DANISH MINISTRY
OF THE ENVIRONMENT
Environmental
Protection Agency

Survey and assessmens of chemical substances in glass and porcelain colours

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COWI

Survey of Chemical Substances in Consumer Products, No. 59 2005

The Danish Environmental Protection Agency will, when opportunity offers, publish reports and contributions relating to environmental research and development projects financed via the Danish EPA.

Please note that publication does not signify that the contents of the reports necessarily reflect the views of the Danish EPA.

The reports are, however, published because the Danish EPA finds that the studies represent a valuable contribution to the debate on environmental policy in Denmark.

Contents

Preface

The Danish Environment Protection Agency (DEPA) has taken an initiative to illustrate the consumers' exposure to chemical substances in consumer products. Several product categories, e.g. hair styling products, hygiene products and glass and porcelain colours for hobby use are covered by the process.

The aim of the project is to give an overview of substances in both CE labelled and non-CE labelled glass and porcelain colours. The survey is based on information from producers, suppliers and other relevant sources.

It has furthermore been the intention to make a human and ecotoxicological assessment of selected substances in the products and to estimate the volume of the impact the consumers and the environment are exposed to if possible. The human and eco toxic assessment is carried out in view of giving input to a possible future risk assessment with special focus on the human toxicological impact and children's possible exposure to the substances.

At the same time it is the intention to document the content of selected chemical substances through chemical analysis of a number of products available on the market. Finally, the need for additional chemical analysis has been assessed based on the results from this survey.

The project report "Survey and assessment of chemical substances in glass and porcelain colours" includes an overview of the manufacturers whose products are on the Danish market, the most important suppliers of the products and the products on the Danish market.

In an overview form, the substances of the glass and porcelain colours are categorised as pigments, binders and additives. The chemical name of the substance, formula, CAS no. and selected physical properties are listed.

The project began in October 2001. Phase 1 ended in December 2001 and Phase 2 in June 2003. However a few analyses were repeated on 4 new products in September 2004. The report was sent in hearing in May 2005 and verification that the ingredients in P1 and P2 have been changed so that they no longer contain 2-butanonoxim has been obtained by the Danish EPA. Furthermore we have been informed that product P12 is no longer on the marked. Product P6 contains methylpyrrolidone but the large content has been ascribed to analysis uncertainty as the manufacturer has provided proof of a lower content based on the recipe and therefore hazard labelling is not required.

The project was carried out by COWI A/S. MILJØ-KEMI, Dansk Miljø Center A/S (now Eurofins Denmark A/S) has made the analysis of selected glass and porcelain colours. The project consisted of Sonja Hagen Mikkelsen (project manager), Sven Havelund, Anders Skibsted Mogensen and Frank Stuer-Lauridsen (quality assurance).

Contact persons in DEPA were Shima Dobel, Annette Orloff and Lise Emmy Møller, Consumer Section, Chemicals Division.

List of Abbreviations

BCF	Bioconcentration factor. The bio concentration factor shows how many times higher the content is in the organism than in the surrounding water at equilibrium.
CAS nr.	Chemical Abstracts Service Registry number
C.I. nr.	Colour Index number
EC50	The concentration of a chemical which causes a certain effect at 50% of the test organisms (Effect concentration)
HAD	Hexamethylene diamine
HDI	Hexane diisocyanate
HMDI	Hexamethylene diisocyanate
Kow	Octanol/water partition coefficient
LC50	The concentration of a chemical that causes death of 50% of the test animals (Lethal concentration)
LD50	The dose of a chemical that causes death of 50% of the test animals (Lethal dose)
MW	Molecular Weight
NOAEL	No Observed Adverse Effect Level (the highest level of the chemical which has no effect on the test animals)
NOEC	No Observed Effect Concentration (the highest concentration of the chemical which has no effect on the test organisms)
RSD	Relative Standard Deviation
S	Solubility
TDI	Toluene diisocyanate

Hazard symbols and R-phrases used

Hazard symbols

Xi	Irritant
Xn	Harmful
C	Corrosive
T	Toxic
Tx	Very Toxic
N	Dangerous to the environment

R-phrases

R10	Flammable
R20	Harmful by inhalation
R21	Harmful in contact with skin
R22	Harmful if swallowed
R23	Toxic by inhalation
R24	Toxic in contact with skin
R25	Toxic if swallowed
R34	Causes burns
R35	Causes serious burns
R36	Irritating to eyes
R37	Irritating to respiratory system
R38	Irritating to skin
R40	Possible risk of cancer
R41	Risk of serious damage to eyes
R42	May cause sensitization by inhalation
R43	May cause sensitization by skin contact

R45	May cause cancer
R50	Very toxic to aquatic organisms
R51	Toxic to aquatic organisms
R52	Harmful to aquatic organisms
R53	May cause long-term adverse effects in the aquatic environment
R65	Dangerous: may cause damage to the lungs if swallowed

Combinations of R-phrases

R20/22	Harmful by inhalation and if swallowed
R20/21/22	Harmful by inhalation, in contact with skin and if swallowed
R21/22	Harmful in contact with skin and if swallowed
R23/24/25	Toxic by inhalation, in contact with skin and if swallowed
R36/38	Irritating to eyes and skin
R36/37/38	Irritating to eyes, respiratory system and skin
R37/38	Irritating to respiratory system and skin
R42/43	May cause sensitization by inhalation and skin contact
R51/53	Toxic to aquatic organisms; may cause long-term adverse effects in the aquatic environment.
R52/53	Harmful to aquatic organisms; may cause long-term adverse effects in the aquatic environment.

Summary and conclusions

Survey

Glass and porcelain colours are hobby products for children and adults. CE labelled products are intended for children under 14 years. Products with the CE mark must conform to the prevailing requirements for toys and are restricted in regard to content and release of certain substances dangerous to health. As all private consumers are not familiar with the CE mark, the Danish Environmental Protection Agency expects that children below 14 years will have a risk of getting into contact with glass and porcelain colours that are not CE marked and do not conform with the safety requirements for toys.

Exposure to substances in the products can occur in the form of direct contact with fingers, hands and face and by inhalation. Exposure of the environment is possible when brushes and pencils are cleaned and disposed of after use. Therefore there is a need to examine the substances the consumers and the environment may be exposed to during use of the products.

There are about 15 producers of glass and porcelain colour and window colour worldwide and most products from these producers are on the Danish market. There are fewer glass and porcelain colours which are CE labeled or carry some other labelling than window colours.

17 pigments, of which two are intermediates, including both inorganic and organic substances are identified in the survey. Among the organic pigments, azo-pigments and polycyclic pigments have been identified. Only one pigment, copper phthalocyanine, containing heavy metal has been identified. None of the inorganic pigments identified in the survey contain heavy metals.

All glass and porcelain colours except one included in the survey and test are water based. Binders are primarily acrylates, often thermoplastic (meth)acrylates. Acrylates consist of acrylic acid and methacrylic acid and their methyl-, ethyl- and butyl esters.

Additives include among others thickeners, surfactants, biocides, anti foaming agents and solvents (co-solvents). In glass and porcelain colour, biocides like isothiazolones and bronopol are used. These biocides are also used in CE marked products. A range of glycols and alcohols are also found in this type of products.

Chemical analysis

Screening analysis of substances in glass and porcelain colours show in general that it is alcohols, glycols, ketones, esters and simple hydrocarbons, which are the main constituents among the extractable substances. Some of these are identified by chemical name and some as substance groups.

The levels in the tested products vary between few mg/kg to 150,000 mg/kg in one product for methylpyrrolidone corresponding to 15% in the product (P6). In the safety data sheet it is declared that the content is 1-1.5%. Butanoneoxim is found in concentrations up to 2.9%.

A hydrocarbon mixture (C_6-C_{12}) of alifatic, alicyclic and aromatic hydrocarbons in concentrations of 17% is found in one product (P12) corresponding to the information in the safety data sheet on the white spirit content.

Examples of other substances identified in relatively high concentrations in a single product are buthoxyethanol (2.4-2.5%) (P9) and phthalic acid anhydride (2.3-3.0%) (P12).

Methoxy(propenyl)phenol (Eugenol) was found in two products in concentrations between 21 and 26 mg/kg (0.0021 and 0.0026%). This substance is considered sensitising by skin contact and is covered by the amendment to the Cosmetic Directive of 27 February 2003 with a requirement to indicate the presence of the substance in the ingredients list when its concentrations exceeds 0.001% in leave-on products, and 0.01% in rinse-off products.

Other substances are found in concentrations ranging from about 0.0004% up to 0.5%, most in the lower end. This is also the case for the substances selected for toxicological evaluation based on the results from the chemical analysis. Most of the concentrations are therefore below the general minimum limits stated in Statutory Order no. 329 of 16 May 2002 from the Ministry of the Environment on classification, packaging, labelling, sale and storage of chemical substances and products (classification order).

Among the metals, lead, zinc, copper, cobalt and titanium have been analyzed. Lead is found in three products in concentrations corresponding to 0.0026 and 0.0027% in the products. Consequently the concentration levels are below 0.15% requires special labelling of lead containing products to be used as paint or lacquers according to the classification order.

Health evaluation

Based on the survey and the results from the chemical analyses, 9 substances have been selected for toxicological evaluation. The substances are:

Name of Substance	CAS no.	Conc. (%)	Function	Source
Anthraquinone	84-65-1	-	Intermediate in pigment production	Survey / chemical analysis
2-butanoneoximee	96-29-7	<0.5 [1)] 2.9 [2)]	Viscosity regulating	Survey / chemical analysis
1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantaen chloride	4080-31-3	<0.5	Biocide	Survey
Diarylide	6358-85-6	0-2	Pigment	Survey
2-Naphtol	135-19-3	-	Intermediate in pigment production	Survey
Quinacridone	1047-16-1	0-2	Pigment	Survey
1,2,3,4,5,6,7,8-octahydroacridine	1658-08-8	0.012-0.18	Additive	Chemical analysis
Diisocyanaet hexane	822-06-0	0.058-0.075	Monomer (PUR)	Chemical analysis
Chloroisocyanaet benzene	3320-83-0	0.015	Monomer (PUR)	Chemical analysis

Of the 9 evaluated substances, three are on the List of Dangerous Substances and one substance is on the Danish EPA's guidance list for self classification. For these substances toxicological literature has been available which supports and to some extent supplements the information expressed through the classification. For the five other substances more limited information or no information on toxicological properties has been available in the searched literature. This is also the situation regarding NOAEL values, and exposure data in relation to human exposure.

Critical effects in relation to the evaluated substances for the intended use are acute toxicity (1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride, 2-naphthol, hexamethylene diisocyanate and 5-isocyanate-1-(isocyanatemethyl)-1,3,3-trimethyl-cyclohexane), possible carcinogenic effects (anthraquinone and 2-butanone oxime) and sensitising effects (anthraquinone, 2-butanone oxime, 2-naphtol, 1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride, diarylide, hexamethylene diisocyanate and chloroisocyanate benzene).

Seven of the 9 substances which are evaluated with regard to health and environmental properties have more or less well documented sensitising potential and four are classified as sensitisers.

In the product P12 phthalic acid anhydride has been identified in concentrations of 2.3 - 3%. This substance must be classified as *sensitising* by skin contact and by inhalation in concentrations of 1% or more. The substance must be expected to come from alkyd resin in the product. The substance will therefore exist in chemically combined form in the product, but can be released by thermal decomposition.

Methylpyrrolidone is found in concentrations between 0.8 and 15%. The substance must be classified as *irritating* to skin and eyes in concentrations of 10% or more.

In total, three of the 10 analysed products (P3, P4 and P8) are CE labelled. Based on information from the suppliers and results from the analyses, all three products are considered to comply with the rules.

Environmental evaluation

With regard to the environmental properties, only few data have been found in the literature about the substances. For two of the substances it is known that they are both very dangerous to aquatic organisms and also very persistent in the environment. Hence it is important to minimise the discharge to the water environment.

1 Introduction

Glass and porcelain colours, as well as window colours, are hobby products for children and adults. The products are used for decoration of glass, bowls etc. with following hardening and burning in an ordinary oven for 40 minutes at 160°C. Some products are CE labelled and as such meant for play use for children below the age of 14. CE labelled products must observe current regulations for toys and are submitted to restrictions related to content and emission of certain substances harmful to health. As not all consumers are familiar with the labelling, DEPA assesses that children below the age of 14 have a risk of getting in contact with glass and porcelain colours which are not CE labelled.

The CE labeling indicates that the toy meets the safety requirements, set out the in Danish Consumer Agency's Statutory Order no. 329 of 23 May 1995 on safety requirements to toy and products which, due to their outward appearance, may be mistaken with food products. Considering the chemical properties of the toy, the requirements are that the toy is produced so that it does not present any health risk. It is the responsibility of the toy manufacturer to observe this.

The rules apply both when the toy is:

- used in the intended way, and
- used in a way which children could be expected to use it.

In general, the toy must not contain dangerous substances in amounts that represents a health risk, i.e. substances that are classified as dangerous and on the List of Dangerous Substances, or which meet the criteria for classification according to the Statutory Order no. 329 of the Ministry of the Environment dated 16 May 2002 on classification, packing, labelling, sale and storage of chemical substances and products. Chemical toys, as defined in DS/EN 71-4 on experimental sets for chemistry experiments and equivalent activities and DS/EN 71-5 about chemical toys (sets) other than sets for chemistry experiments, can be marketed if the content of dangerous substances are below a certain low maximum concentration limit if the chemical substances are necessary for the functioning of the toy.

DEPA's assessment is that CE marked hobby paint products must contain maximum 1% substances that are harmful to health, local irritant or corrosive, where 1% is the so-called de minimis limit. However, this is not relevant if the products are comprised by the standards on sets for chemical use or other chemical toy.

The CE labelling also implies that the toy meets the requirements of maximum labelling of substances with a considerable health impact. Such substances as lead, cadmium, mercury, selenium, chromium, barium, arsenic and antimony.

Exposure to the product substances may occur in form of direct contact with fingers, hands and face and by inhalation. Exposure to the environment is

possible when the brushes are cleaned after usage and when the product is disposed of.

A survey of which substances the consumers and the environment may be exposed to by using glass and porcelain colours is thus relevant and necessary.

The products are sold for private use and have a chemical composition that typically does not require application to the product register. It is thus necessary to obtain information of the content from suppliers and producers. Furthermore, a literature search was carried out for typical constituent substances.

The survey was partly based on literature information, available information from the Internet and partly on information from safety data sheets, suppliers, producers and applicators of chemical products. The project team also contacted the Danish Council for Creative and Hobby Materials (Fællesråd for formnings- og hobbymaterialer). From a consultant, Chemtox, working with the assessment of chemical products in view of their registration in the product register and elaboration of safety data sheets, a list of constituents in glass and porcelain colours was supplied. For confidentiality reasons there is no information about amounts or relation to product and producer names.

Finally, a number of stores were visited to examine the product range and product information on the package.

10 different glass and porcelain colours in different colours were purchased in view of chemical analysis. Subsequently, 9 chemical substances were selected and based on the survey and on results from the chemical analysis of these substances; a toxicological profile was made covering both human toxicological and eco toxicological data.

In agreement with the importers the analyses of 2-butanonoxime were repeated in 2004 on new versions of four products.

2 Composition of and typical constituent substances in hobby colours

Colours and paint contain four basic components. There is a large difference between the selected basic components depending on the function of the colour and requirement to appearance and durability. The four basic components are:

- Pigments
- Binders
- Diluent/vehicle
- Additives

A short description is given in the following of the four types of content.

2.1 Pigments

Primary pigments add whiteness and colour to the product. TiO_2, titandioxid is typically used as white pigment. Colour pigments add colour by selective absorption of light. Organic colour pigments are used (bright/sparkling colours) and inorganic colour pigments (earth colours). Of organic pigments can be mentioned phthalo blue. Inorganic pigments could for example be metal oxides (iron oxide). The actual pigments are normally powder form and they are mixed with the binder and thinned with a dilutent in order to obtain the actual colour.

2.2 Binders

Binders are used to bind the pigment and act as glue. There are oil based and latex based binders. The oil based binder dries/oxidises when exposed to air. Oil based binders may consist of linseed oil or soya oil. Also alkyd can be used in oil based binders.

Latex based binders are used in water based paints. The binder is a solid, plastic like material. The particles are microscopic and contained in the paint. Latex based binders may consist of acrylic or vinyle acrylic (poly vinyl acetate, PVA) or styrene acrylic. Polyurethanpolymerer may also act as a binder.

2.3 Diluent

For oil based paint and alkyd paint a diluter is used. Typically an organic solvent and for latex based paint, water is used as vehicle.

2.4 Additives

Additives are for example:

- Thickeners
- Surface active substances
- Biocides
- Anti-foam material
- Solvents (co-solvents)

Thickeners are used to give the paint the right consistency when used. Surface active substances stabilise the paint so it does not divide and give increased dispersion of pigments. Preservatives prevent undesired bacteria in the paint when stored or after being used. Anti-foam materials prevent foam at blending and applied. Co-solvents are used for non-water based paint and are typically an organic solvent that improves the dissolution of one or several of the components.

3 Survey of suppliers and producers

Glass and porcelain colours are sold in many stores but do not seem to be as prevalent as for example window colours for hobby use. In Denmark the products mainly come from European and American producers. A short overview presenting producers, suppliers and products in the market is shown in the following.

3.1 Producers

The European producers are dominant on the Danish market. Worldwide there are approx. 15 producers of hobby paint /23/. The producers of glass and porcelain colours also make window colours. Table 3.1 presents an overview of the main producers on the Danish market.

Table 3.1 Producers of glass and porcelain colours on the Danish market.

Producer	Country	Internet address
DecoArt	USA	www.decoart.com
Lefranc & Bourgeois	France	www.lefranc-bourgeois.com
Marabu	Germany	www.marabu-links.com
Pébéo Industries	France	www.pebeo.com
Royal Talens	Holland	www.talens.com/
Schjerning Farver A/S	Denmark	www.schjerning-farver.com/

Glass and porcelain colours are popular and can be purchased in both special shops for hobby products, book shops, toy shops and supermarkets and the colours are also sold directly to institutions. You can also buy the colours on-line from suppliers on the Internet.

3.2 Suppliers

Table 3.2 shows a selection of suppliers of glass and porcelain colours in Denmark. Normally, the suppliers only have products from one or two producers.

Table 3.2 Selected Danish suppliers of glass and porcelain colours.

Supplier	Internet address
AV Form A/S	www.avform.dk/
Bøttzauw ApS	www.bottzauw.dk/
Klitgaard ApS	-
Nethobby	www.nethobby.dk
Panduro Hobby	www.panduro-hobby.dk/
Pébéo Color Scandinavia ApS	www.pebeo.dk/
Terapi-hobby ApS	www.terapi-hobby.dk/

3.3 Glass and porcelain colours

Table 3.3 shows the main part of glass and porcelain colours on the Danish market. The label on the package is also listed.

Table 3.3 Glass and porcelain colours on the Danish market

Product Name	Producer	Label
Deco Gloss	Lefranc & Bourgeois	CE
Decorfin Porcelain	Royal Talens	N/A
Decorfin Glass	Royal Talens	N/A
Glasfarve	Schjerning Farver A/S	CE
Glass&Tile	Lefranc & Bourgeois	CE
Porcelaine 150	Pebeo	N/A
Vitrea 160	Pebeo	N/A
Ultra Gloss	DecoArt	AP Non Toxic

Apart from the above there are a number of contour paints for drawing the outline.

4 Survey of constituent substances in glass and porcelain colours

The survey of constituent substances is based on information from producers, suppliers and other relevant sources. As a starting point available information has been obtained from safety data sheets and other product information from suppliers and producers. Furthermore it has been tried, after agreement with the suppliers, to obtain additional information from the producers. All producers have, as a minimum, been contacted by letter, either via the Danish supplier or directly. With this contact the producers have also received an accompanying letter from DEPA with product information and reference to the responsible in DEPA. The request has been followed up by phone and in writing. Two producers have given additional information on constituent substances which is not in the safety data sheets.

However, the survey has not been so extensive that it allowed a very comprehensive collection of data.

Furthermore, a list of constituent substances in a number of glass and porcelain colours has been obtained from the consultant Chemtox. The information covers products in relation to possible registration in the Product Register and the elaboration of safety data sheets.

It is thus safety data sheets on glass and porcelain colours, product information from suppliers and producers and the previously mentioned gross list which are the basis of the survey. All together it has been assessed that this information gives a satisfactory overview of the constituent substances in glass and porcelain colours.

As a minimum, safety data sheets must contain information on dangerous substances as defined in the Statutory Order no. 559 of the Danish Working Environment Service dated 4 July 2002 on special requirements to producers, suppliers and importers etc. of substances and materials according to law on working environment. In some cases, the data sheets also have information about other substances in the product. In total, data sheets or other information from eight products have been used in this survey. For two products there is no information. The result of the survey has also been presented to the Danish Council for Creative and Hobby Materials. The Council has confirmed conformity with the Council's information and the result of the survey.

The constituent substances are divided into the categories:

- Pigments
- Binders
- Diluent/Vehicle
- Additives

4.1 Pigments

Several of the used pigments are both used in other paints and other product types for colouring of e.g. textiles. It is shown in Table 4.1 that both inorganic and organic pigments are used in the glass and porcelain colours.
Of organic pigments azopigments and polyclyclic pigments have been found. There has only been found one pigment, copper phthalocyanine, which contains a dangerous heavy metal. None of the inorganic pigments contain environmentally hazardous heavy metals.

Table 4.1Pigments in glass and porcelain colours and their physical-chemical properties (data from 26, 16 and 17). "-": the value is unknown. "ir": irrelevant.

Subtance (formula)	Trivial name / synonym	CAS nr.	C.I. nr.	Conc. (%)	Used in cosmetic products 1)	MW	S (g/l)	$LogK_{ow}$
Anthraquinone ($C_{14}H_8O_2$)	(medium product)	84-65-1	-	-	No	208,2	< 1	3,39
Carbon black	Pigment black 7	1333-86-4	77266	0-2	1	12,0	insoluable	ir
Diarylide ($C_{32}H_{26}Cl_2N_6O_4$)	Pigment yellow 12	6358-85-6	21090	0-2	*	629,5	< 1	5-7
Dioxazine ($C_{34}H_{22}Cl_2N_4O_2$)	Pigment violet 23	6358-30-1	51319	0-2	4	-	-	-
Isoindolinone	Pigment yellow 110	5590-18-1	56280	-	No	-	-	-
Copper phthalocyanine ($C_{32}H_{16}CuN_8$)	Pigment blue 15	147-14-8	74160	-	1	576,0	< 1	6,6
Mica	Pigment white 20 0g 16	12001-26-2	77019	-	*	-	-	ir
Iron(II)oxide (FeO)	Ironoxide	1345-25-1	77489	-	1	71,8	-	ir
Iron(III)oxide (Fe_2O_3)	Pigment red 101	1309-37-1	77491	0-2	1	159,7	insoluable	ir
2-Naphthol ($C_{10}H_8O$)	(medium product)	135-19-3	-	-	No	144.2	0,755	2,70
Phthalocyanine ($C_{32}H_{16}N_8$)	Pigment blue 16	574-93-6	74100	0-2	4	512,5	< 1	-
N-(4-chloro-2,5-dimethoxyphenyl)-3-hydroxy-4-[[2-methoxy-5-[(phenylamino)carbonyl]phenyl]azo]naphthalene-2-carboxamide ($C_{33}H_{27}ClN_4O_6$)	Pigment red 146	5280-68-2	12485	-	No	-	-	-
2,2'-((3,3'-dichloro-(1,1'-bisphenyl)-4,4'-diyl)-bis-(azo)-bis(N-4'-chloro-2,5-dimethyloxy-phenyl)-3-oxo-butanamide ($C_{36}H_{32}Cl_4N_6O_8$)	Pigment yellow 83	5567-15-7	21108	-	4	818,5	$7,6 \times 10^{-10}$	-7,54
3,4,5,6-tetrachloro-N-[2-(4,5,6,7-tetrachloro-2,3-dihydro-1,3-dioxo-1H-indene-2-yl)-8-quinolyl]phthalimide ($C_{26}H_6Cl_8O_8$)	Pigment yellow 138	30125-47-4	56300	-	No	-	-	-
Quinacridone ($C_{20}H_{12}N_2O_2$)	Pigment violet 19	1047-16-1	73900	0-2	4	312,3	insoluable	-
Quino[2,3-b]acridine-7,14-dione, 5,12-dihydro-2,9-dimethyl ($C_{22}H_{16}N_2O_2$)	Pigment red 122	980-26-7	73915	-	4	340,4	-	-
Titaniumdioxide (TiO_2)	Pigment white 6	13463-67-7	77891	0-2	1	79,9	insoluable	ir

1) The numbers in this column shows how the pigments may be used in cosmetic products.
1: Pigments allowed in all cosmetic products.
2: Pigments allowed in all cosmetic products with the exception of cosmetic products used around the eye, especially eye make-up and cleansing products for eye area.
3: Pigment only allowed in cosmetic products which do not get in contact with the mucous membranes.
4: Pigments only allowed in cosmetic products which have short skin contact.
* May be used in cosmetics, but not as a pigment.

Of pigments and medium products, only 2-napthol is on the List of Dangerous Substances in the danger classes *harmful to health* and *dangerous to the environment* and with the classification Xn;R29/22, N;R50. Isoindolinon is on the recommended list for self classification in the danger class *dangerous to the environment* and with N;R51/53.

4.2 Binders

Acrylate and polyurethanpolymer are used as binders in glass and porcelain colours. Acrylates and metacrylates are used broadly as binders in both water soluble colours and solvent middle based colours. Poly(met)acrylates represent a large group of substances and the composition may vary depending on the desired properties. /25/. Termoplastic (met)acrylates are often used as binders. Acrylates consist of acryl acid and metaacryl acid ant their methyl, ethyl and botylesters (2).

Table 4.2 shows a list of binders in glass and porcelain colours.

Table 4.2 Binders and residual monomers in glass and porcelain colours and their physical-chemical properties (data from 26, 16 and 17). "-": the value is unknown.

Substance (formula)	Content (%)	CAS no.	MW	S (g/l)	$LogK_{ow}$	Danger class	Classification
Acrylis acid ($C_3H_4O_2$)	-	79-10-7	72,1	> 100	0,35	Flammable, harmful, corrosive, dangerous to the environment	R10 Xn;R20/21/22 C;R35 N;R50
Polyurethane polymer	-	68400-67-9	-	-	-	No	No

4.3 Fluid/Vehicle

All of the found glass and porcelain colours are water based - with the exception of one product.

4.4 Additives

According to the information there is a number of additives in glass and porcelain colours.

In Table 4.3 is shown the additives used in glass and porcelain colours and selected physical-chemical properties.

Table 4.3 Additives in glass and porcelain colours and their physical-chemical properties (data from 26, 16 og 17) and classification. "-" : the value is unknown, "ir": irrelevant.

Substance (formula)	Content (%)	CAS no.	MW	S (g/l)	LogK_{ow}	Danger class	Classification [1)]
Aluminium hydroxide ($Al(OH)_3$)	-	21645-51-2	78,0	-	-	-	-
Barium sulfate ($BaSO_4$)	-	7727-43-7	233,4	unsolv.		-	-
Benzylalkohol (C_7H_8O)	-	100-51-6	108,8	42,9	1,1	**Harmful**	**Xn;R20/22**
Benzoic acid p-hydroxy methylester ($C_8H_8O_3$)	-	99-76-3	152,1	2,5	1,96	-	-
Benzoic acid p-hydroxy propylester ($C_{10}H_{12}O_3$)	-	94-13-3	180,2	<1	3,04	-	-
2-Bromo-2-nitropropane-1,3-diol ($C_3H_6BrNO_4$) (Bronopol)	-	52-51-7	200,0	>100	-0,64	**Harmful, irritant, dangerous to the environment**	**Xn;R21/22 Xi;R37/38-41 N;R50**
2-butanoneoxime (C_4H_9NO)	< 0,5	96-29-7	87,1	100	0,63	**harmful , carcinogenic, irritant, sensitizing**	**Xn;R21 Carc3;R40 Xi;R41 R43**
2-(2-Buthoxyethoxy)ethanol ($C_8H_{18}O_3$)	-	112-34-5	162,2	>100	-	**Irritant**	**Xi;R36**
5-Chlor-2-methyl-4-isothiazol-3-one (C_4H_4ClNO)	<0,0012	26172-55-4	149,6	-	-	*Sensitizing*	*R43*
1-(3-Chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride ($C_9H_{16}Cl_2N_4$)	< 0,5	4080-31-3	251,2	> 100	-5,92	-	-
2-Dimethylaminoethanol ($C_4H_{11}NO$)	1-1,5	108-01-0	89,14	1000	-0,94	**Flammable, harmful, corrosive**	**R10 Xn;R20/21/22 C;R34**
Dipropyleneglycol ($C_6H_{14}O_3$)	-	25265-71-8	134,2	> 100	-1,07	-	-
Formaldehyde (CH_2O)	-	50-00-0	30,0	400	0,35	**Toxic, corrosive, carcinogenic, sensitizing**	**T;R23/24/25 C;R34 Carc3;R40 R43**
Naphtha (petroleum) hydrosulphorized, heavy		64742-82-1	-	unsolv.	-	**carcinogenic, harmful**	**Carc2;R45 Xn;R65 Anm. Ae,H,P,4**
Isocyanic acid (CHNO)		75-13-8	43,0	-	0,24	-	-
2-Methyl-4-isothiazol-3-one (C_4H_5NOS)	<0,0004	2682-20-4	115,1	-	-	*Sensitizing*	*R43*
1-Methyl-2-pyrrolidinone (C_5H_9NO)	1-5	872-50-4	99,1	> 100	-0,38	**Irritant**	**Xi;R36/38**
Polypropylene glycol	-	25322-69-4	-	-	-	-	-
Propylene glycol ($C_3H_8O_2$)	1-5	57-55-6	76,1	> 100	-0,92	-	-
Siliciumdioxide (SiO_2)		7631-86-9	60,08	-	ir	-	-
Siliciumdioxide, amorphous (SiO_2)		112945-52-5		-	ir	-	-
Triethanolamine ($C_6H_{15}NO_3$)	-	102-71-6	149,2	> 100	-1,0	*Sensitizing*	*R43*

1) According to List of dangerous substances (in bold) or from the recommended list for own classification (italic).

The most widespread preservative in glass and porcelain colours are isothiazolinones, 2-bromo-2-nitropropane-1, 3-diol (bronopol) and formaldehyde, but also other preservatives are used as listed in the table. For example the parabenes benzo acid p-hydroxy methylester and benzo acid p-hydroxy propylester and the formaldehyde releaser, 1-(3-chloroallyl)-3,5,7-triasa-1-azoniaadamantan chloride (Quarternium-15). These substances have also been found in CE labelled products.

The two isothiazolinones 5-chloro-2-methyl-4-isothiazol-3-one (cas no. 26172-55-4) and 2-methyl-4-isothiazol-3-one (Cas no. 2682-20-4) which are marketed under the name Kathon, are often found in glass and porcelain colours. This also applies for 2-bromo-2-nitropropane-1,3-diol and formaldehyde, which often derives from impurities in the used raw materials or from release of formaldehyde releasers (preservatives).

The two isothiazolinone derivatives are both in a low concentration in glass and porcelain colours and are under the de minimis limit according to the safety data sheets for the examined products. The substances are also present in for example cosmetic products, where the permitted limit is 0,0015%.

5 Chemical analyses

5.1 Test products

Table 5.1 shows the products included in the project.

Table 5.1 Test products selected for qualitative analysis

P-No.	Colour
P1	Blue Ming
P2	Turquoise
P3	Sky blue
P4	Ultramarine
P6	Sky blue
P8	Mandarine
P9	Lemon yellow
P10	Oriental green
P11	Citrus yellow
P12	Red

5.2 Methods of analysis

5.2.1 GC/MS screening (extractable substances)

Approximately 5 g of the product was taken and extracted with dichloor-methane added internal standard by using Soxhlet extraction for 16 hours. A part sample of the extract was taken and analysed directly as well as concentrated at combined gas chromatography and mass spectrometry (GC/MS) by scanning over a large mass area. The content is calculated compared to internal standards.

The analyses were carried out as genuine double specifications. The detection limit is 1-5mg/kg for components that are semi-quantified. The uncertainty is 10-20% RSD.

The analyses of 2-butanoneoxime were repeated in 2004 on four new versions of the products P1, P2, P10 and P11. The detection limit is 50 mg/kg. The uncertainty is 15% RSD.

5.2.2 X-ray

A part sample was examined using x-ray technique to discover the content of 40 elements. This analysis was outsourced.

The analyses were carried out as genuine double specifications. The detection limit is 10 mg/kg. The uncertainty of the analysis is 5-10% RSD.

5.2.3 Water content by Karl Fisher titration

The water content of the sample is determined by automatic titration using the Karl Fisher titration method (KF).

The analyses are made as genuine double specifications. The uncertainty of the analysis is 10% RSD.

5.2.4 IR-screening

A part sample was taken which was pressed into a potassium bromide tablet to be analysed by the FT-IR analysis to determine content of organic main parts by comparison with data library spectra.

The analyses were carried out as genuine double specifications. The analysis will not be reported separately. The result of the screenings has been used to support the result of the GC/MS screening.

5.2.5 Identification of azo pigments

A part sample test is refluxed with alkaline sodium dithionite and the azo pigment is transformed to arylamine by a reductive decomposition. An analysis for arylamines is made by use of high pressure chromatography (HPLC).

The detection limit is 5 mg/kg and the uncertainty is 10% RSD.

The analysis includes the following amines:

4-Aminodiphenyl, Benzidine, 4-Chloro-o-toluidin, 2-Naphthylamine, p-Chloraniline, 2,4'-Diaminoanisol, 4,4'-Diaminodiphenylmethan, 3,3'-Dichlorbenzidin, 3,3'-Dimethoxybenzidine, 3,3'-Dimethylbenzidine, 3,3'-Dimethyl-4,4'-diaminodiphenylmethane, p-Cresidine, 4,4'-Methylene-bis-(2-chloraniline), 4,4'-Oxydianiline, 4,4'-Thiodianiline, o-Toluidine, 2,4-Toluendiamine, 2,4,5-Trimethylaniline, o-Aminoazotoluene and 2-Amino-4-nitrotoluene.

The analysed amines are all covered by restrictions in the Statutory Order no. 755 of the Ministry of the Environment on prohibition of import, sale and use of certain pigments dated 15 August 2003. Azo pigments, which can emit these amines in concentrations above 30 ppm in the final products or in the coloured parts hereof, are not allowed to be used in textile or leather colours which may be in direct contact with human skin or mouth in for a longer period.

5.3 Test results

5.3.1 GC/MS screening (extractable substances)

The results from the GC/MS screening are shown below. The two results indicate the double specification. The substances were identified from the mass spectre by comparing with the mass specter in a data library. Specters, which represent the best match, are in each case assessed by "scientific judgment". In those cases where identification is not possible, the components

are part of a group designation with a total sum. The detection limit is 1-5 mg/kg.

The DEPA requested that standards for each component were included, some were detected in the GC/MC screening and others were found at the survey.

These components are thus calculated compared to the equivalent external reference substances and marked by a ^ in the table. For all other organic components a semi quantative calculation has been made against internal standards. The detection limit for components compared to external standard is 1 mg/kg and the uncertainty is 10-15% RSD.

For a few components the content was so large that it was necessary to dilute the sample in order to calculate the content correctly. Those components are listed by
** in Table 5.2 and Table 5.3.

Because of findings in the survey DEPA wished to include the pigment diarylide (C.I. pigment yellow 12) as external standard. This component could not be obtained as standard why it was decided to analyse for a number of azo pigments in the two relevant samples of porcelain colours (yellow colours). The analysis for azo pigments is made by changing possible azo pigments into arylamines and then analyse for a total of 20 arylamines.

The results of the repeated analyses on the four products P1, P2, P10 and P11 are presented in table 5.4.

Table 5.2. Analysis results of extractable substances in glass and porcelain colours. The two results refer to the double specification. The results are in mg/kg. The detection limit is described above.

	P1		P2		P3		P4		P6	
1,2 propandiol*	-	-	-	-	27000	10000	5700	3200	5000	6900
2-butanoneoxime ^	43000	24000	33000	36000	-	-	-	-	-	-
Ethylbenzene	41	36	-	-	-	-	-	-	-	-
Xylen (sum of isomers subst.)	300	250	19	16	-	-	-	-	-	-
Toluene	-	-	-	-	-	-	-	-	-	-
Methylheptan (two tops)	-	-	-	-	-	-	-	-	-	-
Trimethylcyclohexan	-	-	-	-	-	-	-	-	-	-
Styrene^	-	-	-	-	1600	1500	460	610	240	180
Methylpyrrolidon^	12000	8000	15000	13000	-	-	-	-	120000 **	150000 **
Hydrocarbon mixture: alifatic, alicyclic and aromatic hydrocarbons (C6-C12)	-	-	-	-	-	-	-	-	-	-
Dodecan	-	-	-	-	-	-	-	-	-	-
Dimethylundecan	-	-	-	-	-	-	-	-	-	-
Dimethylamino methylpropanol	-	-	-	-	2100	1500	-	-	-	-
Ethylhexanol	-	-	-	-	680	320	-	-	-	-
Butoxy ethanol	-	-	-	-	-	-	-	-	1700	1600
Phenylethyl alcohol	27	47	-	-	-	-	-	-	-	-
(1-methyl-4-(1-methylethyl)-3-cyclohexen-1ol)	-	-	-	-	-	-	-	-	-	-
Ethylhexyl acetic acid ester	-	-	-	-	-	-	-	-	-	-
Methylpropensyre butyl ester	-	-	-	-	-	-	-	-	230	174
Methylpentyl cyclohexan	-	-	-	-	-	-	-	-	-	-
Chloroanilin^	-	-	-	-	-	-	-	-	-	-
Chloroisocyanat benzen^	-	-	-	-	-	-	-	-	-	-
Isocyanat ethoxyphenyl^	-	-	-	-	-	-	-	-	-	-
Methoxy benzenamin	-	-	-	-	-	-	-	-	-	-

	P1		P2		P3		P4		P6	
Benzoic acid	470	350	15	8,8	-	-	-	-	-	-
(2,4-dimethyl-pentandisyre dimethylester)	-	-	-	-	17	8,7	-	-	-	-
Butoxyethoxy ethanol	-	-	2300	2400	-	-	-	-	2400	2300
Methenamin^	-	-	-	-	-	-	-	-	-	-
Menthenol	150	120	-	-	-	-	-	-	-	-
Terpineol	39	33	-	-	-	-	-	-	-	-
Ethylhexylakrylat	-	-	13	18	1400	650	71	56	42	20
Phthalsyre anhydrid^	840	990	-	-	190	250	190	180	-	-
Phthalsyre anhydrid, isomere	110	77	-	-	-	-	-	-	-	-
Anthraquinon^	-	-	-	-	-	-	-	-	-	-
2-naphtalenol^	-	-	-	-	-	-	-	-	-	-
1,2,3,4,5,6,7,8-octahydroacridin^	-	-	-	-	-	-	-	-	-	-
Bis(2-methylpropyl) butandiene acid ester	-	-	-	-	4800	2200	2800	2500	-	-
Dibutyl pentandisyre ester	-	-	-	-	4000	4200	4500	4300	-	-
Bis(2-methylpropyl) hexandisyre ester	-	-	-	-	4400	4300	3100	2900	-	-
Hexamethylen-1,6-diisocyanat	750	680	610	580	-	-	-	-	-	-
Isocyanat methoxy benzene	-	-	-	-	-	-	-	-	-	-
2-methyl-propansyre 3-hydroxy-2,4,4-trimethylpentyl ester	-	-	-	-	-	-	-	-	-	-
Chloro nitro benzeneamin	-	-	-	-	-	-	-	-	-	-
Tributyl phosphate	-	-	-	-	-	-	-	-	-	-
Cyclodecan	-	-	16	17	-	-	-	-	-	-
Methoxy(propenyl)phenol	21	21	-	-	-	-	-	-	-	-
Methylbiphenyl^	29	26	-	-	-	-	-	-	-	-
BHT	-	-	17	15	-	-	-	-	8,9	11
5-isocyanat-1-(isocyanatmethyl)-1,3,3-trimethyl-cyclohexan and isomere combinations	< 0.5 ***	< 0.5 ***	-	-	-	-	-	-	-	-
Benzylbenzoat	5,6	6,7	-	-	-	-	-	-	-	-
1-[4-(1,1-dimethylethyl)-2,6-dimethyl-3,5-dinitrophenyl]-ethanon	16	13	-	-	-	-	-	-	-	-
Hexadecaneacid	57	63	11	11	28	10	-	-	-	-
Octadecandienacid	-	-	-	-	-	-	-	-	-	-
Phthalat (sum of to tops)	29	31	-	-	-	-	-	-	-	-
DEHP	-	-	-	-	11	9,4	-	-	-	-
Unid. alkanes, alkenes, alcohols, cycloalkanes/- alkenes	4500	3600	7800	7700	260	150	36	34	950	1500
Unid. carboxylsyrer, esters, ketoner, aldehydes og amides	340	200	250	230	13000	5400	1000	890	130	110
Unid. glycol og oxysubstances	320	270	510	490	940	430	670	580	890	1000
Uidentificerede aromatiske substances	640	560	52	55	880	780	110	90	13	12
Other unidentified substances	5000	4700	1100	1000	1500	1500	270	250	510	520

-: below the detection limit
*: underestimated due to top before GC/MS start
**: the sample is diluted due to a large content
^: the components are calculated against an external standard.

Table 5.3 Analysis results of extractable substances in glass and porcelain colours. The two results refer to the double specification. The results are in mg/kg. The detection limit is described above.

	P8		P9		P10		P11		P12	
1,2 propandiol*	6200	13000	180	240	-	-	4600	5000	-	-
2-butanoneoxime^	-	-	-	-	18000	30000	79000	92000	17000	29000
Ethylbenzen	5,7	4,1	-	-	-	-	49	82	-	-
Xylen (sum of isomere comb.)	12	8,9	-	-	26	29	560	460	-	-
Toluen	-	-	-	-	-	-	-	-	45	50
Methylheptan (two tops)	-	-	-	-	-	-	-	-	157	155
Trimethylcyclohexan	-	-	-	-	-	-	-	-	700	700
Styren^	1000	1600	730	700	1800	2100	330	240	-	-
Methylpyrrolidon^	-	-	-	-	21000 **	22000 **	28000 **	30000 **	-	-
Kulbrinteblanding: alifatiske, alicycliske and aromatic kulbrinter (approx. C6-C12)	-	-	-	-	-	-	-	-	170000	170000
Dodecan	-	-	-	-	-	-	-	-	1600	2100
Dimethylundecan	-	-	-	-	-	-	-	-	300	400
Dimethylamino methylpropanol	2800	4800	-	-	-	-	-	-	-	
Ethylhexanol	370	480	-	-	-	-	-	-	-	-
Butoxy ethanol	-	-	25000	24000	-	-	-	-	-	-
Phenylethyl alcohol	-	-	-	-	-	-	37	37	-	-
1-methyl-4-(1-methylethyl)-3-cyclohexen-1ol	-	-	-	-	-	-	13	7,8	-	-
Ethylhexyl eddikesyre ester	46	59	32	30	-	-	-	-	-	-
Methylpropensyre butyl ester	-	-	970	890	-	-	-	-	-	-
Methylpentyl cyclohexan	-	-	-	-	-	-	-	-	99	170
Chloroanilin^	-	-	250	240	-	-	-	-	-	-
Chloroisocyanat benzen^	-	-	150	150	-	-	-	-	-	-
Isocyanat ethoxyphenyl^	-	-	-	-	-	-	-	-	-	-
Methoxy benzenamin	-	-	93	87	-	-	-	-	-	-
Benzosyre	-	-	-	-	-	-	490	530	-	-
(2,4-dimethyl-pentandisyre dimethylester)	-	-	-	-	-	-	-	-	-	-
Butoxyethoxy ethanol	-	-	-	-	2600	2800	-	-	-	-
Methenamin^	81	140	350	390	-	-	-	-	-	-
Menthenol	-	-	-	-	-	-	160	300	-	-
Terpineol	-	-	-	-	-	-	44	54	-	-
Ethylhexylakrylat	670	1000	140	130	210	230	120	84	-	-
Phthalsyre anhydrid^	89	63	39	50	-	-	246	193	23000	30000
Phthalsyre anhydrid, isomere	-	-	-	-	-	-	170	170	-	-
Anthraquinon^	-	-	-	-	-	-	-	-	34	55
2-naphtalenol^	-	-	-	-	-	-	-	-	-	-
1,2,3,4,5,6,7,8-octahydroacridin^	-	-	-	-	-	-	-	-	1200	1800
Bis(2-methylpropyl) butandisyre ester	3400	3800	-	-	-	-	-	-	-	-
Dibutyl pentandisyre ester	5000	4700	-	-	-	-	-	-	-	-
Bis(2-methylpropyl) hexandisyre ester	3200	3100	-	-	-	-	-	-	-	-
Hexamethylen-1,6-diisocyanat^	-	-	-	-	450	520	640	490	-	-
Isocyanat methoxy benzene	-	-	29	30	-	-	-	-	-	-
2-methyl-propansyre 3-hydroxy-2,4,4-trimethylpentyl ester	-	-	260	280	-	-	-	-	-	-
Chloro nitro benzenamin	-	-	5,2	5,2	-	-	-	-	-	-
Tributyl phosphate	-	-	170	160	-	-	-	-	-	-
Cyclodecan	-	-	-	-	-	-	-	-	-	-
Methoxy(propenyl)phenol	-	-	-	-	-	-	26	24	-	-
Methylbiphenyl^	-	-	-	-	-	-	52	65	-	-
BHT					7,1	9,9	-	-	-	-
5-isocyanat-1-(isocyanatmethyl)-1,3,3-trimethyl-cyclohexan and isomers substances	-	-	-	-	< 0.	< 0	< 0.5	< 0.5	-	-
Benzylbenzoat	-	-	-	-	-	-	-	-	-	-

	P8		P9		P10		P11		P12	
1-[4-(1,1-dimethylethyl)-2,6-dimethyl-3,5-dinitrophenyl]-ethanon	-	-	-	-	-	-	16	20	-	-
Hexadecanacid	9,0	18	-	-	7,1	13	83	120	440	1100
Octadecandienacid	-	-	-	-	-	-	-	-	1800	3600
Phthalat (sum of two tops)	-	-	-	-	-	-	-	-	-	-
DEHP	-	-	-	-	-	-	-	-	-	-
Uid. alkaner, alkener, alkoholer, cycloalkaner/- alkener	49	68	200	180	7200	8500	6600	4600	7900	10000
Unid. carboxylsyrer, esters, ketones, aldehydes and amides	1800	3200	230	230	2100	2400	1400	810	11000	12000
Unid. glycols and oxycombinations	850	1000	2000	2000	1500	2100	240	190	-	-
Unidentified aromatic combinations	580	1000	200	180	710	670	55	49	1400	1500
Other unidentified	890	1400	560	550	560	750	2600	2400	17000	22000

-: below the detection limit
*: underestimated due to top before GC/MS start
**: the sample is diluted due to a high content
^: the components are calculated against an external standard.

Table 5.4 Analysis results of repeated analyses of 2-butanoneoxime in four products. The two results refer to the double specification. The results are in mg/kg. The detection limit is described above.

	P1		P2		P10		P11	
2-Butanonoxime^	14000	16000	18000	16000	20000	21000	18000	19000

^: betyder at komponenter er regnet overfor ekstern standard.

The new analyses in 2004 show concentrations of 2-butanonoxime in the range from 1.4 to 2.1%.

The substances in table 5.2, table 5.3 and table 5.4 are listed in Appendix A with CAS numbers.

5.3.2 X-ray analyses

Table 5.4 shows the results of the x-ray analyses. The elements not listed in the table were not detected at the analysis. The analysis is made by a single specification for reliability reasons. The detection limit is 10 mg/kg.

Table 5.4 The results from the x-ray analyses of glass and porcelain colours. The results are in mg/kg.

	P1	P2	P3	P4	P6	P8	P9	P10	P11	P12
Sodium	-	-	-	-	-	-	-	-	-	180
Magnesium	-	-	-	-	480	-	790	-	-	-
Aluminium	170	-	-	170	-	-	2400	19	300	4200
Silicium	320	440	650	1300	1400	650	3500	180	310	950
Phosphorus	28	200	-	23	-	-	550	220	33	2800
Sulphur	21	200	510	590	54	490	270	210	21	280
Chlorine	92	180	33	580	220	850	900	11000	330	670
Potassium	-	-	-	-	-	-	-	-	-	97
Calcium	18	16	-	43	14	-	19	-	21	1700
Titanium	3300	-	-	7100	-	-	59000	-	5300	-
Vanadium	-	-	-	25	-	-	190	-	16	-
Iron	-	-	-	-	-	-	70	-	-	52
Cobalt	-	-	-	-	-	-	-	-	-	560
Copper	190	1400	85	1200	1100	-	-	840	-	74
Zinc	-	-	-	-	-	-	-	-	-	980
Tin	-	-	-	17	15	-	16	-	-	-

Lead	-	-	26	-	-	27	-	-	-	27

-: below the detection limit.

5.3.3 Water content

Table 5.5 and 5.6 show the results of water content analyses. The two values refer to the double specifications.

Table 5.5 Results of water analyses of glass and porcelain colours. The results are in %.

	P1		**P2**		**P3**		**P4**		**P6**	
Water	62	62	58	58	51	50	45	43	40	37

Table 5.6 Results of water analyses of glass and porcelain colours. The results are in %.

	P8		**P9**		**P10**		**P11**		**P12**	
Water	47	48	39	40	58	58	58	58	1,2	1,0

5.4 Azo pigments

Table 5.7 shows the results of the analysis of azo pigments. The analysis was only carried out in two yellow porcelain colours as agreed between COWI and DEPA.

Table 5.7 The results for arylmines of two selected glass and porcelain colours. The results are in mg/kg.

	P9		**P11**	
4-Aminodiphenyl	-	-	-	-
Benzidine	-	-	-	-
4-Chloro-o-toluidine	-	-	-	-
2-Naphthylamine	-	-	-	-
p-Chloraniline	-	-	-	-
2,4'-Diaminoanisol	-	-	-	-
4,4'-Diaminodiphenylmethane	-	-	-	-
3,3'-Dichlorbenzidine	-	-	-	-
3,3'-Dimethoxybenzidine	-	-	-	-
3,3'-Dimethylbenzidine	-	-	-	-
3,3'-Dimethyl-4,4'-diaminodiphenylmethane	-	-	-	-
p-Cresidine	-	-	-	-
4,4'-Methylene-bis-(2-chloraniline)	-	-	-	-
4,4'-Oxydianiline	-	-	-	-
4,4'-Thiodianiline	-	-	-	-
o-Toluidine	-	-	-	-
2,4-Toluene diamine	-	-	-	-
2,4,5-Trimethylaniline	-	-	-	-
o-Aminoazotoluene	-	-	-	-
2-Amino-4-nitrotoluene	-	-	-	-

-: below the detection limit.

5.5 Summary of analyses

The screening analyses of constituent substances in glass and porcelain colours generally show that it is especially alcohols, glycols, ketones, esters, and simple hydrocarbons. Some of them are identified by name and others as substance groups. The levels in the different products vary from a few mg/kg to 150,000 mg/kg equivalent to 15%.

Methylpyrrolidone which is found in the highest concentration among these substances, are at a double specification measured to be between 8,000 and 150,000 mg/kg equivalent to 0.8-15.0% in the three products (P1, P2, P6, P10 and P11). 2-butanone oxime has been found in five products in concentrations between 1.4 and 2.9% (P11) and butoxyethanol in a concentration 2.4-2.5%.

Among the other substances it is a hydrocarbon composition (C_6-C_{12}) of alifatic, alicyclic and aromatic hydrocarbons that are found in the highest concentration (17%). Furthermore phthalic acid anhydride (2.3-3.0%) is an example of another substance and group of substances that by double specification has been found in relatively high concentrations in one product. Toluene diisocyanate has been measured to 3.0-7.4% in one product.

Methoxy(propenyl)phenol (Eugenol) has been found in 2 products in concentrations between 21 and 26 mg/kg (0.0021 and 0.0026%).

Other substances have been found in concentrations from approx. 4 mg/kg (0.0004%) and up to approx. 5000 mg/kg (0,5%), most in the lower end. This also applies for the substances selected for toxicological assessment based on the chemical analyses. The substances are listed in Table 5.8.

Anthraquinone and 2-butanoneoxime were selected in the first place on the basis of the survey. 2-butanonoxime was at the first analyses found in concentrations in the range from 1.7 to 9.2%. The repeated analysis in 2004 has shown concentration levels from 1.4 to 2.1% for the four products P1, P2, P10 and P11.

Table 5.8 Selected substances for environmental and health assessment

Substance	Measured concentration in mg/kg	% in the product
Anthraquinone	34-55	0.0034-0.0055
2-Butanone oxime	14000-29000	1.4-2.9
Chloroisocyanate benzene	150	0.015
Hexamethylene-1,6-diisocyanate	450-750	0.045-0.075
1,2,3,4,5,6,7,8-octahydroacridine	1200-1800	0. 12-0.18

Of metals lead, zinc, copper, cobalt and titanium have been found. Lead has been found in concentrations of 26 and 27 mg/kg equivalent to 0.0026 and 0.0027% in the products. In this way the concentration limits below 0.15% which requires special labelling of lead products to be used for chemical products as paint or varnish according to the Statutory Order no. 329 of the Ministry of the Environment dated 16 May 2002 on classification, packing, labelling, sale and storage of chemical substances and products.

The adjusted analytical result for lead in accordance with Danish Standard, DS/EN 71-3:1995 on safety requirements to toys and migration of particular materials is maximum 18.9 mg/kg (calculated based on the maximum

measured concentration of 27 mg/kg). The adjusted analytical result is considerably below the standards requirements to the marginal value for migration of lead from toys of 90 mg/kg. The marginal value for migration of lead has been calculated based on the requirement of set out in the Statutory Order no. 1161 dated 12. December on safety requirements to toy.

Copper has been found in concentrations of up to 0.14%, cobalt in one product with a concentration of 0.056% and zinc also in one product in a concentration of 0.098%.

Two yellow porcelain colours have been examined for content of azo pigments with a negative result.

The analyses have thus determined approx. 50% (weight) of the content of all the products. Other constituent substance components are primarily binders and fillers.

6 Selection of substances and data search

6.1 Background for selection of substances

At the initial survey 17 substances were identified in the pigment group (including two intermediate products), two substances in the group of binders and their residual monomers and 22 substances in the group of additives. Among these substances which both has been identified based on general information about content in glass and porcelain colours and concrete information about the test products only 3 substances have been found in connection with the chemical analyses. In this connection it should be underlined that the screening analyses do not specify all substances. A number of substances are grouped under the designations alkanes, alkenes, alcohols, cycloalkanes/-alkenes, glycols and oxy compounds, aromatic compounds and other unidentified substances. Many of the substances found during the survey must be assumed to be covered by these unit designations. This also applies for the additives which are identified in the survey and shown in Table 6.1. The survey also includes a number of pigments which you would not expect to find at screening analysis of only 10 products.

Based on the results from the survey and the chemical analysis of the test products, DEPA has selected a number of test products which should be assessed in view of their health and environmental profile. For these 10 substances a toxicological profile has been elaborated based on available literature.

At the selection the concentration of the substances has been considered and existing knowledge on/or assessments of the substances in connection with consumer products. The selected substances thus represent substances that are found in the highest concentrations in the test products and the substances which DEPA requested to be analysed.

6.2 Selected substances

Table 6.1 gives an overview of selected substances to be assessed for health and environmental properties:

Table 6.1 Overview of selected substances to be assessed for environment and health properties

Substance	CAS no.	Conc. (%)	Function	Source
Anthraquinone	84-65-1	-	Intermediate substance in pigment production	Chemical survey / chemical analysis
2-Butanone oxime	96-29-7	<0,5 [1)] 2.9 [2)]	Regulating viscosity	Chemical survey / chemical analysis
1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride	4080-31-3	<0.5	Biocide	Chemical survey
Diarylide	6358-85-6	0-2	Pigment	Chemical survey
2-Naphtol	135-19-3	-	Intermediate substance in pigment production	Chemical survey

Substance	CAS no.	Conc. (%)	Function	Source
Quinacridone	1047-16-1	0-2	Pigment	Chemical survey
1,2,3,4,5,6,7,8-octahydroacridine	1658-08-8	0.012-0.18	Additive	Chemical survey
Hexamethylene-1,6-diisocyanate	822-06-0	0.045-0.075	Monomer (PUR)	Chemical survey
Chloroisocyanate benzene	3320-83-0	0.015	Intermediate substance in pigment production	Chemical survey

6.3 Data search

Data for the substances' physical-chemical properties were collected from a number of internet based databases.

1. Chembank
2. Chemfinder
3. Ullmann
4. NTP
5. SAX
6. TOXLINE
7. MEDLINE
8. HSDB
9. IRIS
10. CCRIS
11. GENETOX
12. IUCLID
13. PHYSPROP
14. BIODEG
15. BIOLOG
16. ECOTOX

There will be a certain overlap between several of these databases. Table 6.2 gives an overview of the result of the data search. The overview shows whether the 14 databases contained data for each substance.

Table 6.2. Overview of the result of the data search. The number of the databases refer to:
1. Chembank, 2. Chemfinder, 3. Ullmann, 4. NTP, 5. SAX, 6. TOXLINE, 7. MEDLINE, 8. HSDB, 9. IRIS, 10. CCRIS, 11. GENETOX, 12. IUCLID, 13. PHYSPROP, 14. BIODEG, 15. BIOLOG, 16. ECoTOX. +: data was found. -: data was not found.

		Database															
Substance	**CAS Nr.**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**	**16**
Anthraquinone	84-65-1	+	+	+	+	+	+	+	+	-	+	+	+	+	+	+	+
2-butanoneoximee	96-29-7	+	+	+	+	+	+	+	-	-	+	-	+	+	+	+	+
1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride	4080-31-3	+	+	+	+	+	+	+	-	-	+	-	-	+	+	+	+
Diarylide	6358-85-6	+	+	+	+	+	+	+	+	-	+	+	+	+	-	+	+
2-Naphthol	135-19-3	+	+	+	-	+	+	+	+	-	-	+	+	+	+	-	+
Quinacridone	1047-16-1	+	+	+	-	-	+	-	+	-	-	-	-	-	-	-	-
1,2,3,4,5,6,7,8-octahydroacridine	1658-08-8	-	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Hexamethylene-1,6-diisocyanate	822-06-0	-	+	+	-	+	+	+	+	+	+	-	+	+	-	-	-
Chloroisocyanate benzene	3320-83-0	+	+	-	-	-	+	-	-	-	-	-	-	+	-	-	-

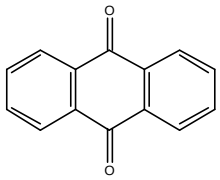
It can be seen from the above that for some substances, only limited data are available in the searched literature.

7 Toxicological profile of selected substances

7.1 Toxicological profile of anthraquinone

7.1.1 Identification of the substance and physical-chemical properties

7.1.1.1 Identification

Chemical name	anthraquinone
EINECS name	anthraquinone
CAS no.	84-65-1
Molecular formula	$C_{14}H_8O_2$
Structural formula	

Applications
Anthraquinone is used in the manufacture of dyestuffs and pigments, as an organic inhibitor and through the impairment of taste as a bird repellent on seeds (6, 18). The substance is also used as a catalyst in connection with the manufacture of paper pulp (2).

Synonyms
The following synonyms have been found for anthraquinone (1, 5):

- anthracenedione
- 9,10-anthracenedione
- anthracenequinone
- anthradione
- Anthrapel
- 9,10-anthraquinone
- corbit
- 9,10-dihydro-9,10-dioxoanthracene
- 9,10-dioxoanthracene
- diphenylenketon
- hoelite
- morkit

Regulation

EU classification	not classified
DK guideline list for self-classification	not classified
Cosmetics Statutory Order	not regulated
Foodstuffs (the positive list)	not on the positive list
Foodstuffs (the flavour list, 2002)	not on the flavour list 2002
The Danish Working Authority occupational exposure limit list	not on the EOL list

7.1.1.2 Physico/chemical properties

Table 7.1. Physico-chemical properties of anthraquinone.

Physico/chemical properties		Reference
Physical form	solid substance	1
Molecular weight (g/mol)	208.22	17
Melting point (ºC)	286	17
Boiling point (ºC)	377	17
Vapour pressure (Pa)	0.000016	17
Specific weight (kg/L)	1.438	1
Log Kow	3.39	17
Water-solubility (mg/l)	1.35	17

7.1.2 Toxicological properties

Absorption
No relevant data was found in the literature examined.

Metabolism
No relevant data was found in the references examined.

7.1.2.1 Acute toxicity

Inhalation
Data from the literature points to relatively low toxicity by inhalation, since the LC50 for rats is reported at >1,300 mg/m^3 given exposure of more than 4 hours/6,16/.

Ingestion
Studies of acute toxicity indicate that anthraquinone is of low acute toxicity. The literature mentions LD50 values for rats of >5 g/kg by ingestion. A LDLo value for rats has been reported as being 15,000 mg/kg /16/.

Skin contact
The literature reports a LD50 for dermal exposure of >5,000 mg/kg /16/.

Irritation and corrosiveness
The substance was not found to be a skin irritant in tests on rabbits /6/. Eight human male test subjects exposed to a non-specified quantity of the substance showed no signs of irritation after 24-hour application on the upper arm /16/. Safety datasheets and other secondary literature often describe the substance as being a possible irritant.

The application of the substance in powder form to the eyes of rabbits has caused irritation. This effect is assumed to be principally mechanical in nature, as the substance cannot be dissolved in the eye. Other tests with the application of the substance in dissolved form showed no signs of eye irritation /16/.

7.1.2.2 Subacute/chronic toxicity

Allergy and hypersensitivity
No primary data was found documenting the substance's sensitization properties /16/. Secondary literature describes the substance as possibly sensitizing /6/.

Organ damage
In rats subject to inhalation of 0.0052 and 0.0122 mg/l respectively for 5-6 hours/day for four months, bodyweight and blood picture were effected and there were histopathological findings in the lungs of the high dose group /16/.

Daily oral dosing of rats with 1, 10 or 100 mg/kg for three months resulted in a decline in food intake and bodyweight, liver weight increases and changes in clinical-chemical parameters. NOAEL was determined at 1 mg/kg /16/.

Daily dosing of rats via stomach pump with 2, 10, 20, 50 or 250 mg/kg for 28 days resulted in a decline in bodyweight and increases in the weight of certain organs including the liver, kidneys, spleen, thyroid gland, heart, testes and ovaries. NOAEL was determined at 2 mg/kg /16/.

The literature makes reference to acute and chronic effects on the nervous system /9/. Mentioned as acute effects are convulsive fits, paralysis of the spinal cord, while chronic effects mentioned include visual disorders.

Genetic damage
The substance has been examined in a number of Ames' tests on a variety of strains, both with and without metabolic activation with both negative and positive results.

Cancer
In tests on rats which were administered anthraquinone in their food corresponding to daily doses of 20, 45, 90 or 180 mg/kg for males and 25, 50, 100 or 200 mg/kg for females, increased incidence of non-neoplastic damage to kidneys, liver, spleen and bone marrow was observed in both males and females. It was concluded that there was some evidence of carcinogenic activity in males, but clear evidence of carcinogenic activity in females /18/.

In equivalent tests on mice exposed to daily doses of 90, 265 or 825 mg/kg for males and 80, 235 or 745 mg/kg for females, non-neoplastic damage to liver, bladder and spleen was observed in both males and females and to thyroid gland and kidneys in males. It was concluded that there was clear evidence of carcinogenic activity in both males and females /18/.

In other tests involving dermal and oral administration of the substance to mice no carcinogenic activity was observed /16/.

Damage to the reproductive process and the foetus
No relevant data was found in the references examined.

7.1.3 Ecotoxicological properties

The table below summarises the effects of anthraquinone on aquatic organisms.

Table 7.2. Ecotoxicological data for anthraquinone (16, 20). - No data
Length of test is stated in parentheses immediately after the concentration.

Group of organisms	Latin name	EC_{50}/LC_{50} (mg/l)	LOEC (mg/l)
Bacteria	*Oscillatoria chalybea*	-	0.02 (5 d)
Active sludge		7264 (3 h)	-
Algae	*Lemna gibba*	0.01-1.5 (7 d)	-
Algae	*Selenastrum capricornutum*	-	20.8 (5 d)
Algae	*Blue-green algae*	-	20.8 (5 d)
Crustaceans	*Americamysis bahia*	0.1-2.2 (48 h)	-
	Pimephales promelas	2650 (96 h)	-
Fish	*Tilapia mossambica*	12-26 (48 h)	-

7.1.4 Fate in the environment

7.1.4.1 Degradation

Table 7.3. Reported minimum and maximum degradation for anthraquinone (14). - No data. Length of test is stated in parentheses immediately after the degradation ratio.

	Minimum (%)	Maximum (%)
Aerobic conditions	15 (28 d)	100 (14 d)
Anaerobic conditions	-	-

7.1.4.2 Bioaccumulation

No data was found on anthraquinone's bioaccumulation potential. Based on Log Kow, the bioconcentration factor can be calculated using the following equation (21):

$$\log BCF = 0.76 \log Kow - 0.23$$

Based on this equation, log BCF for anthraquinone comes out at 2.35. The BCF value is not considered to be critical with regard to the risk of accumulation in the food chain of living organisms until it reaches 100.

7.1.5 Conclusion

Anthraquinone is of limited acute toxicity through inhalation, ingestion and skin contact and has not been found to irritate skin and eyes. The substance is described as possibly sensitizing, but additional documentation of this effect was not found.

The lowest identified NOAEL in connection with repeated exposure was determined to be 1 mg/kg after 3 months' administration of the substance in food. At higher doses, effects observed included weight increase in liver and other organs.

In tests, the substance showed carcinogenic activity in female rats and in both male and female mice. However, there is insufficient information on cancer studies to constitute the basis for self-classification. No data was found on reproduction toxic effects.

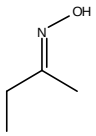
In the light of the data gathered on anthraquinone's environmental properties, the substance would be classified as a hazard to the environment due to its high acute toxicity relative to aquatic organisms and its bioaccumulation potential.

The analysis results show that the substance is contained in one of the analysed products in concentrations of 0.0034 and 0.0055% respectively. At such low concentrations it is unlikely the substance will constitute an environmental or health hazard. However, there are grounds for being attentive to the substance's carcinogenic properties, which may be considered to be the critical effect.

7.2 Toxicological profile of 2-butanoneoxime

7.2.1 Identification of the substance and physical-chemical properties

7.2.1.1 Identification

Chemical name	2-butanoneoxime
EINECS name	butanoneoxime
CAS no.	96-29-7
Molecular formula	C_4H_9NO
Structural formula	

Applications
Among other uses, 2-butanoneoxime is used in paint and varnish as an additive for the regulation of viscosity /16/.

Synonyms
The following synonyms have been found for 2-butanoneoxime /1.9/:

- aron m 1
- ethyl methyl ketone oxime
- ethyl methyl ketoxime
- mek-oxime
- methyl ethyl ketone oxime
- methyl ethyl ketoxime
- skino #2
- troykyd anti-skin b
- USAF AM-3
- USAF EK-906

Regulation

EU classification	Xn;R21 Carc3;R40 Xi;R41 R43
DK guideline list for self-classification	not assessed
Cosmetics Statutory Order	not regulated
Foodstuffs (the positive list)	not on the positive list
Foodstuffs (the flavour list, 2002)	not on the flavour list 2002
The Danish Working Environment Authority occupational exposure limit level list	not OEL list

7.2.1.2 Physico/chemical properties

Table 7.4. Physico-chemical properties of 2-butanoneoxime.

Physico/chemical properties		Reference
Physical form	liquid	1
Molecular weight (g/mol)	87.12	17
Melting point (ºC)	-29.5	17
Boiling point (ºC)	152.5	17
Vapour pressure (Pa)	120.5	17
Specific weight (kg/L)	0.923	1
Log Kow	0.63	17
Water-solubility (mg/l)	10,000	17

7.2.2 Toxicological properties

Absorption
No relevant data was found in the references examined.

Metabolism
2-butanoneoxime is largely metabolised and does not accumulate in the tissues /18/.

7.2.2.1 Acute toxicity
Inhalation
In tests on rats LC50 values of 20 mg/l were observed upon four-hour exposure /16/. TCLo for rats has been recorded as 400 and 1000 ppm respectively upon six-hour exposure (1.4 mg/l and 3.6 mg/l) /6/.

Ingestion
The literature contained LD50 values for rats of 930 mg/kg body weight for males and between 1620 and 3700 mg/kg bodyweight for females /6, 16/. The majority of values found exceeded the classification limit of 2000 mg/kg.

Skin contact
The substance is classified as *Harmful* with R21, *Harmful in contact withsSkin*, on the List of Dangerous Substances.

Irritation and corrosiveness
Exposure of rabbit skin resulted in no, mild or moderate skin irritation. Moderate irritation was presumed to have occurred in tests following

American guidelines, where the exposure time was 24 hours instead of the 4 hours used under the EU's classification criteria /16/.

The substance has been found to be highly irritating to the eyes of rabbits and is classified as *Irritant* with *R41, Risk of serious damage to eyes*, on the List of Dangerous Substances.

7.2.2.2 Subacute/chronic toxicity

Allergy and hypersensitivity
The substance caused sensitization in tests on guinea pigs /16/ and is classified as *Sensitizing* with *R43, May cause sensitization by skincContact*, on The List of Dangerous Substances.

Organ damage
In a 28-day inhalation test on rats, significant changes to most of the blood parameters of both males and females were observed at concentrations of 400 ppm (1.4 mg/l). Raised methaemoglobin was observed in females at 100 ppm (0.3 mg/l). NOAEL was determined at 25 ppm (0.09 mg/l) /16/. In a corresponding study only minor changes to blood parameters were observed at concentrations of 1.92 mg/l and 2.57 mg/l. In this study NOAEL was determined at 1.02 mg/l /16/.

Oral dosing (stomach pump) of rats over 90 days with 25, 75 and 225 mg/kg/day resulted in dose-related changes to blood parameters and a change in the weight of spleen and liver. No neurological effects were observed and there were no fatalities. Based on the results NOEL was extrapolated to be 10 mg/kg. The blood is the primary target organ with effects such as haemolytic anaemia and the compensatory formation of blood cells (hematopoiesis).

Changes were observed to blood parameters at all in dose groups in a 90-day neurotoxicity study using oral (stomach pump) dosing of rats with 40, 125 and 400 mg/kg respectively. Transitory behavioural changes were observed at 400 mg/kg. NOEL for neurotoxicity was established at 125 mg/kg/day /16/.

Genetic damage
2-butanoneoxime has been examined both in *in vitro* and *in vivo* test batteries with largely negative results /10, 16/. Positive results were found in an Ames' test with metabolic activation and in an *in vitro* sister chromatide exchange test /18/.

Cancer
The substance is suspected of having carcinogenic properties, and in the EU is classified as a category 3 *Carcinogenic* with *R40, Possible risk of cancer.*

This is confirmed by inhalation studies on rats and mice where the substance proved to be a liver oncogen at 75 ppm in male rats and at 374 ppm in male mice /16/.

Damage to the reproductive process and the foetus
No damage to the reproductive process was found in a two generation study on rats using oral (stomach pump) doses of 10, 100 and 200 mg/kg. Dose-related effects to the parents were observed in both generations /16/.

Rats administered 2-butanoneoxime in drinking water (stomach pump) in doses of 60, 200 and 600 mg/kg/day showed no treatment-related effects on the foetuses and NOAEL was established at 600 mg/kg/day /16/. Corresponding tests on rabbits dosed with 8, 14, 24 and 40 mg/kg also failed to cause any treatment-related effects on the foetuses /16/.

7.2.3 Ecotoxicological properties

The table below summarises the effects of 2-butanoneoxime on aquatic organisms.

Table 7.5. Ecotoxicological data for 2-butanoneoxime (16, 20). - No data
Length of test in days (d) is listed in parentheses after the concentration.

	Latin name	EC50/LC50 (mg/l)	LOEC (mg/l)
Bacteria	*Pseudomonas putida*	281 (17 h)	-
Bacteria	*Pseudomonas sp.*	-	630 (-)
Algae	*Scenedesmus subspicatus*	83 (72 h)	-
Crustaceans	*Daphnia magna*	> 500 (48 h)	-
Crustaceans	*Daphnia magna*	750 (48 h)	-
Fish	*Poecilia reticulata*	760 (96 h)	-
Fish	*Leuciscus idus*	320-1000 (96 h)	320 (96 h)
Fish	*Pimephales promelas*	843 (96 h)	-

7.2.4 Fate in the environment

Standard tests for determining the aerobic biodegradation of 2-butanoneoxime show that the substance is relatively easily degradable, cf. **Table 7.6**. No data was found on 2-butanoneoxime's degradability under anaerobic conditions.

Table 7.6. Reported minimum and maximum degradation for 2-butanoneoxime (16). - No data. Length of test is listed in parentheses after the degradation ratio.

	Minimum (%)	Maximum (%)
Aerobic conditions	25 (28 d)	70 (18 d)
Anaerobic conditions	-	-

7.2.4.1 Bioaccumulation

2-butanoneoxime's bioaccumulation potential is low. Based on Log Kow, Log BCF may be calculated at 0.25 (see section **7.1.4.2**). The bioconcentration factor for freshwater fish has been established at 0.5-0.6 /14/.

7.2.5 Conclusion

2-butanoneoxime is rapidly metabolised and does not accumulate in the tissues. The substance is classified as *Harmful* with R phrase R21, *Harmful in contact with skin, Carcinogenic in Category 3* with *R40, Possible risk of cancer, Local Irritant* with *R41, Risk of Serious Eye Damage,* and *Sensitizing* with *R43, May cause sensitization by skin contact.* The blood system (the red blood cells) is the primary target organ given repeated exposure.

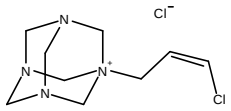
Based on the data on 2-butanoneoxime's environmental properties the substance does not require classification as being an environmental hazard.

Chemical analyses detected 2-butanoneoxime in concentrations of between 1.8 and 9.2% in five products in the first analyses. The second analyses of 2-butanonoxime detected concentrations between 1.4 and 2.1% for the products P1, P2, P10 and P11. Glass and porcelain paints containing such high concentrations of the substance must be considered unsuitable as hobby products for children and adults both by virtue of the sensitizing and the carcinogenic properties.

7.3 Toxicological profile of 1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride

7.3.1 Identification of the substance and physical-chemical properties

7.3.1.1 Identification

Chemical name	1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride
EINECS name	methenamine 3-chloroallylochloride
CAS no.	4080-31-3
Molecular formula	$C_9H_{16}Cl_2N_4$
Structural formula	

Applications
The substance is a formaldehyde releaser used as a biocide in e.g. paint, glue, ink and similar products. It is also used as a preservative in cosmetics.

Synonyms
The following synonyms have been found for 1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride

- cis-N-(3-chloroallyl)hexaminium chloride
- 1-(3-chloro-2-propenyl)-3,5,7-triaza-1-azoniatricyclo[3.3.1.1(3,7)]decan chloride
- cinartc 200
- dexamethylenetetramine chloroallyl chloride
- dowicide 184
- dowicide Q
- dowicil 75
- dowicil 100
- dowco 184
- Quaternium-15

Regulation

EU classification	not classified
DK guideline list for self-classification	not classified
Cosmetics Statutory Order	preservative permitted to max. 0.2%
Foodstuffs (the positive list)	not on the positive list
Foodstuffs (the flavour list, 2002)	not on the flavour list 2002
The Danish Working Environment Authority occupational exposure limit list	not on the OEL list

7.3.1.2 Physico/chemical properties

Table 7.7. The physico-chemical properties of 1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride -no data was found

Physico/chemical properties		Reference
Physical form	-	
Molecular weight (g/mol)	251.12	17
Melting point (ºC)	-	
Boiling point (ºC)	-	
Vapour pressure (Pa)	5.586e-7	17
Specific weight (kg/L)	-	
Log Kow	-5.92	17
Water-solubility (mg/l)	1E+006	17

7.3.2 Toxicological properties

Absorption
No relevant data was found in the references examined.

Metabolism
No relevant data was found in the references examined.

7.3.2.1 Acute toxicity
Inhalation
No relevant data was found in the references examined.

Ingestion
The reviewed literature contains an old (1966) oral LD50 value in rats of 500 mg/kg /6/. This value lies within the concentration limits which according to the classification criteria result in classification as *Harmful* with *R22, Harmful is swallowed.* No other LD50 values were found.

Skin contact
In the references examined we found a single dermal LD50 value for rabbits of 565 mg/kg /6/. This value also lies within the concentration limits which according to the classification criteria result in classification as *Harmful to Health* with *R21, Harmful in contact with skin.*

Irritation and corrosiveness
1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride is described as a moderate skin irritant in test animals in concentrations of over 5% and is not

considered to be a primary skin irritant in humans. In tests on rabbits the substance did not show significant eye irritating properties /7/.

7.3.2.2 Subacute/chronic toxicity

Allergy and hypersensitivity
The substance, which is a formaldehyde releaser, is described in the literature as potentially skin sensitizing. Results from test animals are ambiguous, but partly depend on test method. Cross sensitization with formaldehyde can occur. From its widespread use as preservative in e.g. cosmetics it is well known that the substance may result in skin allergies. However, it is considered to be safe for use in concentrations of less than 0.2% as stipulated by the Cosmetics Statutory Order.

Organ damage
No relevant data was found in the references examined.

Genetic damage
1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride has not been found to be a mutagen in various Ames' tests with and without metabolic activation. Point mutations have been shown in mice lymphoma tests with and without metabolic activation /10/.

Cancer
No relevant data was found in the references examined.

Damage to the reproductive process and the foetus
1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride administered orally (stomach pump) to gestating rabbits produced teratogenic effects at doses in excess of 25 mg/kg/day. NOAEL for teratogenic effects was established at 5 mg/kg/day. Dermal application of the substance did not result in toxic effects either in the parent animal or foetuses, nor were there other teratogenic effects at doses up to and including 500 mg/kg/day /7/. Testicular atrophy and reduced spermatogenesis has been reported in connection with a sub-chronic, dermal test on incompletely developed rabbits, but no further information was found in the test conditions in the reference used /7/.

7.3.3 Ecotoxicological properties

Table 7.8 shows data on the aquatic toxicity of the substance. No EC50 value was found for algae or NOEC for any of the organism groups.

Table 7.8. Ecotoxicological data for 1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride /20/. Length of test (in hours (h)) is stated in parentheses after the concentration.

Group of organisms	Latin name	EC50/LC50 (mg/l)
Molluscs	*Crassostrea virginica*	180 (48 h)
Molluscs	*Crassostrea virginica*	11 (96 h)
Crustaceans	*Daphnia magna*	27-40 (48 h)
Crustaceans	*Penaeus duorarum*	182 (96 h)
Crustaceans (crab)	*Uca pugilator*	560 (96 h)
Fish	*Pimephales promelas*	29-34 (96 h)
Fish	*Menidia beryllina*	34 (96 h)
Fish	*Lepomis macrochirus*	28-148 (48 h)
Fish	*Oncorhynchus mykiss*	20-144 (96 h)

7.3.4 Fate in the environment

Table 7.9. Reported minimum and maximum degradation of 1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantan chloride /14/ - no data.

	Minimum (%)	Maximum (%)
Aerobic conditions	35 (1.5 d)	95 (7 d)
Anaerobic conditions	-	-

The little data found on aerobic degradability of 1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantan chloride shows that the substance degrades relatively rapidly. The minimum and maximum values given in Table 7.9 have been determined for a substance concentration of 10 mg/l with active sludge as inoculum. At 50 mg/l the layer phase was longer, but the degradation ratio after 7 days corresponded to that of the lower concentration.

7.3.4.1 Bioaccumulation

No experimental data was found on the bioaccumulation potential of 1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride. Based on Log Kow the bioconcentration factor (log BCF) may be calculated to – 4.7 (see paragraph **7.1.4.2**), and the substance is not expected to bioaccumulate in aquatic organisms.

7.3.5 Conclusion

The literature describes the substance as moderately toxic depending on animal species, concentration and exposure pathway. Only one oral LD50 value was found for rats and one dermal LD50 value for rabbits. According to the classification criteria both values would require classification as *Harmful to Health*, but they constitute too flimsy a basis for classification.

The substance has displayed sensitizing potential, which is confirmed by clinical experience. Cross reaction with formaldehyde can occur.

The substance does not appear to possess significant mutagenic activity. Foetal damage effects have been observed in rabbits following oral administration. One test established NOAEL for foetal-damaging effects at 5 mg/kg/day.

However, in general the data found does not provide sufficient basis for a classification or its health hazard properties.

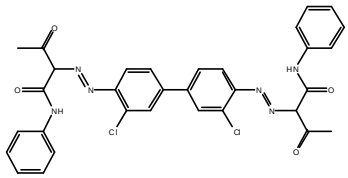
Based on the data collected on 1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantan chloride's environmental properties the substance does not require classification relative to environmental hazards. Reservations stem from uncertainty about the degradability profile and rate.

Based on the results of the survey, the substance is expected to occur in concentrations of less than 0.5%. The substance is permitted in cosmetics and thus considered safe in concentrations up to 0.2%. At higher concentrations the risk of sensitization cannot be ruled out. However, no data has been found that would throw light on the substance's sensitization potential. There is too little information on the reproduction toxic properties of the substance for ingestion and skin contact to draw conclusions about any risks to children and pregnant women at the concentration levels used.

7.4 Toxicological profile of diarylide

7.4.1 Identification of the substance and physical-chemical properties

7.4.1.1 Identification

Chemical name	diarylide
EINECS name	2,2'-[(3,3'-dichloro[1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis [3-oxo-N-phenylbutyramid]
CAS no.	6358-85-6
Molecular formula	$C_{32}H_{26}Cl_2N_6O_4$
Structural formula	

Applications
Diarylide is an azo dyestuff used in a large number of products, including printer ink, where heat resistance and colour intensity is required. The pigment is also used in paper products, in connection with textile printing and in linoleum /9/.

Synonyms
There are a large number of synonyms for diarylide /1, 9/. The following have been selected as examples:

- amazon yellow x2485
- benzidine yellow
- C.I. 21090

- C.I. pigment yellow 12
- dainichi benzidine yellow gt
- diarylanilide yellow
- isol benzidine yellow gbpropyl
- monolite yellow

Regulation

EU classification	not classified
DK guideline list for self-classification	not classified
Cosmetics Statutory Order	not regulated
Foodstuffs (the positive list)	not on the positive list
Foodstuffs (the flavour list, 2002)	not on the flavour list 2002
The Danish Working Environment Authority's occupational exposure limit list	not on the OEL list

7.4.1.2 Physico/chemical properties

Table 7.10. Physico-chemical properties of diarylide - no data was found.

Physico/chemical properties		Reference
Physical form	solid	1
Molecular weight (g/mol)	629.51	17
Melting point (ºC)	320	17
Boiling point (ºC)	-	
Vapour pressure (Pa)	~ 0	17
Specific weight (kg/L)	-	
Log Kow	6.80	17
Water-solubility (mg/l)	3.61E-5	17

7.4.2 Toxicological properties

Absorption
Diarylide is not absorbed through the skin or from the gastro- and intestinal tract of rats, but is excreted in the faeces following oral ingestion /16/.

Metabolism
Tests on rats detected no signs of metabolic reduction and segregation via the urine of 3,3'-dichlorobenzidine, which is an experimental carcinogen /16/. One single study on rabbits observed 3,3'-dichlorobenzidine in the urine following oral administration of 20 mg/kg. After 48 hours the quantity excreted amounted to approx. 0.05% of the administered dose /16/.

7.4.2.1 Acute toxicity

Inhalation
No relevant data was found in the references examined.

Ingestion
The data examined points to a limited acute toxicity upon ingestion, as oral LD50 values in rats in the order of >2000 mg/kg and up to >15,000 mg/kg have been reported /16/. No exact figures were found.

Skin contact
No data was found on acute toxicity in the case of skin contact in the references examined.

Irritation and corrosiveness
The substance has been found to be mainly non-irritative or slightly irritating to skin and eyes in tests on rabbits /16/. Some individual trade names have result in more pronounced eye irritation /7, 16/.

7.4.2.2 Subacute/chronic toxicity

Allergy and hypersensitivity
A single study was found on a non-specified animal species where a positive reaction on the skin was observed upon patch testing with 1% and 10% solutions respectively /16/. In addition, cases of skin allergy in humans have been reported /7/.

Organ damage
No relevant data was found in the references examined.

Genetic damage
Diarylide was found to be negative in a large number of Ame's tests with and without metabolic activation. This may be ascribed to the poor solubility of the substance /16, 10, 7/.

Cancer
A number of studies have been carried out on the substance's carcinogenic properties relative to oral dosing of rats and mice, all with negative results /10, 16/.

Damage to the reproductive process and the foetus
No relevant data was found in the references examined.

7.4.3 Ecotoxicological properties

Table 7.11. Ecotoxicological data for diarylide (16, 22). Length of test (in days (d) is stated in parentheses after the concentration.

Group of organisms	Latin name	EC50/LC50 (mg/l)	NOEC
Fish	*Brachydanio rerio*	5-10 (48 h)	-
Fish	*Cyprinus carpio*	> 420 (48 h)	
Fish	*Leuciscus idus*	> 500 (48 h)	-
Fish	*Leuciscus idus*	10-100 (96 h)	-

Data on diarylide's acute ecotoxicity has only been found for fish (see **Table 7.11**). Two results indicate that the substance is potentially acutely toxic. The two other results indicate that the substance is not toxic to aquatic organisms. Note that the substance has a water-solubility of less than 1 µg/L.

No conclusions can be drawn as to whether diarylide shows negative ecotoxicological effects due to a lack of data on diarylide's chronic toxicity and as data on acute toxicity only comprises a single group of organisms.

7.4.4 Fate in the environment

7.4.4.1 Degradability

The little data on the degradability of diarylide shows that the substance is either not degradable or is slightly degradable with a degradation ratio of 81 per cent after 15 days /16, 22/. No data was encountered on the substance's anaerobic degradability.
However, water solubility is so low that the substance must be considered to be non-degradable, as its bioaccessibility is very low.

Table 7.12. Reported minimum and maximum degradation of diarylide /16, 22/. - No data. Test duration is given in parentheses immediately after the degradation ratio.

	Minimum (%)	Maximum (%)
Aerobic conditions	0 (14 d)	81 (15 d)
Anaerobic conditions	-	-

7.4.4.2 Bioaccumulation

According to the Danish EPA (1999), diarylide has a low bioconcentration factor (-0.42-0.51). Based on Log Kow, the bioconcentration factor (log BCF) may be calculated at 7.3 (see section **7.1.4.2**). The large gap between the experimental and the calculated BCF may be due to the fact that azo pigments such as diarylide besides being of low water solubility also have very little potential for accumulating in fatty tissues /16/.

7.4.5 Conclusion

Diarylide is not absorbed through the stomach and intestinal tract and is excreted mainly unconverted in the faeces. However, under certain circumstances the formation and excretion of 3,3'-dichlorobenzidine, which is an experimental carcinogen, is possible.

The substance has limited acute toxicity by ingestion, but there is no information on other exposure pathways. The substance causes no or very little irritation of the skin and eyes. Cases of skin sensitization have been reported in humans. The substance has not been found to be mutagenic or carcinogenic in the tests referred to. No data was found on reproduction toxicity.

The data found does not give cause for self-classification of the substance for the effects investigated.

The data materials describing diarylide's fate in the environment is insufficient to make an accurate evaluation of the substance. It will primarily be found in solid form and water solubility is extremely low. The substance has been assessed to persist in the aquatic environment and its acute toxicity is low.

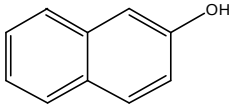
Based on the data on diarylide's environmental properties the substance does not require classification as being an environmental hazard.

Based on the results of the survey, the substance is expected to occur in concentrations of between 0 and 2%. In animal tests skin sensitization was seen at concentrations of 1% of the substance.

7.5 Toxicological profile of 2-naphthol

7.5.1 Identification of the substance and physical-chemical properties

7.5.1.1 Identification

Chemical name	2-naphthol
EINECS name	2-naphthol
CAS no.	135-19-3
Molecular formula	$C_{10}H_8O$
Structural formula	

Applications
2-Naphthol is used in the manufacture of dyestuffs and pigments. The substance is also used as an antioxidant in e.g. rubber, oils and insecticides and in connection with the production of perfumes and pharmaceutical products. It is used as a lubricant in electric motors and hydraulic equipment /9/.

Synonyms
The following synonyms are used for 2-naphthol /1/:

hydroxynaphthalene
2-hydroxynaphthalene
beta-hydroxynaphthalene
isonaphthol
naphthalenol
2-naphthalenol
2-naphthol
beta-naphthol
naphthyl alcohol
naphthyl hydroxide

Regulation

EU classification	Xn; R20/22, N; R50
DK guideline list for self-classification	not assessed
Cosmetics Statutory Order	not permitted in cosmetics products
Foodstuffs (the positive list)	not given
Foodstuffs (the flavour list, 2002)	not regulated
The Danish Working Environment Authority occupational exposure limit list	not on the OEL list

7.5.1.2 Physico/chemical properties

Table 7.13. Physico-chemical properties of 2-naphthol.

Physico/chemical properties		Reference
Physical form	solid	9
Molecular weight (g/mol)	144.17	9
Melting point (ºC)	121.6	9
Boiling point (ºC)	285	9
Vapour pressure (Pa)	0.043	9
Specific weight (kg/L)	1.28	9
Log Kow	2.70	9
Water-solubility (mg/l)	756	9

7.5.2 Toxicological properties

Absorption
2-naphthol can be absorbed through the skin. No data was found on the extent of absorption /7/.

Metabolism
The substance is excreted through the urine, primarily in conjugated form as sulphate or glucuronide. In humans up to 41% is excreted unconjugated and up to 59% in conjugated form following dermal application /7/.

7.5.2.1 Acute toxicity

Inhalation
LC50 for rats is reported at 2.2 mg/l. The substance is classified as *Harmful* with *R20, Harmful by inhalation*, on the List of Dangerous Substances.

Ingestion
Oral LD50 for rats is reported at 1320 mg/kg and above /16/. The substance is classified as *Harmful* with R22, *Harmful if swallowed*, on the List of Dangerous Substances.

Skin contact
Tests on rats produced LD50 values for dermal toxicity of >2500 mg/kg /16/.

Irritation and corrosiveness
2-naphthol causes mild or no irritation to rabbit skin. The substance is a moderate eye irritant for rabbits and in a single test it was found to be irritating with risk for serious eye damage.

Turbidity of the cornea and damage to the conjunctiva have been reported in humans who have got the substance in their eyes /7/.

7.5.2.2 Subacute/chronic toxicity

Allergy and hypersensitivity
The substance was found to be sensitizing in a single study on guinea pigs. In addition, there is both positive and negative sensitization data for human sensitization subsequent to patch tests with the substance /16/.

Organ damage
In an inhalation study, rats were exposed to concentrations of 0.45, 1.35 or 10.1 mg/m^3. The highest concentration led to fatalities among 25% of the animals, reduced weight gain, changes in haematological parameters and histopathological changes in liver and kidneys. Medium concentration resulted in reduced weight gain, changes in the haematological and clinical-chemical parameters and in histopathological changes in liver and kidneys. The lowest concentration exclusively resulted in a reduction in the nitrogen content of the urine /16/.

Clinical studies have shown that chronic poisoning by the substance may be associated with lesions in the kidneys and effects on the gastro-intestinal tract and nervous system. Effects on kidney function seem to be the clearest sign of harmful effects /7/.

Genetic damage
The substance has not been found to be mutagenic in a number of *in vitro* and *in vivo* mutagenicity tests. The substance was found to be genotoxic in a single DNA repair test /16/.

Cancer
Data was found from a single cancer study in mice in which 2-naphthol failed to show cancer-promoting activity on mouse skin upon application of 25 µl of a 20% solution, twice//week for 12 weeks /7, 16/.

Damage to the reproductive process and the foetus
No relevant data was found in the references examined.

7.5.3 Ecotoxicological properties

Data for 2-naphthol's ecotoxicity is shown in Table 7.14. No figures were found for NOEC.

Table 7.14. Ecotoxicological data for 2-naphthol /15/. Length of test is stated in parentheses after the concentration.

Group of organisms	Latin name	EC50/LC50 (mg/l)
Molluscs	*Strongylocentrotus droebachiensis*	1.9 (96 h)
Algae	*Nitzschia palea*	6.3 (4 h)
	Selenastrum capricornutum	18.8 (4 h)
Crustaceans	*Daphnia magna*	3.5 (24 h)
Fish	*Oncorhynchus mykiss*	0.07 (27 d)
	Micropterus salmoides	1.0 (7 d)
	Gadus morhua	3.0 (96 h)

In the List of Dangerous Substances the substance is classified as *Hazardous to the Environment* with R-phase R50, *Highly toxic to aquatic organisms.* No data was found in support of this classification in the literature examined.

7.5.4 Fate in the environment

7.5.4.1 Degradability

Table 7.15. Reported minimum and maximum degradation of 2-naphthol /16/. - No data Test duration is given in parentheses after the degradation ratio.

	Minimum (%)	Maximum (%)
Aerobic conditions	8 (24 h)	100 (5 d)
Anaerobic conditions	0 (75 d)	-

7.5.4.2 Bioaccumulation

No data was found on 2-naphthol's bioaccumulation properties. Based on Log Kow, the bioconcentration factor (log BCF) may be calculated at 1.8 (see section **7.1.4.2**).

7.5.5 Conclusion

2-naphthol can be absorbed through the skin. The substance is classified as *Harmful* with R-phrases R20/22, *Harmful by Inhalation and if Swallowed*.

The substance causes mild or no irritation of the skin and moderate eye irritation. The cornea and conjunctiva may be effected. Sensitization has been reported in animals and humans, but data does not indicate any significant effect. A number of studies have been made of the genotoxic properties of the substance, but no convincing evidence of genotoxic activity has been found. Nor has the substance shown tumour-promoting activity upon dermal application. The kidneys are the primary target organ given repeated exposure.

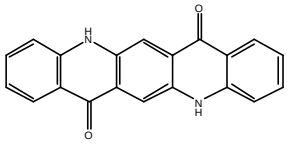
In the light of 2-naphthol's relatively broad area of application, the environment will be exposed via a number of dispersal pathways. The substance is classified as *Hazardous to the Environment* with R phrase R50, *Highly Toxic to Aquatic Organisms.*

2-naphthol is an intermediate product in pigment manufacture and no information has been found on concentration of the substance in glass and porcelain paints. The substance was found in none of the ten analysed products.

7.6 Toxicological profile of quinacridone.

7.6.1 Identification of the substance and physical-chemical properties

7.6.1.1 Identification

Chemical name	quinacridone
EINECS name	5,12-dihydroquino[2,3-b]acridine-7,14-dione
CAS no.	1047-16-1
Molecular formula	$C_{20}H_{12}N_2O_2$
Structural formula	

Applications
Quinacridone is a red/violet pigment used in e.g. paints, printer ink, plastic and rubber /9/.

Synonyms
The following synonyms are used for quinacridone /9/.

- CI Pigment red 122/CI 46500
- CI Pigment violet 19/CI 73900
- cinquasia violet/ red B
- histaperm red E 3B/ violet ER
- linear trans quinacridone
- monastral red / red B/ red Y/ violet R
- paliogen red BG
- permanent red E3B/E5B
- pigment quinacridone red
- pigment Violet #19
- PV fast red E 3B/E 5B
- quinacridone red/ MC/ violet / violet MC
- quino[2,3-b]acridine-7,14-dione, 5,12-dihydro-
- dihydroquino[2,3-b]acridine-7,14-dione

Regulation

EU classification	not classified
DK guideline list for self-classification	not classified
Cosmetics Statutory Order	permitted in cosmetics products which are only intended to be in short-term contact with the skin
Foodstuffs (the positive list)	not on the positive list
Foodstuffs (the flavour list, 2002)	not on the flavour list 2002
The Danish Working Environment Authority occupational exposure limit list	not on the OEL list

7.6.1.2 Physico/chemical properties

Table 7.16. Physico-chemical properties of quinacridone. - no data was found.

Physico/chemical properties		Reference
Physical form	solid	9
Molecular weight (g/mol)	312.18	9
Melting point (ºC)	-	
Boiling point (ºC)	-	
Vapour pressure (Pa)	-	
Specific weight (kg/L)	1.5	9
Log Kow	1.9	9
Water-solubility (mg/l)	insoluble	9

7.6.2 Toxicological properties

Absorption
No relevant data was found in the references examined.

Metabolism
No relevant data was found in the references examined.

7.6.2.1 Acute toxicity
Inhalation
No relevant data was found in the references examined.

Ingestion
The LD50 for oral ingestion in rats is recorded as >20 ml/kg /6/.

Skin contact
The LD50 for skin contact in rabbits is recorded as >2 ml/kg /6/.

Irritation and corrosiveness
Investigations of the pigments used in tattooing have shown that substances in the quinacridone substance group may cause skin inflammations /9/.

7.6.2.2 Subacute/chronic toxicity

Allergy and hypersensitivity
No relevant data was found in the references examined.

Organ damage
No relevant data was found in the references examined.

Genetic damage
Quinacridone was not found to be mutagenic in Ames' tests /6/.

Cancer
No relevant data was found in the references examined.

Damage to the reproductive process and the foetus
No relevant data was found in the references examined.

7.6.3 Ecotoxicological properties

No data was found on quinacridone's ecotoxicological properties.

7.6.4 Fate in the environment

No data was found on the degradability and bioaccumulation properties of quinacridone.

Based on Log Kow, the bioconcentration factor (log BCF) may be calculated at 1.2 (see section **7.1.4.2**).

7.6.5 Conclusion

The literature contains very little information on quinacridone. The LD50 values for ingestion and skin contact cannot be used for an evaluation of the toxicity, as there is insufficient information about the test conditions. Isolated items of information would indicate that the substance may cause skin inflammation when used in tattooing inks. Results of a single Ames' test were negative. Against this background it is not possible to assess the human toxicological properties of the substance.

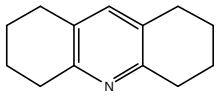
Insufficient data was found on quinacridone's environmental properties to assess the environmental hazardousness of the substance.

Based on the results of the survey, the substance is expected to occur in concentrations of between 0 and 2%. The substance was not identified in conjunction with the chemical analysis of the selected products.

7.7 Toxicological profile of 1,2,3,4,5,6,7,8-octahydroacridine

7.7.1 Identification of the substance and physical-chemical properties

7.7.1.1 Identification

Chemical name	1,2,3,4,5,6,7,8-octahydroacridine
EINECS name	1,2,3,4,5,6,7,8-octahydroacridine
CAS no.	1658-08-8
Molecular formula	$C_{13}H_{17}N$
Structural formula	

Applications
No data was found on octahydroacridine´s areas of application.

Synonyms
No synonyms were found for octahydroacridine.

Regulation

EU classification	not classified
DK guideline list for self-classification	not classified
Cosmetics Statutory Order	not regulated
Foodstuffs (the positive list)	not on the positive list
Foodstuffs (the flavour list, 2002)	not on the flavour list 2002
The Danish Working Environment Authority occupational exposure limit list	not on the OEL list

7.7.1.2 Physico/chemical properties

Table 7.17. Physico-chemical properties of 1,2,3,4,5,6,7,8-octahydroacridine. - no data was found.

Physico/chemical properties		Reference
Physical form	-	
Molecular weight (g/mol)	187.284	1
Melting point (ºC)	-	
Boiling point (ºC)	-	
Vapour pressure (Pa)	-	
Specific weight (kg/L)	-	
Log Kow	-	
Water-solubility (mg/l)	-	

7.7.2 Toxicological properties

Absorption
No relevant data was found in the references examined.

Metabolism
No relevant data was found in the references examined.

7.7.2.1 Acute toxicity

Inhalation
No relevant data was found in the references examined.

Ingestion
No relevant data was found in the references examined.

Skin contact
No relevant data was found in the references examined.

Irritation and corrosiveness
No relevant data was found in the references examined.

7.7.2.2 Subacute/chronic toxicity

Allergy and hypersensitivity
No relevant data was found in the references examined.

Organ damage
No relevant data was found in the references examined.

Genetic damage
No relevant data was found in the references examined.

Cancer
No relevant data was found in the references examined.

Damage to the reproductive process and the foetus
No relevant data was found in the references examined.

7.7.3 Ecotoxicological properties

No data was found on octahydroacridine's ecotoxicological properties.

7.7.4 Fate in the environment

No data was found on the degradability and bioaccumulation properties of octahydroacridine.

7.7.5 Conclusion

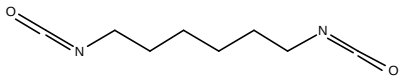
Insufficient data has been found to allow an assessment of octahydroacridine's toxicological and ecotoxicological properties.

During chemical analysis the substance was found in a single product in concentrations of 0.12 – 0.18%.

7.8 Toxicological profile of hexamethylene-1,6-diisocyanate

7.8.1 Identification of the substance and physical-chemical properties

7.8.1.1 Identification

Chemical name	hexamethylene-1,6-diisocyanate
EINECS name	hexamethylene diisocyanate
CAS no.	822-06-0
Molecular formula	$C_8H_{12}N_2O_2$
Structural formula	

Applications
Hexamethylene-1,6-diisocyanate is primarily used in the production of polyisocyanate products, which are added to polyurethane-based paint and varnish /9/.

Synonyms
The following synonyms are used for hexamethylene-1,6-diisocyanate /1/:

- desmodur h
- desmodur n
- 1,6-diisocyanatohexan
- evafanol AS-1
- HDI
- hexane 1,6-diisocyanate
- 1,6-hexanediol diisocyanat
- 1,6-hexamethylene diisocyanat
- 1,6-hexylene diisocyanat
- HMDI
- isocyanic acid, hexamethylene ester
- TL 78

Regulation

EU classification	T; R23, Xi; R36/37/38, R42/43
DK guideline list for self-classification	not assessed
Cosmetics Statutory Order	not regulated
Foodstuffs (the positive list)	not on the positive list
Foodstuffs (the flavour list, 2002)	not on the flavour list 2002
The Danish Working Environment Authority exposure limit level list	Limit level list: 0.005 ppm; 0.035 mg/m^3

7.8.1.2 Physico/chemical properties

Table 7.18. Physico-chemical properties of hexamethylene-1,6-diisocyanate.

Physico/chemical properties		Reference
Physical form	liquid	1
Molecular weight (g/mol)	168.20	17
Melting point (ºC)	-67	17
Boiling point (ºC)	255	17
Vapour pressure (Pa)	4	17
Specific weight (kg/L)	1.04	1
Log Kow	3.20	17
Water-solubility (mg/l)	117	17

7.8.2 Toxicological properties

Absorption
The substance is primarily absorbed through the lungs /9/.

Metabolism
The substance is hydrolysed and 1,6-hexamethylendiamine (HDA) is excreted in the urine. In a volunteer exposed to 0.03 mg/m^3 for 7.5 hours (absorbed hexamethylene-1,6-diisocyanate estimated at 0.1 mg) 0.01 mg of HDA was measured in the urine within 28 hours, equivalent to 10% of the absorbed HDA. HDA half life was approx. 1.4 hours and more than 90% was excreted in the urine during the first hour /16/.

7.8.2.1 Acute toxicity

Inhalation
LC50 values for rats have been reported between 0.15 and 0.35 mg/l/4 hours /16/. On the List of Dangerous Substances the substance is classified as *Toxic* with *R23, Toxic by inhalation*.

Ingestion
LD50 values for oral ingestion in rats have been found in the range between 710 mg/kg and 959 mg/kg /16/. These values correspond to a classification as *Harmful* with *R22, Harmful if swallowed*.

Skin contact
LD50 for rabbits has been recorded at 570 mg/kg and 599 mg/kg bodyweight, respectively /16/. These values correspond to a classification as *Harmful* with *R21, Harmful in contact with skin*.

Irritation and corrosiveness
On the List of Dangerous Substances the substance is classified as a *Local Irritant* with *R36/37/38, Irritating to eyes, respiratory system and skin*.

Studies involving 41 car painters employed for an average of seven years and exposed to HDI in concentrations of approx. 0.001 mg/m^3 showed an increased incidence of eye, nose and throat irritation and chronic bronchitis /16/.

7.8.2.2 Subacute/chronic toxicity

Allergy and hypersensitivity
The substance is skin sensitizing in tests on guinea pigs. Experience from the work environment also shows that the substance is sensitizing to human skin and respiratory organs /16/. Hexamethylene diisocyanate is classified as *Sensitizing* on the List of Dangerous Substances with *R42/43, May cause sensitisation by inhalation and skin contact.*

The literature reports several incidences of cross reactivity between various isocyanates in exposed workers /16/.

Organ damage
Repeated inhalation results in damage to the lungs in animal tests with both macroscopic and histopathological signs of severe lung irritation or pneumonia with diffuse bleeding. This latter symptom has been observed in rats at concentrations of 14 mg/m^3 and above /16/

Genetic damage
Hexamethylene diisocyanate was not found to be mutagenic in Ames' tests with and without metabolic activation /10, 16/.

Cancer
In a cancer study in which rats inhaled concentrations of 0.035, 0.175 or 1.2 mg/m^3 of the substance, no increase in the incidence of tumours in the animals was observed/16/.

Damage to the reproductive process and the foetus
Gestating rats were exposed to hexamethylene diisocyanate (HDI) in concentrations of 0.005, 0.050 or 0.300 ppm HDI through whole body exposure in a test to investigate foetal damage. Toxic effects were observed in the mother animals at the highest concentration and to a lesser extent at the medium concentration level. The effects included histopathological changes, and in severe cases, degeneration of the olfactory epithelium. Pathological changes were not observed in the lungs, throat or trachea in any of the exposed groups. No foetal damage, effects on litter size, the number of foetuses per implantation site, effects on foetus weight or placenta weight were observed /7/.

7.8.3 Ecotoxicological properties

Table 7.19. Ecotoxicological data for hexamethylene-1,6-diisocyanate /16/. Test times are stated in parentheses immediately after the concentration.

Group of organisms	Latin name	LC100 (mg/l)	EC0 (mg/l
Crustaceans	*Daphnia magna*		> 0.33 (24h)
Fish	*Brachydanio rerio*	31 (96 h)	

7.8.4 Fate in the environment

7.8.4.1 Degradation
Data was only found from one test, which showed that the substance is not degradable under aerobic conditions over 28 days /16/.

7.8.4.2 Bioaccumulation
Based on Log Kow, the bioconcentration factor (log BCF) may be calculated at 2.2 (see section **7.1.4.2**).

7.8.5 Conclusion

HDI is classified as *Toxic* on the List of Dangerous Substances with *R23, Toxic by inhalation, Irritant,* with R36/37/38, *Irritating to eyes, respiratory system and skin,* and *sensitizing* with R42/43, *May cause sensitisation by inhalation and skin contact.* The LD50 values found also indicate that the substance should be classified as *Harmful to Health R21/22, Harmful in contact with skin and if swallowed.* The eyes are particular sensitive to isocyanates, which also have a primary irritating effect on the respiratory tract. No data was found to indicate that substance has mutagenic, carcinogenic or reproduction toxic effects.

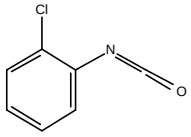
The information collected on hexamethylene-1,6-diisocyanate is insufficient to assess the extent to which the substance represents a hazard to the environment. The toxicity results found indicate a certain degree of toxicity to fish, and there may be a bioaccumulation potential.

During chemical analysis the substance was found in four of the products in concentrations between 0.045 and 0.075%. No data was found to document sensitization at these concentration levels, but potent isocyanates can constitute a problem for sensitive people even at low concentrations.

7.9 Toxicological profile of chloroisocyanate benzene

7.9.1 Identification of the substance and physical-chemical properties

7.9.1.1 Identification

Chemical name	chloroisocyanate benzene
EINECS name	2-chlorophenyl isocyanate
CAS no.	3320-83-0
Molecular formula	C_7H_4ClNO
Structural formula	

Applications
No information was found about the applications of the substance.

Synonyms
The following synonyms were found for chloroisocyanate benzene:

- 2-chlorophenyl isocyanate
- benzene, 1-chloro-2-isocyanato
- isocyanic acid, o-chlorophenyl ester
- o-chlorophenyl isocyanate

Regulation

EU classification	not classified
DK guideline list for self-classification	Xn;R22 R43
Cosmetics Statutory Order	not regulated
Foodstuffs (the positive list)	not on the positive list
Foodstuffs (the flavour list, 2002)	not on the flavour list 2002
The Danish Working Environment Authority occupational exposure limit list	not on the OEL list

7.9.1.2 Physico/chemical properties

Table 7.20. Physico-chemical properties of chloroisocyanate benzene /17/. -no data was found

Physico/chemical properties		Reference
Physical form	-	
Molecular weight (g/mol)	153.57	17
Melting point (ºC)	30.5	17
Boiling point (ºC)	200	17
Vapour pressure (Pa)	-	
Specific weight (kg/L)	1.273	1
Log Kow	3.24	17
Water-solubility (mg/l)	-	

7.9.2 Toxicological properties

Absorption
No relevant data was found in the references examined.

Metabolism
No relevant data was found in the references examined.

7.9.2.1 Acute toxicity

Inhalation
No relevant data was found in the references examined.

Ingestion
Based on QSAR models the substance is classified as *Harmful to Health* on the guideline list for self-classification of hazardous substances with *R22, Harmful if Swallowed.*

Skin contact
No relevant data was found in the references examined.

Irritation and corrosiveness
No relevant data was found in the references examined.

7.9.2.2 Subacute/chronic toxicity

Allergy and hypersensitivity
Based on QSAR models the substance is classified as *Sensitizing* on the guideline list for self-classification of hazardous substances with *R43, May cause sensitization by skin contact.*

Organ damage
No relevant data was found in the references examined.

Genetic damage
No relevant data was found in the references examined.

Cancer
No relevant data was found in the references examined.

Damage to the reproductive process and the foetus
No relevant data was found in the references examined.

7.9.3 Ecotoxicological properties

No data was found on chloroisocyanate benzene's ecotoxicological properties.

7.9.4 Fate in the environment

7.9.4.1 Degradation
No data was found on chloroisocyanate benzene's degradability.

7.9.4.2 Bioaccumulation
Based on Log Kow, the bioconcentration factor (log BCF) may be calculated at 2.2 (see section **7.1.4.2**).

7.9.5 Conclusion

Insufficient data has been found to allow an assessment of chloroisocyanate benzene's toxicological and ecotoxicological properties.

Upon chemical analysis the substance was found in just one of the ten products at a concentration of 0.015%. The critical effect of the substance is sensitization, but no documentation was found to show that concentrations of the magnitude of 0.015% could trigger allergies.

7.10 Summary

Table 7.21 summarises the substances' intrinsic toxicological properties with regard to the key parameters: acute effects, local effects, sensitization, the effects of repeated exposure, and carcinogenicity(C), mutagenicity (M), and reproduction toxicity (R). Moreover, the most highly critical effects of the substances have been listed based on the available data.

Table 7.22 summarises information on the environmental effects of the substances and their environmental classification.

Table 7.23 summarises information about regulatory requirements applying to the substances together with specification of concentrations of those substances identified through chemical analysis.

In the cases of butanoneoxime, methylpyrrolidone and phthalatic acid anhydride the percentage contents found by chemical analysis are above the lower limits classification. With the exception of methylpyrrolidone all substances require classification as sensitizing. Both the first and the second analysis of 2- butanoneoxime require classification as category 3 carcinogens. All other detected compounds are present in concentrations below the classification limits.

As regards the environmental properties of the substances, two of them (anthraquinone and 2-naphthol) were both extremely harmful to aquatic organisms and also persistent in the environment. As a consequence, there are grounds for limiting discharge into the aquatic environment.

Table 7.201 List of toxicological properties and critical effects of the ten substances. ? Positive test results/data, ? Negative test results/data, and – no data. Exposure pathways are specified as follows: I = ingestion, S =skin contact, E = eyes, R = respiratory organs

Name of substance	CAS no.	Acute effects			Local effects			Sensitization		Repeated exposure			CMR			Critical effect
		I	S	R	E	S	R	S	R	I	S	R	C	M	R	
Anthraquinone	84-65-1	?	?	?	?	?	-	?	-	?	-	?	?	?	-	Carc. activity, sensitizing
2-butanoneoxime	96-29-7	?	?	?	?	?	-	?	-	?	-	?	?	?	-	Carc3, sensitizing
1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride	4080-31-3	?	?	-	?	?	-	?	-	-	-	-	-	?	?	Acute toxicity (I,H), sensi-tizing (H)
Diarylide	6358-85-6	?	?	-	?	?	-	?	-	-	-	-		?	-	Sensitization (S)
2-Naphtol	135-19-3	?	?	?	?	?	-	?	-	?	-	?	-	-	-	Acute tox., sensitizing kidney damage
Quinacridone	1047-16-1	-	-	-	-	?	-	-	-	-	-	-	-	?	-	Skin irritation
1,2,3,4,5,6,7,8-octahydroacridine	1658-08-8	-	-	-	-	-	-	-	-	-	-	-	-	-	-	No data
Hexamethylene-1,6-diisocyanate	822-06-0	?	?	?	?	?	?	?	?	-	-	?	?	?	-	Acute tox., sensitizing (S,R), lung damage (R)
chloroisocyanate benzene	3320-83-0	?	-	?	-	-	-	?	-	-	-	-	-	-	-	Sensitization (S)

Table 7.2221 Summary of environmental impact and classification
I= Impact, P = Persistence, A = Accumulation

Name of substance	CAS no.	Env. impact			Classification
		I	P	A	
Anthraquinone	84-65-1	?	?	?	N;R50/53 (self evaluation)
2-butanoneoxime	96-29-7	?	?	?	None (several algae tests desirable however)
1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride	4080-31-3	?	?	?	None (possibly R52/53)
Diarylide	6358-85-6	?	?	?	None
2-Naphthol	135-19-3	?	?	?	N;R50
Quinacridone	1047-16-1	-	-	-	No data
1,2,3,4,5,6,7,8-octahydroacridine	1658-08-8	-	-	-	No data
Hexamethylene-1,6-diisocyanate	822-06-0	?	-	-	Very little data
Chloroisocyanate benzene	3320-83-0	-	-	-	No data

Table 7.23 Summary of regulations applying to the ten substances

Name of substance	CAS no.	Conc. (%)	Classification[1]	Max. permissible value in work environment	Cosmetic Statutory Order	The positive list	The Flavour List 2002
Anthraquinone	84-65-1	-	Not classified	No	Not stated	No	No
2-butanoneoxime	96-29-7	<0.5 9.2	**Xn;R21 Carc3; R40** **Xi;R41 R43**	No	Not stated	No	No
1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride	4080-31-3	<0.5	Not classified	No	Permitted as preservative, max. 0.2%	No	No
Diarylide	6358-85-6	0-2	Not classified	No	Not permitted	No	No
2-Naphtol	135-19-3	-	**Xn;R20/22 N;R50**	No	Not stated	No	No
Quinacridone	1047-16-1	0-2	Not classified	No	Permitted in products in short-term contact with the skin	No	No
1,2,3,4,5,6,7,8-octahydroacridine	1658-08-8	0.012-0.18	Not classified	No	Not stated	No	No
Hexamethylene-1,6-diisocyanate	822-06-0	0.058-0.075	**T;R23** **Xi;R36/37/38** **R42/43**	0.005 ppm 0.035 mg/m^3	Not stated	No	No
Chloroisocyanate benzene	3320-83-0	0.015	Xn;R22 R43	No	Not stated	No	No

1) Classifications from the List of Dangerous Substances are specified in bold type and classifications from the Danish EPA's guideline list for self-classification are specified in normal type.

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Appendix A Extractable substances

In table A-1 the chemical substances have been identified by analysis of extractable substances in the 20 porcelain coloures by a CAS no. For many of the substances it is not a unique identification and thus not a unique CAS no. The number listed is an example of one of the substances that may be covered by the chemical name.

Tabel A-1 Chemical substances identified by analysis of extractable substances.
- means that CAS no. cannot be listed.

Substance	CAS nr.
1,2 propanediol*	57-55-6
2-Butanoneroxime ^	96-29-7
Ethyl benzene	100-41-4
Xylene (sum of isomers fora.)	1330-20-7
Toluene	108-88-3
Methylheptane (two peaks)	50985-84-7
Trimethylcyclohexane	30498-63-6
Styrene^	100-42-5
Methylpyrrolidinone^	872-50-4
Hydrocarbon mixture: alifatic, alicyclic and aromatic hydrocarbons (approx. C6-C12)	64742-82-1
Dodecane	112-40-3
Dimethylundecane	79004-83-4
2-(Dimethylamino)2-methylpropanol	7005-47-2
Ethylhexanol	104-76-7
Butoxy ethanol	111-76-2
Phenylethyl alcohol	60-12-8
1-methyl-4-(1-methylethyl)-3-cyclohexene-1-ol	586-82-3
Ethylhexyl acetate	103-09-3
Methylpropenoic acid butyl esso	94159-12-3
Methylpentyl cyclohexane	61142-20-9
Chloroaniline^	27134-26-5
Chlorophnyl isocyanate^	3320-83-0
Isocyanate ethoxyphenyl^	-
Methoxy aniline (anisidine)	29191-52-4
Benzoic acid	65-85-0
Pentanediocc acid 2,4-dimethyl-, climetage ester	2121-68-8
2-(Butoxyethoxy) ethanol	112-34-5
Methenamine^	100-97-0
Menthenol	10482-56-1
Terpineol	8006-39-1
Ethylhexylacrylate	103-11-7
Phthalic acid anhydride^	85-44-9
Phthalic acid anhydride, isomers	-
2,4-Toluene diisocyanate	584-84-9
Anthraquinone^	84-65-1
2-naphtol^	135-19-3
1,2,3,4,5,6,7,8-octahydroacridine^	1658-08-8
Bis(2-methylpropyl) butandic acid ester	925-06-4
Dibutyl pentandic acid ester	6624-57-3
Bis(2-methylpropyl) hexandic acid ester	141-04-8
Hexamethylene-1,6-diisocyanate	822-06-0
Isocyanate methoxy benzene	700-87-8
2-methyl-propansyre 3-hydroxy-2,4,4-trimethylpentyl ester	74367-34-3
Chloro nitro aniline	41587-36-4
Tributyl phosphate	126-73-8
Cyclodecane	293-96-9

Substance	CAS nr.
2-Methoxy-4-prop-2-enylphenol	97-53-0
Methylbiphenyl^	28652-72-4
BHT	128-37-0
Isophorone diisocyante	4098-71-9
Benzyl benzoate	120-51-4
1-[4-(1,1-dimethylethyl)-2,6-dimethyl-3,5-dinitrophenyl-ethanone	81-14-1
Hexadecan oic acid	57-10-3
Octadecandien acid	871-70-5
Phthalate (sum of two peaks)	-
DEHP	117-81-7
Uid. alkanes, alkenes, alcohols, cycloalkanes/- alkenes	-
Uid. carboxyluc acids, esters, ketones, aldehydes and amides	-