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COMMISSION IMPLEMENTING DECISION

of 7.9.2016

granting an authorisation for some uses of lead sulfochromate yellow and of lead chromate molybdate sulfate red under Regulation (EC) No 1907/2006 of the European Parliament and of the Council

(Text with EEA relevance)

[ONLY THE ENGLISH TEXT IS AUTHENTIC]

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THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC¹, and in particular Article 64(8) thereof,

Whereas:

- (1) Lead sulfochromate yellow and lead chromate molybdate sulfate red are listed in Annex XIV to Regulation (EC) No 1907/2006 and are therefore subject to the authorisation requirement referred to in Article 56(1) of that Regulation.
- (2) In accordance with Article 62 of Regulation (EC) No 1907/2006, an application for authorisation was submitted on 19 November 2013 by DCC Maastricht BV, acting as only representative, for the placing on the market of lead sulfochromate yellow and lead chromate molybdate sulphate red, for six uses. The six uses applied for are the same for both substances and consist of the distribution and mixing of pigment powder in an industrial environment into solvent-based paints for non-consumer use; the industrial application of paints on metal surfaces (such as machines vehicles, structures, signs, road furniture, coil coating, etc.); the professional, non-consumer application of paints on metal surfaces (such as machines, vehicles, structures, signs, road furniture, etc.) or as road marking; the distribution and mixing of pigment powder in an industrial environment into liquid or solid premix to colour plastic/plasticised articles for non-consumer use; the industrial use of solid or liquid colour premixes and pre-compounds containing pigment to colour plastic or plasticised articles for non-consumer use and the professional use of solid or liquid colour premixes and pre-compounds containing pigment in the application of hot melt road marking.
- (3) The Committee for Risk Assessment (RAC) and the Committee for Socio-economic Analysis (SEAC) of the European Chemicals Agency ('Agency') adopted their

¹ OJ L 396, 30.12.2006, p. 1.

opinions on the application on 11 December 2014. The Commission received those opinions on 2 January 2015.

- (4) The RAC is of the opinion that it is not possible to determine a derived no-effect level in accordance with Annex I to Regulation (EC) No 1907/2006 for either the carcinogenic (category 1B) properties or the reproductive toxic (category 1A) properties of lead sulfochromate yellow and lead chromate molybdate sulfate red. In accordance with Article 60(3)(a) of Regulation (EC) No 1907/2006, the provisions in Article 60(2) of that Regulation do not apply to that substance, and therefore an authorisation may only be granted on the basis of Article 60(4) of that Regulation.
- (5) The RAC is further of the opinion that the exposure assessment in the application demonstrates that the risk management measures and operational conditions are appropriate and effective in limiting the risk, provided that they are applied as described in the application. This is especially relevant in relation to personal protective equipment, particularly respiratory equipment, used in the different workplaces by employees, which must meet the assigned protection factors defined for them.
- (6) The SEAC confirmed the applicant's conclusion that the overall benefits arising from the uses applied for, outweigh the risks to human health or the environment arising from those uses. It further confirmed that there are no suitable alternative substances or technologies in terms of their technical and economic feasibility for the applicant's downstream users.
- (7) In accordance with Article 60(4) of Regulation (EC) No 1907/2006, the six uses applied for should therefore be authorised, provided that the risk management measures and operational conditions described in the application, in particular in the chemical safety report, are fully applied.
- (8) In its opinion, the SEAC recommended the review period referred to in Article 60(9)(e) of Regulation (EC) No 1907/2006 to be set at twelve years for four uses of the two substances applied for, namely for the distribution and mixing of pigment powder in an industrial environment into solvent-based paints for non-consumer use; the industrial application of paints on metal surfaces (such as machines, vehicles, structures, signs, road furniture, coil coating, etc.); the distribution and mixing of pigment powder in an industrial environment into liquid or solid premix to colour plastic/plasticised articles for non-consumer use; and the industrial use of solid or liquid colour premixes and pre-compounds containing pigment to colour plastic or plasticised articles for non-consumer use. This recommended review period takes into account the lack of suitable alternatives to replace the two substances in the uses applied for, the fact that the innovation cycle in the pigments sector is very long, the particular importance of the technical suitability of alternatives for some specific applications where safety is required, and the very low risks arising from the uses of the two substances and also very low associated health benefits in case the substances are not authorised. However due to the difficulties in fully ascertaining the lack of technically feasible alternatives for the entire scope of those four uses, the authorisation should be reviewed earlier than recommended by the SEAC. It is therefore appropriate to set the review period for those four uses at seven years.
- (9) In its opinion, the SEAC recommended the review period referred to in Article 60(9)(e) of Regulation (EC) No 1907/2006 to be set at seven years for the remaining two uses of the two substances applied for, namely for the professional, non-consumer application of paints on metal surfaces (such as machines, vehicles,

structures, signs, road furniture, etc.) or as road marking and for the professional use of solid or liquid colour premixes and pre-compounds containing pigment in the application of hot melt road marking. This recommended review period takes into account the lack of suitable alternatives to replace the two substances in the uses applied for, the fact that the innovation cycle in the pigments sector is very long, the particular importance of the technical suitability of alternatives when safety is required for some specific applications and the very low risks arising from the uses of the two substances and also very low associated health benefits in case the substances are not authorised. At the same time it takes account of the uncertainties related to the applicant's claim regarding the lack of technical feasibility of alternatives for the road marking sector. After further verification with Member States, it appears that the use of the two substances in road marking has been substituted or is prohibited in some Member States, but not in others. Because of the difficulties in fully ascertaining the lack of technically feasible alternatives for the entire scope of those two uses, it is appropriate to set the review period at four years.

- (10) The application emphasised the importance of the use of the personal protective equipment, and in particular of respiratory protective equipment, described in that application to effectively limit the health risks. The RAC therefore recommended in its opinion the setting in place and documenting of a programme for the selection, appropriate use and maintenance of personal protective equipment (particularly respiratory protective equipment), as well as for training in its use, as a condition of the authorisation.
- (11) In their opinions, the RAC and the SEAC did not recommend any further additional risk management measures and operational conditions. The RAC recommended however that any possible review report to be submitted in accordance with Article 61(1) of Regulation (EC) No 1907/2006 should contain data from the health surveillance of workers with regard to lead, as well as data from regular air monitoring of chromium VI at the workplace, carried-out in accordance with the requirements of Union legislation on the protection of the health and safety of workers. This data should be used to improve the overall effectiveness of the risk management measures. Given the importance of this data in ensuring that the risk management measures remain effective and appropriate to limit the health risks to workers, the authorisation holder's downstream users should keep this information available for the enforcement authorities and submit it upon request.
- (12) Due to the difficulties in fully ascertaining the lack of technically feasible alternatives for the entire scope of the uses covered by the application, it is appropriate to further specify the authorised uses, in terms of the technically required performance characteristics of pigment premixes, paints and pre-compounds and of articles containing them, imparted by the two substances that cannot be achieved by any other suitable alternative substance or technology. The authorisation should therefore be subject to the condition that the authorisation holder submits a report on the status of the suitability and availability of alternatives for his downstream users and on that basis refines the description of the authorised uses. Furthermore, in the event that the review report referred to in Article 61(1) of Regulation (EC) No 1907/2006 is submitted, the authorisation holder should refine the description of the authorised uses, based on information on alternatives from downstream users within its supply chain.
- (13) In order to ensure that the quantities of lead sulfochromate yellow and lead chromate molybdate sulphate red placed on the market for the uses within the scope of this authorisation do not increase above the quantities reported in the application for

authorisation, it is appropriate to accordingly define maximum annual tonnage limits for each substance.

- (14) The language used for the description of the risk management measures and operational conditions included in the application for authorisation may be different from the official language(s) of the Member State(s) where the use(s) take(s) place. Therefore, in order to facilitate the enforcement of the authorisation, it is appropriate to include a monitoring arrangement requiring the holder of the authorisation to submit a succinct summary of those risk management measures and operational conditions in an official language of the Member State(s) concerned.
- (15) The Global Alliance to Eliminate Lead in Paint (GAELP) is a voluntary international initiative led by the United Nations Environment Programme (UNEP) and the World Health Organisation within the framework of the United Nations Strategic Approach to International Chemicals Management (SAICM)². By adopting the Dubai Declaration on International Chemicals Management, the Union and its Member States have committed to achieving SAICM goals. In this context, the primary goal of the GAELP is to prevent children's exposure to paints containing lead and to minimise occupational exposures to lead paint, with a broad objective to achieve the phase-out of the manufacture and sale of paints containing lead and to eliminate eventually the risks that such paints pose. This authorisation is not incompatible with the primary goal of the GAELP because the uses applied for do not concern consumers and therefore should not lead to their exposure to the substances. Furthermore, proper control of occupational risks will be ensured via the authorisation conditions.
- (16) The measures provided for in this Decision are in accordance with the opinion of the Committee established under Article 133 of Regulation (EC) No 1907/2006,

HAS ADOPTED THIS DECISION:

Article 1

1. Subject to the conditions in paragraph 3, an authorisation is granted in accordance with Article 60(4) of Regulation (EC) No 1907/2006 for the following uses of lead sulfochromate yellow (EC No 215-693-7, CAS No 1344-37-2), under the condition that the performance of the pigment premixes, paints and pre-compounds containing that substance, or of finished articles containing them, in terms of shade functionality and chroma, opacity (hiding power), dispersibility, durability (light and weather fastness), heat stability or non-leaching behaviour, or a combination thereof, is technically achievable only by using that substance and that such performance is necessary for the intended use. The authorised uses are identified by the following authorisation numbers:

[REACH/16/3/0] Use: distribution and mixing of pigment powder in an industrial environment into solvent-based paints for non-consumer use

[REACH/16/3/1] Use: industrial application of paints on metal surfaces (such as machines vehicles, structures, signs, road furniture, coil coating, etc.)

² <http://www.saicm.org>

- [REACH/16/3/2] Use: professional, non-consumer application of paints on metal surfaces (such as machines, vehicles, structures, signs, road furniture, etc.) or as road marking
- [REACH/16/3/3] Use: distribution and mixing pigment powder in an industrial environment into liquid or solid premix to colour plastic/plasticised articles for non-consumer use
- [REACH/16/3/4] Use: industrial use of solid or liquid colour premixes and pre-compounds containing pigment to colour plastic or plasticised articles for non-consumer use
- [REACH/16/3/5] Use: professional use of solid or liquid colour premixes and pre-compounds containing pigment in the application of hot melt road marking

2. Subject to the conditions in paragraph 3, an authorisation is granted in accordance with Article 60(4) of Regulation (EC) No 1907/2006 for the following uses of lead chromate molybdate sulfate red (EC No 235-759-9, CAS No 12656-85-8), under the condition that the performance of the pigment premixes, paints and pre-compounds containing the substance, or of finished articles containing them, in terms of shade functionality and chroma, opacity (hiding power), dispersibility, durability (light and weather fastness), heat stability or non-leaching behaviour, or a combination thereof, is technically achievable only by using that substance and that such performance is necessary for the intended use. The authorised uses are identified by the following authorisation numbers:

- [REACH/16/3/6] Use: distribution and mixing of pigment powder in an industrial environment into solvent-based paints for non-consumer use
- [REACH/16/3/7] Use: industrial application of paints on metal surfaces (such as machines vehicles, structures, signs, road furniture, coil coating, etc.)
- [REACH/16/3/8] Use: professional, non-consumer application of paints on metal surfaces (such as machines, vehicles, structures, signs, road furniture, etc.) or as road marking
- [REACH/16/3/9] Use: distribution and mixing pigment powder in an industrial environment into liquid or solid premix to colour plastic/plasticised articles for non-consumer use
- [REACH/16/3/10] Use: industrial use of solid or liquid colour premixes and pre-compounds containing pigment to colour plastic or plasticised articles for non-consumer use
- [REACH/16/3/11] Use: professional use of solid or liquid colour premixes and pre-compounds containing pigment in the application of hot melt road marking

3. The authorisations referred to in paragraphs 1 and 2 shall be subject to the following conditions:
- (a) the risk management measures and operational conditions for the respective use³, which are described in the chemical safety report submitted pursuant to Article 62(4)(d) of Regulation (EC) No 1907/2006, shall be fully applied;
 - (b) the authorisation holder and the downstream users to whom this Decision applies by virtue of Article 56(2) of Regulation (EC) No 1907/2006 shall set in place and document a programme for the selection, appropriate use and maintenance of personal protective equipment (particularly respiratory protective equipment), as well as for training of employees for all the uses of the two substances as referred to in paragraphs 1 and 2 and in all the sites where those uses take place;
 - (c) the amount of lead sulfochromate yellow placed on the market by the authorisation holder for the uses referred to in paragraph 1 shall not exceed 2100 tonnes per year and the amount of lead chromate molybdate sulfate red placed on the market by the authorisation holder for the uses referred to in paragraph 2 shall not exceed 900 tonnes per year;
 - (d) for all the uses referred to in paragraphs 1 and 2, the authorisation holder's downstream users to whom this Decision applies by virtue of Article 56(2) of Regulation (EC) No 1907/2006 shall submit no later than by 30 June 2017 to the European Chemicals Agency ('Agency'), for transmission to the authorisation holder, information on the status of the suitability and availability of alternatives for their use(s), providing a detailed justification of the need to use lead sulfochromate yellow or lead chromate molybdate sulfate red, including information on the status of the performance requirements referred to in those paragraphs, as well as any national legal requirements;
 - (e) the authorisation holder shall submit a report to the Commission on the elements referred to in point (d) by 31 December 2017 with regard to the uses with authorisation numbers REACH/16/3/0, REACH/16/3/1, REACH/16/3/3, REACH/16/3/4, REACH/16/3/6, REACH/16/3/7, REACH/16/3/9 and REACH/16/3/10. In the report, the authorisation holder shall also refine the description of the authorised uses, based on information on alternatives provided by downstream users within its supply chain. That report shall be sent to the European Commission, DG Internal Market, Industry, Entrepreneurship and SMEs, REACH Unit, rue de la Loi, 200, 1049 – Brussels, Belgium or by electronic means to GROW-ENV-REACH-AUTH@ec.europa.eu.

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<http://ec.europa.eu/DocsRoom/documents/8900/attachments/1/translations/en/renditions/native>,
<http://ec.europa.eu/DocsRoom/documents/8901/attachments/1/translations/en/renditions/native>,
<http://ec.europa.eu/DocsRoom/documents/8902/attachments/1/translations/en/renditions/native>,
<http://ec.europa.eu/DocsRoom/documents/8904/attachments/1/translations/en/renditions/native>,
<http://ec.europa.eu/DocsRoom/documents/8905/attachments/1/translations/en/renditions/native>,
<http://ec.europa.eu/DocsRoom/documents/8906/attachments/1/translations/en/renditions/native>,
<http://ec.europa.eu/DocsRoom/documents/8907/attachments/1/translations/en/renditions/native>,
<http://ec.europa.eu/DocsRoom/documents/8908/attachments/1/translations/en/renditions/native>,
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<http://ec.europa.eu/DocsRoom/documents/8910/attachments/1/translations/en/renditions/native>,
<http://ec.europa.eu/DocsRoom/documents/8912/attachments/1/translations/en/renditions/native>,
<http://ec.europa.eu/DocsRoom/documents/8913/attachments/1/translations/en/renditions/native>

4. The authorisation of the professional, non-consumer application of paints as road marking and of the professional use of solid or liquid colour premixes and pre-compounds containing pigment in the application of hot melt road marking, referred to in paragraphs 1 and 2, shall not apply in Member States where a national measure in force on the date of this Decision prohibits the use of the substances referred to in paragraphs 1 and 2 in road marking applications.

Article 2

1. The review period referred to in Article 60(9)(e) of Regulation (EC) No 1907/2006 shall expire on 21 May 2022 with regard to the following uses of the two substances referred to in Article 1:
 - distribution and mixing of pigment powder in an industrial environment into solvent-based paints for non-consumer use (REACH/16/3/0; REACH/16/3/6);
 - industrial application of paints on metal surfaces (such as machines vehicles, structures, signs, road furniture, coil coating, etc.) (REACH/16/3/1; REACH/16/3/7);
 - distribution and mixing pigment powder in an industrial environment into liquid or solid premix to colour plastic/plasticised articles for non-consumer use (REACH/16/3/3; REACH/16/3/9);
 - industrial use of solid or liquid colour premixes and pre-compounds containing pigment to colour plastic or plasticised articles for non-consumer use (REACH/16/3/4; REACH/16/3/10).
2. The review period referred to in Article 60(9)(e) of Regulation (EC) No 1907/2006 shall expire on 21 May 2019 with regard to the following uses of the two substances referred to in Article 1:
 - professional, non-consumer application of paints on metal surfaces (such as machines, vehicles, structures, signs, road furniture, etc.) or as road marking (REACH/16/3/2; REACH/16/3/8);
 - professional use of solid or liquid colour premixes and pre-compounds containing pigment in the application of hot melt road marking ((REACH/16/3/5; REACH/16/3/11).

Article 3

The following monitoring arrangements referred to in Article 60(9)(f) of Regulation (EC) No 1907/2006 shall apply:

- (a) At the request of the competent authority of the Member State where the authorised use takes place, the holder of the authorisation shall submit to that authority a succinct summary of the applicable risk management measures and operational conditions referred to in point (a) of Article 1(3), in an official language of that Member State.
- (b) At the request of the competent authority of the Member State where the authorised use takes place, the downstream users to whom this Decision applies by virtue of Article 56(2) of Regulation (EC) No 1907/2006 shall substantiate why the conditions of Article 1(1) and (2) apply and why the performance parameters are necessary for the intended use.

- (c) In the review report referred to in Article 61(1) of Regulation (EC) No 1907/2006, the authorisation holder shall refine the description of the authorised uses referred to Article 1(1) and (2), based on information on alternatives provided by downstream users within its supply chain.
- (d) The authorisation holder's downstream users to whom this Decision applies by virtue of Article 56(2) of Regulation (EC) No 1907/2006 shall, when requested to do so, provide the competent authorities of the Member States where the use takes place the following information concerning the uses referred to in Article 1(1) and (2):
- (i) data from the biomonitoring programme for lead, in accordance with Article 10 of Council Directive 98/24/EC⁴,
 - (ii) data from regular air monitoring of chromium, obtained in accordance with Article 6(4) of Directive 98/24/EC.
- (e) The downstream users to which this Decision applies by virtue of Article 56(2) of Regulation (EC) No 1907/2006 shall make available the information from these air monitoring and biomonitoring programmes to the Agency, for transmission to the authorisation holder for the purpose of the review report referred to in Article 61(1) of that Regulation.
- (f) The information collected in accordance with point (d) shall be included in the review report referred to in Article 61(1) of Regulation (EC) No 1907/2006.

Article 4

This Decision is addressed to DCC Maastricht BV OR, Sortieweg 39, 6219 NT Maastricht, Netherlands.

Done at Brussels, 7.9.2016

For the Commission
Elżbieta BIENKOWSKA
Member of the Commission

⁴ Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (OJ L 131, 5.5.1998, p. 11).