Survey of chemical substances in consumer products

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Survey and assessment of chemical substances in window colours

Sonja Hagen Mikkelsen, Sven Havelund and Anders Skibsted Mogensen, COWI A/S



MINISTRY OF THE ENVIRONMENT ENVIRONMENTAL PROTECTION AGENCY

Contents

PREFACE	5
LIST OF ABBREVIATIONS Hazard symbols and R-phrases used	6 6
SUMMARY AND CONCLUSIONS	9
Survey Chemical analysis Health evaluation	9 9 10
1 INTRODUCTION	13
2 COMPOSITION OF AND TYPICAL CONSTITUENT SUBSTANCES IN HOBBY PAINTS	15
2.1 PIGMENTS2.2 PAINT BINDERS2.3 VEHICLE2.4 ADDITIVES	15 15 15 16
3 SURVEY OF MANUFACTURERS AND SUPPLIERS	17
3.1 MANUFACTURERS3.2 SUPPLIERS3.3 WINDOW COLOURS	17 17 18
4 SURVEY OF CONSTITUENT SUBSTANCES IN WINDOW COLOURS	19
 4.1 PIGMENTS 4.2 PAINT BINDERS 4.3 MEDIUM 4.4 ADDITIVES 	20 22 23 23
5 CHEMICAL ANALYSIS	27
 5.1 TEST PRODUCTS 5.2 METHODS OF ANALYSIS 5.2.1 GC/MS screening (extractable organic substances) 5.2.2 X-ray analysis (elements) 5.2.3 Water content using Karl Fisher titration 5.2.4 IR screening 5.3 ANALYSIS RESULTS 5.3.1 GC/MS screening (extractable organic substances) 5.4 SUMMARY OF ANALYSIS 	27 27 27 28 28 28 28 28 31
6 SELECTED SUBSTANCES AND DATA SEARCHING	33
6.1 BASIS FOR THE SELECTION OF SUBSTANCES6.2 THE SELECTED SUBSTANCES6.3 DATA SEARCH	33 33 34
7 TOXICOLOGICAL PROFILE OF SELECTED SUBSTANCES	37
7.1 TOXICOLOGICAL PROFILE OF 1-NAPHTHOL 7.1.1 Identification of the substance and physical-chemical properties	37 37

<i>7.1.2</i>	Toxicological properties
<i>7.1.3</i>	Conclusion
7.2 TO	XICOLOGICAL PROFILE OF DIOXAZINE
<i>7.2.1</i>	Identification of the substance and physical-chemical properties
7.2.2	Toxicological properties
7.2.3	Conclusion
7.3 To	XICOLOGICAL PROFILE OF DIMETHYLOXAZOLIDINE
<i>7.3.1</i>	Identification of the substance and physical-chemical properties
<i>7.3.2</i>	Toxicological properties
<i>7.3.3</i>	Conclusion
7.4 To	XICOLOGICAL PROFILE FOR ETHYLMETHYLPYRIDINE
7.4.1	Identification of the substance and physical-chemical properties
<i>7.4.2</i>	Toxicological properties
<i>7.4.3</i>	Conclusion
7.5 TO	XICOLOGICAL PROFILE FOR METHYLBENZENESULFONAMIDE
7.5.1	Identification of the substance and physical-chemical properties
<i>7.5.2</i>	Toxicological properties
<i>7.5.3</i>	Conclusion
7.6 TO	XICOLOGICAL PROFILE OF METHENAMINE
<i>7.6.1</i>	Identification of the substance and physical-chemical properties
7. 6 .2	Toxicological properties
7. 6 .3	Conclusion
7.7 To	XICOLOGICAL PROFILE OF DODECANTHIOL
7.7.1	Identification of the substance and physical-chemical properties
7.7.2	Toxicological properties
<i>7.7.3</i>	Conclusion
7.8 TO	XICOLOGICAL PROFILE OF 2-ETHYLHEXYLACRYLATE
7. 8 .1	Identification of the substance and physical-chemical properties
7. 8 .2	Toxicological properties
7.8.3	Conclusion
7.9 To	XICOLOGICAL PROFILE OF PIGMENT RED 146
<i>7.9.1</i>	Identification of the substance and physical-chemical properties
<i>7.9.2</i>	Toxicological properties
<i>7.9.3</i>	Conclusion
7.10	OXICOLOGICAL PROFILE OF PIGMENT YELLOW 138
7.10.	<i>I Identification of the substance and physical-chemical properties</i>
7.10.2	? Toxicological properties
7.10.	3 Conclusion
7.11 S	SUMMARY
3 REFE	IRENCES
OTHER	LITERATURE AND DATABASES CONSULTED:

PREFACE

The Danish EPA has undertaken an initiative to examine consumer exposure to chemical substances in consumer products and the associated risks. A variety of different product categories are involved including window colours for hobby use, which are the object of the present report.

The object of the project is to carry out a survey of the constituent ingredients of water-based window colours, both those which are CE marked and those which are not. The survey is based on information from producers, suppliers and independent consultants.

Yet another object is to carry out a human toxicological evaluation of selected substances in the products and, if possible, give an estimate of the extent of consumer exposure to these products. The human toxicological evaluation was undertaken with a view to producing input for a possible subsequent risk assessment with emphasis on the possible exposure of children to these substances.

Moreover, the project is aimed at documenting the content of selected chemical substances through chemical analysis of a number of products to be found in the market. Finally, the purpose was to assess the need for further chemical analysis based on the results produced.

The project report "Examination and Evaluation of Chemical Substances in Window Paints" contains a review of the producers whose products are available on the Danish market, the most important suppliers of these products and of the products available on the Danish market.

The constituent substance are presented in table form – classified as pigments, vehicles and additives. The chemical name, chemical formula, CAS no. and selected physical properties are given for each substance.

The project was initiated in November 2001. The first stage was completed in December 2001 and the second in June 2003.

The project was carried out by COWI. MILJØ-KEMI Dansk Miljø Center A/S, now named Eurofins Danmark A/S carried out analysis on selected window colours. The project team consisted of Sonja Hagen Mikkelsen (project officer), Sven Havelund, Anders Skibsted Mogensen and Frank Stuer-Lauridsen (quality assurance).

The contact person at the Danish EPA was Shima Dobel, Chemicalsdivision, The Consumer Section.

During the hearing Panduro have pointed out that the product "SunArt" manufactured by Palmer Paint Products cannot be described as a "window paint". The product is a very thin fluid paint, which may be used on glass or acrylic.

List of abbreviations

CAS no.	Chemical Abstracts Service Registry number
C.I. no.	Colour Index number
Kow	Octanol-Water Partition Coefficient
LC 50	The concentration of a chemical that results in the death of
	50% of test animals (Lethal Concentration)
LD50	The dose of a chemical that results in the death of 50% of test
	animals (Lethal Dose)
MW	Molecular Weight
NOAEL	No observed adverse effect level (the greatest amount of
	chemical that produces no detectable effects on the test
	animals)
S	Solubility

Hazard symbols and R-phrases used

Hazard symbols

F	Highly flammable
Xi	Local irritant
Xn	Harmful to health
С	Corrosive

N Dangerous to the environment

R-phrases

IV pinasw	
R10	Flammable
R11	Highly 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
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
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

Combinations of R-phrases

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

Combinations of R-phrases

	▲
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

Window coulours are a hobby product used by children and adults. CE marked products are intended for children under the age of 14. CE marked products must conform with the current regulations applying to toys and are subject to restrictions with regard to the content and emission of substances harmful to health. As not all consumers are familiar with the marking, the Danish EPA assesses that children below the age of 14 will be at risk of coming into contact with window colours that are not CE marked and which do not comply with the current regulations for toys.

Exposure to substances contained in the products may occur by direct contact with fingers, hands and face, and to some extent by inhalation. As a consequence, there is a need to chart the substances that consumers may be exposed to during use.

Worldwide, there are approximately 15 window paint producers and most producers' products are also available on the Danish market. Most of the products are CE marked – or bear other types of marking such as, for example, the American AP Non Toxic mark, which is allocated to arts and crafts materials that are certified as non-toxic by the ACMI¹ in accordance with ASTM D 4236².

20 pigments have been found comprising both inorganic and organic substances. Of organic pigments, azo pigments and polycyclic pigments were found. Only one pigment, copper phthalocyanine, containing a heavy metal was found. One of the inorganic pigments identified during the survey contained heavy metals.

All the window colours included in the survey were water-based. The primary paint binders were acrylates, often thermoplastic (meth)acrylates. Acrylates consist of acrylic acid and meta acrylic acid and their methyl, ethyl and butyl esters.

Additives include thickening agents, surfactants, preservatives, anti-foaming agents and solvents (cosolvents). Preservatives such as isothiazolones and bronopol are used in window colours. These preservatives are also found in CE marked products. The window colours also contain a number of glycols and alcohols.

Chemical analysis

The screening analysis of constituent substances in window colours generally show that the highest concentrations of extractable substances consist of alcohols, glycols, ketones, esters and simple hydrocarbons, of which some are

¹ ACMI: Art & Creative Materials Institute, Inc.

² ASTM D 4236: American standard for the marking of arts and crafts materials for chronic health hazards.

identified by name and others by substance group. The levels contained in the various products vary between 2.3 and 5500 mg/kg, equivalent to 0.00023% to 0.55% in the products. Other substances found in high concentrations in a single product are unidentified phthalates (two peaks), which upon double determination were measured at 2700-3100 mg/kg, equivalent to 0.27-0.31% in the product. Other substances were found in concentrations from approx. 1 mg/kg (0.0001%) and up to approx. 1000 mg/kg (0.1%), mostly at the lower end. This was also the case with products selected for toxicological assessment based on the chemical analysis. Thus we are dealing with concentrations below the general triviality limits stipulated in the Danish EPA's Statutory Order No. 329 of 16 May 2002 on the classification, packaging, labelling, sale and storage of chemical substances and products (the Classification Statutory Order).

Among the metals found were lead, copper, aluminium and titanium. Lead was detected in two products in concentrations of 12 and 17 mg/kg, respectively, equivalent to 0.0012 and 0.0017% in the products, and thus concentration limits are below the 0.15% which triggers requirements for special labelling of lead-containing products for use as paint or varnish under the Classification Statutory Order.

Health evaluation

On the basis of the survey and the results of the chemical analysis carried out, 10 substances were selected for toxicological assessment. These are as follows:

Name of substance	CAS no.	Application	Source
1-Naphthol	90-15-3	Intermediary	Data search
Dioxazine	6358-30-1	Pigment	Chemtox
Dimethyloxazolidine	51200-87-4	Preservative	Chemical analysis
Ethylmethyl pyridine	644-98-4	FlavourFlavourF	Chemical analysis
Methyl-benzensulfonamid	5183-78-8	Plasticizer	Chemical analysis
Methenamin	100-97-0	Preservative (formaldehyde releaser)	Chemical analysis
Dodecanthiol	112-55-0	Softener	Chemical analysis
2-Ethylhexylacrylat	103-11-7	Paint binder	Data search
Pigment red 146	5280-68-2	Pigment	Chemtox
Pigment yellow 138	30125-47-4	Pigment	Chemtox

Of the 10 substances investigated, three are included on the List of Dangerous Substances and two substances are on the Danish EPA's guideline list for selfclassification. Literature has been found for these substances that supports and to some extent adds to the information conveyed by the classification. Only extremely limited or no data at all has been found that would elucidate on the toxicological effects of the five other substances. This also applies to information on possible NOAEL values, which were established/referred to in only very few of the examined studies. Critical effects originating from the actual use of the surveyed substances were acute toxic effects (1-naphthol and dimethyloxazolidine) and sensitization effects (methenamine, docecanethiol and 2-ethylhexylacrylate).

The six substances (dimethyloxazolidine, ethylmethylpyridine, methylbenzenesulfonamide, methenamine, dodecanthiol and 2ethylhexylacrylate) identified as a result of the chemical analysis carried out were found in such low concentrations (0.00012 – 0.097%) that the acute toxic or irritative properties of the substances may not be expected to constitute a problem for children using the products.

Those substances that are known to result in hypersensitivity either through inhalation or skin contact (methenamine, dodecanethiol, 2-ethylhexylacrylate) may even in small quantities (below the regulatory levels) trigger reactions in sensitive individuals. However, in the chemical analysis, methenamine, which causes sensitization both upon inhalation and skin contact, was only found in concentrations of less than a hundred of the maximum permitted concentration for use as a preservative in cosmetics. The permitted limit in cosmetics indicates that the substance is not considered a problem at this concentration. An epidemiological study among industrial workers has concluded that there is no risk of respiratory allergies where average concentrations found in the analysis and taking into account the low vapour pressure, it is unlikely that this concentration could occur during normal use of the product.

Dodecanethiol and 2-ethylhexylacrylate, which have both been classified as skin sensitizing are also found in extremely low concentrations in the analysed products, i.e. <0.047% and 0.018%, respectively.

The literature examined mentioned that dodecanethiol possesses a high sensitization potential. However, no additional documentation was found to substantiate this information, nor was information found on the correlation between exposure and the triggering of an allergic reaction.

Patch tests on humans using solutions of 0.5% 2-ethylhexylacrylate triggered allergic dermatitis in already sensitized individuals. No information on the correlation between exposure and primary sensitization was found. The literature also contains reports on cross-allergy with methylmethacrylate, which is found in glues and other products.

Thus, neither for dodecanethiol or 2-ethylhexylacrylate has any real documentation been found for the sensitizing potential of these substances and consequently the risk children may be exposed to through the use of window colours containing these substances. If the analysis results are representative of window colours in general, extremely potent allergens would have to be involved before substances in such low concentrations could be considered to constitute a sensitization problem. No data has been found which would elucidate on the risk for already sensitized persons at the mentioned concentrations.

On the whole, it may be concluded that documentation has not be found that would point to the evaluated substances being a risk for children under conditions of normal use. However, there are always reasons for concern when children are exposed to sensitizing substances even at low concentrations, especially in the case of children who suffer from e.g. atopical dermatitis (child eczema) or whose one or both parents have a history of atopical disorders.

1 Introduction

Window colour is a hobby product used by children and adults. The colours can be applied to smooth and non-porous surfaces, and after drying for approximately 24 hours the design can be removed and mounted on other smooth surfaces.

Most window colours on the Danish market are CE marked and are thus classified for play purposes by children under the age of 14. CE marked products must conform with the current regulations applying to toys and are subject to restrictions with regard to the content and emission of certain substances harmful to health. As not all consumers are familiar with the marking the Danish EPA assesses that children below the age of 14 will be at risk of coming into contact with window colours that are not CE marked and which do not comply with the current regulations for toys.

The CE marking indicates that the toy complies with the safety requirements of the Danish Consumer Agency's Statutory Order no. 329 of 23 May 1995 on safety requirements for toys and products which by virtue of their outer appearance might be mistaken for food products. With regard to the toy's chemical properties the regulations require the toy to be manufactured so as not to constitute a health hazard. This is the responsibility of the toy manufacturer.

The regulations apply both when the toy:

- is used for the intended purpose, and
- is used in a way in which children might be expected to use it.

In general, the toy may not contain hazardous substances in quantities that would constitute a health hazard, i.e. substances that are classified as hazardous and thus appear on the List of Dangerous Substances or which conform to the criteria for classification pursuant to Statutory Order no. 329 of the Danish EPA dated 16 May 2002 on the classification, packaging, 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 on Chemical toys (sets) other than experimental sets, respectively may, however, be marketed and sold if the content of hazardous substances lies below a specified upper concentration limit provided the chemical substances are necessary for the functioning of the toy.

According to the assessment of the Danish EPA, CE marked hobby paint products may contain a maximum of 1% of substances which are harmful, irritant or corrosive, 1% being the so-called de minimis limit.

Furthermore, the CE marking also signifies that the toy complies with the requirements concerning the maximum emissions of substances with material implications for health: these are lead, cadmium, mercury, selenium, chromium, barium, arsenic and antimony, but the list will be extended to include other substances in the future. /1/

Exposure to substances contained in the products may occur by direct contact with the stipulated substances on fingers, hands and face, and inhalation.

Consequently, there is a need to chart the substances consumers may be exposed to through use of window colours.

The products have not been recorded in the product register and it is therefore necessary to obtain information about constituent substances from suppliers and producers.

The survey carried out is thus partly based on information obtained from the literature and available data on the Internet and partly on information obtained from safety data sheets, suppliers, producers and reviewers of chemical products. In addition, we have approached the Danish Joint Council for Creative and Hobby Materials. We obtained an overall list of constituent substances in window colours handled by Chemtox, a consultant dedicated to the assessment and evaluation of chemical products with a view to registration in the product register and the drafting of safety data sheets. For reasons of confidentiality there is no information on quantities or links to the names of products and suppliers.

Finally, we visited a number of shops to study the product range and any information on constituent substances on the packaging.

We purchased ten different window colour products in a variety of colours with a view to chemical analysis. Subsequently, we selected ten chemical substances based respectively on the survey and the results of the chemical analysis and drew up a toxicological profile for these substances.

2 Composition of and typical constituent substances in hobby paints

Dyes and paints contain four basic ingredients. The chosen basic ingredients will vary greatly depending on the paint's function and appearance and durability requirements. The four basic components are:

- Pigments
- Paint binders
- Fluid/vehicle
- Additives

A brief description of the four types of constituent substance is given below.

2.1 Pigments

Primary pigments give whiteness or colour to the product. Typically, titanium dioxide, TiO_2 , is used as white pigment. Coloured pigments produce colour through the selective absorption of light. Organic pigments (bright/sparkling colours) and inorganic pigments (earth colours) are used. An example of an organic pigment is phthalo blue. Inorganic pigments might, for example, be metal oxides (iron oxide). The actual pigments usually come in powder form, which are dissolved in a vehicle to obtain the actual colour.

2.2 Paint binders

Paint binders are used to bind pigments and act as an adhesive. There are oilbased or latex-based paint binders. The oil-based ones dry/oxidise upon exposure to air. Oil-based paint binders may consist of linseed oil or soybean oil; alkyds may also be used as oil-based paint binders.

Latex-based paint binders are used in water-based paints. The binder is a solid, plastic-like material. The particles are microscopic in size and are suspended in the paint. Latex-based paint binders may consist of acrylic or vinyl acrylic (polyvinyl acetate, PVA), or styrenated acrylics. Polyurethane polymers may also be used as paint binders.

2.3 Vehicle

Thinners, typically organic solvents, are used for oil-based and alkyd paints, while water is used for latex-based paints.

2.4 Additives

Additives include:

- Thickening agents
- Surfactants
- Preservatives
- Anti-foaming agents
- Solvents (co-solvents)

Thickening agents are used to obtain the correct paint consistency during use. Surfactants stabilise the paint to prevent it cutting and provide increased pigment dispersion. Preservatives prevent undesirable bacteria growth in the actual paint during storage or once it has been applied. Anti-foaming agents prevent the formation of foam during mixing and application. Co-solvents are used with non-water-based paints and are typically organic solvents which improve dissolution of one or more of the components.

3 Survey of manufacturers and suppliers

Window colours are sold in many shops and the products are normally supplied by European and American manufacturers. The following section provides a survey of the market as regards manufacturers, suppliers and products.

3.1 Manufacturers

European manufacturers dominate the Danish market. Worldwide there are about 15 hobby colour manufacturers /2/. Most of these manufacturers are also represented in the Danish market. A list of the manufacturers whose products are represented in the Danish market is given in Tabel 3.1.

Tabel 3.1 List of window colour manufacturers in the Danish market.

Manufacturer	Country	Internet address
AMOS	Korea	www.amoskorea.com
C Kreul	Germany	www.c-kreul.de/
Frech Verlag	Germany	www.frech.de/
Fun Creativ	Germany	www.funcreativ.de/
Havo	Holland	www.havo-holland.nl/
Lacufa AG, Nerchau Mal- und Künstlerfarben	Germany	www.nerchau-farben.de
Marabu	Germany	www.marabu-inks.com
Palmer Paint Products	USA	www.toydirectory.com/PalmerPaintProd ucts/
Pébéo Industries	France	www.pebeo.com
Plaid Enterprises	USA	www.plaidonline.com/
Royal Talens	Holland	www.talens.com/
Schjerning Farver A/S	Denmark	www.schjerning-farver.com/

3.2 Suppliers

Window colours are popular and are available in both specialist hobby shops and in supermarkets. Moreover, window colours are sold directly to institutions. Certain store chains and shops act as both suppliers and retailers. Table 3.2 shows a selection of window colour suppliers in Denmark. Suppliers normally only deal in products from one or two manufacturers. Table 3.2 Selected Danish window paint suppliers. (-: no Internet address or Internet address not known).

Supplier	Internet address
AV Form A/S	www.avform.dk/
Bogpa A/S	www.bog-ide.dk/
BRIO A/S	www.brio.dk/
Bøttzauw ApS	www.bottzauw.dk/
Dica A/S	www.dica.dk/
FDB	www.fdb.dk/
Klitgaard ApS	-
Panduro Hobby	www.panduro-hobby.dk/
Pébéo Color Scandinavia ApS	www.pebeo.dk/
Stenboden A/S	www.stenboden.dk
Terapi-hobby ApS	www.terapi-hobby.dk/
TOP-TOY	www.top-toy.dk/
Vestergaard ApS	-

3.3 Window colours

Table 3.3 lists the product names of the majority of window colours available on the Danish market. Any labelling on the product packaging are also listed.

Product name	Marking
Arti'stick	CE
C2 window pen	CE
Crystal Clear window color	CE
Fun & Easy	CE
Fun & Fancy	CE
Funny Window Color	CE
Gallery Glass Window Color	AP Non Toxic
Glass Deco	none
Mak'easy window color	CE
SunArt stain	CE
Vinduesmaling	CE
Window Art	CE

Table 3.3 Window colours on the Danish market and their labelling.

In addition to these, there are a number of outline paints for drawing outlines. These paints are normally black or white.

4 Survey of constituent substances in window colours

The survey of constituents substances is based on information obtained from manufacturers, suppliers and other relevant sources. As point of departure we set out to obtain available information in the form of safety data sheets and other product information from suppliers and manufacturers. Moreover, we have made every effort possible to obtain additional information from the manufacturers subsequent to agreement with the suppliers. All manufacturers have at least been contacted by post, either directly or through the Danish supplier. When applying to these manufacturers we have included an accompanying letter from the Danish EPA containing information about the project and reference to the responsible person at the Danish EPA. We followed up our requests for information both by telephone and post. We received information in the form of safety data sheets on seven of the ten products, which were adopted for chemical analysis. In addition, we received safety data sheets and supplementary information on constituent ingredients in window colours from one other supplier.

However, the survey was not of a scope that would allow the undertaking of an extremely comprehensive data collection process. Therefore, to supplement information a list of constituent substances in window colours was obtained from the consultancy firm, Chemtox. The list contains all the constituent substances in window colour products handled by Chemtox with the purpose of evaluation whether registration in the Product Register and the drafting of a safety datasheet was necessary.

Thus the survey is based on the window colour safety data sheets, additional information obtained directly from suppliers and manufacturers and the above-mentioned overall list. The safety data sheets must at least contain information on hazardous substances as defined in Statutory Order no. 559 off the Danish Working Environment Authority dated 4 July 2002 on special obligations imposed on manufacturers, suppliers and importers, etc. of substances and materials comprised under the Work Environment Act. In certain cases the data sheets also provide information on other substances in the product. The survey included data sheets and other information from a total of eight suppliers. Furthermore, the results of the survey have been presented to the Danish Joint Council for Creative and Hobby Materials. The Joint Council has confirmed that there is agreement between the Council's information and the results of the survey. The data collected from the suppliers taken together with the list from Chemtox may thus be assumed to present an acceptable picture of the constituent substances in the majority of window colours on the Danish market. Naturally there may be other products which are imported directly to specialist shops, etc. where assessment of the constituent substances has not been may pursuant to current legislation.

In the following lists constituent substances have been classified according to the four basic components.

• Pigments

- Paint binders
- Fluid/vehicle
- Additives

4.1 Pigments

Several of the pigments used are used in other types of paint and also in other types of products used in the dying of e.g. textiles. Table 4.1 shows that both inorganic and organic pigments are used in window colours.

Of organic pigments, azo pigments and polycyclic pigments were found. Only one pigment, copper phthalocyanine, containing a heavy metal was found. None of the other inorganic pigments identified contain heavy metals.

Table 4.1 Pigments in window colours and their physico-chemical properties (data from 11, 14 and 22). - indicates that value is not available, nr, that it is not relevant.

Name of substance (formula)	Trivial name / synonym	CAS no.	C.I. number	Conc. (%)	Use in cosmetics 1)	MW	S (g/L)	LogK _{ow}
Carbon black (C)	Pigment black 7	1333-86-4	77266	0-2	1	12.0	insoluble	in
Diarylids (C ₃₂ H ₂₆ Cl ₂ N ₆ O ₄)	Pigment yellow 12	6358-85-6	21090	0-2	No	629.5	< 1	5-7
Diazopyrazolone $(C_{32}H_{24}Cl_2N_8O_2)$	Pigment orange 13	3520-72-7	21110	0-2	No	623.5	-	-
Dioxazine ($C_{34}H_{22}CI_2N_4O_2$)	Pigment violet 23	6358-30-1	51319	0-2	4	-	-	-
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 and 26	12001-26-2	77019	-	No	-	-	in
Iron(II)oxide (FeO)	Iron oxide	1345-25-1	77489	-	1	71.8	-	in
Iron(III)oxide (Fe ₂ O ₃)	Pigment red 101	1309-37-1	77491	0-2	1	159.7	insoluble	in
Phthalocyanine (C ₃₂ H ₁₈ N ₈)	Pigment blue 16	574-93-6	74100	0-2	4	512.5	< 1	-
(Mono-chlorinated copper phthalocyanine ($C_{32}H_{15}CICuN_8$)	Pigment blue 15:1	12239-87-1	74250	-	No	-	-	-
Phthalocyanine green	Pigment green 7	1328-53-6	74260	-	2		< 1	-
4,4'- (3,3'-dichloro 1,1'-biphenyl -4,4'-diyl)bis(azo) bis 2,4- dihydro-5-methyl-2-(4- methylphenyl)- 3H-pyrazol-3- one	Pigment orange 34	15793-73-4	21115	-	No	-	-	-
N-(4-chloro-2,5- dimethoxyphenyl)-3-hydroxy-4- [[2-methoxy-5- [(phenylamino)carbonyl]phenyl]azo]naphthalene-2- carboxamide (C ₃₃ H ₂₇ CIN ₄ O ₆)	Pigment red 146	5280-68-2	12485	-	No	-	-	-
eq:sphere:sphe	Pigment red 147	68227-78-1	-	-	No	-	-	-
$\begin{array}{l} 2,2'-[(2,2',5,5'-tetrachloro-[1,1'-biphenyl]-4,4'-diyl)-bis(azo)]\\ bis-N-(2,4-dimethylphenyl)-3-oxo-butanamide\\ (C_{36}H_{32}Cl_4N_6O_4) \end{array}$	Pigment yellow 81	22094-93-5	-	-	No	-	-	-
2,2'-[(3,3'-dichloro[1,1'- biphenyl]-4,4'- diyl)bis(azo)]bis[N-(4-chloro- 2,5-dimethoxyphenyl)-3- oxobutyramide] $(C_{36}H_{32}CI_4N_6O_8)$	Pigment yellow 83	5567-15-7	21108	-	4	818.5	-	-
3,4,5,6-tetrachloro-N-[2- (4,5,6,7-tetrachloro-2,3-dihydro-1,3-dioxo-1H-inden-2-yl)-8- quinolyl]phthalimide $(C2_6H_6Cl_8O_8)$	Pigment yellow 138	30125-47-4	56300	-	No.	-	-	-
Quinacridone (C ₂₀ H ₁₂ N ₂ O ₂)	Pigment violet 19	1047-16-1	73900	0-2	4	312.3	insoluble	-
Titandioxide (TiO ₂)	Pigment white 6	13463-67-7	77891	0-2	1	79.9	insoluble	in

1) The figures in this column indicate how the pigments may be used in cosmetics products: 1: Pigment permitted in all cosmetics products; 2: Pigment permitted in all cosmetics products with the exception of cosmetics products for use around the eyes, i.e. eye makeup and associated cleansing products; 4: Pigment only permitted in cosmetics products which are only intended to be in short-term contact with the skin. No: May not be used.

None of the pigments appear on the List of Dangerous Substances or the Danish EPA's guideline list for self-classification of substances. Azo pigments are easily broken down enzymatically, releasing aromatic amines among other substances. Several of these aromatic amines are suspected of having carcinogenic effects.

As Table 4.1 shows, nine of the listed pigments are not included on the list of pigments that are permitted for use in cosmetics products. The Danish EPA assesses that the pigments which under cosmetics regulations may only be used in short-term contact with the skin ought not normally be used in products for children.

4.2 Paint binders

Acrylates and polyurethane polymers are used as paint binders in window colours. Acrylates and methacrylates are widely used as paint binders both in water soluble paints and solvent-based paints. Poly(meth)acrylates represent a major group of substances whose composition can be varied depending on the desired properties /3/. Thermoplastic (meth)acrylates are often used as paint binders. Acrylates consist of acrylic acid and meta acrylic acid and their methyl, ethyl and butyl esters /4/.

Table 4.2 shows which paint binders and residual monomers may be found in window colours according to the survey. In addition, the table shows the hazard classes in which the products are placed and their classification on the List of Dangerous Substances.

Table 4.2 Paint Binders and residual monomers in window colours and their physicochemical properties (data from 11, 14 and 23) and classification. (28). - indicates that value is unknown.

	vurue is ur	INTOWIT:					
Name of substance (formula)	Percentage content (%)	CAS no.	MW	S (g/L)	LogK _{ow}	Hazard classes	Classification
Acrylic acid (C ₃ H ₄ O ₂)	-	79-10-7	72.1	> 100	O.35	Flammable, Harmful to health, Corrosive, Dangerous to the environment	R10 Xn;R21/22 C;R35 N;R50
Ethylacrylate (C₅H ₈ O ₂)	-	140-88-5	100.1	15	1.32	Highly flammable, Harmful to health, Local irritant, Sensitizing	F;R11 Xn;R20/21/22 Xi;R36/37/38 R43
Ethylacrylate-methacrylic acid polymer	-	25212-88-8	-	-	-		No
2-Ethylhexylacrylate (C ₁₁ H ₂₀ O ₂)	-	103-11-7	184.3	< 1	4.09	Local irritant, sensitizing	Xi;R37/38 R43
Methylmethacrylate $(C_5H_8O_2)$	-	80-62-6	100.1	15	1.38	Highly flammable, Local irritant, Sensitizing	F;R11 Xi;R36/37/38 R43
Polyurethanepolymer	-	68400-67-9	-	-	-		No
Vinylacetat (C ₄ H ₆ O ₂)	-	108-05-4	86.1	20	0.73	Highly flammable	F;R11

MW= Molecular Weight; S = Solubility in water;

4.3 Medium

All the window colours encountered were water-based, i.e. their medium is water. In addition, the products may contain small amounts of solvent.

4.4 Additives

According to the information gathered, window colours contain a number of additives.

Table 4.3 shows a list of the additives used in window colours, selected physico-chemical properties and the hazard classes in which the substances are placed and the classification of substances from the List of Dangerous Substances.

Table 4.3 Additives in window colours and their physico-chemical	properties (data from 11, 14 and 23), and
their classification (28, 33) indicates that value is unknown.	

Name of substance (formula)	Percentage content (%)	CAS no.	MW	S (g/L)	LogK _{ow}	Hazard classes	Classification ¹⁾
2-Amino-2-methylpropanol ($C_4H_{11}NO$)	-	124-68-5	89.1	1000	-0.74	Local irritant	Xi; 36/38 R52-53
Ammonia (H₅NO)	-	1336-21-6	35.0	1000	-2.66	Corrosive, Dangerous to the environment	C; R34 N; 50
2-(2-(2- butoxyethoxy)ethoxy)ethanol	-	143-22-6	-	-	-	-	-
Butyl diglycoletheracetate $(C_{10}H_{20}O_4)$	-	124-17-4	204.3	31	1.3	Dangerous to the environment	R52/53
5-Chlor-2-methyl-4-isothiazol- 3-one (C_4H_4CINO)	<0.0012	26172-55-4	149.6	-	-	Sensitizing	R43
Diisopropyleneglycole $(C_6H_{14}O_3)$	-	110-98-5	134.2	-	-	-	-
Dipropyleneglycol (C ₆ H ₁₄ O ₃)	-	25265-71-8	134.2	> 100	-1.07	-	-
Dipropyleneglycolmethylethe r $(C_7H_{16}O_3)$	-	34590-94-8	148.2	1000	-0.35	-	-
Ethanol (C ₂ H ₆ O)	-	64-17-5	46.1	> 100	-0.31	Highly flammable	F;R11
Ethylenglycol (C ₂ H ₆ O ₂)	-	107-21-1	62.1	> 100	-1.36	Harmful to health	Xn;R22
Formaldehyde (CH ₂ O)	-	50-00-0	30.0	400	0.35	Carcinogenic, toxic, corrosive, sensitizing	Carc3;R40 T;R23/24/25 C;R34 R43
2-Methyl-4-isothiazol-3-one (C_4H_5NOS)	<0.0004	2682-20-4	115.1	-	-	Sensitizing	R43
2-Bromo-2-nitropropane-1,3- diol ($C_3H_6BrNO_4$)	-	52-51-7	200.0	>100	-0.64	Harmful to health, Local irritant, Dangerous to the environment	Xn;R21/22 Xi;R37/38-41 N;R50-53
Naphthol (C ₁₀ H ₈ O)	0-2	1321-67-1	144.2	-	2.7	-	-
1-Naphthol (C ₁₀ H ₈ O)	-	90-15-3	144.2	0,866		Harmful to health, local irritant	Xn;R21/22 Xi;R37/38-41
2,2-Oxydiethanol (C ₄ H ₁₀ O ₃)	-	111-46-6	106.1	> 100	-1.47	-	-
Polypropylener glycol	-	25322-69-4	-	-	-	-	-
Propylene glycol (C ₃ H ₈ O ₂)	1-5	57-55-6	76.1	> 100	-0.92	-	-
Triethanolamine (C ₆ H ₁₅ NO ₃)	-	102-71-6	149.2	> 100	-1.0	Sensitizing	R43
Triethylene glycol ($C_6H_{14}O_4$)	-	112-27-6	150.2	>100	-1.98	-	-

1) Classification from the List of Dangerous Substances or from the guideline list for selfclassification (in italics).

During the survey information was found on naphthol with Cas no. 1321-67-1. As no essential data was found for the stated Cas no. (1321-67-1), which is a mixture of isomers, the data specified below is for 1-naphthol with Cas. no. 90-15-3.

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 in a 3:1 mixture are marketed under the trade name of Kathon, occur commonly in window paints. The same applies to 2-bromo-2-nitropropane-1,3-diol (bronopol) and formaldehyde, which presumably most commonly stem from impurities in the constituent raw materials or from releases from formaldehyde-releasers. Isothiazolonone and bronopol are also encountered in CE marked products.

The two isothiazolinone derivatives are both contained by window colours in low concentrations which lie below the de minimis limit according to the safety data sheets for the investigated products. The substances also occur e.g. in cosmetics products, where the permitted limit is 0.0015%.

5 Chemical analysis

5.1 Test products

The window colours were analysed for their content of chemical substances. Table 5.1 lists the products' colours.

V-No.	Colour
V1	White
V2	Glitter green
V3	Ultramarine
V4	Blue
V5	Dark Blue
V6	Oriental Blue
V7	Mixed: Cobalt Blue Sunny Yellow Violet
V8	Mixed: Puppy Red Liner Black Royal Green
V9	Lemon yellow
V10	Bright Red

Table 5.1 test	products selected	l for qualitative ana	lysis.
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5.2 Methods of analysis

5.2.1 GC/MS screening (extractable organic substances)

Approx. 5 g of the product was taken and extracted with dichloromethane added internal standards by Soxhlet extraction for 16 hours. A part sample of the extract was removed and analysed directly and concentrated by combined gas chromatography and mass spectrometry (GC/MS) by scanning over a larger mass area. The contents were analysed compared to relevant external standards (indicated with an * in the Analysis Results) or internal standards (other extractable substances). Quantification of the components calculated compared to internal standards is semi-quantitative, thus implying greater uncertainty (estimated 50-200%). In the case of quantification compared to external standards uncertainty was estimated at 10-20%

The analysis were carried out as true double determinations. The detection limit was 1-5 mg/kg for the components that are semi-quantified and 1 mg/kg for the components where external standards were included.

5.2.2 X-ray analysis (elements)

A part sample was subject to X-ray analysis for the content of 40 elements. This analysis was outsourced.

The analysis were carried out as true double determinations. The detection limit was 10 mg/kg. Analysis uncertainty was 5-10% RSD.

5.2.3 Water content using Karl Fisher titration

The water content of the sample was determined by automatic titration with the help of Karl Fisher (KF) titration.

The analysis were carried out as true double determinations. Analysis uncertainty was 10% RSD.

5.2.4 IR screening

A part sample was removed from the sample which was pressed into a potassium bromide tablet and subject to FT-IR analysis to determine the main organic contents of the sample by comparison with data library spectra.

The analysis were carried out as true double determinations. This analysis will not be reported on separately. The results of the screening were used to underpin the results of the GC/MS screening.

5.3 Analysis results

5.3.1 GC/MS screening (extractable organic substances)

Table 5.2 and Table 5.3 shows the results of the GC/MS screening. The two results refer to double determinations. All identification of substances was made based on the mass spectrum through comparison with mass spectra in the data library. The spectra giving the closest match were assessed using scientific judgement in each case. Where identification is not possible the components are designated by group as a total amount or specified with a substance name in parentheses, this name being the most viable estimate of what the substance might be. The detection limit was 1-5 mg/kg.

In conformity with the wishes of the Danish EPA, standards have been selected based on the results of the survey of individual components. These components have therefore been calculated against the standards. Semiquantitative calculations against internal standards were made for all other organic components. The components calculated against external standards are indicated with * in the table. The detection limit for components calculated against external standards is 1 mg/kg.

For certain components the content was so great that it was necessary to dilute the sample in order to calculate the content correctly. These components are marked with an ^ in the table.

		V1		V2		V3		V4		V5
Dimethyloxazolidine	-	-	74	43	48	29	-	-	75	54
Butylether	-	-	-	-	-	-	51	59	-	-
(Hexylen glycol)	-	-	-	-	-	-	-	-	-	-
2 2-oxydiethanol*	-	-	-	-	-	-	-	-	-	-
Hexanol	36	53	-	-	-	-	-	-	-	-
Ethylhexanol	-	-	170	138	-	-	1200	1300	-	-
Acetophenone	-	-	-	-	-	-	-	-	-	-
Chloromethylisothiazolone	5.4	11	7.9	6.5	-	-	-	-	-	-
Benzoisothiazolone	-	-	-	-	-	-	39	37	-	-
Chloraniline	-	-	-	-	-	-	-	-	-	-
Chloroisocyanatobenzene	-	-	-	-	-	-	-	-	-	-
Caprolactam*	2.0	7.3	-	-	-	-	-	-	-	-
Chloro-nitro-benzenamine	-	-	-	-	-	-	-	-	-	-
(Chloro-benzotriazol)	-	-	-	-	-	-	-	-	-	-
Napthalenol*	-	-	-	-	-	-	-	-	-	-
Naphthalene	-	-	-	-	-	-	-	-	-	-
Nitrotriazaadamantan	83	95	-	-	-	-	-	-	-	-
Ethylbexylacrylat*	3.2	8.7	180	150	87	46	58	63	15	7.6
N-propyl-2-bydroxy-1-	-	-	-	-	4 3	3.8	-	-	-	1.0
oxobexabydro-1H-azenin					т.5	5.0				
Chloralkanes (two peaks)	-	-	-	-	-	-	-	-	-	-
Ethylmethyl pyridine*	-	-	-	-	-	-	-	-	-	-
Methyl-benzensulfonamid	-	-		-		-			-	
(sum of two peaks)*	-	-	-	-	-	-	-	-	-	-
Methyl ninerazine	-	-	-	-	-	-	-	-	-	-
Nonvinhenol*	-	-	-	-	-	-	-	-	-	-
(2.2-dimethyl-1-(2-hydroxy-	-	-		-	-	-	-	-	990	960
1-methylethyl)propyl									//0	700
propansvre ester)										
(2-methyl-propansyre 2-	-	-	-	-	-	-	-	-	1300	1300
ethyl-3-hydroxyhexylester)									1000	1000
(Methenamine)	-	-	-	-	-	-	-	-	-	-
Hydroxy biphenyl	-	-	-	-	-	-	-	-	-	-
Unidentified phthalates	-	-	-	-	3100	2700	-	-	-	-
(sum of two peaks)					0.00	2700				
(Dibutylphthalate)	-	-	-	-	37	35	-	-	-	-
DEHP	-	-	-	-	37	17	-	-	-	-
Benzophenone	-	-	-	-	4.3	3.1	-	-	-	-
Dodecanthiol*	-	-	-	-	-	-	450	470	7.9	2.9
Dodecylmethyl sulfid	-	-	-	-	-	-	88	92	7.6	7.8
Thiabendazole	-	-	-	-	-	-	120	110	-	-
Bis(ethylhexyl)maleat	-	-	-	-	-	-	280	300	-	-
Alkennitrile	-	-	-	-	-	-	13	13	-	-
Unidentified alkanes	240	360	130	100	1500	1500	560	590	370	240
alkenes, alkoholes,	210	000	100	100	1000	1000	000	070	0/0	210
cvcloalkanes/- alkenes										
Unidentified carboxylic	72	120	140	110	85	72	220	220	180	110
acids, esters, ketones,		.20					220	220		
aldehydes and amides										
Unidentified alvcoles and	190	330	1600	1500	365	328	32	56	1200	1100
oxycompounds		-				-				-
Unidentified aromatic	-	-	-	-	19	14	180	250	-	-
compounds							-	-		
Other unidentified	28	26	980	820	220	170	3100	3300	200	190
· · · · · · · · · · · · · · · · · · ·			•				•			

Table 5.2 Results of analysis for extractable substances in V1-V5. The two results refer to the double determinations. Results are given in mg/kg. The detection limit is stated above.

: lower than detection limit
 (): identification not possible; name of substance the most viable estimate
 *: quantified against external standards
 ^: quantified using diluted sample

		V6		V7		VC8	V	/9	l v	/10
Dimethyloxazolidine	-	-	-	-	-	-	12	21	-	-
Butylether	-	-	-	-	-	-	-	-	-	-
(Hexylen alvcol)	-	-	-	-	-	-	-	-	5200	5500
2.2-oxydiethanol*	-	-	-	-	-	-	-	-	-	-
Hexanol	-	-	-	-	-	-	-	-	-	-
Ethylhexanol	71	70	-	-	-	-	-	-	-	-
Acetophenone	-	-	-	-	-	-	11	11	-	-
Chloromethylisothiazolone	-	-	-	-	8.8	14			51	51
Benzoisothiazolone	-	-	-	-	-	-	3.6	49	-	-
Chloraniline							78	78		
Chloroisocyanatobenzene							40	41		
Caprolactam*	27	22					-	-		
Chloro-nitro-benzenamine	21	-	-	-	-		3.8	3.0	-	
(Chloro-benzotriazol)							5.0	5.2		
Nanthalonol*	-	-	-	-	-	-	J.Z	J.Z	-	-
Naphthalopo	-	-	-	-	-	-	-	-	- 11	57
Nitrotriazaadamantana	-	-	-	-	-	-	-	-		5.7
	-	-	-	- 20	- 2.6	- 21	-	-	- 1 /	- 12
	0.9	10	4.9	3.0	2.0	J.1	-	-	1.4	1.5
oxobexabydro-1H-azenine	-	-	-	-	-	-	-	-	-	-
Chloralkanes (two peaks)	-	-	-	-	-	-	260	270	-	-
Ethylmethyl pyridine*	58	59	-	-	-	-	-	-	-	
Methyl-benzensulfonamid	-	57	-	-	-		-	-	070^	850^
(sum of two peaks)*	-	-	-	-	-	-	-		770	030
Methyl piperazine	32	30	-	-	-	-	-	-	-	-
Nonylphenol*	-	-	51	54	81	95	-	-	-	-
(2,2-dimethyl-1-(2-hydroxy-	-	-	-	-	-	-	3500^	3000^	-	-
1-methylethyl)propyl										
propansyre ester)										
(2-methyl-propansyre 2-	-	-	-	-	-	-	4800^	4100^	-	-
ethyl-3-hydroxyhexylester)										
(Methenamine)	-	-	-	-	-	-	-	-	13	1.2
Hydroxybiphenyl	-	-	-	-	-	-	3.6	4.5		
Unidentified phthalates	-	-	-	-	-	-	-	-	-	-
(sum of two peaks)										
(Dibutylphthalate)	-	-	-	-	-	-	-	-	-	-
DEHP	-	-	-	-	-	-	-	-	-	-
Benzophenone	3.0	3.7	2.4	2.3	2.5	2.8	-	-	-	-
Dodecanthiol*	-	-	-	-	-	-	-	-	-	-
Dodecylmethyl sulfid	-	-	-	-	-	-	-	-	-	-
Thiabendazol	-	-	-	-	-	-	-	-	-	-
Bis(ethylhexyl)maleat	-	-	-	-	-	-	-	-	-	-
Alkennitrile	-	-	-	-	-	-	-	-	-	-
Unidentified alkanes,	900	910	27	26	62	62	390	380	27	26
alkenes, alkoholes,										
cycloalkanes/- alkenes										
Unidentified	280	400	44	39	58	60	140	150	63	57
carboxylicacids, esters,										
ketones, aldehydes and										
amides					1					
Unidentified glycoles and	-	-	760	840	730	630	2.5	6.2	1200	1200
oxycompounds					1					
Unidentified aromatic	-	-	-	-	1.5	1.8	3.6	4.2	23	18
compounds							1			
Other unidentified	170	180	68	68	49	72	210	230	15	18

Table 5.3. Results of analysis for extractable substances in V6-V10 The two results refer to the double determinations. Results are given in mg/kg. The detection limit is stated above.

-: lower than detection limit

(): identification not possible; name of substance the most viable estimate
*: quantified against external standards
^: quantified using diluted sample

5.3.1.1 X-ray analysis

Table 5.4 shows the results of the X-ray analysis. The elements not listed in the table were not detected by the analysis. Only single determination analysis were made due to the precision of the analysis. The detection limit is 10 mg/kg.

	1.14	1 1/0	Ú 1/0	114	Ŭ Vr	<u> </u>	1.17	1.0	1/0	140
	V1	V2	V3	V4	V5	V6	V/	V8	V9	V10
Sodium	480	-*	910	740	750	870	440	530	2000	660
Aluminium	77	-	-	-	-	-	-	-	-	-
Silicon	520	740	130	-	330	150	22	81	320	18
Phosphorus	130	-	-	400	-	-	-	-	170	36
Sulphur	880	490	1100	2700	1000	880	440	470	1700	2700
Chlorine	32	-	-	100	41000	-	-	-	350	92
Potassium	-	-	-	360	400	250	-	-	39	-
Calcium	12	-	21	20	17	-	-	-	18	-
Titanium	5100	-	-	-	-	19	-	-	-	-
Copper	-	18	65	260	33	28	-	-	-	-
Lead	-	-	-	-	12	-	-	-	17	-
Bromine	320	150	-	540	24	-	-	-	-	-
-: lower than de	tection li	mit								

Table 5.4. Results of X-ray analysis. Results are given in mg/kg.

: lower than detection limit

(): detection limit increased to 50 mg/kg

5.3.1.2 Water content

The tables below show the results of the analysis for water content. The two results refer to the double determinations.

Tabel 5.5 Results of water analys	/sis of V1-V5. Results are given in %.
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	V	'1	V	2	V	3	V	4	V	5
Water	44	46	47	48	46	46	64	67	62	60

Tabel 5.6 Results of water analysis of V6-V10. Results are given in %.

	V	6	V	7	V	8	V	9	V	10
Water	49	48	46	45	42	41	49	51	49	52

5.4 Summary of analysis

The screening analysis of constituent substances in window paints generally show that the highest concentrations of extractable substances consist of alcohols, glycols, ketones, esters and simple hydrocarbons; of these, some are identified by name and others by substance group. The levels contained in the various products vary between 2.3 and 5500 mg/kg, equivalent to 0.00023% to 0.55% in the products. Other substances found in high concentrations in a single product are unidentified phthalates (two peaks), which upon double determination were measured at 2700-3100 mg/kg, equivalent to 0.27-0.31% in the product.

Other substances were found in concentrations from approx. 1 mg/kg (0.0001%) and up to approx. 1000 mg/kg (0.1%), mostly at the lower end. This was also the case with products selected for toxicological assessment based on the chemical analysis. The substances concerned are those shown in Table 5.7.

Table 5.7 Substances selected for toxicological assessment.

Name of substance	Measured concentration in mg/kg	% in the product
Dimethyloxazolidine	12-75	0.0012 - 0.0075
Ethylmethyl pyridine	58-59	0.0058 - 0.0059
Methylbenzensulfonamid	850-970	0.085 - 0.097
Methenamine	1.2-13	0.00012 - 0.0013
Dodecanthiol	2.9-470	0.00029 - 0.047

Among the metals found were lead, copper, aluminium and titanium. Lead was detected in two products in concentrations of 12 and 17 mg/kg, respectively, equivalent to 0.0012 and 0.0017% in the products. During the survey information was found about one of the products. This information does not indicate that the product contains lead-containing pigments and an impurity might be involved. In the case of the other product, neither supplier nor manufacturer submitted any information. However, the concentration limits found were below the 0.15% which triggers requirements for special marking of lead-containing products for use as paint or varnish under Statutory Order no. 329 of the Danish EPA dated 16 May 2002 on the classification, marking, sale and storage of chemical substances and products.

Thus the analysis determined approx. 50% of the products' contents. Other constituent substances will primarily consist of paint binders such as acrylic resins and fillers.

6 Selected substances and data searching

6.1 Basis for the selection of substances

During the initial survey, 20 substances were identified in the pigment group, 7 in the paint binder and their residual monomers group and 18 substances were identified in the additive group. Among these substances, which were identified based on general information about the constituent substances contained in window colours and specific information on the test products, only 4 were re-encountered in connection with the chemical analysis. In this connection, we must stress that the screening analysis do not identify all substances individually. A number of substances are grouped by their group names alkanes, alkenes, alcohols, cycloalkanes/cycloalkenes, glycols and oxygen compounds, aromatic compounds and other unidentified substances. Many of the substances which were found during the survey must therefore be assumed to be included under these group names. This most certainly applies to the additives identified during the survey and shown in Table 4.3. The survey also covers a relatively large number of pigments, which one would not expect to find through a screening analysis of just 10 products.

Based partly on the results of the survey and partly on the chemical analysis of the test products, the Danish EPA has selected ten substances for assessment of their health implications. A toxicological profile based on the immediately accessible literature was drawn up for these substances.

In making the selection, account was taken of the concentration of the substances and any already existing knowledge on/or assessments of the substances in connection with consumer products. Thus, the selected products represent those products found in the highest concentrations in the test products and those substances about which the Danish EPA wishes further information.

6.2 The selected substances

Tabel 6.1 lists the substances selected with a view to assessment of their implications for health. The table also shows whether the substances were identified by chemical analysis or based on information from suppliers, and the concentrations of the substances. Finally, the table lists the substances' presumed application in the products.

Tabel 6.1 Review of substances selected for assessment of their health implications.						
Name of substance	CAS no.	Conc. (%)	Application	Source		
1-naphthol	90-15-3	-	Intermediate product of pigment production	Data search		
Dioxazine	6358-30-1	0-2	Pigment	Chemtox		
Dimethyloxazolidine	51200-87-4	0.0012-0.0075	Preservative	Chemical analysis		
Ethylmethyl pyridine	644-98-4	0.058-0.059	Flavour	Chemical analysis		
Methyl-benzenesulfonamide	5183-78-8	0.085-0.097	Softener	Chemical analysis		
Methenamine	100-97-0	0.00012-0.0013	Preservative (formaldehyde releaser)	Chemical analysis		
Dodecanthiol	112-55-0	0.00029-0.047	Plasticizer	Chemical analysis		
2-ethylhexylacrylate	103-11-7	0.0013-0.018	Paint binders	Chemical analysis		
Pigment red 146	5280-68-2	-	Pigment	Chemtox		
Pigment yellow 138	30125-47-4	-	Pigment	Chemtox		

6.3 Data search

Data on the physico-chemical properties and the health implications were obtained from a number of Internet-based databases and reference works.

- 1. Chembank
- 2. Chemfinder
- 3. Ullmann
- 4. ECB
- 5. SAX
- 6. TOXLINE
- 7. MEDLINE
- 8. HSDB
- 9. IRIS
- 10. CCRIS
- 11. GENETOX
- 12. IUCLID
- 13. PHYSPROP
- 14. Web of Science
- 15. NTP

There will be some overlapping between several of these databases. Table 6.2 reviews the results of the data search. The list shows whether the 14 databases contain data on the individual substances.

In addition, we examined whether the substances appeared on the chemical lists of the Danish EPA, the annex to the Cosmetics Statutory Order or on the positive list of the Danish Veterinary and Food Administration (list of food additives).

Substance	CAS no.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
1-Naphthol	90-15-3	+	+	+	+	+	-	+	-	+	+	+	+	+	+	-
Dioxazine	6358-30-1	+	+	-	+	-	+	-	-	-	-	-	-	-	-	-
Dimethyloxazolidine	51200-87-4	+	+	-	+	+	-	-	-	-	-	-	-	-	-	-
Ethylmethyl pyridine	644-98-4	-	+	-	+	-	-	-	-	-	-	-	-	+	-	-
Methyl- benzenesulfonamide	5183-78-8	+	+	+	+	-	-	-	-	-	-	-	-	+	-	-
Methenamine	100-97-0	+	+	+	+	-	+	-	+	-	+	+	+	+	+	+
Dodecanthiol	112-55-0	-	+	-	+	-	-	-	-	-	-	-	-	-	-	+
2-Ethylhexylacrylate	103-11-7	+	+	+	+	+	+	-	-	-	+	-	+	+	+	+
Pigment red 146	5280-68-2	+	-	-	+	-	-	-	-	-	-	-	-	-	-	-
Pigment yellow 138	30125-47-4	+	-	-	+	-	-	-	-	-	-	-	-	-	-	-

Table 6.2. Review of data search results. The database and data source numbers refer to the following: 1. Chembank, 2. Chemfinder, 3. Ullmann, 4. ECB, 5. SAX, 6. TOXLINE, 7. MEDLINE, 8. HSDB, 9. IRIS, 10. CCRIS, 11. GENETOX, 12. IUCLID, 13. PHYSPROP, 14. Web of Science, 15. NTP. + indicates data found. - indicates no data found.

The table shows that there is only limited data available in the literature examined on several of the substances, and in the case of some substances, only physico-chemical data. Such is the case with ethylmethyl pyridine (CAS no. 644-98-4), methylbenzenesulfonamide (CAS no. 5183-78-8) and the two pigments, as shown by Table 6.2.

Data on the individual CAS nos. is divided according to the various toxicological properties as illustrated in Tabel 6.3. The table only shows a (+) or (-) if data was found on the mentioned properties, thus the table says nothing about the actual effects of the substances or about the quality of data.

Secondary sources have been used in the main, as a result of which the quality of data varies greatly. In by far the majority of cases results have only been included from the sources referred to where the test conditions are reasonably well described.

		Acute toxicity			Subacute/chronic toxicity				ity	
		Inhalation	Ingestion	Skin contact	Irritation and corrosiveness	Allergy and hyper- sensitivity	Organ damage	Genetic damage	Cancer	Damage to the reproductive process and the foetus
Material	CAS No.									
1-Naphthol	90-15-3	+	+	+	+	-	-	+	-	+
Dioxazine	6358-30-1	-	+	-	+	-	-	+	-	-
Dimethyloxazolidine	51200-87-4	+	+	+	+	-	-	-	-	-
Ethylmethyl pyridine	644-98-4	-	-	-	-	-	-	-	-	-
Methyl- benzenesulfonamide	5183-78-8	-	-	-	-	-	-	-	-	-
Methenamine	100-97-0	-	+	-	+	+	+	+	+	+
Dodecanthiol	112-55-0	+	+	-	+	+	-	-	-	-
2-Ethylhexylacrylate	103-11-7	+	+	+	+	+	-	+	+	-
Pigment red 146	5280-68-2	-	-	-	-	-	-	-	-	-
Pigment yellow 138	30125-47-4	-	-	-	-	-	-	-	-	-

Tabel 6.3 Identified human toxicological data divided by CAS nos. identified.

7 Toxicological profile of selected substances

7.1 Toxicological profile of 1-naphthol

7.1.1 Identification of the substance and physical-chemical properties

7.1.1.1 Identification

Chemical name	1-naphthol
EINECS name	1-naphthol
CAS no.	90-15-3
Molecular	$C_{10}H_{8}O$
formula	10 0
Structural formula	OH

Applications

1-Naphthol is used in the manufacture of paints and colours (e.g. diazo pigments), of synthetic perfumes and of hair dyes. The substance is also used in the production of the insecticide Sevin (carbaryl) and anti-oxidants /12/.

Synonyms

The following synonyms have been found for 1-naphthol /12/:

- alpha-naphthol
- C.I. 76605
- durafur developer D
- fouramine ern
- fourrine 99
- fourrine ern
- furro ER
- 1-hydroxynaphthalene
- nako TRB
- 1-naphthalenol
- oxidation base 33

Regulation

EU/DK classification	Xn; R21/22 Xi; R37/38-41
The Danish EPA's guideline list for self-	not assessed
classification	
The Cosmetics Statutory Order	highest permitted concentration in hair
	dye is 2.0%
Foodstuffs (the positive list)	not on the positive list
Foodstuffs (the flavour list, 2002)	not on the flavour list 2002
The Danish Working Environment	not on the OEL list
Authority's occupational exposure limit	
list	

7.1.1.2 Physical/chemical properties

Table 7.1. Physico-chemical p	roperties of	1-naphthol
Physical/chemical properties		Reference
	solid	
Physical form	substance	
Molecular weight (g/mol)	144.17	22
Melting point (°C)	95	22
Boiling point (°C)	288	22
Vapour pressure (Pa)	0.03653	22
Specific weight (kg/L)	1.22	14
Log Kow	2.85	22
Water-solubility (mg/L)	866	22

7.1.2 Toxicological properties

Absorption

Tests involving the application of 1-naphthol to human skin indicated approx. 50% was absorbed percutaneously /8/.

Metabolism

An old study (1950) shows that 1-naphthol is primarily excreted in the urine following subcutaneous administration. Most of the substance is excreted within three days /16/. Within 35 minutes of application to the skin, the highest organ concentrations were found in the lungs, thyroid gland, heart, adrenal glands, spleen, thymus and brain. Following oral ingestion the highest concentrations were found in the kidneys, blood plasma, skin, liver and thyroid gland /16/.

7.1.2.1 Acute toxicity

Inhalation

The LC50 for rats is recorded as $> 420 \text{ mg/m}^3/\text{hour /8/}$.

Ingestion

The LD50 for oral ingestion in rats is recorded as 1,870 mg/kg body weight /6/.

The presumed lethal dose is recorded as 50-500 mg/kg /8/.

The substance is classified as *Harmful* with R phrase R22, Harmful if swallowed, on the List of Dangerous Substances.

Skin contact

The LD50 value for rabbits in the literature examined was recorded as being 880 to 990 mg/kg body weight /8,12/.

The substance is classified as *Harmful to Health* with R-phrase R21, Harmful in contact with skin, on the List of Dangerous Substances.

Irritation and corrosion

The substance can cause irritation to the respiratory organs /10/.

The substance may cause irritation in contact with the skin and eyes /8,10/. An animal test a concentration of 2.5% did not result in irritation of rabbit skin. The substance resulted in minimal eye irritation at concentrations of up to 1.5%, but was irritating to rabbits' eyes at 2 and 2.5% /16/. No tests using higher concentrations were found, but the substance is classified in its pure form as constituting a risk for serious eye damage.

1-naphthol is classified as *irritant* with R-phrases R37/38, Irritating to respiratory system and skin and with R41 and risk of serious damage to eyes, on the List of Dangerous Substances.

7.1.2.2 Subacute/chronic toxicity

Allergy and hyper-sensitivity

No relevant data was found in the literature examined.

Organ damage

No relevant data was found in the literature examined.

Genetic damage

Both negative and positive results have been found in Ame's tests on different strains of Salmonella Typhimurium. The results of chromosome aberration tests in the eukaryotic fungus, Neurospora Crassa, were negative, whereas chromosome aberration tests on the root cells of the plant Allium Cepa produced positive results /20,21/. Unscheduled DNA synthesis (UDS), which is a test to show repair of primary DNA damage produced negative results in rat liver cells. Negative results were also found in gene mutation assays of mouse lymphoma cells and in two *in vivo* chromosome aberration tests. Positive results were found in DNA repair tests in a single E. coli strain (JC5547). The substance is not considered to be a mutagen /16/.

Cancer

No relevant data was found in the literature examined.

Damage to the reproductive process and the foetus

A solution of 1-naphthol (0.5 %, 1:1 med hydrogen peroxide) applied to shaved rat skin (2 mg/kg/day) on days 1, 4, 7, 10, 13, 16 and 19 of the gestation period did not show teratogenic effects or other toxic effects on the foetus/16/. Oral administration of 1-naphthol in concentrations up to 80 mg/kg on days 6-15 of the gestation period did not result in treatment related effects on either the progeny or the mother animals /16/.

1-naphthol is designated as an experimental teratogen and is attributed reproduction-toxic effects by a single source /12/. However, no details

concerning test results are given and no further data has been found in support of this evaluation.

7.1.3 Conclusion

1-naphthol can be absorbed through the skin. The substance is classified as *Harmful* with R-phrases R21/22, Harmful in contact with skin and if swallowed, and as an irritant with R-phases R37/38, Irritating to Respiratory system and skin, and R41, risk of serious damage to eyes.

In the literature we found positive mutagenicity data relative to the Ames' test and chromosome aberration test on plant cells. Negative Ames' tests were also reported as was one negative chromosome aberration test on a eukaryotic fungus. No immediate conclusions can be drawn on the basis of this data.

We found no studies showing carcinogenic properties. Rat experiments involving skin contact and oral administration of 1-naphthol shows no effects on foetuses or foetal development. However, one single source described the substance as having reproduction-toxic effects, but gives no further details.

7.2 Toxicological profile of dioxazine

7.2.1 Identification of the substance and physical-chemical properties

7.2.1.1 Identification

Chemical name	dioxazine
EINECS name	8,18-dichloro-5,15-diethyl-5,15-dihydrodiindolo[3,2- b:3',2'-m]tripheno dioxazine
CAS no. Molecular formula	$\begin{array}{c} 6358-30-1 \\ C_{34}H_{22}Cl_2N_4O_2 \end{array}$

Structural formula



Application

Dioxazine is used as a colorant in products such as paint and artist's paints.

Synonyms

The following synonyms are used for dioxazine (5):

- diindolo[3,2-b:3',2'-m]triphenodioxazine
- 8,18-dichloro-5,15-diethyl-5,15-dihydro-
- C.I. Pigment Violet 23
- C.I. 51319

Regulation

EU/DK classification	not classified
The Danish EPA's guideline list for self-	not assessed
classification	
	permitted in cosmetics products
The Cosmetics Statutory Order	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	not on the OEL list
Authority occupational exposure limit	
list	

7.2.1.2 Physical/chemical properties

Tabel 7.2 summarises the physico-chemical properties of dioxazine. Dioxazine is a solid substance at room temperature and due to the extremely high melting point, vapour pressure is assessed as being very low at room temperature. No data was found on the partition coefficient and boiling point of the substance.

Physical/chemical properties		Source
Physical form	solid substance	14
Molecular weight (g/mol)	588	14
Melting point (°C)	430 - 455	14
Boiling point (°C)	-	
Vapour pressure (Pa)	very low *	14
Specific weight (kg/L)	1.4 to 1.6	14
Log Kow	-	
Water-solubility (mg/L)	very low*	14

Tabel 7.2 Physico-chemical properties of dioxazine. -no data was found *based on assessment.

7.2.2 Toxicological properties

7.2.2.1 Acute toxicity

Inhalation

No relevant data was found in the literature examined.

Ingestion

In rodents the substance has displayed low acute toxicity upon ingestion /5/.

Skin contact

In rodents the substance has displayed low acute toxicity upon skin contact /5/.

Irritation and corrosion

Tests on rabbits have shown dioxazine to be an eye irritant but not a skin irritant /5/.

7.2.2.2 Subacute/chronic toxicity

Limited studies on rats given repeated oral doses of the substance showed no toxic effects. There is no information on the doses used in the studies /5/.

In studies on the mutagenicity of selected azo dyes, the substance tested negative in Ames' tests /6/.

The substance is also on the US EPA's list of inert substances in pesticides of unknown toxicity /7/.

7.2.3 Conclusion

The data found is insufficient to construct a true toxicological profile of the substance. Except for a certain degree of eye irritation, no trace of the substance having harmful effects was found in the literature examined.

Based on the survey, 0-2% concentrations of the substance are expected to be present in window colours. The limited toxicological data is insufficient to evaluate the possible risks associated with the use of window colours by children.

7.3 Toxicological profile of dimethyloxazolidine

7.3.1 Identification of the substance and physical-chemical properties

7.3.1.1 Identification

Chemical name	dimethyloxazolidine
EINECS name	4,4-dimethyloxazolidine
CAS no.	51200-87-4
Molecular	$C_5H_{11}NO$
formula	0 11
Structural formula	

Applications

Preservative

Synonyms

The following synonyms have been the substance (8, 14):

- 4,4-dimethyl-1-oxa-3-aza-cyclopentane
- 4,4-dimethyl-1,3-oxazolidine
- oxazolidine A

Regulation

EU/DK classification	not classified
The Danish EPA's guideline list for	Xn;R22
self-classification	
The Cosmetics Statutory Order	permitted as preservative (max 0.1%)
Foodstuffs (the positive list)	not on the positive list
Foodstuffs (the flavour list, 2002)	not on the flavour list 2002
The Danish Working Environment	not on the OEL list
Authority occupational exposure limit	
list	

7.3.1.2 Physical/chemical properties

Very little data was found on dimethyloxazolidine, cf. Tabel 7.3.

Tabel 7.3 Physico-chemical	properties of dimethyloxazolidine.
- no data was found	

Physical/chemical properties		Source
Physical form	-	
Molecular weight (g/mol)	101.2	14
Melting point (°C)	-	
Boiling point (°C)	-	
Vapour pressure (Pa)	-	
Specific weight (kg/L)	-	
Log Kow	-	
Water-solubility (mg/L)	-	

7.3.2 Toxicological properties

7.3.2.1 Acute toxicity

Without any specific reference to the underlying studies the US EPA describes dimethyloxazolidine as being of mild acute toxicity upon ingestion, skin contact and inhalation /9/.

We identified the following data on inhalation, ingestion and skin contact in /8/.

Inhalation

The LC50 for inhalation by rats is recorded as 11,700 mg/m³. This value does not require classification under the Danish EPA's regulations.

Ingestion

LD50 for oral ingestion by rats is recorded as 950 mg/kg, which corresponds to a self-classification as *Harmful* (Xn) with R22, Harmful if swallowed. This corresponds with the classification on the guideline list for self-classification.

Skin contact

LD50 for skin contact with rabbits is recorded as 1,400 mg/kg, which corresponds to a self-classification as *Harmful* (Xn) with R21, Harmful in contact with skin.

Irritation and corrosion

The substance is described as a strong eye irritant /9/.

7.3.2.2 Subacute/chronic toxicity

The US EPA has stated that dimethyloxazolidine is not skin sensitizing and that it does not result in damage to foetuses or newborn children. Information from this source on mutagenicity is not accurate, though it does describe the risks stemming from the substance's mutagenic properties as being minimal for humans in connection with the exploitation of the substance's biocide properties in e.g. drilling mud /9/.

7.3.3 Conclusion

Based on the relatively limited data, the substance is assessed as being harmful to health through ingestion and skin contact and as being a strong eye irritant. The hazards of ingestion are also reflected in the classification of the substance on the Danish EPA's guideline list for self-classification.

Analysis results show concentrations of the substance between 0.0012 and 0.0075 % in three of the analysed products. At the these concentration, the substance is not expected to constitute a problem in window colours.

7.4 Toxicological profile for ethylmethyl pyridine

7.4.1 Identification of the substance and physical-chemical properties

7.4.1.1 Identification

Chemical name	ethylmethyl pyridine
EINECS name	2-isopropyl pyridine
CAS no.	644-98-4
Molecular	$C_8H_{11}N$
formula	0 11
Ctmvotvnol	

Structural formula

Application

Flavouring.

Synonyms

No synonyms were found for ethylmethyl pyridine.

Regulation

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

7.4.1.2 Physical/chemical properties

The small amount of available data on the physico-chemical properties of the substance are shown in Tabel 7.4.

Physical/chemical properties		Source
Physical form	-	
Molecular weight (g/mol)	121.2	14
Melting point (°C)	-	
Boiling point (°C)	-	
Vapour pressure (Pa)	-	
Specific weight (kg/L)	-	
Log Kow	2.26	22
Water-solubility (mg/L)	-	

Tabel 7.4 Physico-chemical properties of ethylmethyl pyridine. - no data was found

7.4.2 Toxicological properties

No descriptions of the substance's possible effects on human health were encountered in the literature examined.

7.4.3 Conclusion

No data was found on which to base conclusions on the toxicological properties of the substance.

Analysis results show concentrations of the substance between 0.058 and 0.059 % in one of the analysed products. The limited toxicological data is insufficient to specifically evaluate the possible risks associated with the use of window colours by children. However, the substance is not expected to constitute a problem in such low concentration in window paints.

7.5 Toxicological profile for methylbenzene sulfonamide

7.5.1 Identification of the substance and physical-chemical properties

7.5.1.1 Identification

Chemical name EINECS name CAS no	methylbenzene sulfonamide N-methylbenzenesulphonamide 5183-78-8
Molecular formula	$C_7H_9NO_2S$
Structural formula	O NH

Applications

Softener.

Synonyms

Methylbenzenesulfonamide has the synonym N-(Phenylsulfonyl) methanamine /8/.

Regulation

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

7.5.1.2 Physical/chemical properties

The physico-chemical properties of methylbenzene sulfonamide are shown in Table 7.5.

Table 7.5 Physico-chemical	properties of methyl-
benzene sulfonamide no	data was found

		÷.
Physical/chemical properties		Source
Physical form	powder	4
Molecular weight (g/mol)	171.2	14
Melting point (°C)	30	4
Boiling point (°C)	202	4
Vapour pressure (Pa)	0.095	22
Specific weight (kg/L)	-	
Log Kow	0.92	22
Water-solubility (mg/L)	9940	22

7.5.2 Toxicological properties

No descriptions of the substance's possible effects on human health were encountered in the literature examined.

7.5.3 Conclusion

No data was found on which to base conclusions on the toxicological properties of the substance.

Analysis results show concentrations of the substance between 0.085 and 0.097 % in one of the analysed products. The limited toxicological data is insufficient to specifically evaluate the possible risks associated with the use of window colours by children. However, the substance is not expected to constitute a problem in low concentration in window paints.

7.6 Toxicological profile of methenamine

7.6.1 Identification of the substance and physical-chemical properties

7.6.1.1 Identification

Chemical name	methenamine
EINECS name	methenamine
CAS no.	100-97-0
Molecular	$C_{6}H_{12}N_{4}$
formula	0 16 1
Structural formula	

Applications

Preservative, also a food preservative. Formaldehyde releaser.

Synonyms

Methenamine has a large number of synonyms, including:

- ammoform
- ammonioformaldehyde
- cystogen
- formamine
- formin
- hEXA
- hexaform
- hexamethylene triamine
- hexamethylenetetraamine
- hexamine
- hexilmethylenamine
- hiprex
- HMT
- HMTA
- mandelamine
- methamin
- resotropin
- 1,3,5,7-tetraazaadamantane
- 1,3,5,7-tetraazatricyclo[3.3.1.1(3,7)]decane
- UREX
- uritone
- uroqid
- urotropin

Regulation

EU/DK classification The Danish EPA's guideline list for self- classification	F;R11 R42/43 not assessed
The Cosmetics Statutory Order	permitted as preservative (max 0.15%)
Foodstuffs (the positive list)	not on the positive list
Foodstuffs (the aroma list, 2002)	not listed on the flavour list 2002
The Danish Working Environment	not on the OEL list
Authority's occupational exposure limit	
list	
Migration limit from materials in contact with food	15 mg/kg

7.6.1.2 Physical/chemical properties

The physico-chemical properties of methenamine are shown in Tabel 7.6.

Physical/chemical properties		Source
Physical form	solid substance	8
Molecular weight (g/mol)	140.2	14
Melting point (°C)	280	14
Boiling point (°C)	-	
Vapour pressure (Pa)	0.53	22
Specific weight (kg/L)	1.31	14
Log Kow	-4.15	22
Water-solubility (mg/L)	490000	22

Tabel 7.6 Physico-chemical properties of methenamine. - no data was found

7.6.2Toxicological properties

7.6.2.1 Toxicokinetic properties

Absorption

Following oral ingestion the substance is rapidly absorbed from the gastrointestinal tract /5/.

Metabolism

10-30% is hydrolysed at a relatively low pH in the gastric juices. Following absorption the substance is distributed to the body, maximum serum concentration being reached within an hour. The substance appears in the urine within a few minutes and reaches a maximum within 1 to 3 hours. Within 24 hours, 70-90% or more of a single dose of methenamine or one of its salts is excreted intact in the urine through glomerular filtration or tubular secretion. In acidic urine up to 20% of methenamine is hydrolysed to ammonia and formaldehyde /8/. Methenamine is easily distributed to the tissues and is absorbed into the breast milk /8/. No harmful effects on babies during breast feeding have been reported /10/. The substance can also cross the placenta barrier and has been observed in amniotic fluid of pregnant women treated with the substance. Four hours after dosing the concentration in the umbilical vein was equal to the mother's plasma level /11/. Only very little methenamine decomposes in the blood and other tissues and the substance is described as relatively systemically non-toxic. Toxicological effects seem to be largely linked to the products of hydrolysis /10/.

7.6.2.2 Acute toxicity

Inhalation

No data

Ingestion

Studies of acute toxicity indicate that methenamine is of relatively low toxicity. LD50 values of 9200 mg/kg body weight and above may be found in the literature/11/. For humans, an acceptable daily intake is estimated at 0.5-5 g/kg /5/.

Skin contact

No data.

Irritation and corrosion

Studies of skin and eye irritation in rabbits (OECD guidelines were followed) showed no irritant effects /11/. Very few details of these studies are given. In several places in the survey literature, the substance is described as causing irritation upon contact with the skin /12, 10/.

7.6.2.3 Subacute/chronic toxicity

Allergy and hyper-sensitivity

Studies of methenamine using the guinea pig maximization test on guinea pigs showed the substance to be skin sensitizing. Nine out of ten animals used in the test were sensitized /11/. Moreover, allergic eczema has been reported on several occasions in industrial workers exposed to methenamine-containing products /11/.

To study cross reactions with ethylenediamine, 32 ethylenediamine-sensitive patients participated in a patch test in which they were exposed to methenamine. One person showed a positive reaction to the test /11/. Furthermore, it has been reported that methenamine-sensitized persons can suffer asthma-like symptoms upon inhalation of methamine-containing fumes /11/.

One cross-section study involved 17 industrial employees, 16 control subjects and 4 out of 5 people who had retired from a methenamine-producing

company on medical grounds within the last ten years. On the basis of the test it was concluded that high exposure can result in allergic contact eczema. It was also concluded that there is no risk of respiratory sensitisation at average methenamine concentrations of less than 1 mg/m³/5/.

In the EU the substance is classified as sensitizing both upon skin contact and inhalation.

Organ damage

In a test on rats, which were administered methenamine a) daily, oral gavage (via stomach pump) for 90 days, b) daily, intramuscularly for 90 days and c) repeated oral administration for 333 days (no further information), respectively, the only reaction noted in the animals was a yellow colouration of their fur. The doses administered were a) 400 mg/animal, b) 200 mg/animal and c) 400 mg/animal, respectively. The yellow colouration of the fur was caused by the reaction between the formaldehyde in their urine and the kynurenine in the rats' hair /11/.

In a two-year study on rats that received 50,000 ppm (approx. 2500 mg/kg/day) methenamine in their food showed no effects on food uptake, weight increase or appearance and no histological changes were reported. The test only included two males and three females and NOAEL was determined at 2500 mg/kg /11/. In a two-year rat study using subcutaneous injections of 5000 mg/kg doses in 20 males and females, no treatment-related effects were observed, except for the yellow colouration of the fur /11/.

Genetic damage

Various tests have been carried out to throw light on methenamine's mutagenic properties. The substance was examined in an Ames' test using various strains of Samonella Typhimurium, with and without metabolic activation. The test results were largely negative, but a few positive tests were also reported /13, 11/. Moreover, positive results have been reported from a recombinant test on Bacillus Subtilis and a chromosome aberration test in human HeLa cells. A cell transformation test in BHK cells was also positive, as was a DNA repair test in E. coli P3478 (pol A-) at 6000 mg/plate. The results are probably due to the release of formaldehyde. At 500 mg/plate results were negative /11/.

Negative results were also reported in a gene mutation test in E. coli WP2uvrA, in a mouse lymphoma test and in a chromosome aberration test in human lymphocytes /11/.

A single *in vivo* test on Drosophila has shown mutagenicity in the larvae /11/.

An *in vivo* micronucleus study in mice found no clastogenic activity at 618, 206 or 69 mg/kg (LD50: 1853 mg/kg) after one-day and five-day exposure and oral administration. In a dominant lethal test on mice which received 25,000 mg/kg orally there was a significant rise in dead implants. However, because of the high dose, the results are doubtful. Another dominant lethal test in mice which were administered doses of 8,000 – 10,000 mg/kg intraperitoneally no induced lethal mutations were observed /11/.

In general, the studies referred to gave only scant information about the test conditions.

Cancer

In tests on both mice and rats using methenamine no signs of carcinogenic properties were found.

In a test on mice in which the substance (1.5% in chloroform) was applied to the skin of the animals for 300 days no formations of malignant tumours were observed. Nor where any treatment-related effects noted on Wistar rats that were administered methenamine in their drinking water for 104 weeks. The animals received doses of 1% and 5% respectively, in their drinking water. 50% of the animals in the high-dose group died within two weeks, whilst the others recovered quickly. There was no sign of tumour activity /11/. A group of Sprague Dawley rats were given continuous doses of 0.1% methenamine in their drinking water with or without 0.2% NaNO₂ for a period of 50 weeks. This test also failed to produce any carcinogenic activity /11/.

In an 18-month study involving subcutaneous administration of methenamine sarcomas were observed at the injection site in 8 of the 14 surviving animals. Information about test conditions is limited /11/. Tumour formation was also observed in another 12-18 month test on rats (15 males and 15 females) which received subcutaneous injections of 1 ml 40% solution once a week. Two spindle cell carcinomas, one alveolar mammary carcinoma, one fibrosarcoma and two benign tumours were observed among the animals treated. One malign tumour (blastoma) was observed in the control group. There is no further data /11/.

In a three generation study involving Wistar rats which were daily administered methenamine in their drinking water no signs of carcinogenic effects were observed. The F1 and F2 generations received 1% in the water until they were 40 weeks old. The F3 generation received doses until they were 20 weeks old. A group of the offspring of the treated parents received 2% in their water for 50 weeks /11/.

The studies report that in the case of oral administration no carcinogenic effects were demonstrated. In the case of subcutaneous injection isolated tumours of various kinds were observed at the injection site. However, there was no significant correlation with the treatment.

Damage to the reproductive process and the foetus

Several studies of reproduction toxicity in rats, which were administered between 20 and 2500 mg/kg methenamine per day, in their food, in their drinking water or via gavage (via stomach pump) respectively, failed to show any significant effects on litter size, survival or postnatal weight increase. The fertility of offspring was not effected nor were treatment-related histological changes observed /11/. No NOAEL values were established in any of the mentioned tests.

In a five generation study of rats, which received 5 or 50 mg/kg in their drinking water no treatment-related changes were observed in test animals, embryos or placenta. On the other hand, tumours were diagnosed in three of the 48 rats in the high dose group /11/. There is no further data on the effects /11/.

In a reproduction toxicity study on Beagles, the dogs were administered 600 or 1250 ppm (15 or 31 mg/kg/day) in their food. The animals were exposed from day 4 to day 56 of the gestation period. No treatment-related effects on gestation frequency or length, weight increase or litter size were observed. A

small rise in the number of stillborn puppies and a small decrease in body weight and survival of offspring were observed in the high dose group. No foetal damage effects were reported /11/.

A study of foetal damage in hens showed no effects on chick embryos or foetuses /11/.

7.6.3 Conclusion

Methenamine is absorbed rapidly from the stomach and intestinal tract and distributed to the tissues. The substance can penetrate the placenta barrier and is also found in human beast milk. Studies indicate that methenamine is of low acute toxicity upon ingestion. Information on irritant effects is scant. Methenamine has been found to be skin sensitizing in both humans and animals and human data has also been found that points to respiratory sensitizing properties. In the EU the substance is classified as sensitizing upon skin contact and inhalation.

Its genotoxic properties have been investigated in a number of tests which have given both negative and positive results. The positive results in certain studies may be due to the release of formaldehyde or extremely high doses. Based on the data examined, the substance may be designated as a possible weak mutagen, but further information is needed. Based on the literature examined we encountered no documentation for carcinogenic effects or effects deleterious to reproduction.

For humans, an acceptable daily intake is estimated at 0.5-5 g/kg /5/.

Analysis results show concentrations of the substance between 0.00012 and 0.0013 % in one of the analysed products. Based on the study of industrial workers, it is assessed that the substance will not result in either skin or respiratory tract allergies in such low concentrations. It is unlikely that children will ingest window colours in quantities that would result in the exceeding of the ADI value.

7.7 Toxicological profile of dodecanthiol

7.7.1 Identification of the substance and physical-chemical properties

7.7.1.1 Identification

Applications

Plasticizer.

Synonyms

The following synonyms are used for dodecanthiol /14/:

- lauryl mercaptan
- 1-dodecanethiol

- n-dodecylmercaptan
- n-lauryl mercaptan
- 1-mercaptododecane

Regulation

EU/DK classification	not classified
The Danish EPA's guideline list for self-	R43 N;R51/53
classification	
The Cosmetics Statutory Order	not given
Foodstuffs (the positive list)	not on the positive list
Foodstuffs (the flavour list, 2002)	listed on the flavour list 2002
The Danish Working Environment	not on the OEL list
Authority's occupational exposure limit	
list	

7.7.1.2 Physical/chemical properties The physico-chemical properties of dodecanethiol are shown in Tabel 7.7.

- HO Uata was Fouriu		
Physical/chemical properties		Source
Physical form	liquid	14
Molecular weight (g/mol)	202.41	22
Melting point (°C)	-8	22
Boiling point (°C)	274	22
Vapour pressure (Pa)	1.137	22
Specific weight (kg/L)	0.845	14
Log Kow	6.18	22
Water solubility (mg/L)	0.225	22

Tabel 7.7 Physico-chemical properties of dodecanethiol. - no data was found

7.7.2 Toxicological properties

It is assumed that dodecanethiol will be oxidised and precipitated as sulphate. In the unoxidized form the substance may potentially inhibit coenzyme Q, which forms part of the cell's energy metabolism and also acts as an antioxidant.

Dodecanthiol is of relatively low toxicity if swallowed or inhaled /15/. An oral LD50 value of 4225 mg/kg in mice and an intravenous LD50 in rats of >7000 mg/kg (no fatalities) are mentioned in the literature. The substance is also reported as having a high sensitization potential and as causing irritation to skin and eyes /15/. Chronic exposure, as has occurred in the footwear industry, has resulted in skin irritation and sensitization.

7.7.3 Conclusion

Based on the extremely limited information, the substance may be presumed to be of relatively low toxicity when swallowed or inhaled, to be irritating to skin and eyes and to be potentially skin sensitizing. The latter property is confirmed by the substance's R43 classification in the Danish guideline list for self-classification. Analysis results show concentrations of the substance between 0.00029 and 0.047 % in two of the analysed products. At such low concentrations, skin sensitization is the primary problem. No data was found that would permit an assessment of its sensitizing potential at a concentration of 0.047 %. However, a single source states that the substance has high sensitizing potential.

7.8 Toxicological profile of 2-ethylhexylacrylate

7.8.1 Identification of the substance and physical-chemical properties

7.8.1.1 Identification

Chemical name	2-ethylhexylacrylate
EINECS name	2-ethylhexyl acrylate
CAS no.	103-11-7
Molecular	$C_{11}H_{20}O_2$
formula	

Structural formula



Applications

Paint binder and co-monomer in paints and dyes.

Synonyms

The following synonyms are used for 2-ethylhexylacrylate/14/:

- acrylic acid 2-ethylhexyl ester
- EHA
- 2-ethylhexyl 2-propenoate
- 2-ethylhexyl propenoate
- 1-hexanol, 2-ethyl-, acrylate
- octyl acrylate
- 2-propenoic acid 2-ethylhexyl ester
- 2-propenoic acid octyl ester

Regulation

Xi;R37/38 R43
not assessed
not given
not on the positive list
not listed on the flavour list 2002
not on the OEL list

7.8.1.2 Physical/chemical properties

The physico-chemical properties of 2-ethylhexylacrylate are shown in Tabel 7.8.

Tabel 7.8 Physical/chemical properties of 2-ethyl hexyl acryl ate.

Physical/chemical properties		Source
Physical form	liquid	21
Molecular weight (g/mol)	184,3	22
Melting point (°C)	-90	22
Boiling point (°C)	213,5	22
Vapour pressure (Pa)	23,7	22
Specific weight (kg/L)	0,89	21
Log Kow	4,09	22
Water-solubility (mg/L)	100	22

7.8.2 Toxicological properties

7.8.2.1 Toxicokinetic properties

Absorption

No data,

Metabolism

Following intraperitoneal administration most of the 2-ethylhexylacrylate is rapidly metabolised and the C14 labelled substance was distributed mainly to the liver, kidneys and lungs. Elimination from the bloodstream takes place in two stages, where the half-life for the first stage in young rats is 30 or 60 minutes following intravenous or intraperitoneal administration, respectively, and for older rats about 2 hours. The half-life during the slow stage is 6 or 14 hours for young and old rats, respectively /11/. More than half of 2-ethylhexylacrylate is exhaled as carbon dioxide. Exhalation of unchanged 2-ethylhexylacrylat was 0.05% (i.v.) and 0.3% (i.p.) respectively, and 14% (i.v.) and 7% (i.p.) was secreted in the urine. Over 72 hours, a greater percentage of intraperitoneally administered substance is exhaled than when administered orally /11/.

7.8.2.2 Acute toxicity

Inhalation

In rats, 8 hours inhalation of a saturated atmosphere caused no fatalities /11/. LC50 in mice is reported as being greater than 7713 mg/l after 30 minutes' exposure and LCLo in mice as being 600 mg/l /11/.

Inhalation of concentrated fumes induces lethargy and spasms in humans /8/.

Ingestion

Studies with rats have reported LD50 values down to 1540 mg/kg in /8/ and between 4435 mg/kg and 12,800 mg/kg body weight in /11/. The majority of figures are around 5600 mg/kg body weight.

Skin contact

Dermal LD50 in rabbits has been reported from >700 mg/kg to 14,192 mg/kg body weight. The value for rats has been given at >12,000 mg/kg/11/. Frequent reference is made to values around 8500.

Irritation and corrosion

Undiluted 2-ethylhexylacrylate has been found to be irritating to the skin in trials with rabbits and mildly irritating in contact with rabbit eyes /8, 11/.

The substance is classified as *irritating* to respiratory organs and skin on the List of Dangerous Substances.

7.8.2.3 Subacute/chronic toxicity

Allergy and hyper-sensitivity

2-ethylhexylacrylate has shown sensitizing effects in both sensitization tests on guinea pigs and in patch tests on humans /11/. The substance is also classified as R43, May cause sensitization by skin contact, on the List of Dangerous Substances. Cross allergy with methylmethacrylate has been reported /11/.

Organ damage

Repeated dosing of rats through inhalation of concentrations of respectively 1 mg/l and 0.375 mg/l for 2.5 weeks, 6 hours/day, 5 days/week produced no toxic effects at the lower dose. At the higher dose the beginning signs of weight loss, drowsiness and laboured breathing were observed. There was no change in the blood picture and autopsies revealed no signs of pathological changes /11/. In a corresponding study covering 90 days using doses of respectively 0.075 mg/l, 0.225 mg/l and 0.75 mg/l there were no fatalities and no toxic effects at the lower dose. The animals in the highest dose group showed signs of mild drowsiness, closed eyelids during exposure and retarded physical development. Increased liver test figures and degeneration of the olfactory epithelium in the nasal fossae were also observed. At 0.225 mg/l the same effects were observed as at the highest dose but to a considerably lesser degree and without impact on the liver test figures /11/. In one 4-month study involving rats no effects were observed at a dose of 0.359 mg/l administered 5 hours/day /11/.

Dermal exposure of mice for periods of between 12 days and three months produced no systemic effects but primarily irritation effects on the site of application /11/. Daily application of 1 ml on the skin of rabbits for 2.5 weeks produced serious skin changes (inflammation, necrosis and ulcer formation) and treatment had to be terminated after 12 applications /11/.

Genetic damage

2-ethylhexylacrylate has been tested using the Ames' test on several strains of Salmonella Typhimurium with and without metabolic activation with negative results. A HGPRT assay for point mutations in mammal cells (CHO) was also negative. Cell transformation tests in fibroblast cells from C3H-mouse embryos and micro-nuclear tests on mouse L5178Y lymphoma cells were also negative /11/.

On the other hand, unambiguous results were not obtained in gene mutation tests with L5178Y mouse lymphoma cells, in sister chromosome exchange tests in CHO cells and in Unscheduled DNA synthesis in primary rat liver cells /11/. There is no detailed information on these tests.

In an *in vivo* cytogenetic test in mice, which were dosed orally once a day or five times in five days to 2500 mg/kg, exposure produced toxic effects on the animals but did not produce chromosome aberrations in the bone marrow /11/.

Cancer

In a study involving dermal lifetime exposure of male mice to concentrations of 2.5%, 21%, 43% (only 24 weeks) and 86.5% in acetone, papillomas and other skin tumours were observed on the skin treated after 11 months. The authors conclude that the skin tumours could be a consequence of the irritative properties of the substance /11/. Another 2-year study using male mice also failed to show direct signs of any carcinogenic potential for the substance /11/.

The International Agency for research on Cancer (IARC) has assessed the substance and placed it in group 3, which includes substances not classifiable as to their carcinogenicity in humans due to the lack of data /8/.

Damage to the reproductive process and the foetus

No data.

7.8.3 Conclusion

Investigations into 2-ethylhexylacrylate indicate that the substance is rapidly metabolised and is expelled mainly in the exhalation air. The acute toxicity of the substance may be assumed to be low, but one place in the literature quotes an oral LD50 value that would involve classification of the substance under R-phrase R22, *Harmful if swallowed.* This value deviates from the levels most frequently referred to and is thus not considered relevant. 2-ethylhexylacrylate has been found to be irritating to skin and mildly irritating to the eyes. The substance is classified as a skin and respiratory irritant. 2-ethylhexylacrylate has shown sensitizing effects in both sensitization tests on guinea pigs and in patch tests on humans. In the EU the substance is classified as *sensitizing* and assigned risk phrase R43, May cause sensitization by skin contact.

Results of mutagenicity studies are largely negative, but a single test to measure the effects on DNA failed to produce unambiguous results. Tests on mice have found no direct signs of the substance having carcinogenetic potential. The IARC has assessed the substance and placed it in group 3, which includes substances not classifiable as to their carcinogenicity in humans due to the lack of data. No data was found on reproduction toxic effects.

Analysis results show concentrations of the substance between 0.0013 and 0.018 % in nine of the analysed products. At such low concentrations skin sensitization is the primary problem associated with the identified toxicological properties. Data was not found that would permit an evaluation of sensitization potential at a concentration of 0.018 %, which is, however, considerably below the Classification Statutory Order's general de minimis limit of 1 % for products containing sensitizing substances.

7.9 Toxicological profile of pigment red 146

7.9.1 Identification of the substance and physical-chemical properties

7.9.1.1 Identification

Chemical name	pigment red 146
	N-(4-chloro-2,5-dimethoxyphenyl)-3-hydroxy-4-[[2-
EINECS name	methoxy-5-[(phenylamino)carbonyl]
	phenyl]azo]naphthalene-2-carboxamide
CAS no.	5280-68-2
Molecular	$C_{33}H_{27}CIN_4O_6$
formula	

Structural formula



Applications

Pigment.

Synonyms

The following synonyms were found for Pigment red 146:

- 2-Naphthalenecarboxamide, N-(4-chloro-2,5-dimethoxyphenyl)-3-• hydroxy-4-[[2-methoxy-5-[(phenylamino)carbonyl]phenyl]azo]-
- C.I. 12485 •
- Permanent Pink FBB •

Regulation

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

7.9.1.2 Physical/chemical properties

The physico-chemical properties of Pigment red 146 are shown in Table 7.9. Physico-chemical properties of Pigment red 146.

Physical/chemical properties		Source
Physical form	solid	24
Molecular weight (g/mol)	611,1	6
Melting point (°C)	320	6
Boiling point (°C)	880*	6
Vapour pressure (Pa)	-	
Specific weight (kg/L)	1,42	16
Log Kow	-	
Water-solubility (mg/L)	1.49 E-05*	6

Table 7.9. Physico-chemical properties of Pigment red 146. *based on QSAR. - no data was found.

7.9.2Toxicological properties

No relevant data was found in the literature examined.

7.9.3 Conclusion

No data was found on which to base conclusions on the toxicological properties of the substance.

No information was found on constituent concentrations during the survey, which taken together with the limited toxicological data also makes it difficult to specifically evaluate the possible risks associated with the use of window colours by children.

7.10 Toxicological profile of pigment yellow 138

7.10.1 Identification of the substance and physical-chemical properties

7.10.1.1 Identification

Chemical name	pigment yellow 138
EINECS name	3,4,5,6-tetrachloro-N-[2-(4,5,6,7-tetrachloro-2,3-dihydro- 1,3-dioxo-1H-inden-2-yl)-8-quinolyl]phthalimide
CAS no.	30125-47-4
Molecular formula	$C_{26}H_{6}C_{18}N_{2}O_{4}.$
Structural formula	

Applications Pigment.

Synonyms

The following synonyms were found for Pigment yellow 138:

- 1H-Isoindole-1,3(2H)-dione, 4,5,6,7-tetrachloro-2-[2-(4,5,6,7-tetrachloro-2,3-dihydro-1,3-dioxo-1H-inden-2-yl)-8-quinolinyl]-
- C. I. 56300
- Quinophthalone yellow.

Regulation

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

7.10.1.2 Physical/chemical properties

The physico-chemical properties of the substance are shown in Table 7.10.

Physical/chemical properties		Source
Physical form	solid	25
Molecular weight (g/mol)	694,0	25
Melting point (°C)	-	
Boiling point (°C)	-	
Vapour pressure (Pa)	-	
Specific weight (kg/L)	2,02	25
Log Kow	-	
Water-solubility (mg/L)	insoluble	25

Table 7.10. Physico-chemical properties of Pigment yellow 138. - no data was found.

7.10.2 Toxicological properties

No relevant data was found in the literature examined.

7.10.3 Conclusion

No data was found on which to base conclusions on the toxicological properties of the substance.

No information was found on constituent concentrations during the survey which taken together with the limited toxicological data also makes it difficult to specifically evaluate the possible risks associated with the use of window colours by children.

7.11 Summary

Table 7.11 summarises the substances' intrinsic 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 7.12 summarises information about regulatory requirements applying to the substances together with specification of concentrations of those substances identified through chemical analysis. Information about dioxazine originates from one producer and specifies typical contents of the substance in window colours.

Common to all the substances is the fact that the content percentages found in the survey and through chemical analysis respectively are lower than the levels at which known health harmful effects can be expected to occur in connection with the use of window colours.

Table 7.11 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.	Ao ef	cute fects	i	Lc eff	ocal fects	i	S	Sensit	ization		Re ex	epe (po	ated sure		CMF	2	Critical effects
		I	S	R	E	S	R	_	S	R			S	R	С	Μ	R	
1-Naphthol	90-15-3	•	•	0	•	•	•		-	-	-		-	-	-	0	0	Harmful to health (I,S)
Dioxazine	6358-30-1	0	0	0	٠	0	-		-	-	0		-	-	-	0	-	Eye irritation
Dimethyloxazolidine	51200-87-4	•	٠	0	•	-	-		0	-	-		-	-	-	0	0	Acute toxicity (I,S)
Ethylmethyl pyridine	644-98-4	-	-	-	-	-	-		-	-	-		-	-	-	-	-	No data
Methyl- benzenesulfonamide	5183-78-8	-	-	-	-	-	-		-	-	-		-	-	-	-	-	No data
Methenamine	100-97-0	0	-	-	0	0	-		•	•	•		-	-	0	0	0	Sensitization
Dodecanethiol	112-55-0	0	-	0	0	0	-		•	-	-		-	-	-	-	-	Sensitization (S)
2-Ethylhexylacrylate	103-11-7	0	0	0	0	•	•		•	-	-		-	•	0	0	-	Sensitization (S)
Pigment red 146	5280-68-2	-	-	-	-	-	-		-	-	-		-	-	-	-	-	No data
Pigment yellow 138	30125-47-4	-	-	-	-	-	-		-	-	-		-	-	-	-	-	No data

Table 7.12 List of regulations applying to the ten substances.

Name of substance	CAS no.	Conc. (%)	Classification ⁾	Max. permissible value in work environment	Cosmetic Statutory Order	The positive list	The Flavour List 2002
1-Naphthol	90-15-3	-	Xn;R21/22 Xi;R37/38-41	No	Max. 2.0% in hair dye	No	No
Dioxazine	6358-30-1	0-2	Not specified	No	Permitted in products in short-term contact with the skin	No	No
Dimethyloxazolidine	51200-87-4	0.0012- 0.0075	Xn;R22	No	Permitted as preservative, max 0.1%	No	No
Ethylmethyl pyridine	644-98-4	0.058- 0.059	Not specified	No	Not specified	No	No
Methyl- benzenesulfonamide	5183-78-8	0.085- 0.097	Not specified	No	Not specified	No	No
Methenamine	100-97-0	0.00012- 0.0013	F;R11 R42/43	No	Permitted as preservative, max	No	No
Dodecanthiol	112-55-0	0.00029- 0.047	R43 N;R51/53	No	Not specified	No	No
2-Ethylhexylacrylate	103-11-7	0.0013- 0.018	Xi;R37/38 R43	No	Not specified	No	No
Pigment red 146	5280-68-2	-	Not specified	No	Not permitted	No	No
Pigment yellow 138	30125-47-4	-	Not specified	No	Not permitted	No	No

1) Classifications form 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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