Third party submission of information on alternatives for
Applications for Authorisation

Legal name of submitter: BASF SE

Substance: Lead sulfochromate yellow (C.I. Pigment Yellow 34)*
Lead chromate molybdate sulphate red (C.I. Pigment Red 104)*

* For "Lead sulfochromate yellow (C.I. Pigment Yellow 34)" and
"Lead chromate molybdate sulphate red (C.I. Pigment Red 104)" the shortened wording "Lead chromate" will be used in the following text.
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1. ALTERNATIVE ID AND PROPERTIES

We, BASF SE, are a producer and internal coatings and plastics Downstream User (DU) of pigments and decided at a very early stage, that we will comply with the defined sunset date 21st May 2015 for PY34 and PR104 worldwide by ceasing production and use. We follow the efforts of the European Community towards a lead pigments free world. We informed all our external customers thereof many global players shortly after ECHA publication of the sunset day and got the feedback that they go in line with our decision even in a global approach and switch to solutions without lead.

Most of our customers have either successfully converted to lead chromates free formulations or are prepared to do so because they have already worked out alternative recipes, partly even earlier than 2012. Thus the reformulation cost is spent already. Our expectation is that for lead chromate alternatives sufficient production capacities exist worldwide and the components are available broadly.

In the pigment industry, decent paints or plastic parts or other applications are in all known cases formulated at the downstream user with pigment combinations from one or several suppliers rather than with a single pigment. Withdrawal of a pigment class consequently means the formulations need to be changed to match the color. The future recipes thus will consist of different combinations of pigments without usage of PY34 or PR104. We, other competitors and even the applicant offer a range of products which, depending on the specific use, contribute to all needs of the DUs in achieving formulations without lead chromate.

The applicant listed a lot of alternatives and stated that no 1:1 alternatives for PY34 and PR104 fulfill all needs of uses where he applied for. The statement of the applicant is not practically relevant as blends of different pigments to match a color is the key.

The applicant emphasizes the economic risks involved by the “non-use” scenario of PY34 and PY104. Our perception is that these risks of a change towards alternative formulations are very limited because the DUs will be supplied with a bunch of different products across a wide range of inorganic and organic pigments based on their specific uses resp. their needed performance levels. Most of the colorant alternatives are already in use since decades. There is a lot of established experience, especially in substituting PY34 and PY104 by organic and/or inorganic pigments.

With regard to the described hazards of the alternative substances our view is different. Based on the current knowledge of the substances and of the manufacturing processes alternative colorants have a less problematic toxicological profile compared to lead chromates.

Currently capacities for alternative pigments are available.
2. TECHNICAL FEASIBILITY

All in this Chapter mentioned pigments are well known and continuously used in the entire European and global plastic and fiber industry. Since more than 30 years the pigment manufacturers are offering lead free alternatives to the plastics and fiber industry. Many customers in fibers, packaging, food logistics and packaging and toys manufacturing have already switched to lead chromate free formulations. Some customers have internally worked out alternative formulations in order to be prepared for the replacement.

Using colour matching tools (software and equipment) is a common standard within the entire plastics industry. That means the industry is experienced to match all important shades by a selection of pigments. Usually plastic companies offer a broad range of colours which are achieved easily via blending of selected pigments even for small batches. Colour matching supported by electronic tools is technical standard in the industry.

The available alternative pigments are able to:

- cover the entire colour space (from yellow, via orange to red)
- supply clean colour shades
- fulfill high opacity requirements e.g. by combining organic and inorganic pigments
- cover different performance levels for interior and exterior uses of plastics and fibers
- fulfill even very high requirements in light and weather resistance
- offer excellent heat stability in standard polymers such as PVC and Polyolefins
- selected pigments even offer excellent heat stability (> 300 °C) in most demanding technical polymers such as Polyester and Polyamide
- offer excellent migration resistance and many pigments are suitable for Food Contact applications
- fulfill technical requirements regarding all relevant plastic processing technologies

There is no practical need for a single lead-free pigment alternative which covers all of the a.m. technical properties in one. There are many alternatives available in the concerned shade areas (yellow, orange and red) but on different performance levels.

Depending on required shade it is possible and common practice to match the same shade based on selected pigments shown in the table. There are many more pigments on different performance levels available in the market.

Selection of suitable and in plastics industry already used pigments.

A) by substances,  B) by chem. groups

A) Substances**

<table>
<thead>
<tr>
<th>Colour Index</th>
<th>CAS-No.</th>
<th>Chemical Character</th>
<th>REACH-Reg.</th>
</tr>
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<tbody>
<tr>
<td>1. P.Y.53</td>
<td>CAS 8007-18-9</td>
<td>Antimony Nickel Titanium Oxide</td>
<td>01-2119491302-44-0000</td>
</tr>
<tr>
<td>2. P.Br.24</td>
<td>CAS 68186-90-3</td>
<td>Chrome Antimony Titanium Oxide</td>
<td>01-2119486965-17-0000</td>
</tr>
<tr>
<td>3. P.Y.184</td>
<td>CAS 14059-33-7</td>
<td>Bismuth Vanadium Tetraoxide</td>
<td>01-2119468965-17-0000</td>
</tr>
<tr>
<td>4. P.Y.138</td>
<td>CAS 30125-47-4</td>
<td>Quinophthalone</td>
<td>01-2119966146-32-0000</td>
</tr>
</tbody>
</table>

[Consultation number: 0012-07 to 0012-12] [Mixtures of organic and inorganic pigments] [08-04-2014]
| 5. | P.Y.139 | CAS 36888-99-0 | Isoindoline | 01-2119965154-36-0000 |
| 6. | P.Y.14  | CAS 5468-75-7  | Diarylide   | 01-2119475454-33-0001 |
| 7. | P.R.254 | CAS 84632-65-5 | Diketopyrrolopyrrole | 01-0000015139-70-0005 |
| 8. | P.Y.93  | CAS 5580-57-4  | Disazo-Condensation | 01-2119960203-46-0000 |
| 9. | P.Y.95  | CAS 5280-80-8  | Disazo-Condensation | 01-2119960150-49-0000 |
| 10.| P.W. 6  | CAS 13463-67-7 | Titandioxide | 01-2119489379-17-0071 |
| 12.| P.Y.168 | CAS 71832-85-4 | Azo-salt    | 01-2119966147-30-0000 |
| 13.| P.Y.83  | CAS 5567-15-7  | Diarylide   | 01-2119475484-30-0005 |
| 14.| P.Y.95  | CAS 5280-80-8  | Disazo-Condensation | 01-21199960150-49-0000 |
| 15.| P.Y.128 | CAS 79953-85-8 | Disazo-Condensation | 01-2119960151-47-0000 |
| 16.| P.O.64  | CAS 72102-84-2 | Benzimidazolone | 01-2119970553-33-0000 |
| 17.| P.O.71  | CAS 84632-50-8 | Diketopyrrolopyrrole | 01-2120029512-66-0000 |
| 18.| P.O.73  | CAS 84632-59-7 | Diketopyrrolopyrrole | 01-21199912157-43-0000 |
| 19.| P.Y.128 | CAS 12286-66-7 | Diarylide   | 01-2119960203-46-0000 |
| 20.| P.Y.79  | CAS 25064-08-5 | Azo-salt    | 01-2119972291-37-0000 |
| 21.| P.O.82  | CAS 923954-49-8 | Tin Titanium Zinc Oxide | 01-0000020286-72-0000 |
| 22.| P.O.34  | CAS 15793-73-4 | Diarylide   | 01-2119970554-31-0001 |
| 23.| P.R.48:2| CAS 7023-61-2  | BONA (Ca)   | 01-2119475324-38-0000 |
| 24.| P.R.48:3| CAS 15782-05-5 | BONA (Sr)   | 01-2119974693-28-0000 |
| 25.| P.R.144 | CAS 5280-78-4  | Disazo-Condensation | 01-21199959306-31-0000 |
| 26.| P.R.149 | CAS 4948-15-6  | Perylene    | 01-2119972291-37-0000 |
| 27.| P.R.166 | CAS 3905-19-9  | Disazo-Condensation | 01-2119959307-29-0000 |
| 28.| P.Y.164 | CAS 68412-38-4 | Manganese Antimony Titanium Buff Rutile | 01-2119941276-31-0000 |
| 29.| P.R.214 | CAS 40618-31-3 | Disazo-Condensation | 01-2119959308-27-0000 |
| 30.| P.R.101 | CAS 1309-37-1  | Diiron Trioxide | 01-2119457614-35-0001 |
| 31.| P.R.57:1| CAS 5281-04-9  | BONA (Ca)   | 01-2119473978-15-0000 |
| 32.| P.Y.216 | CAS 85536-73-8 | Tin Zinc Rutile | 01-2119980988-10-0000 |
| 33.| P.Y.155 | CAS 68516-73-4 | Disazo-condensation | 01-2119960152-45-0000 |
| 34.| P.Y.110 | CAS 5590-18-1  | Isoindolinone | 01-2119965154-36-0000 |
| 35.| P.Y.183 | CAS 6521-77-3  | Azo-salt    | 01-2119965154-36-0000 |
| 36.| P.Y.215 | CAS 34679-25-9 | Pteridine   | 01-2119965154-36-0000 |
| 37.| P.O.61  | CAS 76168-74-6 | Isoindolinone | 01-2119965154-36-0000 |
| 38.| P.R.255 | CAS 120500-90-5 | Diketopyrrolopyrrole | 01-2119965154-36-0000 |
39. P.R.272   CAS 350249-32-0  Diketopyrrolopyrrole
40. P.R.265   CAS 12014-93-6   Cerium Sulfide
41. P.Y.61    CAS 12286-65-6   Arylide  

** substances in bold letters are substances mentioned in DCC-dossier

B) Chemical groups

Organic pigments
1. Arylide and Diarylide
2. Disazopyrazolone
3. Isoindoline
4. Isoindolinone
5. Quinophthalone
6. Pteridine
7.1. Azo-Salts
7.2. BONA
8. Benzimidazolone
9. Disazo-condensation
10. Diketopyrrolopyrrole
11. Perylene

Inorganic pigments
1. Bismuthvanadate
2. CICP (Complex Inorganic Colored Pigments)
3. Titandioxide
4. Iron Oxide
5. Others

Comments to some of the chemical groups

Organic pigments
1. Arylide and Diarylide

Technical properties: clean shades (from greenish yellow to orange), high tinting strength, reasonable prices, limited light- and weather resistance, medium heat resistance, can be used for PVC and LDPE

2. Disazopyrazolone

Technical properties: clean shades (orange), high tinting strength, reasonable prices, limited light- and weather resistance, medium heat resistance, can be used for PVC and LDPE

3. Isoindoline

Technical properties: clean shades (green shade to red shade yellow), high color strength high light- and medium weather resistance, especially suitable for Polyolefin Films and Fibers.
4. Isoindolinone

5. Quinophthalone
Technical properties: very clean green shade yellow, high saturation and opacity. Excellent light fastness and weather resistance. Recommended for out-door applications.

6. Pteridine
Technical properties: opaque mid shade yellow with excellent color stability (heat, light, weather). Suitable for most demanding substrates such as Polyamide. Can be used in out-door applications.

7. 1 Azo-salts
Technical properties: from greenish yellow to reddish yellow. High saturation and good opacity, good heat resistance and medium light fastness and weather resistance, very economical solutions for in-door applications.

7.2. BONA
Technical properties: from yellowish red to bluish red. High saturation and good opacity, good heat resistance and medium light fastness and weather resistance, very economical solutions for in-door applications.

8. Benzimidazolone
Technical properties: clean shades (green shade yellow to red), high color strength, high to excellent light- and weather resistance,

Technical properties: Very green shade to red shade yellows, scarlet to bluish reds. High saturation and high color strength, excellent heat resistance, good light resistance. Commonly used in fibers and films, for in-door and selected out-door applications.

10. Diketopyrrolopyrrole
Technical properties: clean and saturated shades from orange to bluish red, excellent light- and weather resistance. Offer economical solutions with very good performance. Suitable for out-door applications.

11. Perylene
Technical properties: excellent heat resistance, high color strength, excellent light- and weather resistance in full shades, suitable for demanding substrates such as Polyester and Polyamide and out-door applications.

Inorganic pigments

1. Bismuthvanadate
Technical properties: very clean green shade yellow, very good opacity, excellent light- and weather resistance, suitable for demanding substrates such as Polyester and Polyamide and out-door applications.

2. CICP (Rutile)
Technical properties: Cr-, Ni- and Mn-titanates. Good to excellent opacity, excellent light- and weather resistance, excellent heat stability also in most demanding substrates such as Polyamide and Polyester, suitable for out-door applications. Offers economical solutions, excellent combination partner for organic pigments.
Lead chromate pigments have been used in the past in all kind of applications because the performance / cost ratio was very attractive. Therefore, Lead chromate pigments are often used in applications, where not all of its performance features are used, e.g. weather resistance and opacity.

Because of above mentioned reasons, it is not necessary to have a one-to-one replacement. Much more important is to understand in which applications lead chromate pigments are used and then to find alternative formulations without performance compromises.

Selection of alternative is like a new color matching process. It is necessary to define:

- the respective polymers and select alternatives for each single one
- Maximum processing requirements, bearing the possibility of compromise in mind.
- the end-use properties (indoors, outdoors, food packaging, …)
- In the colour matching process, it is worthwhile considering the following parameters:
  - Chromaticity: achieved by organic pigments.
  - Opacity: achieved by inorganic pigments or TiO2.
  - Shading: organic or inorganic pigments that maintain the required performance.

For Plastics the applications can be grouped into several performance levels, for instance:

**Top Performance**
- Applications for longest life outdoors.
  *Roofing, siding, tarpaulins, decorative films for cars and advertisement light boxes, crates, shading nets*

**High Performance**
- Applications for longest life indoors and specific outdoors
  *Higher quality flooring, decorative films for cars and advertisement light boxes, crates, shading net.*

**Mid Performance**
- Indoor applications and end products exposed to weather for short periods
  *Pipes (storage time), fairly high quality packaging, standard flooring, furniture films and household machines.*

**Good enough Performance**
- Cost driven short lifetime applications
  *Industrial and non-food packaging, self decorative films and low cost flooring*

**BASF** among others provide a broad range of alternatives available:

- based on organic and inorganic pigments
- covering the whole color space
- covering all polymers and performance levels
- with coloration costs per kilo, depending on chemistry and performance.

The technical solution is blending suitable pigments to the required shade:

1. for clean shades: take organic yellow / orange / red pigments
2. for opacity: take inorganic pigments (CICP, iron oxide reds, Bismuth Vanadate)
3. for shading: take organic pigments
### 3. ECONOMIC FEASIBILITY

Based on actual market prices, a comparison of lead free formulation to lead containing formulations was done for selected color areas (RAL shades) and different performance levels (as described above).

In the most demanding performance level the cost for lead free formulations are 2-3 times higher, in the mid-performance area already comparable and in the good-enough area already cheaper. Information below provides a rough estimate per performance level.
Above cost factors have been determined by matching the exact color shade and by achieving exactly the same opacity levels. If customers can accept small compromises on shade or opacity, these cost factors can even be significantly reduced:

As example: coloristic target: 2% Sicomin® Yellow K 1922 (P.Y.34) in f-PVC – Mid performance, full shade

<table>
<thead>
<tr>
<th>Similar Opacity</th>
<th>Higher Transparency</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.00% Pigment Yellow 62</td>
<td>0.085% Pigment Yellow 180</td>
</tr>
<tr>
<td>0.15% Pigment Yellow 83</td>
<td>0.100% Pigment Yellow 139</td>
</tr>
<tr>
<td>0.50% Pigment White 6</td>
<td></td>
</tr>
</tbody>
</table>

Cost factor: ~1.7  Cost factor: ~0.4

Conclusion: An acceptable combination can be achieved between opacity and coloration costs.

4. HAZARDS AND RISKS OF THE ALTERNATIVE

All under Chapter 2 mentioned pigments are not listed in the candidate list for Annex XIV of REACH Regulation 1907/2006/EC.
All organic and inorganic pigments are primarily supplied in powder or granule dust free form.
Safe handling of the products is described in each MSDS (Material Safety Data Sheet). Following these recommendations hazards can be managed and risks can be avoided.
In addition most of the organic pigments also available in non-dusting pre-dispersed preparation form.
All manufacturing processes to synthesize these products are approved by the relevant authorities.

Following toxicological summaries are based on already submitted registration dossiers. These comments based on the current knowledge of the substances and of the manufacturing processes demonstrate that alternative colorants have a less problematic toxicological profile compared to lead chromates.

P.Y.53 CAS 8007-18-9 Antimony Nickel Titanium Oxide

Pigment Yellow 53 (antimony nickel titanium oxide) belongs to the group of inorganic pigments with a rutile lattice in which titanium ions are partially replaced by other metal ions (antimony, nickel, chrome). Transformation/dissolution studies with these pigments revealed that even under strongly acidic (pH 1) or alkaline conditions (pH 8.5), which simulate different body fluids, both antimony and nickel ions remain bound in the matrix. These in vitro results were substantiated by an oral 90-day study with repeated administration. This 90-day study revealed no substance related effects up to the limit dose and proved that only trace amounts of metal ions, most likely stemming from impurities, are bioavailable in vivo. A further 5 day inhalation study with a 60 day post exposure period with 60 mg C.I. Pigment Yellow 53/m³ showed significant deposition of the pigment in the lung (~ 2 mg/lung), while nickel and antimony values were similar in exposed and unexposed animals in the liver and only slightly elevated on day 3 post exposure due to impurities in the pigment. A combined reproductive toxicity screening/28-day study according to OECD guideline 422 confirmed the low toxicity of this class of substances and found no effects on reproductive parameters. Negative gene mutation and cytogenetic studies provided further evidence that these rutile-type pigments should not be seen as nickel, antimony or chrome releasing.
substances. The combined data prompted the European authorities to exempt these pigments from the antimony group entries and legal classification of nickel compounds.

P.Br.24 CAS 68186-90-3 Chrome Antimony Titanium Oxide

Pigment Brown 24 belongs to the group of inorganic pigments with a rutile lattice in which titanium ions are partially replaced by other metal ions (antimony, nickel, chrome). Transformation/dissolution studies with these pigments revealed that even under strongly acidic (pH 1) or alkaline conditions (pH 8.5), which simulate different body fluids, both antimony and nickel ions remain bound in the matrix. These in vitro results were substantiated by an oral 90-day study with repeated administration. This 90-day study revealed no substance related effects up to the limit dose and proved that only trace amounts of metal ions, most likely stemming from impurities, are bioavailable in vivo. A further 5 day inhalation study using the archetype rutile substance, C.I. Pigment Yellow 53 (antimony nickel titanium oxide), which included a 60 day post exposure period with 60 mg test material/m³ showed significant deposition of the pigment in the lung (~ 2 mg/lung), while nickel and antimony values were similar in exposed and unexposed animals in the liver and only slightly elevated on day 3 post exposure due to impurities in the pigment. A combined reproductive toxicity screening/28-day study according to OECD guideline 422 with C.I. Pigment Yellow 53 confirmed the low toxicity of this class of substances and found no effects on reproductive parameters. Negative gene mutation and cytogenetic studies provided further evidence that these rutile-type pigments should not be seen as nickel, antimony or chrome releasing substances. The combined data prompted the European authorities to exempt these pigments from the antimony group entries and legal classification of nickel compounds.

P.Y.184 CAS 14059-33-7 Bismuth Vanadium Tetraoxide

C.I. Pigment Yellow 184 is of very low acute toxicity and neither irritating to the skin and eye nor skin sensitizing. In addition, it does not cause systemic effects following repeated oral or inhalation exposure and proved non-genotoxic in a number of in vitro and one in vivo study. This is in contrast to data on bismuth vanadate and other vanadium(V)-compounds mentioned in the report “Analysis of Alternatives” by DCC Maastricht B.V. OR. Also, both vanadium and vanadium pentaoxide are not legally classified as possible human carcinogens nor is bismuth vanadate a skin, eye or respiratory sensitizer. While it is true that vanadates are viewed as secondary genotoxicants when bioavailable by most experts, there are conflicting genotoxicity studies in the public domain. While some studies with soluble ammonium and sodium vanadates proved positive, all genotoxicity studies with the equally soluble vanadium pentaoxide were negative. However, it is true that the toxicological profile of soluble vanadates is different from bismuth vanadate (C.I. Pigment Yellow 184). The soluble vanadium(V)-compounds tend to be acutely toxic, irritating to eyes and respiratory system and cause systemic toxicity to the hematopoietic system and the sex cycle following repeated administration. The main reason for this discrepancy, as it turned out, was the bioaccessability of the vanadium ions. Transformation/dissolution studies in acidic to basic buffer systems revealed no leaching of bismuth or vanadate ions from the pigment while leaching of these ions from vanadium pentaoxide was 300-5000 fold higher, depending on the pH tested. Inhalation studies with the pigment confirmed the low bioaccessability as no organ translocation of vanadate or bismuth ions was detectable. It can therefore be concluded that results obtained with soluble vanadium(V)compounds have no relevance for C.I. Pigment Yellow 184.

While it is true that during production of C.I. Pigment Yellow 184 soluble vanadium(V)compounds are used, they are present as aqueous solutions. This eliminates the risk of inhaling the substances and in turn, because effective industrial hygiene measure are implemented in Europe to prevent oral exposure, prevents the risk of systemic or lung effects otherwise exerted by these substances.
P.R.101  CAS 1309-37-1  Diiron Trioxide

Iron oxides are not acutely toxic, irritating to eyes and skin or skin sensitizing. Various tests revealed that iron oxides do not cause gene mutations or chromosomal damage. Following repeated inhalation exposure, systemic toxicity was not observed and neither iron particles nor bioavailable iron were translocated to extrapulmonary organs. Unsurprisingly, concentrations that cause lung overload also caused increased lung and lung-associated lymph nodes weight consistent with effects found for poorly soluble particles.

P.Y. 110 CAS 5590-18-1  Isoindolinone

Experimental data has been collected and generated for the purpose of registration under REACH at the tonnage band of 100 - 1000 tpa. Pigment Yellow 110 is not toxic upon acute ingestion. A structural analogue was nontoxic after single skin contact. It is not irritating to skin and eyes and does not cause skin sensitization in experimental animals. A screening study for subacute toxicity and repeated dose and reproductive toxicity on a structural analogue gave no indication of substance-related effects, of a fertility impairing effect or malformations. In the majority of tests performed (bacteria) a mutagenic effect was not found. A mutagenic effect was also not observed in in-vivo assays. No hazard for the environment was identified.

P.Y. 138 CAS 30125-47-4  Quinophthalone

Experimental data has been collected and generated for the purpose of registration under REACH at the tonnage band of 100 - 1000 tpa. Pigment Yellow 138 is not toxic upon acute ingestion and nontoxic after single skin contact. It is not irritating to skin and eyes and does not cause skin sensitization in experimental animals. A screening study for subacute toxicity and repeated dose and reproductive toxicity gave no indication of substance-related effects, of a fertility impairing effect or malformations. In the majority of tests performed (bacteria) a mutagenic effect was not found. Genotoxicity was not observed. No hazard for the environment was identified.

P.Y. 139 CAS 36888-99-0  Isoindoline

Experimental data has been collected and generated for the purpose of registration under REACH. Pigment Yellow 139 is not toxic upon acute ingestion and skin contact. It is not irritating to skin and eyes and did not cause skin sensitization in animals. A screening study for reproductive toxicity showed no effect up the limit dose. No genotoxicity was observed. Overall, experimental data indicates that the pigment is not taken up after ingestion. This is consistent with the insolubility in water and octanol. Pigment Yellow 139 is structurally related to Pigment Yellow 185 for which no hazard was identified in experimental studies. No hazard for the environment was identified.

P.Y. 155 CAS 68516-73-4  Diarylide

Experimental data has been collected and generated for the purpose of registration under REACH. Pigment Yellow 155 is not toxic upon acute ingestion. It is not irritating to skin and eyes and did not cause skin sensitization in the LLNA. A screening study for subacute toxicity and repeated dose and reproductive toxicity showed no effect up the limit dose. No genotoxicity was observed. Overall, experimental data indicates that the pigment is not taken up after ingestion. This is consistent with the insolubility in water and octanol. Pigment Yellow 155 belongs to a group of five yellow disazocondensation pigments. No adverse results were found in any toxicity study for any of the pigments. No hazard for the environment was identified.
P.Y. 183 CAS 65212-77-3  Arylide

Experimental data has been collected and generated for the purpose of registration under REACH at the tonnage band of 100 - 1000 tpa. Pigment Yellow 183 is not toxic upon acute ingestion, single skin contact and inhalation. It is not irritating to skin and eyes and does not cause skin sensitization in experimental animals. No adverse effects were observed after repeated exposure to an analogue structure in animal studies. There is also no indication of a fertility impairing effect or a developmental toxic / teratogenic effect after administration of the analogue. No genotoxicity was observed. No hazard for the environment was identified.

P.O. 73 CAS 84632-59-7  Diketopyrrolopyrrole

Pigment Orange 73 is not toxic upon acute ingestion and skin contact. It is not irritating to skin and eyes and does not cause skin sensitization in experimental animals. The subacute oral dose toxicity showed no adverse effects at the limit dose. No genotoxicity was observed. No hazard for the environment was identified. All studies were performed according to OECD guidelines and GLP. Overall, experimental data indicates that the pigment is not taken up after ingestion. This is consistent with the insolubility in water and octanol.

P.R. 254 CAS 84632-65-5  Diketopyrrolopyrrole

Pigment Red 254 is not toxic upon acute ingestion, skin contact and inhalation. It is not irritating to skin and eyes and does not cause skin sensitization in experimental animals. The subacute oral dose toxicity showed no adverse effects at the limit dose. No genotoxicity was observed. A toxicokinetic study showed that the pigment is not taken up after ingestion. No hazard for the environment was identified. All these studies were performed according to OECD guidelines and GLP. A recently performed 5-day inhalation study with 28-day observation period showed no substance-specific hazard. Overall, experimental data indicates that the pigment is not taken up after ingestion. This is consistent with the insolubility in water and octanol.

P.R. 57:1 CAS 5281-04-9  BONA

Experimental data has been collected and generated for the purpose of registration under REACH at the tonnage band of > 1000 tpa. Pigment Red 57:1 is not toxic upon acute ingestion, skin contact and inhalation. It is not irritating to skin and eyes and does not cause skin sensitization in experimental animals. A screening study for subacute toxicity and repeated dose and reproductive toxicity showed adverse effects on the kidney at high doses. The pigment is a complex between an organic acid and calcium and dissociates at extreme pH, such as present in the stomach. Therefore, solubility is higher than for other pigments and uptake after ingestion is observed. The analogue sodium salt (Pigment Red 57) did not cause adverse effects in a life-long feeding study starting with in utero exposure. The substance will undergo testing for teratogenicity and fertility in the near future. No genotoxicity was observed. No hazard for the environment was identified.

P.Y. 168 CAS 71832-85-4  Azo-Salt

Experimental data has been collected and generated for the purpose of registration under REACH at the tonnage band of 100 - 1000 tpa. Pigment Yellow 168 is not toxic upon acute ingestion. A structural analogue was nontoxic after single skin contact. It is not irritating to skin and eyes and does not cause skin sensitization in experimental animals. No adverse effects were observed after repeated exposure to a structural analogue in animal studies. There is also no indication of a fertility
impairing effect or a developmental toxic / teratogenic effect after administration of the analogue. No genotoxicity was observed. No hazard for the environment was identified.

P.Y. 61 CAS 12286-65-6 Arylide

Experimental data has been collected and generated for the purpose of registration under REACH at the tonnage band of 10 - 100 tpa. A structural analogue of Pigment Yellow 61 is not toxic upon acute ingestion, Pigment Yellow 61 nontoxic after a single skin contact. The analogue is not irritating to skin and eyes. Pigment Yellow 61 does not cause skin sensitization in experimental animals. No adverse effects were observed after repeated exposure to a structural analogue in animal studies. There is also no indication of a fertility impairing effect or a developmental toxic / teratogenic effect after administration of the analogue. No genotoxicity was observed at analogue substances. No hazard for the environment was identified.

P.Y. 62 CAS 12286-66-7 Azo-Salt

Experimental data has been collected and generated for the purpose of registration under REACH at the tonnage band of 100 - 1000 tpa. Pigment Yellow 62 is not toxic upon acute ingestion. A structural analogue was nontoxic after single skin contact. It is not irritating to skin and eyes and does not cause skin sensitization in experimental animals. No adverse effects were observed after repeated exposure in animal studies. There is also no indication of a fertility impairing effect or a developmental toxic / teratogenic effect. No genotoxicity was observed. No hazard for the environment was identified.

P.O. 64 CAS 72102-84-2 Benzimidazolone

Unpublished study reports owned by BASF show that Pigment Orange 64 is of low acute oral toxicity (LD50 rat > 6000 mg/kg bw). No mortality upon acute inhalation was observed at 2.1 mg/L which was the highest attainable concentration. The pigment is not irritating to skin and eyes and does not cause skin sensitization. No adverse effects up to the limit dose were observed upon subacute oral exposure of rat. No genotoxicity was observed in the Ames test and in the micronucleus study in vivo. Effects on aquatic organisms were not observed at concentrations in the range of water solubility.

5. AVAILABILITY

All under Chapter 2 mentioned pigments are available on European and/or global market. Most of the substances are available at more than one manufacturer / supplier. The plastics industry has choices to find the most suitable product under the following aspects:

- Quality
- Price
- Technical and commercial service
- Alternative suppliers

Currently capacities for alternative pigments are available.
6. CONCLUSION ON SUITABILITY AND AVAILABILITY OF THE ALTERNATIVE

Most of our customers have either successfully converted to lead chromates free formulations or are prepared to do so because they have already worked out alternative recipes, partly even earlier than 2012. Thus the reformulation cost is spent already. The paint, coating and plastics industry has choices to find the most suitable product combination under the following aspects:

- Quality/performance
- Price
- Technical and commercial service
- Alternative suppliers
- 

Our expectation is that for lead chromate alternatives sufficient production capacities exist worldwide and the components are available broadly. All under Chapter 2 mentioned pigments are available on European and/or global market. Most of the substances are available from more than one manufacturer / supplier.

In the pigment industry, decent paints or plastic parts or other applications are in all known cases formulated at the downstream user with pigment combinations from one or several suppliers rather than with a single pigment. The future recipes thus will consist of different combinations of pigments without usage of PY34 or PR104. We, other competitors and even the applicant offer a range of products which, depending on the specific use, contribute to all needs of the DUs in achieving formulations without lead chromate. There is a lot of established experience, especially in substituting PY34 and PY104 by organic and/or inorganic pigments.

Based on the current knowledge of the substances and of the manufacturing processes alternative colorants have a less problematic toxicological profile compared to lead chromates.

Depending on shade and performance lead chromate free formulations could be more cost efficient than lead chromate containing manufactured plastics.

7. OTHER COMMENTS

Customer comments which were submitted to us during the public consultation phase:

1. Source: CLARIANT Masterbatches

“Clariant MB Europe stepped completely out to produce Masterbatch based on Lead chromates in the different European facilities. The reformulation of the existing products was done together with the influenced costumers and in most of the cases without significant problems”

2. Source: PolyOne

“Regarding lead replacement: PolyOne replaced already lead formulation. If DCC would get any positive answer the consequence will be negative for PolyOne.”

3. Source: Renolit
Original text:
„Alle BU´s der Renolit bleiben bei der Entscheidung, dass im Laufe des Jahres alle Farbrezpturen mit Bleichromate und -molybdate, durch Pb-freie Alternativen ersetzt werden.“
Translated text:
„All business units of Renolit stay with their decision to change all colored formulations based on Leadchromate and Leadchromate/molybdate within 2014. It will be exchanged by lead free alternatives.”

REFERENCES
no references

APPENDIXES
no appendixes