NON-CONFIDENTIAL SUMMARY OF SEA

Legal name of applicant(s):	*DCC Maastricht B.V. OR (Only Representative)*
Submitted by:	*DCC Maastricht B.V. OR (Only Representative)*
Substance:	*C.I. Pigment Yellow 34 (PY.34) and C.I. Pigment Red 104 (PR.104)*
Use title:	*Professional application of coating containing C.I. Pigment Yellow 34 and C.I. Pigment Red 104 on non-consumer articles.*
Use number:	*3*

NON-CONFIDENTIAL SUMMARY OF SEA

C.I. Pigment Yellow 34 and C.I. Pigment Red 104 (PY.34 and PR.104) are classified in the European Union as non-threshold carcinogenic and reprotoxic substances. This SEA, therefore, aims to demonstrate that the benefits of continued use of PY.34 and PR.104 in Use 3[1] outweigh the risks to human health and environment.

Since the applicant is not a downstream user, a great number of its most representative customers[2] have been interviewed. They have pointed out that if the authorization is refused, they would be forced to switch to a number of alternatives, deemed unsuitable from a technical and/or economic point of view.

The majority of companies have identified bismuth vanadate pigment (PY.184) as the best alternative to PY.34. The estimation of compliance cost and analysis of economic impact will therefore assume that this pigment will be used by the stakeholders concerned as the alternative to PY.34. For PR.104 two organic pigments C.I. Pigment Orange 73 and C.I. Pigment Orange 67 (PO.73 and PO.67) are assumed as replacements.

This SEA includes the most important impacts foreseen under the “non-use” scenario, such as health, economic and social impacts, with the exception of the environmental impact, which is not relevant for this authorization application.

As regards the health impact, the estimated cost components include: a) the cost of medical treatment, b) the loss of productivity, c) the welfare loss from mortality and d) the welfare loss from morbidity. The total annual economic burden associated with 1.50E-04 lung cancer cases attributable to the use of PY.34 and PR.104 in Use 3 has been estimated at € 269.

Concerning economic impact, the interviewed stakeholders[3] do not expect either relevant investment cost or administrative costs. However, it is reasonable to think that at least in the beginning companies will experience some costs for reformulations.

The estimation of the replacement cost that will be borne by paint/coating professional end-users under the “non-use” scenario includes the following elements: a) the high price of alternative pigments, b) the need to use a greater quantity of alternative pigments when compared to PY.34 and PR.104 and c) the need to apply an additional layer when paint[4] based on alternatives is used. Based on these three elements, the total annual replacement cost has been estimated at € 35,770,880.

This amount most likely underestimates the real cost, taking into account that it does not consider the poor performance of alternative pigments in terms of either durability or the labour costs associated with the need of applying additional layers.

Finally, it is important to point out that paint/coating based on PY.34 and PR.104 is used for safety reasons. It provides bright yellows and reds for road marking on public roads and airports, whereas alternative pigments present a number of problems, such as lack of opacity and weather fastness[5].

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[1] Professional application of coating containing C.I. Pigment Yellow 34 and C.I. Pigment Red 104 on non-consumer articles.

[2] Companies from paint industry.

[3] Companies from paint industry.

[4] The words paints and coatings are used as synonyms and disorderly in this document. Although strictly speaking they refer to different stages, we use them with the same intention.

[5] In particular organic pigments.

The main social cost which will be therefore borne by the society as whole in the “non-use” scenario is related to the reduced safety standards due to the application of less powerful colours in ground markings and road markings.

SOCIO-ECONOMIC ANALYSIS

Legal name of applicant(s):	*DCC Maastricht B.V. OR (Only Representative)*
Submitted by:	*DCC Maastricht B.V. OR (Only Representative)*
Substance:	*C.I. Pigment Yellow 34 (PY.34) and C.I. Pigment Red 104 (PR.104)*
Use title:	*Professional application of coating containing C.I. Pigment Yellow 34 and C.I. Pigment Red 104 on non-consumer articles.*
Use number:	*3*

CONTENTS

1. AIMS AND SCOPE OF SEA

1.1. Aims and scope of SEA

C.I. Pigment Yellow 34 and C.I. Pigment Red 104 (PY.34 and PR.104) are classified in the European Union as non-threshold carcinogenic and reprotoxic substances. This implies that an authorization can only be granted if there are no suitable alternatives and if the socio-economic benefits related to their use outweigh the risks to human health and environment.

The purpose of this SEA is, therefore, to demonstrate that the benefits of continued use of PY.34 and PR.104 in Use 3 outweigh the risks to human health and environment. The potential alternatives have been reviewed and discussed in the part on the analysis of alternatives.

The following analysis is based on the assumption that the stakeholders (paint/coating[1] manufactures and paint/coating professional end-users) currently using PY.34 and PR.104 under the non-granted authorization scenario will have a number of unsuitable alternatives to their disposal. The properties and flaws of these alternatives have been described in the Analysis of Alternatives.

The scope of the SEA:

- The geographical coverage of the analysis is the EU market.
- The impacts which can be quantified will be discounted[2] over 7[3] and 12[4] years at 4% and 30 years at 3%.
- The identification of likely responses under the "non-use" scenario is based on inputs collected from actors along the supply chain during the consultation process[5]. As the applicant is not the downstream user, a great number of downstream users, specialized in paint/coating, have been consulted. The majority of these companies invest a large percentage of their turnover in R&D (from 2% to 10%).
- No comments from third parties have been collected.

This SEA will consider the main relevant impacts expected under "non-use" scenario, such as health, economic and social impacts, with the exception of the environment impact which is not relevant for this authorization application.

[1] The words paints and coatings are used as synonyms and disorderly in this document. Although strictly speaking they refer to different stages, we use them with the same intention.

[2] The discounting starts at the beginning of the year.

[3] Because this is the normal authorization review period.

[4] It draws on the assumption that 12 is the average number of years which are usually required to develop any new pigment. By adopting an extremely optimistic approach, it has been assumed that this is the time required to develop a new red or yellow pigment.

[5] The paper is based on knowledge of the applicant, direct contact with the downstream supply chain throughout its customers in Belgium, Germany, UK, Greece, Netherlands, Poland, Sweden and customers in most European countries.

1.2. Definition of "applied for use" scenario

PY.34 and PR.104 are used in industrial, professional, non-consumer applications to provide colour and other properties intrinsic to these two pigments to many plastic, paint and coatings formulations and applications.

The "applied for use scenario" is the continued use of PY.34 and PR.104 in Use 3 under the conditions indicated in the Chemical Safety Report (CSR)[6].

Use 3 has been titled as follows:

"Professional application of coating containing C.I. Pigment Yellow 34 and C.I. Pigment Red 104 on non-consumer articles".

Examples include painted road marking on public roads and airports, as well as small scale repair activities on damaged coating layers containing these specific pigments on high grade equipment, for protection and to maintain the replacement value. The high quality of the coating is crucial for the long-term functioning of road or airport marking as fading of the colour could jeopardise public or worker safety; regular repainting could create dangerous situations (traffic jams); frequent temporary closing of airport operations would incur high costs.

The selection of a coating containing these pigments is governed by requirements for the end application related to:

- VISIBILITY AND SAFETY - Based on their bright, vivid, durable colours, these pigments are used when visibility and safety play an important role. In particular for road/airport markings, various national regulations require the use of precisely these pigments.

- DURABILITY - The pigments respond to the demand for high performance pigments, e.g. in aggressive atmospheric conditions in industrialized areas, providing excellent light and weather fastness, preventing applications to darken or fade if exposed to light and humidity; excellent resistance to sulfur dioxide, preventing discolouration (greyness) and loss of gloss, required for exterior applications;

- SHADE FUNCTIONALITY - Their colour covers a wide range from green to red shade yellow and yellow to blue shade red;

- COLOURISTIC AND TECHNICAL PERFORMANCE - Within the listed colour range, these pigments provide clean, vivid colours (chroma); excellent opacity or hiding power; excellent weather fastness. The perceived colour remains the same regardless of the light source, i.e. does not exhibit metamerism. They also provide excellent rheology in coatings; excellent non-bleeding properties, non-migration properties and impact resistance in coatings

[6] Chemical Safety Report for C. I. Pigment Red 104 (section no. 9) and Chemical Safety Report for C. I. Pigment Yellow 34 (section no. 9).

It should be noted that the analysis for Use 3 also takes into account the human health impacts and economic impacts of Use 1 (Distribution and formulation of C.I. Pigment Yellow 34 and C.I. Pigment Red 104 powder into paste/dispersions and solvent-based coloured paints with specific functions for industrial or professional use on non-consumer articles).

1.3. Definition of "non-use" scenario

On the basis of the responses received during the stakeholders' consultation, which involved the applicant and a great number of its most representative customers, the likely "non-use" scenario that will be considered in the SEA implies switching from PY.34 and PR.104 to a number of alternatives. As indicated in the Analysis of Alternatives these are not deemed suitable from a technical and/or from an economic point of view. As assessed in the AoA document, any choice among the alternatives presents a significant negative compromise.

Taking their technical performances and input from the applicant's customers into account, our quantification of compliance costs and other economic impacts assumes that under the "non-use" scenario bismuth vanadate pigment (PY.184) will replace PY.34. This assumption is based on the evidence received from the paint industry stakeholders, which have indicated that PY.184is the most suitable choice among alternatives.

As indicated in the AoAs, PY.184 is probably the pigment that comes closest to a possible alternative to PY.34. Many stakeholders also confirmed this during the consultation process. PY.184 has all the positive properties of the PY.34. It has very high durability and opacity. It is therefore likely that PY.34 will be replaced by PY.184 under the "non-use" scenario. However, it is only a green shade yellow and has to be mixed with other colour pigments to make other colours. This results in decreasing the opacity and weather fastness.

A number of possible alternatives to PR.104 in Use 3 have been described in the AoAs document. Some of the potential alternative pigments are: PO.36, PO.13, PO.16, PO.73 and PO.67. According to inputs received from stakeholders, C.I. Pigment Orange 67 (PO.67)[7] and C.I. Pigment Orange 73 (PO.73)[8] are those which probably will be used the most under the "non-use" scenario.

As described in the AoAs, PO. 67 is often touted as a potential replacement for PR.104. Although it has reasonable durability and a quite bright shade, it raises insurmountable technical problems for applications where PR.104 is still used today. The pigment in particular lacks the shade functionality. With regard to PO.73, the main problem concerns the limited supply by technical, risk, sustainability and production controls.

The estimation of compliance costs and other economic impacts therefore assumes that PO.67 and PO.73 will replace PR.104 under the "non-use" scenario.

[7] C.I. Pigment Orange 73

[8] CAS# 84632-59-7

2. ANALYSIS OF IMPACTS

2.1. Human health and environmental impacts

The current EU classification for the carcinogenicity of PY.34 and PR.104 was based on read across from significantly more soluble hexavalent chromium compounds. Since PY.34 and PR.104 have extremely low water solubility, the carcinogenic risk is considered very low due to poor bioavailability of the substances. Three epidemiological studies in PY.34 and PR.104 manufacturing plants "did not produce evidence supporting any association between PY.34 and PR.104 and lung cancer". However limitations in cohort size, due to the limited number of workers in this industry, could limit the use of such studies (Cooper 1983, Davies 1979 and 1984, and Kano 1993).

With regard to lead chromate, publications and reviews are (amongst others) available in an EU Risk Assessment Report (RAR) from 2005, from the Scientific Committee on Occupational Exposure Limits (SCOEL;2004), Seidler et al. (2012) and NTP, 2008. The Seidler el al. (2012) study, in which a health-based Risk Assessment for Hexavalent Chromium was presented, was used as a basis for the derivation of the DMEL for inhalation exposure. Several health effects are associated with occupational exposure to hexavalent chromium compounds, with carcinogenicity (specifically lung cancer) being the most serious. Therefore, lung cancer is taken as the critical effect upon which the occupational exposure limit was based. In addition, the excess lifetime intestinal cancer risk for workers after oral exposure to hexavalent chromium was calculated, based on the observation of excess risk after oral exposure in a well conducted NTP carcinogenicity study in mice.

For lead, the voluntary Risk Assessment Report (vRAR) from 2008 was taken into account, as well as the SCHER opinion on the vRAR, which was published in 2009. The main effect that was taken into account for the pigments was the effect on reproduction and possible developmental neurotoxicological effects. Furthermore, the Panel on Contaminants in the Food Chain (CONTAM) of the European Food Safety Authority published a scientific opinion on lead in food, in which a Benchmark Dose Level (BMDL) was determined for the effects of lead on neurobehavioral development.

2.1.1 Health hazards of C.I. Pigment Yellow 34 and C.I. Pigment Red 104

Two health hazards of the two pigments require the use of Derived Minimal Effect Levels (DMELs), i.e. neurodevelopmental damage and lung cancer. This means that the risk of these hazards cannot be reduced to zero. For intestinal cancer related to the theoretical risk from muco-cilliary clearance into the gastro-intestinal system of these pigments a Derived No Effect Level (DNEL) for the oral route is set. If the exposure is below this DNEL then the risk of intestinal cancer is reduced to zero. For exposure above the DNEL we cannot conclude that the risk is controlled. For those uses the excess intestinal cancer is calculated. Subsequently the economic impact of this intestinal cancer is calculated.

Based on the exposure estimations in the contributing scenarios described in the CSR (Chemical Safety Report) pertaining to the application for Authorisation of the pigments, it was concluded that no significant neurodevelopmental toxicity will occur through the use of PY.34 and PR.104. This lack of impact on human health automatically means that no costs are associated with this hazard.

The monetisation of the health impact of the lung cancer hazard is based on the exposure / DMEL ratios for this hazard as determined in the CSA for PY.34 and PR.104, without the application of correction for frequency and duration of exposure as these are stipulated in the contributing scenarios. This means that the calculated costs of the carcinogenic health impact of each worker's task, involving the pigments, is performed for 40 hours a week and 220 days a year. Per type of activity we have established the number of man years involved in the activity. This is also used in the monetisation calculation. The result is an exaggerated assumption, resulting in a conservative calculation of the costs.

The potential oral dose that is possible through muco-cilliary clearance into the gastro-intestinals system is calculated by multiplying the concentration per contributing scenario, as determined in the CSA, without taking into account the correction for frequency and duration of exposure, with the total inhaled volume per working day and dividing it by the assumed worker body weight. This is a clear overestimation of the potential dose for this route. If this potential oral intake is below the DNEL-oral, the additional intestinal cancer is zero. If the potential exposure is above the DNEL-oral, the risk is calculated by multiplying the potential dose with the established number of man years for the task and the oral intake is associated with a risk of intestinal cancer with a linear extrapolation of the intestinal tumour risk. We have estimated the oral intake based on the concentration of pigments in the air, without the application of correction for frequency and duration. For the inhaled weight per kilograms bodyweight per day we have used the assumptions listed in section 2.1.2.

2.1.2 Basic assumptions

In this paragraph we list the assumptions we have used in calculating the health risks of the use of the pigments. These assumptions are derived from a range of sources, varying from ECHA guidance, technical documentation of the models used, good industrial hygiene practices from either the British or Dutch Industrial Hygiene associations, to information provided by downstream users.

A standard work week is set at 40 hours/week and a worker is considered active for 220 days/year. As the health impact of the carcinogenic hazard is related to the long-term average exposure, the average long-term worker exposure is used as the measure for the risk characterisation. A worker career is considered to last 40 years.

The inhalatory DMEL for carcinogenicity (lung cancer related to the respirable fraction of the pigments) is set at such a level that exposure at DMEL for the duration of 8 hours a day, 220 days a year over 40 years leads to an additional individual lung cancer risk of $4*10^{-5}$, taking into account the percentage of the pigments which is respirable. Within the uses defined only a limited percentage is respirable. The percentage respirable ranges from 2.2%[9] to 12%[10] for the spraying of

[9] Value calculated based on the dustiness studies performed in order to document the particle size distribution field in the IUCLID dossier. 2.2% is the 95% percentile tolerance upper limit, with a reliability of 70% as calculated using the Non-Central Student, tolerance limit Tuggle NVvA/BOHS method of calculation, for the pigment with the highest respirable / inhalable fraction ratio

[10] Size Distribution of Chromate Paint Aerosol Generated in a Bench-Scale Spray Booth. RANIA A. SABTY-DAILY (Health Science Program, 5151 State University Drive, California State University, Los Angeles, CA 90032-8171), USA, WILLIAM C. HINDS,and JOHN R. FROINES (both from Center for Occupational and Environmental Health, School of Public Health, 650 Charles E. Young Drive South, University of California, Los Angeles, CA 90095-1772, USA). Annals of occupational Hygiene, Vol. 49, No. 1, pp. 33–45, 2005. ©2004 British Occupational Hygiene Society.

chromium containing pigment paints. For the determination of the DMEL for Chromium, the value of 12% is used.
The DNEL for oral intake for carcinogenicity is set at 0.22 µg Chromium VI / kg bodyweight / day. In order to calculate the oral intake we have assumed that the entire inhalable intake is digested, except for the spraying of paint, for which we have a published reference to the respirable fraction[10]. It is assumed that a worker inhales 10 m^3 of air during a standard 8-hours shift[11]. The concentration used is the calculated concentration with the exposure model used, adjusted for the use of the prescribed respiratory protection using the listed assigned protection factor.

The volume of PY.34 used, is 2100 tonnes per year and the volume for PR.104 is 900 tonnes per year. 40% of the pigments are used in Uses 1, 2 and 3 and 60% are used in Uses 4, 5 and 6. This is an estimation made by DCC. In both the paint and the plastic sector, about 80% of the pigment used has an end use in the industrial sector (Use 2 and 5) and 20% has an end use in the professional sector (Use 3 and 6). We will therefore attribute 80% of the calculated additional cancer risk that is related to the use of the pigment during formulation to the industrial use and 20% of that additional risk to the professional use for both of the sets of uses.

In the production of paints, pigment is mixed with other ingredients into paste dispersion. This paste dispersion is stored, packaged, shipped and added to other ingredients of the paint. During the formulation of paste, a worker typically handles 1000 kg of powdered pigment (value taken from site visits). The average concentration of pigments in paste is 50%. The average pigment concentration in paints is 7.5%. The relative density of paint is 1.8. The amount of paint transferred during the filling of paint to colli, is set at 10 litres per minute, which is the lowest value used in our exposure estimations. As up to 10% of the turnover is spent at R&D we estimate that the time used at R&D activities is also 10%.

The number of man-years associated with production of PY.34 coloured paint is 3.82 (40% of 2100 tonnes, divided by 220). As up to 10% of the turnover is spent at R&D we estimate that the time used at R&D activities is also 10%.
The amount of coloured paint produced is 6,222,222 litres (40% of 2100 tonnes, multiplied by 1000 and divided by the weight of the pigment in the paint per litre 7.5% of 1.8). The number of man years needed to transfer the prepared paint to packaging is 7.86 (6,222,222 litres, divided by the minimum flow used in the calculation of the exposure assessment for transfer which is 10 l/min, divided by 360 minutes per day, divided by 220 working days per year).

The thickness of a single coating of coloured paints is 20 µm. In an industrial setting a worker uses up to 20 litres of paint per hour. In a professional setting this volume is 10 litres per hour. The application time per worker is 6 hours per day. These values were determined during site visits to stakeholders.

The application of 80 % of PY.34 coloured paint in an industrial setting takes 188.6 man-years (80% of volume divided by the product of total working days per year (220), application hours per day (6) and application volume per hour (20 litres).

[11] Commonly used default value. Documented amongst others in Guidance on information requirements and chemical safety assessment, Chapter R.8: Characterisation of dose [concentration]-response for human health. Version 2.1, November 2012.

The application of 20 % of PY.34 coloured paint in a professional setting takes 94.3 man-years (20% of volume divided by the product of total working days per year (220), application hours per day (6) and application volume per hour (10 litres).

The number of man-years associated with production of PR.104 coloured paint is 1.64 (40% of 900 tonnes, divided by 220). The amount of coloured paint produced is 2,666,667 litres (40% of 900 tonne, multiplied by 1000 and divided by the weight of the pigment in the paint per litre 7.5% of 1.8).

The application of 80 % of PR.104 coloured paint in an industrial setting takes 80.8 man-years (80% of volume divided by the product of total working days per year (220), application hours per day (6) and application volume per hour (20 litres).

The application of 20 % of PR.104 coloured paint in a professional setting takes 40.4 man years (20% of volume divided by the product of total working days per year (220), application hours per day (6) and application volume per hour (10 litres).

We have assumed that preparatory work, maintenance and cleaning accounts for less than 10% of a workers day. We consider this a worst case estimation, given our knowledge of the industry and the results of the company visits.

We have calculated the risks related to industrial and professional service life by multiplying the exposure estimate with the combined number of man-years listed above for the industrial or professional use and the factor of 10% listed above. We have assumed that 80% of the service life as viewed from a worker perspective occurs in a professional setting.

2.1.3 Aggregated lung cancer risk for the use of PR.104 and PY.34 in Use 1, 3

All the exposure / DMEL ratios (EDRs) of the contributing scenarios in Use 1 and 3 are calculated based on the 90th percentile exposure estimation and the application of the assigned protection factor of the respiratory protection as listed in the contributing scenarios. These EDRs per activity were multiplied with the number of man years associated with the activity, the additional lung cancer risk associated with exposure at EDR and a percentage for worst case time expenditure per task, where relevant. This is added for all the contributing scenarios. If a single activity (i.e. transfer of pigment powder) is described with more than one contributing scenario (i.e manual transfer and automated transfer) only the activity with the highest EDR is included in the calculation.

A table with an overview of the calculations per contributing scenario is provided in Annex B.

Table 1 Aggregated lung cancer risk for the use of C.I. Pigment Yellow 34 in paints (Use 1, 2, 3)

Use applied for number	**Life cycle stages Use 1, 2, 3**	**Aggregated lung cancer risk**
	C.I. Pigment Yellow 34	
1	Distributing and mixing pigment powder in an industrial environment into solvent-based paints for non-consumer use. Pigment choice depends on product specifications on colouristic properties, safety, durability or other requirements and Regulations	**7.64E-06**
3	Professional, non-consumer application of paints on metal surfaces (machines, vehicles, structures, signs, road furniture) or as road marking. Pigment choice is governed by requirements on colour, safety, durability, technical performance and Regulations	**8.90E-05**
(associated with Use 3)	Professional Service life of painted/coated articles. Performance and longevity are governed by pigment quality, providing bright colours improving visibility and safety, light and weather fastness (durability), chemical fastness, impact resistance and heat stability	**3.92E-06**
	Total risk associated with Use 3 Professional uses in paints C.I. Pigment Yellow 34 (20% of aggregated risk for Use 1 + Use 3 + Professional service life)	**9.45E-05**

Table 2 Aggregated lung cancer risk for the use of C.I. Pigment Red 104 in paints (Use 1, 2, 3)

Use applied for number	**Life cycle stages Use 1, 2, 3**	**Aggregated lung cancer risk**
	C.I. Pigment Red 104	
1	Distributing and mixing pigment powder in an industrial environment into solvent-based paints for non-consumer use. Pigment choice depends on product specifications on colouristic properties, safety, durability or other requirements and Regulations	**3.45E-06**
3	Professional, non-consumer application of paints on metal surfaces (machines, vehicles, structures, signs, road furniture) or as road marking. Pigment choice is governed by requirements on colour, safety, durability, technical performance and Regulations	**3.82E-05**
(associated with Use 3)	Professional Service life of painted/coated articles. Performance and longevity are governed by pigment quality, providing bright colours improving visibility and safety, light and weatherfastness (durability), chemical fastness, impact resistance and heat stability	**1.68E-06**
	Total risk associated with Use 3 Professional uses in paints C.I. Pigment Red 104 (20% of aggregated risk for Use 1 + Use 3 + Professional service life)	**4.05E-05**[12]

The calculation in the tables above is made on the assumption that 80% of the paints made with the pigments is used in an industrial setting and 20% in a professional setting. This figure is based on our site visits. The risks associated with professional and industrial use are not identical, mainly because of the less sophisticated implementation of the risk management measures. The risks in the professional setting are somewhat higher. If we were to use a worst case estimation and assume all use of paints made with the pigments is professional, than the total risk associated with this use would be 4.59E-04 for C.I. Pigment Yellow 34 and 1.98E-04 for C.I. pigment Red 104.

2.1.4 Aggregated intestinal cancer risk for the use of PR.104 and PY.34 in paints (Use 1, 2, 3)

For the non-respirable fraction there is a theoretical risk from muco-cilliary clearance into the gastro-intestinal system. Non-respirable particles are included in the oral risk assessment following conversion of exposures to a mean daily oral dose in µg/kg bw. A value of 70 kg[11] for the body weight of a worker was used. It was assumed that the amount of air a worker inhales during the 8 hour shift is 10 m^3 [11]. As a worst case estimate we used the total concentration estimate, including

[12] The values listed in the table for C.I. Pigment Red 104 are slightly different than the one used for the calculation of the health costs. The value used in the monetization is a grand total risk of C.I. Pigment Red 104 in use 3 of 4.07*10-5.This stems from an adaptation to the contributing scenario of manual dosing of pigment in the exposure scenario formulation, where we increased the prescribed assigned protection factor of the respiratory protection for 40 to 100, in order to provide a higher level of protection. Using the original value slightly overestimates the overall cancer risk and the costs associated with it.

the respirable fraction which is not available for oral exposure for all uses. In the contributing scenario 5 of Use 3 we also included a maximum duration per shift of 4 hours.

In all contributing scenarios the oral dose is below the DNEL (0.22 of Cr(VI) / kg body weight / day). This means that the risk is controlled under the conditions listed in the CSR.

2.1.5 Lung Cancer Medical Costs

Cancer causes the second highest number of deaths in Europe after cardiovascular diseases. Among different types of cancer, lung cancer is one of the most lethal and common forms with a particularly poor rate of survival. In 2008, there were 288,000 diagnosed lung cancer cases in the European Union, with a ratio of mortality to incidence at 0,86 (GLOBOCAN, 2008). Almost 90% of those diagnosed with lung cancer die within 5 years (Stockholm School of Economics, 2008). Only around 5% of those diagnosed with lung cancer are expected remain alive after 10 years[13] from the diagnosis (Cancer Research UK, 2012). As with incidence, the mortality rates are generally higher in Eastern Europe than Western and Northern Europe. The highest mortality rates in Europe have been found in Hungary, the Former Yugoslav Republic of Macedonia and Serbia while the lowest rates are in Sweden, Cyprus and Switzerland (IARC, 2012).

Lung cancers can be grouped into two main groups: small-cell lung cancers (SCLC) and non-small cell lung cancers (NSCLC), which account for 85% of all lung cancers. Lung cancer is particularly difficult to treat and the outcome of the medical treatments depends on its form and stage. Common treatment includes: surgery, radiotherapy and chemotherapy. Small cell lung cancer is usually treated with chemotherapy while non-small cell lung cancer can be treated with surgery, chemotherapy, radiotherapy or a combination of the three, taking into account the stage of the cancer.

The economic burden of cancer to the EU economy was estimated at € 124 billion annually in 2009 (€ 247 per citizen), with health care accounting for 39% of costs (€ 48,36 billion) and 4% of total health care expenditure (Leal, 2012). With regard to lung cancer, it represented 15% of the overall cancer costs followed by breast cancer and colorectal cancer (Leal, 2012). According to the Health Research Centre of the University of Oxford, lung cancer costs more than other cancer because of the potential wage losses due to premature death of people in employment – about 60% of the total economic costs - and high health care costs.

The purpose of this part of the study is to estimate the total direct costs associated with 1.50E-04[14] (1.35E-04[15]/0.9[16]) annual lung cancer cases among workers, which could be attributed to PY.34 and PR.104 for uses associated with Use 3 (see Tables 1 and 2).

A great number of studies have been screened in order to find a reasonable estimation of the medical costs attributable to a lung cancer case. The health service costs included in the table below describe costs of the resources used in the treatment of lung cancer, including inpatients stays, outpatient and general practitioner visits and medications received.

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[13] Survival rates for 1 and 5 year are for Europe while the one for 10 years is for England and Wales.

[14] Total cases (9.45E-05 + 4.07E-05)/0.9

[15] Fatal cases

[16] Ratio of patients who die within 5 years from diagnosis (Stockholm School of Economics, 2008).

Table no. 3 - Medical cost of treating a patient diagnosed with lung cancer

Literature covering medical treatment costs associated with lung cancer case				
	Study	**Time period of costs (or case)**	**Average direct cost in original currency**	**Direct cost converted in € (at prices in 2012)**
1	Leal (UK Health Economics Research Center, University of Oxford, 2012)	1 year	£ 9,071[17]	€ 11,282[18]
2	Gómez (Ministry of Health, Social Services and Equality in Spain, 2012)	1 year	€ 8,261[19] (at 2008 price level)	€ 8,583[20]
3	Braud, Lévy et al. (France 2003)	1 year	€ 12,518[21] (at 2001 price level)	€ 14,703[22]
4	Dedes, Szucs et al. (Switzerland, 2004)	1 year	€ 20,102[23] (at 1999 price level)	€ 24,827[24]
5	OECD (2011)	1 lung cancer case	US$ 11,000	€ 8,556[25]

With the exception of the Swiss cost estimation, there is a certain consistency in studies' outcomes. However, we have decided to put forward the average value of € 14,849 per year based on the above studies. Furthermore, the average value of € 14,849 is approximately in line with the OECD recommendation of US$ 11,000 (€ 8,556) based on a great number of studies which have been carried out in Europe and Canada. Among them, 7 studies have been carried out in Northern Europe, one in Southern Europe (Spain) and one of the most recent in the Czech Republic. The

[17] Health care costs include expenditure on primary, outpatient, emergency, and inpatient care as well medications.

[18] In converting the value in € the average reference exchange rate gdp/€ of November 2012 (1. 2437) has been applied (ECB, 2012).

[19] The value is the mean health care cost of lung and bladder cancer attributable to work. The estimation is based on 10,652 cases of lung and bladder cancer which were estimated to cost to Spanish National Healthcare System almost € 88 million in 2008, of which 61.2 million belong to lung cancer and 26.5 to the bladder.

[20] Price indices (deflators) have been used for adjusting data to the price level of 2012. The value in 2012 has been calculated multiplying the original amount (expressed in 2008 prices) by the price adjuster (ratio between the price index for 2012 and price index for 2008). The value for 2012 is a forecast (EUROSTAT, 2012).

[21] The study was based on data of 100 patients coming from 4 different hospitals. 78% of patients were diagnosed with non-small lung cancer and 22% with small cell lung cancer. The average healthcare cost was estimated at 13,969 € for a patient with a non-small cell lung cancer and at 7,369 € for a small cell lung cancer.

[22] The value has been calculated multiplying the original amount (expressed in 2001 prices) by the price adjuster (ratio between the price index for 2012 and price index for 2001) (EUROTAT, 2012).

[23] The study investigated costs of lung cancer management at a Swiss University Hospital. The sample included 118 patients with a mean age of 64,2 years and a mean smoking history of 45 pack-years. The mean annual cost per non-small cell cancer was estimated at 19,212 € and for small cell lung cancer was 20,992 €.

[24] The value has been determined multiplying the original amount (expressed in 1999 prices) by the price adjuster (ratio between the price index for 2012 and price index for 1999) (EUROSTAT, 2012).

[25] The value has been converted in € on the basis of the annual average exchange reference rate US$/€ at 1,2857, covering the period from 30 November 2011 to 30 November 2012 (ECB, 2012).

OECD value has been excluded from the calculation of the average healthcare cost since unlike other studies, which take into account 1 year as time period of cost, it considers cost per case without defining the time period.

The average cost per case has been quantified on the basis of the average value of € 14,849[26] and taking into account the average survival years for lung cancer.

In line with the above studies on the average survival years for lung cancer, the below analysis assumes that in 90% of cases the patient will live 5 years from when the diagnosis is given, in 5% up to 8 years and in 5% up to 10 years. The calculation is reported in the table below:

Table no. 4 – Average health care cost per case

Assumed number of survival years	Percentage (%)	Estimated annual average medical treatment cost per case (€)	Total average cost based on survival years (€)
5	90%	14,849	66,821
8	5%	14,849	5,940
10	5%	14,849	7,424
Total average health care cost			€ 80,185

Taking into account that the number of annual lung cancer cases which could be attributed to PY.34 and PR.104 in Use 3 has been estimated at 1.50E-04 per year, the approximate annual direct cost of treating these cases is around € 12[27].

2.1.6 Productivity costs

A very important element of the economic cost of lung cancer is represented by the production loss due to numerous disease-related work disabilities, such as restricted working capacity, cessation of work, lost working days, reduced working hours, etc. Studies show that the indirect costs of lung cancer are much higher than the health care cost, even though one should bear in mind that this component is characterized by a high level of uncertainty.

The productivity loss has been estimated according to the human capital approach, which quantifies this component of indirect costs on the basis of estimated lost gross earnings due to the disease.

The lost gross earnings have been estimated taking into account the assumed working years lost because of the disease. In the EU, the average retirement age is 61.2 (OECD, 2011)[28] and 80% of lung cancer cases concern people aged 60 and over (Cancer Research UK, 2012).

[26] The assumption that the annual cost will be constant might lead to an overestimation in patients with a high life expectancy, since the follow-up costs are always much lower than the treatment cost.
[27] 1.50E-04* € 80,185
[28] Average effective age of retirement: men (2006-2011).

The average gross salary for plant and machine operators and assemblers is € 35,770.5[29] (EUROSTAT, 2008). Assuming a constant annual increase of 1% during the last five years, the average gross salary in 2013 has been estimated at € 37,595.

It has been assumed that in 80% of cases, the lung cancer is diagnosed in employees aged ≥ 60 years, in 10% of cases when they are 52-59 years old and in the remaining 10% when they are 45-52 years old. Furthermore, in order to maintain a prudential approach, it has been assumed that employees contracting lung cancer stop working completely once the cancer has been diagnosed[30] and do not resume work during the treatment period.

Table no. 5 – Productivity loss

Assumed age range of workers diagnosed with lung cancer	**Assumed age of workers diagnosed with lung cancer**	**Percentage**	**Estimated number of working years lost because of the lung cancer**	**Productivity loss per case assuming a salary increase of 1% per year**
45-52	48.5	10%	12.7[31]	51,143
52-59	55.5	10%	5.7[32]	22,154
>60 years	60	80%	1.2[33]	36,464
			Total productivity loss per case	109,761

Considering that the total number of lung cancer cases which can be associated with Use 3 is 1.50E-04, the annual productivity loss in this scenario can be quantified at around € 16[34].

The calculated productivity loss per case of € 109,761 is within the range of estimations which have been found in literature and which range between US$ 27,000 to US$ 273,000.

[29] The value has been calculated taking into account the average gross earnings of a male full-time employee in: Denmark, Germany, Cyprus, Austria, Portugal, Romania, Finland, Sweden and Iceland.
[30] This assumption may overestimate the productivity loss since in reality people diagnosed with cancer are usually able to work at least temporarily.
[31] 61.2 - 48.5
[32] 61.2 - 55.5
[33] 61,2 - 60
[34] 1.50E-04* 109,761

On the other hand, OECD[35] recommends using a value of US$ 70,000 (€ 54,445[36]) as an estimation of productivity lost, which is considered as a reasonable value among other studies.

The same average value of US$ 70,000 has been also recommended in the HEIMTSA [37] project co-funded by the European Commission within the Sixth Framework Programme (2002-2006).

2.1.7 Welfare loss

The last component of the economic burden associated with lung cancer is the individual welfare loss, which encompasses two elements: costs in terms of pain and suffering associated with lung cancer specifically and the welfare loss from increased mortality.

The estimation of the welfare loss from increased mortality can be calculated according to two methods. With the first one the welfare loss has been quantified taking into account the value of statistical life (VSL) and the number of fatal cases that could be avoided under the non-granted authorization scenario, while the second one is based on the value for a life year.

A great number of sources of a value of statistical life have been consulted, keeping in mind numerous elements of uncertainties which are inherent to this method. The estimation of the value of the statistical life, in the sense of individual's money-risk trade-off for small risks of death, has been at the centre of numerous studies which showed a great heterogeneity in their results. This heterogeneity can be attributed to various elements, such as individual risk-taking behaviour, the segmentation of the labour markets and the length of the remaining life[38]. The idea that the benefits of reducing risks of death to older are less significant when compared to younger age groups have been at the centre of numerous debates among academics and policymakers. Some of the empirical approaches however showed a certain consistency in the trend of the VSL over the life cycle. In Aldy and Viscusi's studies[39], the VSL rises and then falls over the life cycle with a peak in the 30s, and a subsequent decline so that the VSL for workers in their 60s has been estimated at about 2,5 – US$ 3 million. In particular in their cross-sectional analysis the value of statistical life for workers in their 60 years has been estimated at around US$ 2 million at 2000 prices (€ 2,016,607 at 2012 prices[40]). This value is approximately in line with the most recent estimates for VSL used at EU level and quoted in the ECHA Guidance on the Restrictions of € 2,258,000 at 2003 prices (€ 2,586,122[41] at 2012 prices), as an upper bound and € 1,052,000 in 2003 prices (€ 1,204,872[42] at 2012 prices) as a lower central estimate.

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[35] OECD Environmental Working Papers No. 35 (2011), *"Policy Interventions to Address Health Impacts Associated with Air, Pollution, Unsafe Water, Supply and Sanitation and Hazardous Chemicals".*

[36] The value has been converted in € on the basis of the annual average exchange reference rate US$/€ at 1, 2857, covering the period from 30 November 2011 to 30 November 2012 (ECB, 2012).

[37] Health and Environment Integrated Methodology and Toolbox for Scenario Development (2008).

[38] Viscusi, W. Kip, "*Policy Challenges of the Heterogeneity of the Value of Statistical Life*" (2011).

[39] Viscusi W and J. Aldy "Adjusting the value of a statistical life for Age and Cohort Effects" (2006).

[40] The value has been determined by using the US Implicit Price Deflator and then converting it into € at the average exchange rate US$/€ of 2012 (1,286). The Gross Domestic Product (Implicit Price Deflator) was 115.984 in 2012 and 89.447 in 2000.

[41] The value has been determined multiplying the original amount (expressed in 2003 prices) by the price adjuster (ratio between the price index for 2012 and price index for 2003) (EUROSTAT, 2012).

The central estimate of € 1,204,872 has been considered an appropriate value for the quantification of welfare loss from mortality. Thus considering that the number of fatal cases has been estimated at 1.35E-04[43], the total welfare loss from mortality has been quantified at € 163[44]**.**

Taking into account the on-going discussion among policymakers on the relationship between the age and the VSL, it was considered appropriate to calculate the welfare loss in connection with mortality also by using the value of life years lost (VOLY) instead of VSL, which could be considered more suitable in the case of regulations affecting people with a very short remaining life expectancy.

In this second method, the total welfare loss from mortality has been calculated multiplying the value for a life year[45] of € 63,909 (in 2012 prices), by the number of fatal cases and by the number of years saved. Huijbregts M., Rombouts L., Ragasand A. and van de Meent D[46]. estimated that the average number of years of life lost (YLL) due to lung cancer is 16.2.Thus taking into account that the number of years saved is 11.2[47] on the assumption that the method is applied to those that would not survive cancer beyond 5 years from diagnosis; welfare loss from mortality in the VOLY approach has been estimated at 97 €[48].

It has been decided to carry forward the value of statistical life (VSL) and not value for a life year (VOLY) estimation, since Aldy and Viscusi's studies on VSL for people over the age of 60 are in line with the EU estimation of the value of statistical life and the use of VSL approach was also recommended by the Danish Ministry of Environment in 2004[49].

The second welfare component, which measures costs in terms of pain and suffering, has been determined on the basis of the existing studies on the willingness to pay to avoid a lung cancer. Jeanrenaud and Priez (1999)[50] found values between CHF 512,500 and CHF 600,000 at 1995 prices[51], therefore the average value of CHF 556,250[52] (€ 516,345 at 2012 prices[53]) could be

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[42] The value has been determined multiplying the original amount (expressed in 2003 prices) by the price adjuster (ratio between the price index for 2012 and price index for 2003) (EUROSTAT, 2012).

[43] Fatal cases are considered patients who do not survive lung cancer beyond 5 years from the diagnosis (90% of1.50E-04).

[44] 1.35E-04* 1,204,872

[45] ECHA Guidance on the preparation of socio-economic analysis as part of an application for authorization reported € 55,800 as the value of a life year lost (in 2003 prices). The conversion in 2012 prices has been done by multiplying the value expressed in 2003 prices by the price adjuster (see above).

[46] *"Human-toxicological effect and damage factors of carcinogenic and noncarcinogenic chemicals for life cycle impact assessment"*(2005).

[47] 16.2 - 5

[48] 11.2 *1.35E-04 * € 63,909

[49] Danish Ministry of the Environment (2004), Environmental Project Nr. 929, *"Valuation of Chemical Related Health Impacts".*

[50] Jeanrenaud and Priez "*Valuing intangible costs of lung cancer"* (1999).

[51] The element evaluated in their study was a 95% risk reduction of contracting lung cancer. The estimation concerns only intangible costs, since interviewees were informed that patients with lung cancer suffered non-economic damage. They were informed that all resource costs were borne by health and social security systems.

[52] RPA Guidance (2011), "*Assessing the Health and Environmental Impacts in the Context of Socio-economic Analysis under REACH in the Context of Socio-economic Analysis Under REACH*".

[53] The value has been determined by multiplying the original value, 556,250, by price adjuster (ratio between the Swiss GDP deflator index of 2012 and GDP deflator index of 1995). The index of 2012 is an IMF forecast. The value

considered as a reasonable estimation of the willingness to pay to avoid lung cancer. Taking into account that the number of annual cases linked to Use 3 has been estimated at 1.50E-04, the total welfare loss from morbidity has been estimated at € 78[54].

Table no. 6 – Welfare loss associated with lung cancer cases attributable to the use of PY.34 and PR.104 associated with Use 3

Welfare loss from mortality		**Welfare loss from morbidity**	
Method	*Value*	*Method*	*Value*
VSL	€ 163	WTP	€ 78

On the basis of the four cost components estimated, the total annual economic burden that could be avoided under non-granted authorization scenario is summarized in the table below:

Table no. 7 – Total annual economic cost associated with lung cancer cases attributable to the use of PY.34 and PR.104 associated with Use 3

	Cost components	**Value (€)**
1	Direct cost of medical treatments	12
2	Loss of productivity	16
3	Welfare loss from mortality	163
4	Welfare loss from morbidity	78
Total annual economic burden of lung cancer cases associated with PY.34 and PR.104		269

The table below shows the total annual economic burden and the value discounted over 7, 12 and 30 years.

Table no 8. - Total economic burden associated with lung cancer cases attributable to the use of PY.34 and PR.104 in Use 3 (discounted over 7, 12 and 30 years)

Annual cost (value not discounted) (€)	**Cost discounted over 7 years (at 4%) (€)**	**Cost discounted over 12 years (at 4%) (€)**	**Cost discounted over 30 years (3%) (€)**
269	1,615	2,525	5,273

expressed in CHF has been converted into € on the basis of the average exchange rate €/CHF 1.2281 (covering 1st February 2012 - 1st February 2013) and published on the website of ECB.

[54] 1.50E-04* € 516,345.

2.1.11 Environmental Impact

Not relevant for this authorization application.

2.2. Economic impacts

This part of the SEA is aimed at analysing all the relevant compliance costs expected under the "non-use" scenario, such as changes in operative, investment and administration costs. The estimations will be based on real data, when possible. In order to avoid an overestimation of costs, a prudent approach will be applied when assumptions are required.

According to inputs received from stakeholders, the replacement of PY.34 and PR.104 by alternatives does not require significant investments in new technologies and equipment along the supply chain. No relevant changes in investment costs are therefore expected under the likely "non-use" scenario. The interviewed stakeholders do not expect an increase in administrative costs either. However, it is reasonable to think that at least in the beginning companies will experience some costs for reformulations.

2.2.1 C.I. Pigment Yellow 34

In order to quantify the direct replacement cost under the "non-use" scenario, a wide range of alternatives have been evaluated from a technical and economic point of view. We decided to apply the price of PY.184 in our estimation of the compliance cost, assuming that paint industry will replace PY.34 with this pigment under the "non-use" scenario. According to inputs received from stakeholders, PY.184is considered the most suitable alternative to PY.34, despite that it, like other alternative pigments, poses many technical problems.

Based on information received from the applicant, the average price of PY.34 is € 4.72/kg. The prices of PY.184 range between € 22/kg and € 35/kg.

Taking the annual EU consumption of PY.34 by the paint industry[55] into account, the direct annual replacement cost of PY.34 can be quantified in three scenarios:

- € 14,515,200[56], on the assumption that PY.34 is replaced by PY.184 that costs € 22/kg
- € 19,975,200[57], on the assumption that PY.34 is replaced by PY.184 that costs € 28.5/kg
- € 25,435,200[58], on the assumption that PY.34 is replaced by the alternative PY.184which costs € 35/kg.

With the purpose of maintaining a prudential approach, it has been decided to bring forward the central value of € 19,975,200.

One should bear in mind that the above estimation of additional operative costs on downstream users, which are currently using PY.34 in the paint sector, does not take the expected price

[55] 0.7 PY.34 + 0.3 PR.104 = 1,200,000 kg (PY.34 and PR.104). Sales ratio is based on input received from applicant.
[56] 0.7 * 1,200,000 kg * (€ 22/kg – € 4.72/kg)
[57] 0.7 * 1,200,000 kg * (€ 28.5/kg – € 4.72/kg)
[58] 0.7 * 1,200,000 kg * (€ 35/kg – € 4.72/kg)

transmission along the supply chain into account. In the above calculation, it has been assumed that downstream users in the paint sector would bear all additional costs due to the high price of the alternative pigment. It is reasonable to think that part of additional costs, due to a higher price of alternative pigment, will be passed on to end-users. This analysis assumes that the demand for paint is characterized by low price elasticity and this has been also confirmed by many companies during the consultation process. Therefore we assume that, in the "non-use" scenario, the paint industry would pass on 100%[59] of replacement costs to end-users.

It is important to point out that the above calculation only takes additional costs related to the price difference between the average price of PY.34 and PY.184 into account. The additional operative costs, which are due to a higher price of PY.184, only represent the first and direct economic impact that would occur in the "non-use" scenario.

The consultation with stakeholders suggests that a number of indirect costs, because of the technical flaws of PY.184, described in details in the Analysis of Alternatives, are expected in the non-granted authorization scenario. The expected additional costs are relevant because:

- More coats are required when PY.184 is used in paint applications. The reason is that in order to match certain shades, PY.184 has to be mixed with organics which lowers the opacity of paint.
- It is necessary to paint more often. PY.184has the same durability as PY.34, however to match the required shades it has to be mixed with other pigments with lower durability resulting in reduced performance.
- A greater quantity of pigment is required to achieve the color spectrum which is close to the one obtained with PY.34.

In summary, downstream users will have to bear the additional costs due to a higher price of PY.184, while the quality of the paint will be lower. Therefore, besides the additional costs expected because of the higher price of PY.184, the end-users will incur a welfare loss due to the lower quality of the paint.

According to stakeholders, PY.34 represents 7.5%[60] of the value of the paint. Taking into account that the quantity of pigment used in the yellow paint sector is 840,000 kg, the corresponding total market value of yellow paint has been estimated at approximately € 52,864,000[61].

One litre of paint is generally made up of solvent (60-80%) and the coating material[62] (20-40%)[63]. In the following analysis, we assume that one liter of the paint is composed of 60% solvent and 40% of solid coating. In line with information provided by stakeholders, we assume that the pigment concentration in paint is 7.5% by weight. As the average density of the paint is 1.8 kg/L,

[59] This assumption implies that the replacement cost for stakeholders manufacturing paints will be zero. The costs related to high price of the alternative pigment will be therefore considered only at the level of end-users. This simplistic assumption is also intended to avoid any double counting of compliance cost.

[60] Pigment concentration in paint and approximately the value of the product.

[61] (840,000 * € 4.72/kg) : 7,5 = x : 100

[62] Pigment together with binder resin.

[63] Environmental Technology Best Practice Programme (1997), *"Cost-effective paint and powder coating: coating materials*".

each litre of paint contains approximately 0,135 kg[64] of PY.34 or PR.104.

Assuming that 1,200,000 kg of PY.34 and PR.104 are used every year to produce paint, the total estimated annual quantity of paint produced is 8,888,889 litres[65] (6,222,222 L of yellow paint and 2,666,667 L of red paint).

In the "non-use" scenario, the entire quantity of PY.34 used in paints will have to be replaced by PY.184[66], which in this case is assumed to cost € 28.5/kg. As indicated above, the total direct cost of replacing 840 tonnes of PY.34 with PY.184 has been estimated at € 19,975,200.

Additional costs, related to the need of increasing the pigment concentration in paints[67], are expected in the "non-use" scenario. This additional cost has been estimated at respectively:

- € 23,940,000[68], assuming that it is necessary to increase pigment concentration to 15%
- € 14,364,000[69], assuming that it is necessary to increase pigment concentration to 12%
- € 7,980,000[70], assuming that it is necessary to increase pigment concentration to 10%.

In order to avoid possible overestimation, we have decided to bring forward the value of € 7,980,000. The above analysis shows that the stakeholders applying paint will have to bear additional costs due to a:

- Higher price of PY.184: € 19,975,200
- Higher concentration of pigments required: € 7,980,000.

Taking into account the higher price of PY.184and the need of increasing the pigment concentration from 7.5% to 10%, the total replacement cost has been estimated at € 27,955,200.

The calculation above is based on the assumption that PY.184 requires the same number of layers as PY.34. According to stakeholders' input, more layers (2-3) are necessary when alternatives are used[71]. In order to match certain shades, PY.184needs to be mixed with organics which lowers the opacity of paint. This means that end users will have to apply a greater quantity of paint and that the final additional cost in the "non- use" scenario will be significantly higher than the above estimate.

According to stakeholders, at least one more layer is necessary when alternatives are used. On this basis, the additional cost[72] that all stakeholders applying paint will have to bear in order to achieve a coverage which is close to the one provided by PY.34 has been estimated at € 80,819,200[73].

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[64] 7.5% : 1 kg = x : 1.8 kg
[65] 0.135 kg :1l = 1,200,000 kg : x
[66] Which normally has to be mixed with other pigments to match the required shades.
[67] According to stakeholders, it is necessary to increase pigment concentration up to 15% of the paint.
[68] 840,000 kg * € 28.5/kg
[69] 504,000 kg * € 28.5/kg
[70] 280,000 kg * € 28.5/kg
[71] Lead free coating typically requires double the paint thickness to achieve the same level of hiding.
[72] The calculation of the replacement cost for the first layer has considered only the difference in terms of price between PY.34 and PY.184, since the stakeholders in question would have born all other costs in any case. Cost related to one

The total annual replacement costs, in terms of direct and indirect impacts, have been therefore quantified at € 108,774,400[74].

Table no. 9 - Total compliance costs and indirect costs for replacing PY.34 in paint (discounted over 7, 12 and 30 years)

Annual cost (value not discounted) (€)	Cost discounted over 7 years (at 4%) (€)	Cost discounted over 12 years (at 4%) (€)	Cost discounted over 30 years (3%) (€)
108,774,400	652,869,895	1,020,855,767	2,132,026,248

In summary, the above analysis assumes that paint formulators will not bear any additional cost, while the final users will have to bear replacement costs due to:

- Higher price of PY.184
- Need to increase the pigment concentration in paint
- Need to apply one additional layer.

Since paint is used by industrial and professional users, the total replacement cost will be split between these two categories of end-users if the authorization is not granted.

Based on input from stakeholders, around 80% of paint is used by industrial end-users and 20 % by professional end-users. The total direct and indirect substitution costs in professional use are indicated in the table below:

additional layer that stakeholders have to apply when using the paint based on PY.184, takes into account all cost components (value of the paint under the "applied for use" scenario increased by the replacement costs).

[73] Value of the paint under the "applied for use" scenario increased by the value of the replacement cost € (52,864,000 + 27,955,200)

[74] The total annual replacement cost has been estimated as the sum of direct replacement cost and the cost due to one additional layer (€ 27,955,200 + € 80,819,200).

Table no. 10 - Total compliance costs and indirect costs for replacing PY.34 associated with Use 3 (discounted over 7, 12 and 30 years)

Annual cost (value not discounted) (€)	Cost discounted over 7 years (at 4%) (€)	Cost discounted over 12 years (at 4%) (€)	Cost discounted over 30 years (3%) (€)
€ 21,754,880	€ 130,573,979	€ 204,171,153	€ 426,405,250

2.2.2 C.I. Pigment Red 104

According to stakeholders, PR.104 represents approximately 7.5%[75] of the value of the paint. Taking into account that the quantity of pigment used in the red paint sector is 360,000 kg, the corresponding total market value of red paint based on PR.104 has been estimated at approximately at € 33,600,000[76].

As indicated above, the estimation of compliance costs for replacing PR.104 in paint assumes that the industry will switch to PO.73 and PO.67. According to the applicant's customers, the price of PO.67 ranges between € 30 and € 40, while the price of PO.73 is approximately € 60-70[77]. In order to maintain a prudential approach, we decided to consider lower bounds in the estimation of compliance cost. The direct compliance cost for the replacement of 360,000[78] kg of PR.104 in red paint has been estimated at € 13,680,000[79].

Additional costs are expected in the "non-use" scenario. They are related to the need of increasing the pigment concentration in paints[80]. This additional cost has been estimated at:

- € 13,680,000[81], assuming that it is necessary to increase pigment concentration to 15%
- € 8,208,000[82], assuming that it is necessary to increase pigment concentration to 12%
- € 4,560,000[83], assuming that it is necessary to increase pigment concentration to 10%.

In order to avoid possible overestimation we have decided to bring forward the value of € 4,560,000. The above analysis shows that the stakeholders will have to bear additional costs due to a:

[75] Pigment concentration in paint and approximately the value of the product.
[76] (360,000 * € 7/kg) : 7,5 = x : 100
[77] But it can be even higher.
[78] 1,200,000 kg * 0.3
[79] 360,000 kg * € [(60 + 30)/2 - 7]/kg
[80] According to stakeholders, it is necessary to increase pigment concentration with up to 15% of the paint when alternatives are used.
[81] 360,000 kg * € (45 – 7)/kg
[82] 216,000 kg * € (45 – 7)/kg
[83] 120,000 kg * € (45 – 7)/kg

- Higher price of alternative pigments: € 13,680,000
- Higher concentration of pigments required: € 4,560,000.

The direct replacement cost due to the higher price of alternative pigments and the need to increase the pigment concentration in paint has been quantified at € 18,240,000. As in the estimation of compliance cost for PY.34, the analysis assumes that the replacement costs are passed on to end-users.

According to inputs from stakeholders, at least one more layer is necessary when alternatives are used. The additional cost[84] facing the stakeholders applying paint will have to bear, in order to achieve a coverage which is close to the one provided by PR.104, has been estimated at € 51,840,000[85].

On the basis of the above three elements, the total annual cost of replacing PR.104 in paint has been estimated at € 70,080,000[86].

Table no. 11 - Total compliance costs and indirect costs for replacing PR.104 in paint (discounted over 7, 12 and 30 years)

Annual cost (value not discounted) (€)	Cost discounted over 7 years (at 4%) (€)	Cost discounted over 12 years (at 4%) (€)	Cost discounted over 30 years (3%) (€)
70,080,000	€ 420,623,991	657,705,969	1,373,598,930

Based on input from stakeholders, around 80% of paint is used by industrial end-users and 20 % in the professional sector. The total direct and indirect substitution cost that the professional end-users applying PR.104 based paint will experience in the "non-use" scenario are indicated in the table below:

Table no.12 - Total compliance costs and indirect costs for replacing PR.104 associated with Use 3 (discounted over 7, 12 and 30 years)

Annual cost (value not discounted) (€)	Cost discounted over 7 years (at 4%) (€)	Cost discounted over 12 years (at 4%) (€)	Cost discounted over 30 years (3%) (€)
14,016,000	84,124,798	131,541,194	274,719,786

[84] The calculation of the replacement cost for the first layer has considered only the difference in terms of price between PR.104 and alternative pigments (PO.67 and PO.73), since the stakeholders in question would have born all other costs in any case. Cost related to one additional layer, that stakeholders have to apply when using the paint based on alternative red pigments, considers all cost components (value of the paint under the "applied for use" scenario increased by the replacement costs).

[85] Value of the paint under the "applied for use" scenario increased by the value of the replacement cost (€ 33,600,000 + € 18,240,000).

[86] The total annual replacement cost has been estimated as the sum of direct replacement cost and the cost due to one additional layer € (18,240,000 + 51,840,000).

In summary, the above analysis assumes that paint formulators will not bear any additional costs, while professional users will experience additional costs due to:

- Higher price of alternative pigments
- Need to increase the pigment concentration in paint
- Need to apply one additional layer.

2.3. Social impacts

This part of the SEA analyses social impacts expected in the "non-use" scenario, with a focus on reduced safety standards expected due to use of less powerful colours in road and airport markings.

PY.34 and PR.104 play an important role for safety reasons in Europe by providing strong and lasting colours.

PY.34 and PR.104 are used in airport ground markings due to the qualities of the paint in terms of coverage (3 year coverage guarantees are offered), drying time, and resistance to heat, UV and wear.

Alternatives to PY.34 and PR.104 do not provide the required coverage or dry as quickly. This represents a serious problem at airports where ground markings typically are painted whilst operational. Light fastness, resistance to heat, UV and wear cannot be obtained in one coat from other pigments. It is also impossible to retrace a line exactly if you have to apply two coating layers.

The quality of the paint using PY.34 and PR.104 has for example also been set out in a norm by operators of European airports. The specifications for MOD airfields and the BA Civil Eng. Spec. outlines that the use of the PY.34 and PR.104 is required. A used standard in the UK, the British Standard BS6044[87], includes references for the lead content in terms of a maximum level. This illustrates that the use already has been regulated and has an acceptable level as dictated in BS6044.

The alternatives present many problems in the part of the spectrum covered by the PY.34 and PR.104. Two issues are opacity and weatherfastness (in particular for organic pigments). Multiple layers of paint are also likely to lead to leaching or bleeding (for example a red paint painted over with a white stripe). In terms of the organic alternative, it will release some of the solvent and the paint is likely to mix by giving a reddish hue to the white cover stripe.

The importance of colours for safety reasons has already been recognised by ECHA in the case of cadmium pigments. In fact, an exception was made for safety applications concerning mixtures containing cadmium and its compounds. Paragraph 3 of entry 23 of Annex XVII to REACH states that, "by way of derogation, paragraphs 1 and 2 shall not apply to articles coloured with mixtures containing cadmium for safety reasons". ECHA's report[88] from November 2012, tasked to further

[87] British Standard 6044:1987 (1999), Specification for pavement marking paints

[88] ECHA (2012), *The Use of Cadmium and its Compounds in Articles Coloured for Safety Reasons* (Derogation in Paragraph 3 of Entry 23 of Annex XVII) – Report.

investigate the issue of safety applications for cadmium pigments, clearly stressed that the derogation was still relevant and applicable.

The applications of cadmium pigments relate to situations where environmental or operating conditions are extreme, such as high temperatures or outdoor weather. Like PY.34 and PR.104, the features of cadmium pigments are important for safety reasons in many different ways. They provide colourfastness, which is essential when identifying safety equipment or when attempting to avoid safety critical maintenance errors. Colourfastness is also very useful where the intended lifespan of a given article is relatively long. Similar to PY.34 and PR.104, cadmium pigments thus perform better than alternatives on parameters as weather resistance, lightfastness, heat resistance and thus in providing strong lasting colours over time. Based on these features, it was considered that any amendment or removal of the derogation for cadmium pigments could have significant costs for the industries in question and/or the general public, while reductions in risk would be small. The example shows that exceptions previously have been given on safety grounds following concerns with the feasibility of alternatives and recognizing that the technical properties of pigments in displaying powerful colours do play an important role in safety standards.

In summary the main social impact expected in the “non-use” scenario is the reduced safety given the use of weaker and less lasting colors in airport ground markings and road markings on public roads.

2.4. Wider economic impacts

Due to the lack of data it is difficult to exactly predict the impact on exports. However, it is reasonable to think that paint companies exporting part of their production outside the EU will see their competitiveness reduced in the “non-use” scenario (possible scenarios and relative impacts on the non-EU markets are described in the Analysis of Alternatives document). They may therefore decide to relocate part of their production outside the EU. On this assumption the social costs in terms of job loss might be extremely high.

3. COMBINED ASSESSMENT OF IMPACTS

3.1. Comparison of impacts

This part of SEA compares all costs and benefits expected in the "non-use" scenario, which have been analyzed in previous sections.

The table below describes in qualitative terms the expected relevant impacts, assuming that the paint sector will switch to PY.184 to replace PY.34 and to PO.73 and PO.67 to replace PR.104. In this scenario, the paint manufactures will pass on the replacement costs to end-users, considering the low price elasticity of the demand[89].

Table no. 13 – Comparison of impacts

Type of impact	**Qualitative analysis of impacts expected in the "non-use" scenario (Use 3)**
Health impacts	Total economic burden related to lung cancer cases associated with the use of PY.34 and PR.104 in professional sector would be avoided. This includes: direct cost of medical treatments, loss of productivity, welfare loss from mortality and welfare loss from morbidity
Economic impacts on professional end-users	Direct and indirect replacement costs due to: higher price of PY.184, PO.73 and PO.67, poor performance of the alternative pigment in terms of coverage and durability, need to increase the concentration of the alternative pigment, need to apply additional layers and need to repeat the application after few years.
Social impacts	Incompliance with safety standards because of alternatives' inability to provide powerful and lasting colours when compared to PY.34 and PR.104.

[89] Based on inputs received from stakeholders.

Table no. 14 - Net cost in the "non-use" scenario

The table below describes in quantitative terms all relevant impacts expected in the "non-use" scenario.

Difference between the "applied for use" and the "non-use" scenario				
Type of impact	**Quantitative analysis of impacts expected in the "non-use" scenario (1 year) value (€)**	**Discounting over 7 years, value in (€)**	**Discounting over 12 years, value in (€)**	**Discounting over 30 years, value in (€)**
Benefits in economic terms of avoiding lung cancer cases associated with the use of PY.34 and PR.104	269	1,615	2,525	5,273
Cost for replacing PY.34	-21,754,880	-130,573,979	-204,171,153	-426,405,250
Cost for replacing PR.104	-14,016,000	-84,124,798.25	-131,541,193	- 274,719,785
Net cost in the "non-use" scenario	- 35,770,611	- 214,697,162	-335,709,822	-701,119,762

3.2. Distributional impacts

This part of the SEA analyses how the impacts expected in the examined "non-use" scenarios would be distributed across different sections of society. In particular, this part of the work identifies sections of society which would mostly benefit from the continued Use 3 of PY.34 and PR.104 and the stakeholders who would most likely suffer in the "applied for use" scenario.

With regard to the health impact, the economic burden related to the number of annual lung cancer cases attributed to the use of PY.34 and PR.104 would be avoided in the "non-use" scenario. Since the quantified economic burden takes tangible and intangible cost components into account, both the workers directly dealing with PY.34 and PR.104 and the EU health care system will benefit in the non-use scenario. However, a greater quantity of solvents is required when alternatives are used and their negative impact on workers' health should not be overlooked.

Finally, an intangible cost which will be borne by society as a whole in the "non-use" scenario is related to reduced safety standards due to application of less powerful colors.

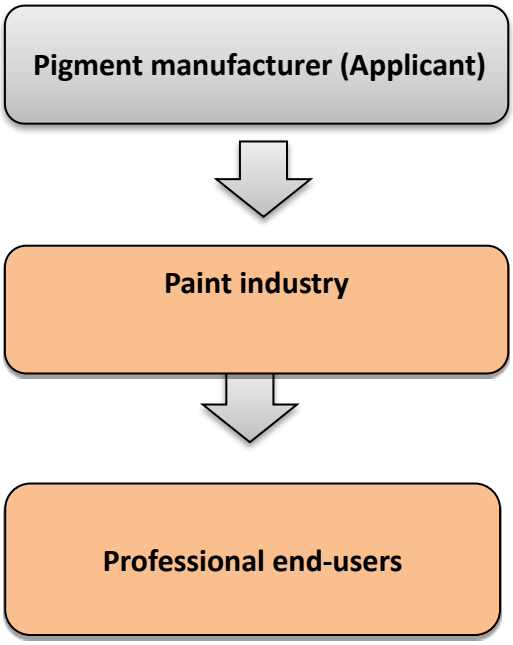
The table below gives an overview of the distributional impact on the basis of the analysis carried out in the parts of the SEA on health, economic and social impacts.

Table no. 15 - Distributional impacts

Distributional analysis	**Benefit of continued use**	**Cost of continued use**
Workers directly dealing with PY.34 and PR.104	n/a	Economic burden associated with 1.50E-04 lung cancer cases attributed to PY.34 and PR.104 in Use 3: • Loss of productivity • Welfare loss from mortality • Welfare loss from morbidity
EU health care system	n/a	Direct medical cost of treating 1.50E-04 lung cancer cases per year attributed to PY.34 and PR.104 in Use 3.
Applicant	Possibility to continue to import/supply PY.34 and PR.104 in the EU.	n/a
Downstream users – paint sector	Possibility to benefit from high technical performance and low price of PY.34 and PR.104.	n/a
Professional end-users	Possibility to benefit from high quality and low price of paint.	n/a
Manufacturer/importer of alternative pigments	n/a	Lost profit opportunities considering the high price of alternative pigments.

Taking into account that the demand for paint is characterized by low price elasticity, it is reasonable to think that the greatest part of the replacement costs will be passed on to the end-users. This was also confirmed by several companies interviewed in this process.

Supply chain (Use 3)



3.3. Uncertainty analysis

This part of the dossier focuses on the main sources of uncertainty of the SEA and analyses how the underlying assumptions could potentially impact the SEA's outcome.

The analysis and quantification of the health impact associated with diseases have always been extremely difficult considering the numerous uncertainties that cannot be avoided and which mostly relate to the estimate of intangible elements.

In terms of the estimate of the health care costs of lung cancer, one should bear in mind that a certain degree of uncertainty cannot be avoided. The fact that there are different studies (based on different approaches, different samples, etc.) means that there is no common vision on costs. The table below shows how medical treatment costs relating to the number of annual cases associated with PY.34 and PR.104 differ in the lower, central and upper bound.

Table no. 16 – Total health care costs in three scenarios

Lower bound (€)	Central value (€)	Upper bound (€)
7[90]	12[91]	20[92]

[90] Assuming that the annual health care cost is € 8,556.
[91] € 80,185 * 1.50E-04
[92] Assuming that the annual health care cost is € 24,827.

However, considering that no significant differences among studies have been found and that costs of medical treatments represent a very negligible part of the total economic burden, it is possible to conclude that a very high reliability can be placed in the estimate of the health care costs associated with the uses of PY.34 and PR.104 in Use 3.

A second source of uncertainty is related to the medicine's progress in treating lung cancer. It is reasonable to think that thanks to the future cures, the number of survival years for people affected by lung cancer will dramatically improve. Therefore, the following calculations assumes that, given future discoveries in medical treatments for lung cancer, 20% of patients will live up to 5 years, 30% up to 8 years and the rest 50% will live 10 years from when the diagnosis is given.

Table no. 17 – Total healthcare cost assuming that there is a probability of 50% that the patient lives 10 years from when the diagnosis is given

Assumed number of survival years	Percentage (%)	Estimated annual average medical treatment cost per case (€)	Total average cost based on survival years (€)
5	20%	14,849	14,849
8	30%	14,849	35,638
10	50%	14,849	74,245
Total average health care cost per case			124,732

Taking into account that the number of annual lung cancer cases associated with PY.34 and PR.104 has been estimated at 1.50E-04 the healthcare cost has been quantified to 19 €[93] for treating these cases in the above scenario.

It is important to point out that a certain level of uncertainty also is inevitable in the estimate of productivity loss. Firstly, the assumption that all employees leave work completely when the diagnosis is given is not met in reality. The value could thus overestimate the real productivity loss since most workers will keep working, at least for a certain period of time from when the diagnosis is made. Other source of uncertainty relates to the methodology applied, since there is no agreement among academics about the best method[94] for quantifying the productivity loss.

The table below shows how the productivity loss associated with the number of annual cases associated with PY.34 and PR.104 differs in the lower[95], central[96] and upper[97] bound.

[93] 1.50E-04* € 124,732

[94] The two most debated methods for the quantification of productivity loss are human capital approach and cost friction method.

[95] US$ 27,000 (€ 21,000)

[96] € 109,761

[97] US$ 273,000 (€ 212,336)

Table no. 18 – Productivity loss in three scenarios

Lower bound (€)	Central value (€)	Upper bound (€)
3[98]	16	32[99]

In terms of quantification of welfare loss from increased mortality, the VSL average value recommended by the Commission has been used. Applying the upper EU estimate of € 2,586,122, the quantification of the annual welfare loss from mortality increases from € 163 to € 350. It is important to keep in mind that there is no consensus among policymakers and academics about the best methods (VOLY or VSL) for the quantification of welfare loss from mortality. Additional uncertainties arise from the fact that there is a range of estimates for the value for a life year, from 63,863 € to 143,339 € at 2012 prices.

Concerning the welfare loss linked to pain and suffering, Priez and Jeanrenaud estimate of 556,250 chf[100] (516,345 € at 2012 prices[101]) has been applied. According to OECD[102], unlike many other surveys, Priez and Jeanrenaud's: "study has a significant advantage in its relatively high sample size of 757 respondents and did not ask them to make trade-offs between other forms of cancer; we may see this as a merit in limiting their cognitive burden".

The table below shows how the net cost in the "non-use" scenario changes:

- On the assumption that health care cost per case is € 124,732 (upper bound)
- On the assumption that productivity loss per case is € 212,336 (upper bound)
- Taking into account the upper EU estimate of VSL (€ 2,586,122).

[98] 1.50E-04* € 21,000

[99] 1.50E-04* € 212,336

[100] RPA Guidance (2011), "*Assessing the Health and Environmental Impacts in the Context of Socio-economic Analysis under REACH in the Context of Socio-economic Analysis Under REACH*".

[101] The value has been determined by multiplying the original value, 556,250, by price adjuster (ratio between the Swiss 2012 GDP deflator index and GDP deflator index of 1995). The index of 2012 is an IMF forecast. The value expressed in chf has been converted into € on the basis of the average exchange rate €/CHF (covering 1st February 2012- 1st February 2013) and published on the website of ECB.

[102] OECD Environmental Working Papers No. 35 (2011), *"Policy Interventions to Address Health Impacts Associated with Air, Pollution, Unsafe Water, Supply and Sanitation and Hazardous Chemicals".*

Table no. 18 – Net costs (based on upper estimates of the economic burden of lung cancer)

Difference between the "applied for use" and the "non-use" scenario				
Type of impact	**Quantitative analysis of impacts expected in the "non-use" scenario (1 year) value [€]**	**Discounting over 7 years, value in [€]**	**Discounting over 12 years, value in [€]**	**Discounting over 30 years, value in [€]**
Benefits in economic terms of avoiding lung cancer cases associated with the use of PY.34 and PR.104	478	2,869	4,485	9,366
Cost for replacing PY.34	-21,754,880	-130,573,979	-204,171,153	-426,405,250
Cost for replacing PR.104	-14,016,000	-84,124,798	-131,541,194	-274,719,786
Net cost in the "non-use" scenario	-35,770,402	- 214,695,908	-335,707,862	-701,115,669

Turning to economic impacts, it is important to bear in mind that it has been assumed that PY.34 will be replaced in the "non-use" scenario by PY.184, which costs from € 22 to € 35 /kg. The price of PO.73 ranges from € 60 /kg to € 70 /kg, while the price of PO.67 is between € 30/kg and € 40/kg.

Further sources of uncertainty are related to the existence of different paint formulations. It is also important to point out that according to stakeholders, generally prices of alternative pigments range between 2 to 10 times the price of PY.34 and PR.104.

Furthermore, it is likely that the replacement cost is underestimated since it has been quantified on the assumption that PY.184[103], PO.67 and PO.73 require one additional coating layer when compared to PY.34 and PR.104. The companies interviewed during the consultation process, made it clear that alternative pigments[104] may require up to 8 additional coats. Finally, the replacement cost does not take into account the poor performance of alternative pigments in terms of durability and the labor costs associated with one additional layer.

As seen in the previous sections, the calculation of compliance cost is based on very conservative assumptions and in the meantime the main sources of uncertainty have been analyzed.

However, it is important to point out that in reality the economic impacts on the end user of the coating is expected to be much higher. Based on data from one of the applicant's customer, end customers will experience a total cost increase of 633%, due mainly to poor technical performance

[103] Which is usually mixed with other pigments.

[104] In particular organic pigments.

of alternative pigments. The company in question has underlined that switching from coating formulation[105] based on PY.34[106] to a formulation that is PY.34 free[107] will lead to an increase in cost for the pigment part from € 4.03/kg to € 9.85/kg (+144%). However, in order to achieve the same coverage, the end users will have to triple the use of paint[108]. This means that for the end user the cost for the pigment formulation for paint will increase from € 4.03/kg to € 29.56/kg (633%[109]). This cost increase considers only the pigment, while the end users will obviously have to bear further additional costs related to other coating components and labor cost. In addition to that weather fastness also will be lower.

In summary:

- The end users will experience a cost increase of 633% due to the higher price of alternative pigments and the need to triple the use of paint;
- Shade functionality, weather fastness and hiding will be compromised.

  It is clear that on one hand the end users would have to bear a great cost increase while on the other hand they will experience a welfare loss due to the poor quality of PY.34 and PR.104 free paint/coating.

105 The shade that formulations in question match is: "RAL 1012"

106 The pigment formulation is based on: PY.34 (63.5%), PY.42 (6.29%), Titanium Dioxide (30.10 %) and PBl.7 (0.11%).

107 The pigment formulation is based on: PY.154 (26.2%), PG.7 (0.12%), PBr.24 (33.5%), PY.42 (7.18%) and Titanium Dioxide (33%).

108 Thickness will increase from 0.8 mils to 2.4 mils.

109 {[(9.85 * 3) – 4.03]/4.03} * 100

4. CONCLUSIONS

The SEA quantifies the main impacts expected in the "non-use" scenario, while adopting a qualitative approach when impacts were particularly difficult to quantify.

The analysis shows that the benefits related to the number of lung cancer cases that could be avoided in the "non-use" scenario are not significant, taking into account that the carcinogenic risk associated with PY.34 and PR.104 is considered very low.

While the expected benefits in the granted authorisation scenario are negligible, the replacement costs facing the professional users under the "non-use" scenario are likely to be extremely high. The expected economic burden is mainly based on the poor technical performance of alternative pigments when compared to PY.34 and PR.104. As the concerned stakeholders applying the paint will have to use larger quantity of the alternative pigment and apply additional layers, the replacement cost in the "non-use" scenario will be extremely high.

Moreover, if one considers the poor technical performance in terms of durability of organic pigments, which have to be mixed with PY.184 to replace PY.34, or with PO.73 and PO.67 to replace PR.104, and the additional costs related to labour[110], it is likely that the final economic burden will be even much higher.

Moreover, one should not overlook further additional costs, which are extremely difficult to monetize. This is in particular the case when PY.34 and PR.104 are used for safety purposes, by providing strong and lasting colours. Being aware of the difficulty to place a money value to this impact, it was considered opportune, however, to point out the importance of PY.34 and PR.104 in providing high safety standards. The cadmium exemption (REACH, Annex XVII) also underlines that technical properties of pigments in displaying powerful colours do play an important role for safety reasons. The main social cost which will be therefore borne by society as a whole in the "non-use" scenario is related to reduced safety standards due to application of less powerful colours in ground markings and road markings on public roads.

Please note that the present SEA has been prepared by the industry itself. Yet it aims to be as neutral as possible and cover all possible impacts to the extent that they are close to real-life conditions. As explained in the uncertainty analysis, a great number of assumptions had to be made, both in the monetization of health impacts and in the estimate of compliance costs. However, all of them are based on studies found in literature or on inputs received from stakeholders. We are therefore confident that a high level of certainty can be placed both in the monetization of health impacts and in the quantification of compliance costs.

On the basis of the above analysis, we think that the benefits of continued use of PY.34 and PR.104 associated with Use 3, outweigh the risks to human health and environment. The total benefits in the "non-use" scenario are indeed expected to be negligible, because the estimated cancer risk in the "applied for use scenario" is extremely low. Moreover, no benefits from an environmental point of view are expected in the "non-use" scenario. On the other hand, this SEA has shown that significant replacement costs, direct and indirect, to be borne by end users in the "non-use" scenario are extremely high.

[110] Because more layers have to be applied.

For all the above considerations, we conclude that the benefits related to Use 3 by far outweigh the risks to human health and environment.

APPENDICES

APPENDIX A

Table A1- List of main assumptions used in SEA for Use 3 and relative justifications.

SEA's assumptions		Justifications
1	The alternatives to PY.34 and PR.104 are not deemed to be suitable from a technical and/or economic point of view.	Based on inputs received from downstream users.
2	The estimate of health care costs assumes that the central value of € 14,849 is representative of the annual average medical treatment cost in the EU for treating a patient diagnosed with lung cancer.	No significant differences in listed studies have been found. Therefore it is reasonable to think that a high level of certainty can be placed in the estimate of health care costs.
3	The calculation of the productivity loss assumes that workers diagnosed with lung cancer stop working completely one the disease has been diagnosed	This assumption is aimed at avoiding any possible underestimate that could arise in the calculation of the time that an employee diagnosed with lung cancer spends working.
4	It has been assumed that € 1,204,872 is an appropriate value for the quantification of welfare loss from mortality.	This value is approximately in line with the most recent estimates for VSL used at EU level and quoted in the ECHA Guidance on the Restrictions of € 2,258,000 at 2003 prices (€ 2,586,122 at 2012 prices), as an upper bound and € 1,052,000 in 2003 prices (€ 1,204,872 at 2012 prices) as a lower central estimate.
5	The calculation of welfare loss from mortality applying the VOLY method assumes that the average number of years saved is 11.2.	This value has been calculated on basis of number of years of life lost (YLL) due to the lung cancer and assuming that fatal cases are patients who do not survive beyond five years from when the diagnosis is given. Huijbregts M, Rombouts L., Ragasand A. and van de Meent D[1]. estimated that the average number of years of life lost (YLL) due to lung cancer is 16.2.
6	The estimate of welfare loss from mortality, included among	Studies on VSL for people over 60 years are in line with the EU estimate of the value of

[1] *"Human-toxicological effect and damage factors of carcinogenic and noncarcinogenic chemicals for life cycle impact assessment"(*2005).

	components of the total economic burden of lung cancer cases associated with PY.34 and PR.104, is based on VSL method, instead of VOLY.	statistical life and the use of VSL approach was also recommended by the Danish Ministry of Environment in 2004.
7	The estimate of direct compliance costs for replacing PY.34 (€ 27,955,200) is based on the assumption that average price of PY.184is € 28.5/kg. The direct compliance costs for replacing PR.104 (€ 18,240,000) is based on the assumption that average price of PO.67 is €30/kg and the average price of PO.73 is €60/kg.	Based on inputs received from stakeholders, the price of PY.184ranges between € 22/kg and € 35/kg. Based on inputs received from stakeholders, the price of PO.67 ranges between € 30/kg and € 40/kg and the price of PO.73 is between € 60/kg and € 70/kg.
8	The calculation of compliance costs for replacing PR.104 assumes that PR.104 will be replaced by PO.67 and PO.73 under the “non-use” scenario.	Based on input from applicant. Other possible alternative pigments are: PO.36, PO.13, PO.16.
9	The estimate of economic impacts, assumes that the demand for paint/coating is characterized by low price elasticity.	Based on inputs from stakeholders.
10	The estimate of replacement costs in the “non-use” scenario assumes that a higher use of the use of alternative pigment is required.	Based on inputs from stakeholders.
11	The analysis of social impacts assumes that PY.34 and PR.104 play an important role for safety reasons in Europe by providing strong and lasting colours.	Based on inputs from stakeholders.

APPENDIX B

Tabel B1 Excess cancer risks for the uses and contributing scenarios in use 1 and 3 for C.I. Pigment Yellow 34 (Source: CSR PY.34)

Description of contributing scenario	Inhalation exposure value from Advanced REACH Tool (mg/m3)	Assigned protection factor of respiratory protection	Inhalation exposure value including RPE (mg/m3)	Exposure/ DMEL ratio, including RPE	Man year for activity	Calculated additional cancer risk for EU worker population	Reason for adaptation, size of adaptation	Related dose ug/kg bw/day	RCR	Calculated additional intestinal cancer risk, due to oral intake of inhalatory-non respirable fraction for EU worker population
Distribution of pigment powder and formulation into paste used to colour paints. Subsequent industrial or professional use on non-consumer articles.										
Use#1-Distribution and formulation of C.I.Pigment Yellow 34 powder into paste/dispersions and solvent-based coloured paints with specific functions for industrial or professional use on non-consumer articles.Examples of coated objects are high grade steel based products e.g. piping for the (petro)chemical industry,crane arms,agricultural machinery, street furniture and markings,steel bridges,construction arches,steel skips,coil coated products (e.g. roofing).High quality of the coating is crucial for the long-term functioning and protection of the objects,i.e. where fading of the colour could endanger public or worker safety,where regular repainting could create difficult or risky situations (steel bridges,traffic jams) or where idle time of specialty equipment would incur high costs. Pigment choice is based on requirements for the end application related to: VISIBILITY & SAFETY-Based on their bright,vivid,durable colours, these pigments are used when visibility and safety are important,especially in regulated applications like road marking; DURABILITY-The pigments respond to the demand for high performance pigments,e.g. in aggressive atmospheric conditions in industrialized areas,providing excellent light and weather fastness,preventing applications to darken or fade if exposed to light and humidity; excellent resistance to sulfur dioxide,preventing discolouration (greyness) and loss of gloss,required for exterior applications; SHADE FUNCTIONALITY-Their colour covers a wide range from green to red shade yellow and yellow to blue shade red; COLOURISTIC & TECHNICAL PERFORMANCE-Within the listed colour range,these pigments provide clean,vivid colours (chroma); excellent opacity or hiding power; excellent weather fastness. The perceived colour remains the same regardless of the light source (no metamerism).They also provide excellent rheology in coatings; excellent non-bleeding properties,non-migration properties and impact resistance in coatings.										
Total Use 1						**7.64E-06**				**0.00E+00**
Delivery, storage and handling of closed bags with pigment powder	0.0025	1	0.0025	8.45E-01	3.82	3.87E-07		0.3571429	0.2435065	0
Pigment powder quality control / lab work	0.00076	1	0.00076	2.57E-01	3.82	1.18E-08	Less than 10% of time spent at activity	0.1085714	0.074026	0
Manual dosing of pigment powder	0.23	100	0.0023	7.77E-01	3.82	3.56E-07		0.3285714	0.224026	0
Automated dosing of pigment powder	0.00033	1	0.00033	1.11E-01	3.82	5.11E-08	Activity not used as substance is either manually or automatically dosed and the exposure/DMEL ratio of manual dosing is higher.	0.0471429	0.0321429	0
Re-packaging of pigment powder	0.0033	10	0.00033	1.11E-01	3.82	5.11E-08		0.0471429	0.0321429	0
Mixing of pigment paste	0	1	0	0.00E+00	3.82	0.00E+00		0	0	0
Storage of pigment paste / Transfer of pigment paste through closed piping	0	1	0	0.00E+00	3.82	0.00E+00		0	0	0
Manual cleaning / scraping of mixing vessels, equipment and lids	0.025	10	0.0025	8.45E-01	3.82	3.87E-08	Less than 10% of time spent at activity	0.3571429	0.2435065	0
Cleaning of vessel with solvent	0.036	40	0.0009	3.04E-01	3.82	1.39E-08	Less than 10% of time spent at activity	0.1285714	0.0876623	0

Description of contributing scenario	Inhalation exposure value from Advanced REACH Tool (mg/m3)	Assigned protection factor of respiratory protection	Inhalation exposure value including RPE (mg/m3)	Exposure/ DMEL ratio, including RPE	Man year for activity	Calculated additional cancer risk for EU worker population	Reason for adaptation, size of adaptation	Related dose ug/kg bw/day	RCR	Calculated additional intestinal cancer risk, due to oral intake of inhalatory-non respirable fraction for EU worker population
Pigment paste testing by smearing	0	1	0	0.00E+00	3.82	0.00E+00		0	0	0
Pigment paste charging/discharging by gravity or manual handling	0	1	0	0.00E+00	3.82	0.00E+00		0	0	0
Pigment paste charging/discharging using a dedicated installation	0	1	0	0.00E+00	3.82	0.00E+00		0	0	0
Pigment paste filling into drums/cans at a filling line	0	1	0	0.00E+00	7.86	0.00E+00		0	0	0
Mixing colour paste in closed drum mixing machine with automated dosing of paste	0	1	0	0.00E+00	7.86	0.00E+00		0	0	0
Mixing colour paste into paint in closed mixing vessel	0.0029	1	0.0029	9.80E-01	7.86	9.24E-07		0.4142857	0.2824675	0
Pigment paint filling into drums/cans at a filling line	0.0011	10	0.00011	3.72E-02	7.86	3.50E-08		0.0157143	0.0107143	0
Pigment paint charging/discharging using a dedicated installation	0.001	10	0.0001	3.38E-02	7.86	3.19E-08	Paint is either filled into drum/cans at filling line or charged to bulk in dedicated installation. The exposure/DMEL fraction for the first activity is uses, as this is higherl	0.0142857	0.0097403	0
Equipment cleaning: scraping and brushing	0.0035	10	0.00035	1.18E-01	7.86	1.11E-07	Less than 10% of time spent at activity	0.05	0.0340909	0
Dried pigment paint cleaning	0.064	10	0.0064	2.16E+00	7.86	2.04E-06	Less than 10% of time spent at activity	0.9142857	0.6233766	0
Spray testing of pigment paint in industrial booth	1.7	200	0.0085	2.87E+00	7.86	2.71E-06	Less than 10% of time spent at activity	1.2142857	0.8279221	0
Pigment paint testing by brushing/rolling	0.0029	1	0.0029	9.80E-01	7.86	9.24E-07	Less than 10% of time spent at activity	0.4142857	0.2824675	0
Pigment paste or paint laboratory operations	0.00014	1	0.00014	4.73E-02	7.86	4.46E-08	Less than 10% of time spent at activity	0.02	0.0136364	0

Description of contributing scenario	Inhalation exposure value from Advanced REACH Tool (mg/m3)	Assigned protection factor of respiratory protection	Inhalation exposure value including RPE (mg/m3)	Exposure/ DMEL ratio, including RPE	Man year for activity	Calculated additional cancer risk for EU worker population	Reason for adaptation, size of adaptation	Related dose ug/kg bw/day	RCR	Calculated additional intestinal cancer risk, due to oral intake of inhalatory-non respirable fraction for EU worker population
Use#3-Professional application of coating containing C.I. Pigment Yellow 34 on non-consumer articles. Examples include painted road marking on public roads and airports, as well as small scale repair activities on damaged coating layers containing these specific pigments on high grade equipment, for protection and to maintain the replacement value. The high quality of the coating is crucial for the long-term functioning of road or airport marking as fading of the colour could jeopardise public or worker safety; regular repainting could create dangerous situations (traffic jams); frequent temporary closing of airport operations would incur high costs. The selection of a coating containing these pigments is governed by requirements for the end application related to: VISIBILITY AND SAFETY-Based on their bright, vivid, durable colours, these pigments are used when visibility and safety play an important role. In particular for road/airport markings, various national regulations require the use of precisely these pigments. DURABILITY-The pigments respond to the demand for high performance pigments, e.g. in aggressive atmospheric conditions in industrialized areas, providing excellent light and weather fastness, preventing applications to darken or fade if exposed to light and humidity; excellent resistance to sulfur dioxide, preventing discolouration (greyness) and loss of gloss, required for exterior applications; SHADE FUNCTIONALITY-Their colour covers a wide range from green to red shade yellow and yellow to blue shade red; COLOURISTIC AND TECHNICAL PERFORMANCE-Within the listed colour range, these pigments provide clean, vivid colours (chroma); excellent opacity or hiding power; excellent weather fastness. The perceived colour remains the same regardless of the light source, i.e. does not exhibit metamerism. They also provide excellent rheology in coatings; excellent non-bleeding properties, non-migration properties and impact resistance in coatings.										
Total Use 3						**8.90E-05**				**1.47E-03**
Handling of packaged colour paste and/or paint, including distribution	0.000033	1	0.000033	1.11E-02	94.28	1.26E-08	Less than 10% of time spent at activity	0.0047143	0.0032143	0
Dosing of colour paste into paint premix	0	1	0	0.00E+00	94.28	0.00E+00	Less than 10% of time spent at activity	0	0	0
Mixing colour paste with paint in closed mixing machine with automated dosing of paste	0.000044	1	0.000044	1.49E-02	94.28	1.68E-08	Less than 10% of time spent at activity	0.0062857	0.0042857	0
Filling of spray equipment with pigment paints	0.0011	10	0.00011	3.72E-02	94.28	4.20E-08	Less than 10% of time spent at activity	0.0157143	0.0107143	0
Pigment paint spray application in a make-shift booth on location	18	1000	0.018	6.08E+00	94.28	6.88E-05	Activity not taken into account as it is proposed use advised against	2.2628571	1.5428571	1.47E-03
Pigment paint spray application in a professional spray booth	1.7	400	0.00425	1.44E+00	94.28	1.62E-05		0.5464286	0.3725649	0
Mixing of pigment paint in an open vessel	0.004	10	0.0004	1.35E-01	94.28	1.53E-07	Less than 10% of time spent at activity	0.0571429	0.038961	0
Pigment paint application by rolling/brushing	0.0029	10	0.00029	9.80E-02	94.28	1.11E-06		0.0414286	0.0282468	0
Cleaning of wet pigment paint on equipment by wiping and brushing	0.0035	10	0.00035	1.18E-01	94.28	1.34E-07	Less than 10% of time spent at activity	0.05	0.0340909	0
Cleaning of dried pigment paint on equipment by wiping, brushing, scraping etc.	0.064	10	0.0064	2.16E+00	94.28	2.45E-06	Less than 10% of time spent at activity	0.9142857	0.6233766	0
Manipulation of pigment painted articles (dry)	0.00021	10	0.000021	7.09E-03	94.28	8.03E-08		0.003	0.0020455	0

Description of contributing scenario	Inhalation exposure value from Advanced REACH Tool (mg/m3)	Assigned protection factor of respiratory protection	Inhalation exposure value including RPE (mg/m3)	Exposure/ DMEL ratio, including RPE	Man year for activity	Calculated additional cancer risk for EU worker population	Reason for adaptation, size of adaptation	Related dose ug/kg bw/day	RCR	Calculated additional intestinal cancer risk, due to oral intake of inhalatory-non respirable fraction for EU worker population
Service life of coated articles. Performance and longevity depend on the pigment quality for bright lasting colours improving visibility and safety, light and weather fastness (durability), chemical fastness, impact resistance and heat stability.										
Total Professional service life						**3.92E-06**				**0.00E+00**
Cutting painted metal sheet (dry)	0.000076	10	0.0000076	2.57E-03	226.26	6.97E-09	Less than 10% of time spent at activity	0.0010857	0.0007403	0
Sanding of dried paint on machines, vehicles, other articles etc.	0.08	30	0.002666667	9.01E-01	226.26	2.45E-06	Less than 10% of time spent at activity	0.3809524	0.2597403	0
Welding, torchcutting of painted metal (dry)	0.16	100	0.0016	5.41E-01	226.26	1.47E-06	Less than 10% of time spent at activity	0.2285714	0.1558442	0
Grand total risk of C.I. Pigment yellow 34 associated with use 3, professional use in paints and coating						**9.45E-05**				**0**

Tabel B2 Excess cancer risks for the uses and contributing scenarios in use 1, 3for C.I. Pigment Red 104 (Source: CSR PR.104)

Description of contributing scenario	Inhalation exposure value from Advanced REACH Tool (mg/m3)	Assigned protection factor of respiratory protection	Inhalation exposure value with application of respiratory protection (mg/m3)	Exposure/ DMEL ratio, including RPE	Man year for activity	Calculated additional cancer risk for EU worker population	Reason for exclusion / adaptation	Related dose ug/kg bw/day	RCR	Calculated additional intestinal cancer risk, due to oral intake of inhalatory-non respirable fraction for EU worker population
Distribution of pigment powder and formulation into paste used to colour paints. Subsequent industrial or professional use on non-consumer articles.										
Use#1-Distribution and formulation of C.I.Pigment Yellow 34 and C.I.Pigment Red 104 powder into paste/dispersions and solvent-based coloured paints with specific functions for industrial or professional use on non-consumer articles. Examples of coated objects are high grade steel based products e.g. piping for the (petro)chemical industry, crane arms, agricultural machinery, street furniture and markings, steel bridges, construction arches, steel skips ,coil coated products (e.g. roofing).High quality of the coating is crucial for the long-term functioning and protection of the objects, i.e. where fading of the colour could endanger public or worker safety, where regular repainting could create difficult or risky situations (steel bridges, traffic jams) or where idle time of specialty equipment would incur high costs. Pigment choice is based on requirements for the end application related to: VISIBILITY & SAFETY-Based on their bright, vivid, durable colours, these pigments are used when visibility and safety are important, especially in regulated applications like road marking; DURABILITY-The pigments respond to the demand for high performance pigments, e.g. in aggressive atmospheric conditions in industrialized areas, providing excellent light and weather fastness, preventing applications to darken or fade if exposed to light and humidity; excellent resistance to sulfur dioxide, preventing discolouration (greyness) and loss of gloss, required for exterior applications; SHADE FUNCTIONALITY-Their colour covers a wide range from green to red shade yellow and yellow to blue shade red; COLOURISTIC & TECHNICAL PERFORMANCE-Within the listed colour range, these pigments provide clean, vivid colours (chroma); excellent opacity or hiding power; excellent weather fastness. The perceived colour remains the same regardless of the light source (no metamerism).They also provide excellent rheology in coatings; excellent non-bleeding properties, non-migration properties and impact resistance in coatings.										
Total for Use 1						**3.45E-06**				**0.00E+00**
Delivery, storage and handling of closed bags with pigment powder	0.0076	10	0.00076	2.57E-01	3.82	5.04E-08		0.108571	0.074026	0
Pigment powder quality control / lab work	0.00028	1	0.00028	9.46E-02	3.82	1.86E-09	Less than 10% of time spent at activity	0.04	0.027273	0
Manual dosing of pigment powder	0.68	100	0.0068	2.30E+00	3.82	4.51E-07		0.971429	0.662338	0
Automated dosing of pigment powder	0.00098	10	0.000098	3.31E-02	3.82	6.50E-09	Activity not used as substance is either manually or automatically dosed and the exposure/DMEL ratio of manual dosing is higher.	0.014	0.009545	0
Re-packaging of pigment powder	0.0098	40	0.000245	8.28E-02	3.82	1.63E-08		0.035	0.023864	0
Mixing of pigment paste	0	1	0	0.00E+00	3.82	0.00E+00		0	0	0

Description of contributing scenario	Inhalation exposure value from Advanced REACH Tool (mg/m3)	Assigned protection factor of respiratory protection	Inhalation exposure value with application of respiratory protection (mg/m3)	Exposure/ DMEL ratio, including RPE	Man year for activity	Calculated additional cancer risk for EU worker population	Reason for exclusion / adaptation	Related dose ug/kg bw/day	RCR	Calculated additional intestinal cancer risk, due to oral intake of inhalatory-non respirable fraction for EU worker population
Storage of pigment paste / Transfer of pigment paste through closed piping	0	1	0	0.00E+00	3.82	0.00E+00		0	0	0
Manual cleaning / scraping of mixing vessels, equipment and lids	0.025	10	0.0025	8.45E-01	3.82	1.66E-08	Less than 10% of time spent at activity	0.357143	0.243506	0
Cleaning of vessel with solvent	0.036	40	0.0009	3.04E-01	3.82	5.97E-09	Less than 10% of time spent at activity	0.128571	0.087662	0
Pigment paste testing by smearing	0	1	0	0.00E+00	3.82	0.00E+00		0	0	0
Pigment paste charging/discharging by gravity or manual handling	0	1	0	0.00E+00	3.82	0.00E+00		0	0	0
Pigment paste charging/discharging using a dedicated installation	0	1	0	0.00E+00	3.82	0.00E+00		0	0	0
Pigment paste filling into drums/cans at a filling line	0	1	0	0.00E+00	7.86	0.00E+00		0	0	0
Mixing colour paste in closed drum mixing machine with automated dosing of paste	0	1	0	0.00E+00	7.86	0.00E+00		0	0	0
Mixing colour paste into paint in closed mixing vessel	0.0029	1	0.0029	9.80E-01	7.86	3.96E-07		0.414286	0.282468	0
Pigment paint filling into drums/cans at a filling line	0.0011	10	0.00011	3.72E-02	7.86	1.50E-08		0.015714	0.010714	0
Pigment paint charging/discharging using a dedicated installation	0.001	10	0.0001	3.38E-02	7.86	1.37E-08	Paint is either filled into drum/cans at filling line or charged to bulk in dedicated installation. The exposure/DMEL fraction for the first activity is uses, as this is higherl	0.014286	0.00974	0
Equipment cleaning: scraping and brushing	0.0035	10	0.00035	1.18E-01	7.86	4.78E-08	Less than 10% of time spent at activity	0.05	0.034091	0

Description of contributing scenario	Inhalation exposure value from Advanced REACH Tool (mg/m3)	Assigned protection factor of respiratory protection	Inhalation exposure value with application of respiratory protection (mg/m3)	Exposure/ DMEL ratio, including RPE	Man year for activity	Calculated additional cancer risk for EU worker population	Reason for exclusion / adaptation	Related dose ug/kg bw/day	RCR	Calculated additional intestinal cancer risk, due to oral intake of inhalatory-non respirable fraction for EU worker population
Dried pigment paint cleaning	0.064	10	0.0064	2.16E+00	7.86	8.74E-07	Less than 10% of time spent at activity	0.914286	0.623377	0
Spray testing of pigment paint in industrial booth	1.7	200	0.0085	2.87E+00	7.86	1.16E-06	Less than 10% of time spent at activity	1.214286	0.827922	0
Pigment paint testing by brushing/rolling	0.0029	1	0.0029	9.80E-01	7.86	3.96E-07	Less than 10% of time spent at activity	0.414286	0.282468	0
Pigment paste or paint laboratory operations	0.00014	1	0.00014	4.73E-02	7.86	1.91E-08	Less than 10% of time spent at activity	0.02	0.013636	0
Use#3-Professional application of coating containing C.I. Pigment Yellow 34 and C.I. Pigment Red 104 on non-consumer articles. Examples include painted road marking on public roads and airports, as well as small scale repair activities on damaged coating layers containing these specific pigments on high grade equipment, for protection and to maintain the replacement value. The high quality of the coating is crucial for the long-term functioning of road or airport marking as fading of the colour could jeopardise public or worker safety; regular repainting could create dangerous situations (traffic jams); frequent temporary closing of airport operations would incur high costs. The selection of a coating containing these pigments is governed by requirements for the end application related to: VISIBILITY AND SAFETY-Based on their bright, vivid, durable colours, these pigments are used when visibility and safety play an important role. In particular for road/airport markings, various national regulations require the use of precisely these pigments. DURABILITY-The pigments respond to the demand for high performance pigments, e.g. in aggressive atmospheric conditions in industrialized areas, providing excellent light and weather fastness, preventing applications to darken or fade if exposed to light and humidity; excellent resistance to sulfur dioxide, preventing discolouration (greyness) and loss of gloss, required for exterior applications; SHADE FUNCTIONALITY-Their colour covers a wide range from green to red shade yellow and yellow to blue shade red; COLOURISTIC AND TECHNICAL PERFORMANCE-Within the listed colour range, these pigments provide clean, vivid colours (chroma); excellent opacity or hiding power; excellent weather fastness. The perceived colour remains the same regardless of the light source, i.e. does not exhibit metamerism. They also provide excellent rheology in coatings; excellent non-bleeding properties, non-migration properties and impact resistance in coatings.										
Total use 3						**3.82E-05**				**6.30E-04**
Handling of packaged colour paste and/or paint, including distribution	0.000033	1	0.000033	1.11E-02	94.28	5.41E-09	Less than 10% of time spent at activity	0.004714	0.003214	0
Dosing of colour paste into paint premix	0	1	0	0.00E+00	94.28	0.00E+00	Less than 10% of time spent at activity	0	0	0
Mixing colour paste with paint in closed mixing machine with automated dosing of paste	0.000044	1	0.000044	1.49E-02	94.28	7.21E-09	Less than 10% of time spent at activity	0.006286	0.004286	0

Description of contributing scenario	Inhalation exposure value from Advanced REACH Tool (mg/m3)	Assigned protection factor of respiratory protection	Inhalation exposure value with application of respiratory protection (mg/m3)	Exposure/ DMEL ratio, including RPE	Man year for activity	Calculated additional cancer risk for EU worker population	Reason for exclusion / adaptation	Related dose ug/kg bw/day	RCR	Calculated additional intestinal cancer risk, due to oral intake of inhalatory-non respirable fraction for EU worker population
Filling of spray equipment with pigment paints	0.0011	10	0.00011	3.72E-02	94.28	1.80E-08	Less than 10% of time spent at activity	0.015714	0.010714	0
Pigment paint spray application in a make-shift booth on location	18	1000	0.018	6.08E+00	94.28	2.95E-05	Activity not taken into account as it is proposed use advised against	2.262857	1.542857	6.30E-04
Pigment paint spray application in a professional spray booth	1.7	400	0.00425	1.44E+00	94.28	6.96E-06		0.546429	0.372565	0
Mixing of pigment paint in an open vessel	0.004	10	0.0004	1.35E-01	94.28	6.55E-08	Less than 10% of time spent at activity	0.057143	0.038961	0
Pigment paint application by rolling/brushing	0.0029	10	0.00029	9.80E-02	94.28	4.75E-07		0.041429	0.028247	0
Cleaning of wet pigment paint on equipment by wiping and brushing	0.0035	10	0.00035	1.18E-01	94.28	5.73E-08	Less than 10% of time spent at activity	0.05	0.034091	0
Cleaning of dried pigment paint on equipment by wiping, brushing, scraping etc.	0.064	10	0.0064	2.16E+00	94.28	1.05E-06	Less than 10% of time spent at activity	0.914286	0.623377	0
Manipulation of pigment painted articles (dry)	0.00021	10	0.000021	7.09E-03	94.28	3.44E-08		0.003	0.002045	0
Service life of coated articles. Performance and longevity depend on the pigment quality for bright lasting colours improving visibility and safety, light and weather fastness (durability), chemical fastness, impact resistance and heat stability.										
Total professional service life						**1.68E-06**				**0.00E+00**
Cutting painted metal sheet (dry)	0.000076	10	0.0000076	2.57E-03	94.28	2.99E-09	Less than 10% of time spent at activity	0.001086	0.00074	0
Sanding of dried paint on machines, vehicles, other articles etc.	0.08	30	0.002666667	9.01E-01	94.28	1.05E-06	Less than 10% of time spent at activity	0.380952	0.25974	0
Welding, torchcutting of painted metal (dry)	0.16	100	0.0016	5.41E-01	94.28	6.29E-07	Less than 10% of time spent at activity	0.228571	0.155844	0

Description of contributing scenario	Inhalation exposure value from Advanced REACH Tool (mg/m3)	Assigned protection factor of respiratory protection	Inhalation exposure value with application of respiratory protection (mg/m3)	Exposure/ DMEL ratio, including RPE	Man year for activity	Calculated additional cancer risk for EU worker population	Reason for exclusion / adaptation	Related dose ug/kg bw/day	RCR	Calculated additional intestinal cancer risk, due to oral intake of inhalatory-non respirable fraction for EU worker population
Grand total risk of PR associated with use 3, professional use in paints and coatings						**4.05E-05**				