

These 17 products contained the hair dye substances listed in Table 5-1. The hair dye substances that were selected as a focus for the chemical analysis are marked with grey shading in the table below. The hair dye substances were, as mentioned earlier, selected on basis of their frequency of use (in the total survey) as well as the possibility of performing the chemical analysis of the specific hair dye substances.

When focusing on these selected hair dye substances for the chemical analysis (marked with grey shading), only 5 hair dye products lived up to all the criteria:

1. Did not contain PPD and/or PTD (and their salts and derivatives).
2. Contained one or more of the selected hair dye substances.

All these 5 hair dye products were purchased and analyzed for the content of the selected hair dye substances.

The products from this focus area were analyzed for the content of the selected hair dye substances (see Table 5-1).

TABLE 5-1 HAIR DYE SUBSTANCES WITH EXTREME OR STRONG SENSITIZING POTENTIAL IN PRODUCTS WITHOUT PPD AND/OR PTD (AND THEIR SALTS AND DERIVATIVES). SUBSTANCES SELECTED FOR ANALYSIS ARE MARKED IN GREY SHADING.

CAS Number	INCI Name	Sensitizing potential	In no. of hair dye products (total survey)
108-46-3	RESORCINOL	Strong	218
591-27-5	M-AMINOPHENOL	Strong	193
123-30-8	P-AMINOPHENOL	Strong	132
2835-95-2	4-AMINO-2-HYDROXYTOLUENE	Strong	111
6358-09-4	2-AMINO-6-CHLORO-4-NITROPHENOL	Strong	37
2835-99-6	4-AMINO-M-CRESOL	Strong	26
84041-77-0	N,N'-BIS(2-HYDROXYETHYL)-2-NITRO-P-PHENYLENEDIAMINE	Strong	24
2380-86-1	6-HYDROXYINDOLE	Extreme	22
155601-30-2	1-HYDROXYETHYL 4,5-DIAMINO PYRAZOLE SULFATE	Extreme	10
68391-32-2	BASIC BROWN 17	Strong/moderate	5
68123-13-7	BASIC BLUE 99	Strong/moderate	3
65235-31-6	3-NITRO-P-HYDROXYETHYLAMINOPHENOL	Extreme	2
610-81-1	4-AMINO-3-NITROPHENOL	Extreme	2
83-72-7	LAWSONE	Strong	2
846-70-8	ACID YELLOW 1	Extreme	1

5.1.2.2 Focus area 2.2

13 products in all were selected for the chemical analysis for focus area 2.2.

The 13 products were selected based on the following criteria:

- Did contain either PPD or PTD (and their salts and derivatives).
- Did contain one or more of the selected extreme or strongly sensitizing hair dye substances (marked in Table 5-1).
- Hair dye products from different hair dye brands were chosen. The hair dye brands or specific hair dye products that were used the most or were most popular (according to the survey) were chosen. This means that hair dye products from certain producers were prioritized.
- Both private and professional products were chosen.
- Products were distributed over the entire range of colours.

The products from this focus area were analyzed for the content of:

- PPD and its salts and derivatives
- PTD and its salts
- The other selected hair dye substances.

5.2 SELECTED PRODUCTS FOR CHEMICAL ANALYSIS

In short the following groups of products were selected for chemical analysis for the selected hair dye substances:

- 25 products *with* PPD and/or PTD (and their salts and derivatives) and with one or more of the selected hair dye substances.
 - From four different brands
 - In different colours for each brand
- 5 products *without* PPD and/or PTD (and their salts and derivatives) and with one or more of the selected hair dye substances with an extreme or strong sensitizing potential.

6 Analysis results for selected hair dye substances

6.1 ANALYSIS METHOD FOR HAIR DYE SUBSTANCES

The method used for the quantitative analysis of the selected hair dye substances is based on the method described in a report from NERI “A method for the measurement of intermediates of oxidative hair dyes in cosmetic products” (Rastogi *et al.*, 2001).

The samples were dissolved in a phosphate buffer at pH 6 with ascorbate as antioxidant. The solution was then analyzed by gradient HPLC with UV detection at 220 nm and 275 nm. The hair dye substances were identified via the retention time and the ratio between absorption at the two wavelengths.

For 2-methylresorcinol and 4-amino-2-hydroxytoluen the retention times were almost identical. It was therefore not possible to determine which of the hair dye substances that were present in the sample or if a mixture of the two was present. These two hair dye substances could therefore not be quantified accurately.

By use of this method it was not possible to distinguish between PTD and PTD sulfate. There was an overlap in retention time of 2,4-diaminophenoxy HCl and both p-aminophenol and PTD/PTD sulfate. Whether this overlap was caused by impurities in the reference sample or if the substance at pH 6 was present in two isomers was not possible to determine. Some of the samples had at least two of the three hair dye substances and these were therefore not possible to quantify correctly; especially for 2,4-diaminophenoxyethanol HCl it was not possible to give an exact value. However, it seemed that the content of 2,4-diaminophenoxyethanol HCl always was present in a smaller concentration compared to the two other substances (p-aminophenol and PTD/PTD sulfate).

The detection limits were matrix dependant, as the hair dye products all contained several different substances besides the analytes. Several of these substances absorbed in the UV region and had retention times close to or coincident with the analytes. Especially, in the area between 2-methylresorcinol and 1-naphthol many small overlapping peaks existed, which resulted in higher detection limits for the substances that eluted in the area. This was the case for samples no. 261, 263, 265, 267, and 287, and also in a somewhat weaker tendency in samples no. 142, 122, 118, and 46. Without the influence of the matrix most hair dye substances were generally quantifiable from 0.01 to 0.05% (w/w).

The uncertainty (relatively) was generally 20% based on the results from the duplicate determination and the recovery rates. The uncertainty was a bit higher than 20% for small values and the uncertainty was higher than 20% for sample no. 368 where the results from the duplicate determination had a higher difference than normally seen.

Recovery experiments were carried out for a selection of the substances. Except for sample no. 222 that had a low recovery rate for all three substances, a recovery rate between 80 and 100% was normally observed (see Table 6-1 for details).

TABLE 6-1 RECOVERY RATES FOR SELECTED SUBSTANCES

Substance	Sample No.	Recovery rate (%)
PPD	72	84
PPD	158	76
PPD	266	100
PPD	287	92
PTD/PTD sulfate	83	80
PTD/PTD sulfate	287	84
Resorcinol	158	76
Resorcinol	222	48
4-amino-2-hydroxytoluene	83	80
p-aminophenol	72	96
m-aminophenol	222	40
6-amino-m-cresol	83	84
6-hydroxyindole	158	80
4-amino-3-nitrophenol	222	48
2-methylresorcinol	266	104
1-naphthol	72	88
1-naphthol	266	80
o-aminophenol	287	164

The concentration measured was the concentration (in % (w/w)) in the hair dye paste and not in the final mixed hair dye solution. This was important to notice as the concentration limits that existed for several hair dye substances applied to the final mixed hair dye solution and not on the actual hair dye paste.

6.2 RESULTS

6.2.1 Focus area 1 – PTD concentration in different colours

The purpose of the chemical analysis in focus area 1 was to investigate the quantitative PTD content in different colours for both permanent and semi-permanent hair dyes. Four different hair dye brands were analyzed for the content of PTD in different colours. The results are shown in the tables below (Table 6-2 to Table 6-5).

In general, three products of each brand were analyzed, but one of the brands included four products (a product chosen for focus area 2.1 was included here as well).

TABLE 6-2 RESULTS OF THE QUANTITATIVE ANALYSIS OF SELECTED HAIR DYE SUBSTANCES IN THREE PRODUCTS OF THE SAME BRAND. ALL THREE PRODUCTS WERE FROM BRAND NO. 1, WHICH WAS SEMI-PERMANENT HAIR DYES ON THE PRIVATE MARKET

	Brand 1.A Private and semi- permanent	Brand 1.B Private and semi- permanent	Brand 1.C Private and semi- permanent
Product no.	1	2	3
Hair colour	Dark brown	Dark blonde	Light blonde
Substance	Content in % (w/w)	Content in % (w/w)	Content in % (w/w)
TOLUENE-2,5-DIAMINE or TOLUENE-2,5-DIAMINE SULFATE	2.2	0.34	0.12
RESORCINOL	1.4	0.56	0.1
M-AMINOPHENOL	0.23	0.06	0.015
4-AMINO-2-HYDROXYTOLUENE*	0.3	0.17	no content
2-METHYLRESORCINOL*	0.6	0.22	0.02

* These values were not quantified correctly because of overlap in retention time for the two substances. "No content" means that the product had no declared content of this hair dye substance and no content was detected by the quantitative analysis.

TABLE 6-3 RESULTS OF THE QUANTITATIVE ANALYSIS OF SELECTED HAIR DYE SUBSTANCES IN THREE PRODUCTS OF THE SAME BRAND. ALL THREE PRODUCTS WERE FROM BRAND NO. 2, WHICH WAS PERMANENT HAIR DYES ON THE PRIVATE MARKET

	Brand 2.A Private and permanent	Brand 2.B Private and permanent	Brand 2.C Private and permanent
Product no.	4	5	6
Hair colour	Dark brown	Dark blonde	Light blonde
Substance	Content in % (w/w)	Content in % (w/w)	Content in % (w/w)
TOLUENE-2,5-DIAMINE or TOLUENE-2,5-DIAMINE SULFATE	0.8	0.2	0.08
RESORCINOL	0.51	0.095	0.02
M-AMINOPHENOL	0.18	0.02	trace amount
2-METHYLRESORCINOL	no content	0.03	0.025

"No content" means that the product had no declared content of this hair dye substance and no content was detected by the quantitative analysis.

"Trace amount" means that a small amount around the detection limit has been found, (but the exact amount cannot be quantified).

TABLE 6-4 RESULTS OF THE QUANTITATIVE ANALYSIS OF SELECTED HAIR DYE SUBSTANCES IN THREE PRODUCTS OF THE SAME BRAND. ALL THREE PRODUCTS WERE FROM BRAND NO. 3, WHICH WAS PERMANENT HAIR DYES ON THE PROFESSIONAL MARKET

	Brand 3.A Professional and permanent	Brand 3.B Professional and permanent	Brand 3.C Professional and permanent
Product no.	7	8	9
Hair colour	Black	Dark blonde	Light blonde
Substance	Content in % (w/w)	Content in % (w/w)	Content in % (w/w)
TOLUENE-2,5-DIAMINE or TOLUENE-2,5-DIAMINE SULFATE	1.0	0.45	0.05
RESORCINOL	0.7	0.39	0.03
M-AMINOPHENOL	0.35	0.05	no content
O-AMINOPHENOL	0.15	no content	no content
2,4-DIAMINOPHENOXYETHANOL HCl	Interference from PTD**	no content	0.02
2-METHYLRESORCINOL	0.05*	0.05*	0.03*
4-AMINO-2-HYDROXYTOLUENE	0.035*	0.015*	0.025*

* These values were not quantified correctly because of overlap in retention time for the two substances.

** 2,4-diaminophenoxyethanol HCl overlapped PTD and could not be determined when this was present. "No content" means that the product had no declared content of this hair dye substance and no content was detected by the quantitative analysis.

TABLE 6-5 RESULTS OF THE QUANTITATIVE ANALYSIS OF SELECTED HAIR DYE SUBSTANCES IN FOUR PRODUCTS OF THE SAME BRAND. ALL FOUR PRODUCTS WERE FROM BRAND NO. 4, WHICH WAS PERMANENT HAIR DYES ON THE PROFESSIONAL MARKET

	Brand 4.A Professional and permanent	Brand 4.B Professional and permanent	Brand 4.C Professional and permanent	Brand 4.D Professional and permanent
Product no.	10	11	12	13
Hair colour	Brown mahogany	Dark blonde	Light blonde	Light blonde
Substance	Content in % (w/w)	Content in % (w/w)	Content in % (w/w)	Content in % (w/w)
TOLUENE-2,5-DIAMINE or TOLUENE-2,5-DIAMINE SULFATE	1.4	0.85	0.1	0.12
RESORCINOL	1.2	0.9	0.15	0.4
M-AMINOPHENOL	0.45	0.21	no content	0.04
P-AMINOPHENOL*	1.3	0.9	0.3	0.6
4-AMINO-2- HYDROXYTOLUENE**	0.35	0.2	0.8	no content
6-AMINO-M-CRESOL	0.02	0.1	trace amount	no content
2-METHYLRESORCINOL**	0.55	0.3	0.15	no content
2,4- DIAMINOPHENOXYETHANOL HCl	5*	3*	1.5*	no content
6-HYDROXYINDOLE	0.08	not detected	no content	0.06

* These values were not quantified correctly because of overlap in retention time for the substances (and PTD).

** These values were not quantified correctly because these two compounds overlapped.

"No content" means that the product had no declared content of this hair dye substance and no content was detected by the quantitative analysis.

"Not detected" means that the content of this substance had been declared, but not detected in the quantitative analysis.

"Trace amount" means that a small amount around the detection limit has been found, (but the exact amount cannot be quantified).

The results clearly illustrated that the content of PTD/PTD sulfate and most of the other hair dye substances were highest in the darkest colour (black/dark brown) and lowest in the lightest colour (light blonde).

6.2.2 Focus area 2 – concentration of other sensitizing hair dye substances

The purpose of the chemical analysis in this focus area was to compare the concentrations of other extremely or strongly sensitizing hair dye substances in the two groups of hair dye products – with and without PPD and/or PTD (and their salts and derivatives).

- 5 products *without* PPD and/or PTD (and their salts and derivatives) were analyzed for the content of other selected hair dye substances.
- 13 products *with* PPD and/or PTD (and their salts and derivatives) were analyzed for the content of other selected hair dye substances – and the results of the analyzed content of the 12 hair dye products from focus area 1 could be used for illustration as well (and are therefore presented again below).

6.2.2.1 Focus area 2.1 – products without PPD and/or PTD

TABLE 6-6 RESULTS OF THE QUANTITATIVE ANALYSIS OF SELECTED HAIR DYE SUBSTANCES IN FIVE PRODUCTS WITHOUT PPD AND/OR PTD (AND THEIR SALTS AND DERIVATES).

	Permanent private	Permanent private	Permanent professional	Permanent professional	Semi-permanent professional
Product no.	14	15	16	17	18
Hair colour	Orange/yellow	Red	Red	Red	Light blonde
Substance	Content in % (w/w)	Content in % (w/w)	Content in % (w/w)	Content in % (w/w)	Content in % (w/w)
TOLUENE-2,5-DIAMINE or TOLUENE-2,5-DIAMINE SULFATE	0.07*	no content	no content	no content	no content
RESORCINOL	no content	no content	no content	not detected	no content
M-AMINOPHENOL	no content	0.32	no content	no content	0.01
O-AMINOPHENOL	no content	no content	no content	no content	no content
P-AMINOPHENOL	0.8	no content	0.4	0.21	no content
4-AMINO-2-HYDROXYTOLUENE	0.17	0.26	0.5	0.16	0.009
6-AMINO-M-CRESOL	no content	no content	0.04	no content	no content
2,4-DIAMINOPHENOXYETHANOL HCl	no content	no content	no content	no content	no content
2-METHYLRESORCINOL	no content	0.35**	0.7**	0.21**	no content
4-AMINO-3-NITROPHENOL	no content	no content	0.02	no content	0.018
6-HYDROXYINDOLE	no content	no content	0.08	0.01	0.005
2-AMINO-6-CHLORO-4-NITROPHENOL	no content	no content	no content	no content	0.005

* This content of PTD/PTD sulfate was detected even though such content was not declared on the list of ingredients.

** These values were not quantified correctly because of overlap in retention time for different substances. "No content" means that the product had no declared content of this hair dye substance and no content was detected by the quantitative analysis.

"Not detected" means that the content of this substance had been declared, but not detected in the quantitative analysis.

6.2.2.2 Focus area 2.2 – products with PPD and/or PTD

The 13 products containing PPD and/or PTD as well as the 12 products from focus area 1 are listed in the following tables with their measured contents of the different hair dye substances. The products are grouped according to hair colour, product type and category.

TABLE 6-7 RESULTS OF THE QUANTITATIVE ANALYSIS OF SELECTED HAIR DYE SUBSTANCES IN PRODUCTS CONTAINING PPD AND/OR PTD (AND THEIR SALTS AND DERIVATES).

	Permanent private	Permanent private	Permanent professional
Product no.	19	20	7
Hair colour	Black	Black	Black
Substance	Content in % (w/w)	Content in % (w/w)	Content in % (w/w)
TOLUENE-2,5-DIAMINE or TOLUENE-2,5-DIAMINE SULFATE	1.4	1.15	1.0
RESORCINOL	0.9	0.53	0.7
M-AMINOPHENOL	0.17	0.1	0.35
O-AMINOPHENOL	no content	no content	0.15
P-AMINOPHENOL	no content	no content	no content
4-AMINO-2-HYDROXYTOLUENE*	no content	0.03*	0.035*
6-AMINO-M-CRESOL	trace amount	0.03	no content
2,4-DIAMINOPHENOXYETHANOL HCl	no content	6.6**	uncertain
2-METHYLRESORCINOL*	no content	no content	0.05*
4-AMINO-3-NITROPHENOL	no content	0.03	trace amount
6-HYDROXYINDOLE	no content	no content	no content

* These values were not quantified correctly because of overlap in retention time for the two substances.

** Could not be quantified correctly – the concentration might be overestimated.

“No content” means that the product had no declared content of this hair dye substance and no content was detected by the quantitative analysis.

“Trace amount” means that a small amount around the detection limit has been found, (but the exact amount cannot be quantified).

“Uncertain” means that a positive detection of the substance could not be determined because of overlap in retention time.

TABLE 6-8 RESULTS OF THE QUANTITATIVE ANALYSIS OF SELECTED HAIR DYE SUBSTANCES IN PRODUCTS CONTAINING PPD AND/OR PTD (AND THEIR SALTS AND DERIVATES).

	Semi-permanent professional	Permanent private	Permanent private	Permanent professional	Semi-permanent private
Product no.	21	22	4	23	1
Hair colour	Dark brown	Dark brown	Dark brown	Dark brown	Dark brown
Substance	Content in % (w/w)	Content in % (w/w)	Content in % (w/w)	Content in % (w/w)	Content in % (w/w)
TOLUENE-2,5-DIAMINE or TOLUENE-2,5-DIAMINE SULFATE	0.55	0.8	0.8	0.36	2.2
RESORCINOL	0.06	0.4	0.51	0.2	1.4
M-AMINOPHENOL	no content	0.07	0.18	0.07	0.23

	Semi-permanent professional	Permanent private	Permanent private	Permanent professional	Semi-permanent private
Product no.	21	22	4	23	1
Hair colour	Dark brown	Dark brown	Dark brown	Dark brown	Dark brown
O-AMINOPHENOL	no content	no content	no content	no content	no content
P-AMINOPHENOL	no content	no content	no content	0.22	no content
4-AMINO-2-HYDROXYTOLUENE**	0.43**	uncertain*	no content	0.08**	0.3**
6-AMINO-M-CRESOL	0.05*	no content	no content	0.04	no content
2,4-DIAMINOPHENOXYETHANOL HCl	no content	no content	no content	uncertain*	no content
2-METHYLRESORCINOL**	0.65**	0.07**	no content	0.1**	0.6**
4-AMINO-3-NITROPHENOL	no content	no content	no content	0.01	no content
6-HYDROXYINDOLE	no content	no content	no content	0.02	no content

* These values were not quantified correctly because of overlap in retention time for the three substances.

** These values were not quantified correctly because of overlap in retention time for the two substances.

“No content” means that the product had no declared content of this hair dye substance and no content was detected by the quantitative analysis.

“Uncertain” means that a positive detection of the substance could not be determined because of overlap in retention time.

TABLE 6-9 RESULTS OF THE QUANTITATIVE ANALYSIS OF SELECTED HAIR DYE SUBSTANCES IN PRODUCTS CONTAINING PPD AND/OR PTD (AND THEIR SALTS AND DERIVATES).

	Permanent private	Permanent private	Semi-permanent private	Semi-permanent prof.	Permanent prof.	Permanent prof.
Product no.	5	24	2	25	11	8
Hair colour	Dark blonde	Dark blonde	Dark blonde	Dark blonde	Dark blonde	Dark blonde
Substance	Content in % (w/w)	Content in % (w/w)	Content in % (w/w)	Content in % (w/w)	Content in % (w/w)	Content in % (w/w)
TOLUENE-2,5-DIAMINE or TOLUENE-2,5-DIAMINE SULFATE	0.2	0.385*	0.34	0.52	0.85*	0.45
RESORCINOL	0.095	0.44	0.56	0.055	0.9*	0.39
M-AMINOPHENOL	0.02	0.058	0.06	no content	0.21	0.05
O-AMINOPHENOL	no content	no content	no content	no content	no content	no content
P-AMINOPHENOL	no content	no content	no content	0.05	0.9*	no content
4-AMINO-2-HYDROXYTOLUENE	0.03**	no content	0.17**	0.35**	0.2**	0.015**
6-AMINO-M-CRESOL	no content	no content	no content	0.02*	0.1*	no content
2,4-DIAMINOPHENOXYETHANOL HCl	no content	0.6*	no content	no content	3*	no content
2-METHYLRESORCINOL	0.03**	no content	0.22**	0.46**	0.3**	0.05
4-AMINO-3-NITROPHENOL	no content	no content	no content	no content	0.04*	no content
6-HYDROXYINDOLE	no content	no content	no content	no content	no content	no content
1-NAPHTHOL	no content	no content	no content	0.014	no content	no content

* These values were not quantified correctly because of overlap in retention time for the three substances.

** These values were not quantified correctly because of overlap in retention time for the two substances.

“No content” means that the product had no declared content of this hair dye substance and no content was detected by the quantitative analysis.

TABLE 6-10 RESULTS OF THE QUANTITATIVE ANALYSIS OF SELECTED HAIR DYE SUBSTANCES IN PRODUCTS CONTAINING PPD AND/OR PTD (AND THEIR SALTS AND DERIVATES).

	Permanent professional	Permanent private	Permanent private	Permanent professional
Product no.	10	26	27	28
Hair colour	Brown mahogany	Light chestnut	Light chestnut	Ash blonde
Substance	Content in % (w/w)	Content in % (w/w)	Content in % (w/w)	Content in % (w/w)
P-PHENYLENEDIAMENE	no content	0.25	no content	no content
TOLUENE-2,5-DIAMINE or TOLUENE-2,5-DIAMINE SULFATE	1.4*	no content	0.65*	0.37*
RESORCINOL	1.2	0.16	0.25	0.16
M-AMINOPHENOL	0.45	0.055	0.3	0.03
O-AMINOPHENOL	no content	no content	no content	0.01
P-AMINOPHENOL	1.3*	0.09*	1.2*	0.09*
4-AMINO-2-HYDROXYTOLUENE	0.35**	0.015	0.7**	0.01**
6-AMINO-M-CRESOL	0.02	no content	0.02	no content
2,4-DIAMINOPHENOXYETHANOL HCl	5*	no content	5*	2*
2-METHYLRESORCINOL	0.55**	no content	1.3**	no content**
4-AMINO-3-NITROPHENOL	0.02	no content	0.006	0.02
6-HYDROXYINDOLE	0.08	0.05	no content	no content

* These values were not quantified correctly because of overlap in retention time for the three substances.

** These values were not quantified correctly because of overlap in retention time for the two substances
 "No content" means that the product had no declared content of this hair dye substance and no content was detected by the quantitative analysis.

TABLE 6-11 RESULTS OF THE QUANTITATIVE ANALYSIS OF SELECTED HAIR DYE SUBSTANCES IN PRODUCTS CONTAINING PPD AND/OR PTD (AND THEIR SALTS AND DERIVATES).

	Permanent professional	Permanent private	Semi-permanent private	Permanent private
Product no.	29	6	3	30
Hair colour	Light blonde	Light blonde	Light blonde	Light blonde
Substance	Content in % (w/w)	Content in % (w/w)	Content in % (w/w)	Content in % (w/w)
P-PHENYLENEDIAMENE	0.2	no content	no content	0.04
TOLUENE-2,5-DIAMINE or TOLUENE-2,5-DIAMINE SULFATE	no content	0.08*	0.12	no content
RESORCINOL	0.15	0.02	0.1	0.1
M-AMINOPHENOL	no content	trace amount	0.015	no content
O-AMINOPHENOL	not detected	no content	no content	no content
P-AMINOPHENOL	0.16	no content	no content	0.21
4-AMINO-2-HYDROXYTOLUENE	at detection limit	0.02**	no content	0.02
6-AMINO-M-CRESOL	no content	trace amount	no content	no content
2,4-DIAMINOPHENOXYETHANOL HCl	no content	Interference from PTD*	no content	no content
2-METHYLRESORCINOL	at detection limit	0.025**	0.02**	0.04**
4-AMINO-3-NITROPHENOL	no content	no content	no content	no content
6-HYDROXYINDOLE	no content	no content	no content	no content
1-NAPHTHOL	0.033	no content	no content	no content

* These values were not quantified correctly because of overlap in retention time for the substances.

** These values were not quantified correctly because of overlap in retention time for the two substances
 “No content” means that the product had no declared content of this hair dye substance and no content was detected by the quantitative analysis.

“Not detected” means that the content of this substance had been declared, but not detected in the quantitative analysis.

“Trace amount” means that a small amount around the detection limit has been found, (but the exact amount cannot be quantified).

TABLE 6-12 RESULTS OF THE QUANTITATIVE ANALYSIS OF SELECTED HAIR DYE SUBSTANCES IN PRODUCTS CONTAINING PPD AND/OR PTD (AND THEIR SALTS AND DERIVATES).

	Permanent professional	Permanent professional	Permanent professional
Product no.	9	12	13
Hair colour	Light blonde	Light blonde	Light blonde
Substance	Content in % (w/w)	Content in % (w/w)	Content in % (w/w)
TOLUENE-2,5-DIAMINE or TOLUENE-2,5-DIAMINE SULFATE	0.05*	0.1*	0.12
RESORCINOL	0.03	0.15	0.4
M-AMINOPHENOL	no content	no content	0.04
O-AMINOPHENOL	no content	no content	no content
P-AMINOPHENOL	no content	0.3*	0.6
4-AMINO-2-HYDROXYTOLUENE	0.025**	0.8**	no content
6-AMINO-M-CRESOL	no content	trace amount	no content
2,4-DIAMINOPHENOXYETHANOL HCl	0.02*	1,5*	no content
2-METHYLRESORCINOL	0.03**	0.15**	no content
4-AMINO-3-NITROPHENOL	0.05	no content	no content
6-HYDROXYINDOLE	no content	no content	0.06

* These values were not quantified correctly because of overlap in retention time for the three substances.

** These values were not quantified correctly because of overlap in retention time for the two substances
 "Trace amount" means that a small amount around the detection limit has been found, (but the exact amount cannot be quantified).

The chemical analysis of the 30 hair dye products showed that the following ranges in concentration were measured (see Table 6-13 for details). Not all of the hair dye substances listed below were found in all products.

TABLE 6-13 MINIMUM AND MAXIMUM CONCENTRATION OF THE DIFFERENT HAIR DYE SUBSTANCES COMPARED TO THE ALLOWED MAXIMUM CONCENTRATION ACCORDING TO THE COSMETICS DIRECTIVE.

Measured concentration in % (w/w)	Min	Max	Max conc. after mixing (Cosmetics Directive)
P-PHENYLENEDIAMINE	0.04	0.25	2
TOLUENE-2,5-DIAMINE or TOLUENE-2,5-DIAMINE SULFATE	0.05	2.2	4
RESORCINOL	0.02	1.4	5
M-AMINOPHENOL	0.01	0.45	1.2
O-AMINOPHENOL	0.01	0.15	No longer allowed
P-AMINOPHENOL	0.05	1.3	no restriction
4-AMINO-2-HYDROXYTOLUENE	0.009	0.8	1.5
6-AMINO-M-CRESOL	0.02	0.1	no restriction
2,4-DIAMINOPHENOXYETHANOL HCl	0.02	6.6	2
2-METHYLRESORCINOL	0.02	1.3	1.8
4-AMINO-3-NITROPHENOL	0.005	0.04	1.5
6-HYDROXYINDOLE	0.005	0.08	no restriction
1-NAPHTHOL	0.009	0.045	1.0

The table above showed that in general the measured concentrations were much lower than the allowed concentration limit according to the Cosmetics Directive. Only one product seemed to exceed the concentration limit for 2,4-diaminophenoxyethanol HCl, but it has not been examined if the concentration of the mixed solution actually comply with the concentration limit.

6.3 DISCUSSION OF RESULTS

In this section the following aspects are discussed:

- Concentration of the measured hair dye substances in different colours of hair dyes.
- Concentration of sensitizing hair dye substances in products without PPD/PTD compared to products with PPD/PTD.
- Concentration of hair dye substances in permanent hair dyes compared to semi-permanent hair dyes.

6.3.1 Concentration of hair dye substances in different colours of hair dyes

As presented in section 6.2.1 “Focus area 1 – PTD concentration in different colours” for the four different hair dye brands the results clearly illustrated that the content of PTD/PTD sulfate and most of the other hair dye substances were highest in the darkest colour (black/dark brown) and lowest in the lightest colour (light blonde).

In Table 6-14 the average measured concentration (in % w/w) of the different hair dye substances is given for different colours of the hair dye products analyzed for focus area 2. Only the permanent hair dyes were included in the calculations. This table thus illustrates the average concentration across all the different permanent hair dye products which were analyzed across producers and brands. The table illustrates that for PTD/PTD sulfate, m-aminophenol, 2,4-diaminophenoxyethanol HCl and to some extent for resorcinol the concentration of the hair dye substances was highest in the darkest colours and lowest in the lighter colours (marked with grey shading in the table). However, for the other hair dye substances that had been measured the same pattern had not been seen. This could be due to the fact that different producers used different hair dye substances in different ways.

TABLE 6-14 AVERAGE CONCENTRATION (IN % (w/w)) OF HAIR DYES SUBSTANCES IN DIFFERENT HAIR COLOURS (IN PERMANENT HAIR DYES ONLY)

	Black	Dark brown	Dark blonde	Light blonde
Number of analyzed hair dye products	3	3	4	6
P-PHENYLENEDIAMINE				0.12
TOLUENE-2,5-DIAMINE or TOLUENE-2,5-DIAMINE SULFATE	1.18	0.65	0.47	0.09
RESORCINOL	0.71	0.37	0.46	0.14
M-AMINOPHENOL	0.21	0.11	0.08	0.04
O-AMINOPHENOL	0.15			
P-AMINOPHENOL		0.22	0.90	0.32
4-AMINO-2-HYDROXYTOLUENE	0.03	0.08	0.08	0.22
6-AMINO-M-CRESOL	0.03	0.04	0.10	
2,4-DIAMINOPHENOXYETHANOL HCl	6.60		1.80	0.76
2-METHYLRESORCINOL		0.09	0.13	0.06
4-AMINO-3-NITROPHENOL	0.03	0.01	0.04	0.05
6-HYDROXYINDOLE		0.02		0.06
1-NAPHTHOL				0.033

6.3.2 Concentration of other sensitizing hair dye substances in products with or without PPD/PTD

When comparing the maximum concentration of the measured hair dye substances found in products without PPD or PTD (and their salts and derivatives) – see Table 6-6 – it can be seen that all concentrations were lower (or at the same level) in the products without PPD/PTD compared to the concentration in the products with PPD/PTD. This is illustrated in the table below where the highest measured concentration was given for the different hair dye substances for the permanent hair dye products. However, it must be noted that the number of products for this part of the analysis is very small, and does not permit solid conclusions to be drawn.

TABLE 6-15 HIGHEST MEASURED CONCENTRATION (IN % (W/W)) OF HAIR DYES SUBSTANCES IN PERMANENT PRODUCTS WITH AND WITHOUT PPD/PTD (AND THEIR SALTS AND DERIVATIVES)

Highest concentration measured in products	Without PPD/PTD	With PPD/PTD
P-PHENYLENEDIAMINE	-	0.25
TOLUENE-2,5-DIAMINE or TOLUENE-2,5-DIAMINE SULFATE	-	1.4
RESORCINOL	-	1.4
M-AMINOPHENOL	0.32	0.45
O-AMINOPHENOL	-	0.15
P-AMINOPHENOL	0.8	1.3
4-AMINO-2-HYDROXYTOLUENE	0.26	0.7
6-AMINO-M-CRESOL	0.04	0.1
2,4-DIAMINOPHENOXYETHANOL HCl	-	6.6*
2-METHYLRESORCINOL	0.7	1.3
4-AMINO-3-NITROPHENOL	0.02	0.04
6-HYDROXYINDOLE	0.08	0.08

- not measured

* it was not possible to give an exact value – the concentration might be overestimated.

6.3.3 Concentration of hair dye substances in permanent versus semi-permanent hair dyes

In Table 6-16 the concentration of the different measured hair dye substances is given for permanent hair dyes versus semi-permanent hair dyes. The data was provided only for the colours dark brown and dark blonde, which were the only two colour categories where both permanent and semi-permanent hair dyes were analyzed.

It is difficult to see any clear pattern from this comparison other than perhaps in the dark brown colour where the concentration of all the measured hair dye substances was higher in the semi-permanent hair dyes compared to the permanent hair dyes. This was, however, to some extent, the other way around for the lighter hair colour – dark blonde.

TABLE 6-16 CONCENTRATION (IN % (w/w)) OF HAIR DYES SUBSTANCES IN PERMANENT VERSUS SEMI-PERMANENT HAIR DYES

Concentration of hair dye substances	Permanent hair dyes		Semi-permanent hair dyes	
	Dark brown	Dark blonde	Dark brown	Dark blonde
Number of analyzed hair dye products	3	4	2	2
TOLUENE-2,5-DIAMINE or TOLUENE-2,5-DIAMINE SULFATE	0.65	0.47	1.38	0.43
RESORCINOL	0.37	0.46	0.73	0.31
M-AMINOPHENOL	0.11	0.08	0.23	0.06
O-AMINOPHENOL				
P-AMINOPHENOL	0.22	0.90		0.05
4-AMINO-2-HYDROXYTOLUENE	0.08	0.08	0.37	0.10
6-AMINO-M-CRESOL	0.04	0.10	0.05	0.02
2,4-DIAMINOPHENOXYETHANOL HCl		1.80		
2-METHYLRESORCINOL	0.09	0.13	0.63	0.34
4-AMINO-3-NITROPHENOL	0.01	0.04		
6-HYDROXYINDOLE	0.02			

7 Summary of hazard assessments of selected hair dye substances

The 365 investigated hair dye products contained in all 95 hair dye substances. 44 hair dye products without an extreme, strong or moderate sensitizing potential were found. These contained 12 hair dye substances.

The 44 products are divided into the following types of products:

- 26 products are permanent hair dyes, 14 are semi-permanent hair dyes and 4 are direct dyes. However, none of the direct dyes contains any of the hair dye substances listed in Table 7-1, as the direct dyes only contain cosmetic colorants, i.e. Colour Index substances.
- 35 products are professional hair dyes and 9 products can be bought on the private hair dye market. However, some of the professional products were available at the private market as well.

In order to assess whether the above mentioned products could result in health risks other than allergy, a summary of available hazard assessments was carried out on the 12 substances in these products.

TABLE 7-1 HAIR DYE SUBSTANCES CONTAINED IN HAIR DYE PRODUCTS WITHOUT ANY HAIR DYE SUBSTANCES WITH AN EXTREME, STRONG OR MODERATE SENSITIZING POTENTIAL.

INCI Name	CAS No.	In no. of products	Restriction	Sensitizing potential	References
LAWSONIA INERMIS EXTRACT	84988-66-9	16	No restriction	Not classifiable	SCCP Memorandum, 2006
ACID ORANGE 7	633-96-5	14	IV/1	Not classifiable	SCCS/1382/10
ACID VIOLET 43	4430-18-6	12	IV/1	Not classifiable	SCCP Memorandum, 2006
HC YELLOW NO. 10	109023-83-8	10	III/197	Not classifiable	SCCP/1080/07
ACID RED 52	3520-42-1	3	III/193	Not classifiable	SCCP/1115/07
BASIC VIOLET 16	6359-45-1	2	No restriction	No/inadequate data	No opinion/not included in Søsted et al., 2004
4-HYDROXYPROPYLAMINO-3-NITROPHENOL	92952-81-3	1	III/205	Not classifiable	SCCP/1082/07
ACID GREEN 25	4403-90-1	1	IV/1	Not classifiable	SCCP Memorandum, 2006
ACID YELLOW 3	95193-83-2	1	IV/1	Not classifiable	SCCNFP/0789/04
2-HYDROXYETHYL PICRAMIC ACID	99610-72-7	1	III/222	Not classifiable	SCCP/1208/08
BASIC RED 51	77061-58-6	1	No restriction	Not classifiable	SCCS/1436/11
CURRY RED	25956-17-6	1	III/191	Not classifiable	SCCP Memorandum, 2006

7.1 SOURCES FOR HAZARD ASSESSMENTS OF HAIR DYE SUBSTANCES

The primary source of information has been the SCCS Opinions on the different hair dye substances. However, a search for newer information has also been performed mainly in the following databases:

- TOXLINE

- HSDB
- PUBMED

7.2 SUMMARY OF HAZARD ASSESSMENTS OF SELECTED HAIR DYE SUBSTANCES

7.2.1 LAWSONIA INERMIS EXTRACT (Henna) and LAWSONE

Lawsonia inermis extract can contain up to 2% of lawsone (2-hydroxy-1,4-naphthoquinone) according to SCCP/0943/05 (2005). Therefore both lawsonia inermis extract and lawsone are described below.

7.2.1.1 *Lawsonia inermis* extract – CAS 84988-66-9

Lawsonia inermis extract (also known as henna) is found in 16 of the 44 hair dye products without extreme, strong or moderate sensitizing substances. Lawsonia inermis extract is found in both private and professional products and in both semi-permanent and permanent hair dyes.

A SCCS opinion exists on lawsonia inermis. No other information about the health effects of lawsonia inermis was found.

According to SCCP/0943/05 (2005) lawsonia inermis is not acutely toxic (LD_{50} (rat) > 2000 mg/kg bw).

Lawsonia inermis does not show skin irritating potential in an acute dermal toxicity test, but no skin irritation testing is performed.

Lawsonia inermis is slightly and transiently irritating to the eyes.

Guinea pig test and human repeated insult patch test demonstrated no potential for skin sensitization. Reports on contact allergy from using lawsonia inermis as a hair dye are rare. A few reports on immediate type hypersensitivity (urticaria, rhinitis or asthmatic reactions) exist.

In a sub-chronic (90 days) toxicity test a NOAEL for lawsonia inermis was established at 40 mg/kg bw/day. The effect was hemosiderosis (an increased deposition of iron) in the spleen.

Possible teratogenicity was investigated in a study with rats dosed by gavage on gestation day 6-15 with 0, 40, 200 and 1,000 mg/kg bw/day. The only effect observed in dams was reduced body weight gain and food consumption in the highest dose. Two foetuses of the highest dose showed dilatation of cerebral ventricles and one had cleft palate. Furthermore treatment related reduced ossification was seen in foetuses of both of the two highest dose groups. NOAEL dams = 200 mg/kg bw/day, NOAEL foetuses = 40 mg/kg bw/day.

Mutagenicity tests are inconclusive with regard to clastogenicity. Lawsonia inermis has been shown to induce chromosome aberrations and gene mutation in older studies, whereas newer studies gave negative results from gene mutation testing. It is concluded in the SCCS opinion that additional tests are required.

Conclusion: Lawsonia inermis is not acutely toxic and does not have skin irritating properties, but is slightly irritating to the eyes. Lawsonia inermis does not show sign of being sensitizing. To exclude clastogenic effect of lawsonia inermis additional testing is required. SCCS is of the opinion that the submitted data are insufficient to perform a final safety assessment of lawsonia inermis.

Regulatory status: The European Commission has informed that they are awaiting additional data from industry and a final assessment will be made by the SCCS.

7.2.1.2 *Lawsonia* – CAS 83-72-7

An SCCS opinion and one article found in PubMed have been used for the hazard assessment.

Lawsonia inermis extract can contain up to 2% of lawsone (2-hydroxy-1,4-naphthoquinone, CAS 83-72-7). In the SCCS opinion for lawsonia inermis an analysis shows that the content of lawsone is between 1.17 and 1.48% (SCCP/0943/05, 2005). Almeida et al. (2012) have measured the concentration of lawsone to be between 1.85 and 1.87% in henna leaves. It is stated by the SCCS that the typical concentration in hair dye products is 1.26% (SCCNFP/0798/04, 2004).

According to SCCNFP/0798/04 (2004), lawsone is harmful if swallowed (LD₅₀ value for female rats is 570 mg/kg bw and between 500 and 2000 mg/kg bw for male rats).

Lawsone is mildly irritating to eyes (rabbit), but do not cause appreciable skin irritation. According to the SCCP memorandum on hair dyes, Lawson has a strong sensitizing potential (SCCP Memorandum, 2006).

Two 13 weeks studies on rats have shown clear signs of toxicity to the haemopoietic system (the bodily system of organs and tissues involved in the production of blood, primarily the bone marrow, spleen, tonsils, and lymph nodes), kidney, forestomach and liver. NOAEL was found to be 2 mg/kg bw/day.

It is concluded by the SCCS that the substance shows toxicity to the kidney, stomach and haemopoietic system following repeated oral dosing. It is furthermore concluded that lawsone has mutagenic potential in vitro and in vivo and that therefore no safe threshold for lawsone can be established (SCCNFP/0798/04, 2004). This may also be the reason why some mutagenic activity was shown in some tests of lawsonia inermis (see above).

In a teratogenicity study, rats were dosed 0, 2, 7 and 20 mg/kg bw/day by gavage day 6-15 of gestation. Slight maternal toxicity was seen in the highest dose; reduced food consumption and body weight gain. Foetuses had no treatment related effects. NOAEL dams = 7 mg/kg bw/day, NOAEL foetuses = 20 mg/kg bw/day.

Conclusion: Lawsone is harmful if swallowed, it is not skin irritating, but mildly irritating to the eyes. Lawsone is a strong sensitizer, it has shown some mutagenic potential, but data are inconclusive. SCCS have therefore not established any safe threshold level for lawsone in hair dyes.

Regulatory status: The European Commission has informed that they are awaiting additional data from industry after which a final assessment will be made by the SCCS.

7.2.2 ACID ORANGE 7 - CAS 633-96-5

Acid Orange 7 is found in 14 of the 44 hair dye products without extreme, strong or moderate sensitizing hair dye substances. Acid Orange 7 is in this survey found only in professional products and mostly in permanent hair dyes, but also in some semi-permanent hair dyes.

Two SCCS opinions exist on Acid Orange 7 – information from the newest (SCCS/1382/10, 2011) has been used. In this opinion it is stated that all hits of relevance for a risk assessment of the substance from the databases MEDLINE, TOXNET etc. were included in the opinion. For this reason no search for other information has been performed.

According to SCCS/1382/2010 (2011) Acid Orange 7 is used in hair dyes in a maximum concentration of 0.5%.

Acid Orange 7 has a very low acute toxicity with LD₅₀ values for rats above 10,000 mg/kg bw.

Acid Orange 7 is in available tests not irritating to the skin or eyes. Acid Orange 7 did in guinea pig tests and local lymph node assay not show sign of being a skin sensitizer. Søsted *et al.* (2004) found Acid Orange 7 to have a strong/moderate sensitizing potential in a QSAR model. For the ranking between animal tests and QSAR models in determination of sensitizing potential, see chapter 4.3.8.

The mean dermal absorption of the substance has been found to be 3.43 µg/cm² of skin. This value has been used to calculate the margin of safety (MoS) in the risk assessment of Acid Orange 7.

In a sub-chronic (90 days) oral toxicity study with rats a LOAEL of 2.5 mg/kg bw/day was found. The effects were increased relative weight of the spleen and slight haematological effects (increased met-haemoglobin levels).

In another subchronic study (90 days), the effects of dermal application of 0.1% and 1.0% on rabbits were examined. There were no treatment related effects.

Chronic toxicity was examined by weekly dermal application on 200 mice for 18 months. The dose was 0.1 ml 1%. No adverse reactions were seen in this study.

In a teratogenicity study no other foetal effects than a slight decrease in body weight were observed in highest dose. In the dams reduced food consumption and body weight gain was seen in the highest dose along with discoloured urine and faeces. Two dams had total resorptions in this dose group. In the next highest dose slight decrease in food consumption was seen. In both high dose significant dose-related increased spleen weights was observed. NOAEL of Acid Orange 7 was considered to be 5 mg/kg bw/day for maternal toxicity and 320 mg/kg bw/day for the foetus (SCCS 1382/10, 2011).

Acid Orange 7 has not been found to be mutagenic. Available carcinogenicity studies are not suitable for assessing the carcinogenicity potential of Acid Orange 7.

MoS is calculated to be 25 in the SCCS opinion. A LOAEL of 2.5 mg/kg bw/day adjusted with a factor 3 for LOAEL to NOAEL was used for this calculation. A MoS of at least 100 is necessary in order to conclude that a substance is considered to be safe. Therefore the SCCS concludes that the use of Acid Orange 7 in hair dyes in a maximum concentration of 0.5% is not safe.

Conclusion: Acid Orange 7 has a very low acute toxicity and is not irritating to the skin or eyes. Acid Orange 7 is not considered to be sensitizing. Acid Orange 7 has not been found to be mutagenic or teratogenic. Carcinogenic potential can not be assessed from available studies. The MoS is calculated to be 25 and the SCCS therefore concludes that the use of Acid Orange 7 as a hair dye ingredient poses a risk to the health of the consumer.

Regulatory status: The European Commission has informed that they are awaiting additional data from industry after which the SCCS will perform a reassessment of the safety.

7.2.3 ACID VIOLET 43 – CAS 4430-18-6

Acid Violet 43 is found in 12 of the 44 hair dye products without extreme, strong or moderate sensitizing hair dye substances. Acid Violet 43 is in this survey found primarily in professional hair dyes (only in one single private product), and mostly in permanent hair dyes, but also in some semi-permanent hair dyes.

An SCCS Opinion as well as a single article from PubMed has been used for this assessment.

According to SCCP/0964/05 (2006) Acid Violet 43 is used in hair dyes in a maximum concentration of 0.5%.

Acute oral toxicity tests for Acid Violet 43 do not demonstrate significant toxicity (Fiume, 2001). A study not performed according to modern standards shows an LD₅₀-value of more than 4.640 mg/kg bw (SCCP/0964/05, 2006).

Acid Violet 43 (in 1% solution) is not irritating to rabbit skin or rabbit eyes. Acid Violet 43 is in local lymph node assay not found to be sensitizing. According to Søsted *et al.* (2004) Acid Violet 43 has by use of QSAR been predicted to have a strong/moderate sensitizing potential. For the ranking between animal tests and QSAR models in determination of sensitizing potential, see chapter 4.3.8.

Two oral sub-chronic studies (90 days) with rats are available. NOAEL was found to be 109 mg/kg bw/day and 285 mg/kg bw/day, respectively. The effects were moderate decreases of clinical laboratory values such as values for lymphocytes, phosphate, urea and glucose. Furthermore increased mean clotting time was seen in both males and females.

A dermal sub-chronic study with 0.1 and 1.0% application for 91 days was performed with male rabbits. No treatment related effects were seen.

Two teratogenicity studies are available. In both no effects other than discoloration of faeces (and in one study of placenta as well) were observed. No effects on foetuses were observed. A NOAEL of 435 mg/kg bw/day and 950 mg/kg bw/day for both foetal and maternal toxicity was found.

According to Fiume (2001) Acid Violet 43 is not carcinogenic when applied to mouse skin at a 1% concentration. However the SCCS states that no conclusion regarding carcinogenicity can be drawn.

Acid Violet 43 is not considered to be genotoxic but a clastogenic potential has been shown in high concentrations. It is therefore concluded by the SCCS that further data are needed in order to be able to assess the safe use in hair dyes.

Conclusion: Acid Violet 43 has a low acute toxicity and is not irritating to the skin or eyes. Acid Violet 43 is not considered to be sensitizing. Nor has signs of teratogenicity been demonstrated. Acid Violet 43 has not been found to be genotoxic, but data indicates a clastogenic potential. Carcinogenicity cannot be assessed on the current basis. Further data is needed in order for the SCCS to be able to assess the safety of Acid Violet 43 in hair dyes.

Regulatory status: The European Commission has informed that the substance is under assessment.

7.2.4 HC YELLOW NO. 10 – CAS 109023-83-8

HC Yellow No. 10 is found in 10 of the 44 hair dye products without extreme, strong or moderate sensitizing substances. HC Yellow No. 10 is in this survey only found in professional permanent hair dyes.

An SCCS opinion exists on HC Yellow No. 10. No other information about the health effects of HC Yellow No. 10 was found.

According to SCCP/1080/07 (2007) HC Yellow No. 10 is primarily used in semi-permanent hair dyes and in concentrations of 0.1% (on-head concentration). This is not consistent with the findings in this survey where HC Yellow No. 10 only has been found in permanent hair dyes.

HC Yellow No. 10 is of low acute toxicity as the oral LD₅₀ value for rats was > 2,000 mg/kg.

HC Yellow No. 10 (in 1% solution) is not irritating to rabbit skin or rabbit eyes. According to local lymph node assay HC Yellow No. 10 is not considered to be sensitizing, but according to Søsted *et al.* (2004) HC Yellow No. 10 has by use of QSAR been predicted to have a strong/moderate sensitizing potential. For the ranking between animal tests and QSAR models in determination of sensitizing potential, see chapter 4.3.8.

A maximum dermal absorption of the substance has been found to be 0.134 µg/cm² of skin. This value has been used to calculate the MoS.

In a sub-chronic (90 days) oral toxicity study with rats a NOAEL of 100 mg/kg bw/day was found. The effects were increased weight of liver and spleen.

HC Yellow No. 10 is not found to be mutagenic. There is no data regarding carcinogenicity.

In a teratogenicity study with doses of 0, 100, 300 and 1,000 mg/kg bw/day administered by gavage reduction in maternal weight gain and food consumption was observed in the highest dose. No effects on foetal weight were seen and other effects such as delayed ossification were not considered to be dose related. A NOAEL of 100 mg/kg bw/day for maternal toxicity and for embryo-foetal development was therefore found. No signs of teratogenicity were observed.

A MoS for HC Yellow No. 10 of 62,500 is calculated by SCCS for the maximum concentration of 0.1% in hair dyes . It is concluded that the use of HC Yellow No. 10 in a maximum on-head concentration of 0.1% in hair dyes does not pose a risk to the health of the consumer.

Conclusion: HC Yellow No. 10 has a low acute toxicity and is not irritating to skin or eyes. HC Yellow No. 10 is not considered to be sensitizing. HC Yellow No. 10 has not been found to be mutagenic or teratogenic. No data regarding carcinogenicity exists. Based on a risk assessment SCCS calculates a MoS of 62,500 and therefore concludes that the use of HC Yellow No. 10 as a hair dye ingredient up to a concentration of 0.1% does not poses a risk to the health of the consumer.

7.2.5 ACID RED 52 – CAS 3520-42-1

Acid Red 52 is found in 3 of the 44 hair dye products without extreme, strong or moderate sensitizing hair dye substances. Acid Red 52 is in this survey only found in professional hair dyes and mainly in permanent hair dyes, but also in some semi-permanent hair dyes.

Only an SCCS opinion exists on Acid Red 52.

According to SCCP/1115/08 (2008) Acid Red 52 is used in on-head concentrations up to 1.5% in hair dye formulations.

Acute oral toxicity test for Acid Red 52 established a LD₅₀-value for rats at > 1,000 mg/kg bw/day. An exact value for the acute toxicity of Acid Red 52 has not been established.

Acid Red 52 is considered to be non-irritating to skin and eyes, and has not shown skin sensitizing potential. According to Søsted *et al.* (2004) Acid Red 52 is by use of QSAR predicted to have a weak sensitizing potential. For the ranking between animal tests and QSAR models in determination of sensitizing potential, see chapter 4.3.8.

A dermal absorption value of 1.11 µg/cm² is used for calculation of MoS.

In a sub-chronic (90 days) oral toxicity study with rats a NOAEL of 1,000 mg/kg bw/day was found. No deaths or changes in body weights, food consumption or haematology were seen.

Acid Red 52 is not found to be mutagenic. A carcinogenicity study has been performed with oral administration of test substance in the diet (up to 5%) to rats for 2 years. No treatment related incidence of tumours was seen.

In a teratogenicity study with rats no clinical signs were seen in maternal rats and no foetal effects were observed. Only discoloration of urine and faeces were seen in maternal rats. The differences amongst the relevant reproduction data of the vehicle control group and the dose groups gave no indication of effects related to Acid Red 52. The NOAEL was considered to be 1,000 mg/kg bw/day for maternal toxicity and a NOEL of 1,000 mg/kg bw/day was found for the foetal organism.

A MoS for the maximum concentration of 1.5% in hair dyes was calculated to be 76,923 based on a NOAEL of 1,000 mg/kg bw/day. SCCS therefore concludes that the use of Acid Red 52 in a maximum on-head concentration of 1.5% does not pose any risk to the health of the consumer.

Conclusion: Acid Red 52 has a low acute toxicity and is not irritating to skin or eyes. Acid Red 52 is not considered to be sensitizing. Acid Red 52 has not been found to be mutagenic, carcinogenic or teratogenic. A MoS of about 77,000 has been calculated by the SCCS. The conclusion of the opinion is therefore that the use of Acid Red 52 does not pose a risk to the health of the consumer in a maximum on-head concentration of 1.5%.

7.2.6 BASIC VIOLET 16 – CAS 6359-45-1

Basic Violet 16 is found in 2 of the 44 hair dye products without extreme, strong or moderate sensitizing hair dye substances. Basic Violet 16 is in this survey only found in professional semi-permanent hair dyes.

There is no opinion from SCCS on Basic Violet 16, and no information has been found on the hair dye substance in TOXNET, PubMed or HSDB. No information about the health effects of Basic Violet 16 has been found other than the classification of the substance that has been notified to ECHA (via the C&L Inventory Database).

According to ECHA's C&L Inventory database industry classifies Basic Violet 16 as follows (only the most severe classification regarding human health is listed here):

- Acute Tox. 2 – H300 (Fatal if swallowed) and H330 (Fatal if inhaled)
- Eye Dam. 1 – Causes serious damage to the eyes

Conclusion: According to this classification by the industry it seems that Basic Violet 16 in its concentrated form must be considered as acutely toxic by oral intake and inhalation and to have a potential for causing serious eye damage.

Regulatory status: The European Commission has informed that no data has been submitted by industry. It is not clear whether industry intend to submit a dossier for this substance.

7.2.7 4-HYDROXYPROPYLAMINO-3-NITROPHENOL – CAS 92952-81-3

4-hydroxypropylamino-3-nitrophenol is found in only 1 of the 44 hair dye products without extreme, strong or moderate sensitizing hair dye substances. It is in this survey found mainly in professional products, but also in private products and both permanent and semi-permanent products.

The information in SCCP/1082/07 (2007) is used below as no newer data on the health effects of the substances were found.

According to the opinion 4-hydroxypropylamino-3-nitrophenol is used as a direct hair dye for hair dye products in concentrations up to 2.6% on the head.

The acute oral toxicity of 4-hydroxypropylamino-3-nitrophenol is low as the LD₅₀-values for rats are found to be higher than 2,000 mg/kg bw.

4-hydroxypropylamino-3-nitrophenol is not irritating to rabbit skin, but was found to be irritating to rabbit eyes. According to an LLNA the hair dye substances were determined not to be sensitizing, but Søsted *et al.* (2004) found that 4-hydroxypropylamino-3-nitrophenol was predicted to have a strong/moderate sensitizing potential in a QSAR model. For the ranking between animal tests and QSAR models in determination of sensitizing potential, see chapter 4.3.8.

The maximal dermal absorption of 4-hydroxypropylamino-3-nitrophenol has been determined to be 5.7 µg/cm². This value has been used when calculating the MoS.

A NOAEL of 30 mg/kg bw/day has been demonstrated in a sub-chronic (90 days) oral toxicity study with rats. In the highest dose decrease in ASAT (concentration of an enzyme in amino acid metabolism) in males and increase in absolute thyroid weight in females was seen.

4-hydroxypropylamino-3-nitrophenol is not found to be mutagenic. No data are available on the carcinogenicity of the substance.

In a teratogenicity study with rats no treatment related effects were seen. A NOAEL of 90 mg/kg bw/day for both maternal and foetal toxicity was found.

A MoS was calculated to be 448 for non-oxidative conditions and 1,500 for oxidative conditions for the maximum concentration of 2.6% (“on head”). SCCS therefore concludes that a use of 4-hydroxypropylamino-3-nitrophenol does not pose any risk to the health of the consumer.

Conclusion: 4-hydroxypropylamino-3-nitrophenol has a low acute toxicity and is not irritating to skin, but irritating to the eyes. 4-hydroxypropylamino-3-nitrophenol is not considered to be sensitizing. 4-hydroxypropylamino-3-nitrophenol has not been found to be mutagenic or teratogenic. Data on carcinogenicity is not available. Based on a risk assessment SCCS calculates a MoS of 448 and 1,500 for non-oxidative and oxidative conditions and therefore concludes that the use of 4-hydroxypropylamino-3-nitrophenol in a maximum on-head concentration of 2.6% does not pose any risk to the health of the consumer.

7.2.8 ACID GREEN 25 – CAS 4403-90-1

Acid Green 25 is found in 1 of the 44 hair dye products without extreme, strong or moderate sensitizing hair dye substances. Acid Green 25 is in this survey found only in professional semi-permanent hair dyes.

The information in SCCP/0879/05 (2005) is used below as no newer data on the health effects of the substances were found.

According to the opinion Acid Green 25 is used in semi-permanent hair dyes in a maximum concentration of 0.3% in the finished cosmetic product.

The acute oral toxicity of Acid Green 25 is very low as the LD₅₀-values for rats are found to be higher than 3,160 mg/kg bw in one study and higher than 10,000 mg/kg bw in another.

Data on skin irritation are missing, but SCCS concludes on the basis of the guinea pig maximisation test (GMPT) where a 10% solution has not been found irritating that for the intended use in hair dyes no skin irritating effects are expected. Acid Green 25 is not irritating to rabbit eyes. Acid Green 25 is in the available GPMT not found to be sensitizing. The 5% concentration used for induction is however according to SCCS too low. According to Søsted *et al.* (2004) Acid Green 25 has by use of QSAR been predicted to have a weak sensitizing potential.

A NOEL of 100 mg/kg bw/day has been demonstrated in a sub-chronic (90 days) oral toxicity study with rats. The effects observed were kidney weight increase and a slight decrease in brain weight for the female rats.

No data on reproductive toxicity were available.

Four carcinogenicity studies are apparently performed, but very sparsely reported in the dossier. Almost no information has been submitted to the SCCS on these studies except that two studies with rats were performed with administration of test substance in the diet (up to 1.0%), one in mice (2.0% in the diet) and one in dogs (1.0% in the diet). No carcinogenic effects were reported.

Available data suggests that Acid Green 25 is not mutagenic, but an additional study to exclude chromosomal aberrations should preferably be performed.

The safety of Acid Green 25 can not be assessed based on existing information.

Conclusion: The acute toxicity of Acid Green 25 is very low and the substance is not expected to be skin irritating. It has been found not to be eye irritating and not to be skin sensitizing. Acid Green 25 is not carcinogenic according to available data. Data on the mutagenic properties are few and SCCS concludes that more tests are needed on this point as well as a teratogenicity study in order to assess the safety of the substance.

Regulatory status: The European Commission has informed that Acid Green 25 is under assessment.

7.2.9 ACID YELLOW 3 – CAS 95193-83-2

Acid Yellow 3 is found in 1 of the 44 hair dye products without extreme, strong or moderate sensitizing hair dye substances. Acid Yellow 3 is in this survey only found in professional semi-permanent hair dyes.

Only an SCCS opinion has been used as no other information about the health effects of Acid Yellow 3 was found.

According to SCCNFP/0789/04 (2004) Acid Yellow 3 is used in concentrations up to 0.5% in hair dyes.

Acid Yellow 3 has a low acute oral toxicity in rats and dogs with LD₅₀-values > 2,000 mg/kg bw and > 1,000 mg/kg bw.

Acid Yellow 3 is considered to be slightly irritating to the skin and eyes. Acid Yellow 3 is based on several tests considered not to be sensitizing. According to Søsted *et al.* (2004) the substance is by use of QSAR predicted to have a strong/moderate sensitizing potential. For the ranking between animal tests and QSAR models in determination of sensitizing potential, see chapter 4.3.8.

Several studies have been performed in relation to the evaluation of the substance as a food colour. These studies have not been submitted to the SCCS but only summarized in a table. These data has not shown any signs of the substance being either reproductive toxic, teratogenic or carcinogenic. Toxicity by repeated dose is low. NOAEL of 250 and 50 mg/kg bw/day has been established by different expert groups.

Acid Yellow 3 is not found to be mutagenic, but there are data gaps in the studies.

SCCS assesses that the use of Acid Yellow 3 is acceptable. A MoS of 235 would be the result from using a NOAEL of 50 mg/kg bw/day.

Conclusion: Acid Yellow 3 has a low acute toxicity and is slightly irritating to the skin. Acid Yellow 3 is not considered to be sensitizing. Acid Yellow 3 has not been found to be mutagenic, carcinogenic or teratogenic. The SCCS has based the assessment on other expert opinions as data were not available, but the conclusion is that the use of Acid Yellow 3 in hair dyes is safe.

7.2.10 2-HYDROXYETHYL PICRAMIC ACID – CAS 99610-72-7

2-Hydroxyethylpicramic acid is found in 1 of the 44 hair dye products without extreme, strong or moderate sensitizing hair dye substances. 2-Hydroxyethylpicramic acid is in this survey found in only professional hair dyes, but in both permanent and semi-permanent hair dyes.

No other information on this substance than the SCCS opinion was found.

According to the SCCP/1208/08 (2008) the substance is used in on-head concentrations up to 1.5% in oxidative hair dyes and in on-head concentrations up to 2% in semi-permanent hair dyes.

2-hydroxyethyl picramic acid is harmful if swallowed (LD₅₀ value for female rats were 900 mg/kg bw and 1,134 mg/kg bw for male rats). The acute toxicity by dermal route is low, LD₅₀ > 2,000 mg/kg bw (rats).

2-hydroxyethyl picramic acid is not irritating to rabbit skin, but irritating to rabbit eyes. The substance is reported not to be a sensitizer. Also according to Søsted *et al.* (2004) 2-hydroxyethyl picramic acid is by use of QSAR predicted to have an extremely weak or no sensitizing potential.

A sub-acute study with rats (28 days) was performed with doses up to 450 mg/kg bw/day by gavage administration. Among treatment related effects were increased uric acid level, decreased glucose level, increased absolute and relative adrenal and kidney weights, testicular atrophy and reduced testicular weight. NOAEL was found to be 50 mg/kg bw/day. The effects on the testes were the basis for a classification as toxic to reproduction category 2, former category 3, which was decided in 1993.

A sub-chronic (90 days) oral toxicity study with rats has showed a NOAEL of 20 mg/kg bw/day. The only treatment related effects were activation of the thyroid epithelial cells in males and protein cylinders in the kidney in both sexes. In a second sub-chronic study with rats no treatment related effects were seen. NOAEL was found to be 15 mg/kg bw/day.

2-hydroxyethyl picramic was positive in some *in vitro* mutagenicity assays but the same effects could not be found *in vivo*.

In a teratogenicity study in rats the effects on foetal development were examined. A reduction in food consumption and body weight was reported for maternal rats in the two high dose groups (150 and 450 mg/kg bw/day). An increased incidence of abdominal haemorrhages and a delay in development of the foetuses were noted for the high doses, and an increased incidence of the abdominal haemorrhages was also seen in the mid dose. NOAEL was found to be 50 mg/kg bw/day for both maternal and foetal toxicity.

A 2-generation study in rats is available. A preliminary dose range finding study was performed in which a dose of 450 mg/kg bw/day induced both general systemic toxicity and reproductive toxicity such as prolonged pre-coital time, no implantations, reduced food consumption and reduced body weight gain in dams, abnormal testes and prostate and reduced testes weight. The final dose scheme was on this basis decided to be up to 120 mg/kg bw/day.

In the main 2 generation study no reproductive effects were seen and no general toxicity was seen. The only effect observed was discolouration on the fur in pups of both F1 and F2. NOAEL was found to be 120 mg/kg bw/day.

SCCS states that the classification as toxic to reproduction is based on an assessment from 1993 and the 2 generation study is dated 1996 and does not according to SCCS support this classification.

No data on carcinogenicity has been submitted.

A MoS of 124 for non-oxidative use and 151 for oxidative use has been calculated based on a NOAEL of 20 mg/kg bw/day (sub-chronic toxicity).

Conclusion: 2-hydroxyethyl picramic acid is harmful if swallowed, not irritating to skin, but irritating to eyes, and it is not considered to be sensitizing. It has not been found to have teratogenic or mutagenic potential. It is classified as toxic to reproduction (fertility) but the SCCS has evaluated a 2 generation study of more recent date and does not support the classification.

7.2.11 BASIC RED 51 – CAS 77061-58-6

Basic Red 51 is found in 1 of the 44 hair dye products without extreme, strong or moderate sensitizing hair dye substances. Basic Red 51 is in this survey found in only professional hair dyes, but in both permanent and semi-permanent hair dyes.

The information in the SCCS opinion is used below as no other information on the health effects was found.

According to SCCS/1436/11(2011) Basic Red 51 is used in on-head concentrations up to 1% in both oxidative and non-oxidative hair dyes.

Basic Red 51 is harmful if swallowed (LD₅₀ value for female rats was 250-500 mg/kg bw and 500-1,000 mg/kg bw for male rats). LD₅₀ dermal was > 2,000 mg/kg bw (rats).

Basic Red 51 is not irritating to rabbit skin, but is moderately irritating to rabbit eyes. Basic Red 51 is considered not to be a sensitizer according to guinea pig test.

A 14 day study of dermal toxicity was performed in guinea pigs to investigate the possible cumulative irritation potential. The substance was applied in 0.1, 0.5 and 1.0 %. No skin reaction was observed.

In a sub-acute study (28 days) several minor clinical laboratory effects were seen as well as biochemical changes such as increased cholesterol, triglyceride, phospholipid and albumin level and thyroid discolouration. NOAEL was found to be 12.25 mg/g bw/day.

A NOAEL of 10 mg/kg bw/day is found in a sub chronic (90 days) oral toxicity study with rats. Effects were among others increased level of met-haemoglobin, decreased absolute organ weights, reduced size of thymus, hepatocellular hypertrophy with increased incidence of necrosis and decreased haematopoiesis. Furthermore follicular cell hypertrophy was seen in thyroid and TSH/ACTH cell hypertrophy in pituitary gland.

Basic Red 51 is found to be mutagenic under some circumstances *in vitro*. It was on the other hand not found to have any genotoxic potential *in vivo*.

No data on carcinogenicity has been submitted.

In a teratogenicity study with rats a dose-dependant reduction in food consumption was observed with reduced body weight gain in the high dose group. No effects on the weight of foetuses were noted and no other toxic effects on foetuses were observed except from one cleft palate in the low dose group. NOAEL was found to be 20 mg/kg bw/day for maternal toxicity and 180 mg/kg bw/day for foetal toxicity.

SCCS has calculated a MoS of 1,567 for non-oxidative use and 2,000 for oxidative use. Both are based on a NOAEL of 10 mg/kg bw/day (sub-chronic, oral, rat).

Conclusion: Basic Red 51 is harmful if swallowed, is not irritating to skin, but moderately irritating to the eyes. Basic Red 51 is not considered to be sensitizing, it does not have mutagenic potential and is not considered to be foetotoxic. The SCCS concludes based on MoS values of 1,567 and 2,000 that the use of Basic Red 51 in hair dyes is safe.

7.2.12 CURRY RED – CAS 25956-17-6

Curry Red is found in 1 of the 44 hair dye products without extreme, strong or moderate sensitizing hair dye substances. Curry Red is in this survey only found in one semi-permanent professional hair dye.

The information in the SCCS opinion on Curry Red is used below together with information from HSDB.

According to the SCCNFP/0791/04 (2004) Curry Red is used in semi-permanent hair dyes at a maximum concentration of 0.4% in the finished hair dyes.

Curry Red has a very low acute toxicity as the LD₅₀-value for rats has been found to be more than 10,000 mg/kg bw. Curry Red is not irritating to the eyes of rabbits. Curry Red is slightly irritating to skin according to a test with rabbits not in line with the OECD guidelines. In patch tests with humans a 25% dilution was neither found to be irritating to skin nor skin sensitizing. In LLNA Curry Red did not reveal any potential to be a skin sensitizer and is therefore evaluated not to be a sensitizer (SCCNFP/0791/2004; HSDB). According to Søsted *et al.* (2004) Curry Red has by use of QSAR been predicted to have a strong/moderate sensitizing potential. For the ranking between animal tests and QSAR models in determination of sensitizing potential, see chapter 4.3.8.

As the substance is used as a food colourant several oral studies have been performed. According to the SCCS the studies do not fulfil OECD, EU or EPA guidelines, but scientifically sound evaluation can be made when considering all the available data.

In a 6 weeks study with mice, 0.25 mg/ml drinking water did not induce any treatment related effects. A NOAEL of 3,750 mg/kg bw/day was found in a 7 or 14 days feeding study with rats. Slight reduction of bodyweight was seen. In dogs NOEL of 500 mg/kg bw/day after 6 weeks dosing was found. No effects in any dose were seen.

In a 2 year study with dogs no substance related effects were seen. NOEL was found to be 1,500 mg/kg bw/day. A NOAEL of 1,500 mg/kg bw/day in pigs was found after 76 days of dosing.

In a teratogenicity study with rats no treatment-related effects were noted in either foetuses or maternal rats. Based on the results a NOAEL for Curry Red was considered to be > 1,000 mg/kg bw/day for the maternal and developmental toxicity.

The SCCS has described a long list of studies from the literature concerning embryo/foetotoxicity and reproductive toxicity. No signs of either have been found in the available studies.

Two long term chronic toxicity/carcinogenicity studies were performed with rats and mice respectively. No signs of carcinogenic potential were found. NOAEL was 5.19% in the food.

Mutagenicity has not been tested adequately.

SCCS has calculated a margin of safety, MoS, of 3,000 based on a maximum on-head concentration of 0.4% and a NOAEL of 700 mg/kg bw/day derived from chronic toxicity/carcinogenicity studies with rodents. SCCS concludes that Curry Red does not pose a risk to the health of the consumer in semi-permanent hair dyes.

Conclusion: Curry Red has a very low acute toxicity, is not irritating to skin or eyes and is not considered to be a sensitizer. No sign of carcinogenicity or reproductive toxicity has been demonstrated in numerous studies. The MoS has been calculated to be 3,000 based on a maximum on-head concentration of 0.4% and the SCCS concludes that Curry Red does not pose a risk to the health of the consumer.

7.3 DISCUSSION

Of the 12 hair dye substances, 7 are evaluated as safe by the SCCS, 4 have not adequate data and 1 is assessed not to be safe. For 2 of the 4 substances which needed more data the European Commission has informed that new data is being assessed. For one (lawsonia inermis and lawsone) the European Commission is awaiting further data and for the last of the 4 substances (Basic Violet 16), industry has not yet submitted a dossier and it is not clear whether they intend to do so.

Acid Orange 7 was by the SCCS in an opinion from 2010 considered not to be safe. The European Commission has informed that industry will submit additional studies after which the SCCS will reassess the safety of the substance. A final conclusion on Acid Orange 7 has therefore not been made yet.

The SCCS conclusions and the regulatory status of the abovementioned 12 hair dye substances are summarized in Table 7-2 below.

TABLE 7-2 SUMMARY OF SCCS CONCLUSIONS AND REGULATORY STATUS AS INFORMED BY THE EUROPEAN COMMISSION (COM) OF THE 12 HAIR DYE SUBSTANCES WHICH DO NOT CONTAIN HAIR DYE SUBSTANCES OF EXTREME, STRONG OR MODERATE SENSITIZING POTENTIAL.

INCI Name	SCCS Conclusion	Regulatory status
LAWSONIA INERMIS EXTRACT	Further data needed	COM is awaiting additional data
LAWSONE (a constituent of Lawsonia Inermis)	Further data needed	COM is awaiting additional data
ACID ORANGE 7	MoS < 100 Could pose a health risk	COM is awaiting additional data
ACID VIOLET 43	Further data needed	New data are under assessment
HC YELLOW NO. 10	Safe use	No concern
ACID RED 52	Safe use	No concern
BASIC VIOLET 16	No opinion	No data submitted by industry
4-HYDROXY- PROPYLAMINO-3- NITROPHENOL	Safe use	No concern
ACID GREEN 25	Further data needed	New data are under assessment
ACID YELLOW 3	Safe use	No concern
2-HYDROXYETHYL PICRAMIC ACID	Safe use	No concern
BASIC RED 51	Safe use	No concern
CURRY RED	Safe use	No concern

The purpose of this project was to investigate the market for hair dye products which do not contain hair dye substances with moderate, strong or extreme sensitizing potential – and to investigate whether these hair dye substances might cause other concerns in regard to health. No other ingredients than hair dye substances have been investigated further in this report.

Since not all of the evaluations of the abovementioned 12 hair dye substances have been finalised it is currently not possible to draw a final conclusion regarding possible health concerns on all 12 substances.

Analyzing the distribution of the 7 abovementioned “safe for use” hair dye substances in further details show that only two hair dye products contain only one or more of those 7 hair dye substances. These two products are both red permanent hair dyes for professional use only.

In general it is the responsibility of industry to make sure that any cosmetic product made available on the market is safe for human health when used under normal or reasonably foreseeable conditions of use.

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Survey and occurrence of PPD, PTD and other allergenic hair dye substances in hair dyes

A survey of hair dye products for professional and private use and the content of PPD, PTD and similar substances were performed. In total 365 hair dye products were included in the survey and the hair dye substances were categorised according to sensitizing potential.

Within the group of traditional oxidative hair dye products it was not possible to identify specific types of products or color/tones which posed a reduced risk of hair dye allergy compared to other hair dye products. The survey confirms that practically all oxidative hair dye products contain one or more sensitizing hair dye substances.

A group of alternative non-oxidative hair dye products which did not contain sensitizing hair dye substances to the same degree as the oxidative products were identified, primarily on the professional market. However, several of the hair dye substances in these products have shown signs of other undesirable effects, which are now being further investigated by the scientific committee on consumer safety of the EU.

This survey therefore did not suggest any new recommendations for consumers who wish to dye their hair.



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