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#### COVER NOTE

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From:	European Commission
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To:	General Secretariat of the Council
No. Cion doc.:	D064651/02
Subject:	COMMISSION DECISION of XXX amending Decision 2014/312/EU in order to extend the derogation for zinc oxide to allow its use as a preservative stabilizer to cover “in-can preservation” and preservation of “tinting pastes”

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Delegations will find attached document D064651/02.

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Encl.: D064651/02



Brussels, **XXX**  
D064651/02  
[...] (2019) **XXX** draft

## COMMISSION DECISION

of **XXX**

amending Decision 2014/312/EU in order to extend the derogation for zinc oxide to allow its use as a preservative stabilizer to cover “in-can preservation” and preservation of “tinting pastes”

(Text with EEA relevance)

## COMMISSION DECISION

of **XXX**

**amending Decision 2014/312/EU in order to extend the derogation for zinc oxide to allow its use as a preservative stabilizer to cover “in-can preservation” and preservation of “tinting pastes”**

(Text with EEA relevance)

THE EUROPEAN COMMISSION

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

Having regard to Regulation (EC) No 66/2010 of the European Parliament and of the Council of 25 November 2009 on the EU Ecolabel<sup>1</sup>, and in particular Article 8(2) thereof,

After consulting the European Union Ecolabelling Board,

Whereas:

- (1) Regulation (EC) No 66/2010 provides that the EU Ecolabel may be awarded to products with a reduced environmental impact during their entire life cycle. Specific EU Ecolabel criteria are to be established for each product group.
- (2) Commission Decision 2014/312/EU<sup>2</sup> establishes the criteria, and related assessment and verifications requirements, for indoor and outdoor paints and varnishes.
- (3) A derogation for zinc oxide (ZnO, CAS: 1314-13-2), classified with the hazards: H400, aquatic acute toxicity category 1, and H410, aquatic chronic toxicity category 1 was set out in point 1 (d) of the Appendix to Decision 2014/312/EU for use as a stabiliser for dry film preservative combinations that require zinc pyrithione (ZPT) or 1,2-Benzisothiazol-3(2H)-one (BIT) up to a concentration of 0,05 %.
- (4) BIT is not approved for use as dry film preservative in accordance with the Annex of Commission Decision 2010/72/EU<sup>3</sup>. Therefore, the above mentioned point 1 (d) needs to be amended accordingly.
- (5) Several national competent bodies that award the EU Ecolabel have suggested an extension of the current derogation for zinc oxide in order to allow its use as a

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<sup>1</sup> OJ L 27, 30.1.2010, p.1.

<sup>2</sup> Commission Decision 2014/312/EU establishing the ecological criteria for the award of the EU Ecolabel for indoor and outdoor paints and varnishes (OJ L 164, 3.6.2014, p.45).

<sup>3</sup> Commission Decision 2010/72/EU concerning the non-inclusion of certain substances in Annex I, IA or IB to Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market (OJ L 36, 9.2.2010, p.36)

preservative stabilizer to cover also “in-can preservation” and preservation of “tinting pastes”.

- (6) In line with the conclusions of the EU Ecolabel Fitness check (REFIT) of 30 June 2017, the Commission services, together with the EU Ecolabelling Board, assessed the relevance of this amendment to guarantee a high uptake of the scheme for this product group. Public stakeholders have also been consulted.
- (7) Based on information available from suppliers and paint manufacturers, ZnO is used for stabilizing purposes within paints and varnishes in combination with the two following preservatives: ZPT and BIT, used to fight unwanted microbial growth in paints.
- (8) ZnO provides a stabilizing function to paints in which ZPT and BIT are used as preservatives. ZnO prevents the propensity of ZPT to transchelate with other metal ions, typically iron and calcium, and to form coloured complexes that lead to an unwanted change in colour of the paint. In combinations with BIT, ZnO prevents it from moving from the water phase to the organic phase of paints (e.g. the binder) thus increasing its availability in the water phase where the risk for microbial growth is higher. Without ZnO the paint life-time would be reduced to a few weeks, also reducing its shelf life.
- (9) Decision 2014/312/EU already allows the use of ZPT for the three functions: as in-can preservative, as tinting machine preservative and as dry-film preservative, up to a concentration of 0,05%, and allows the use of BIT at a concentration of 0,05% in the final, ready to use, product. It seems therefore appropriate to allow also the use of stabiliser ZnO for the same applications.
- (10) Where ZnO is used to stabilise “in-can” or “tinting paste” preservation combinations, impacts on the environment are expected to be lower than where used in dry-film preservation combinations, (already derogated within the current criteria), as a typical dose of ZPT for a dry-film preservation application of an outdoor paint would be approximately 10 times higher in magnitude in comparison to that needed for indoor in-can preservation.
- (11) Alternatives in use by manufacturers, in the form of other preservation combinations that would not need ZnO for stabilisation purposes, mostly use MIT (2-methyl-2H-isothiazol-3-one). However, according to the third paragraph of Article 3 of Commission Regulation (EU) 2018/1480<sup>4</sup>, as of 1 May 2020 MIT will be classified, inter alia, as Skin Sens 1A with the Hazard statement Code H317 (may cause an allergic skin reaction). This will trigger the hazard classification Skin Sens 1A with the Hazard Statement Code H317 also for the final paint products in which MIT will be used at or above a concentration of 15 ppm. Current scientific research shows that MIT is not effective, as a preservative, if used in concentrations below 15 ppm.
- (12) ZPT, BIT or their combinations are considered the other viable options to replace MIT, but they will be requiring the use of ZnO in all its possible applications.

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<sup>4</sup> Commission Regulation (EU) 2018/1480 of 4 October 2018 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the European Parliament and the Council on classification, labelling and packaging of substances and mixtures and correcting Commission Regulation (EU) 2017/776 (OJ L 251, 5.10.2018, p. 1).

- (13) Therefore, it is not technically feasible to substitute ZnO.
- (14) Data provided by stakeholders prove that in order to achieve sufficient stabilisation performance, up to 0,030 % ZnO is needed for in-can and tinting preservation combinations containing ZPT while 0,010-0,040% ZnO is needed in combinations with BIT.
- (15) Decision 2014/312/EU should therefore be amended accordingly.
- (16) The measures provided for in this Decision are in accordance with the opinion of the Committee established by Article 16 of Regulation (EC) No 66/2010.

HAS ADOPTED THIS DECISION:

*Article 1*

In the Appendix to Decision 2014/312/EU, in the section headed “1. Preservatives added to colourants, binders and the final product”, point (d) (Preservative stabiliser) is replaced by the following:

Substance group	Scope of restriction and/or derogation	Concentration limits (where applicable)	Assessment and verification
(d) Preservative stabiliser	<p>Zinc oxide is derogated for use as a stabiliser for:</p> <p>in-can preservative combinations and tinting paste preservative combinations that require zinc pyrithione with or without 1,2 Benzisothiazol-3(2H)-one (BIT).</p> <p>in-can preservative combinations and tinting paste preservative combinations that require 1,2 Benzisothiazol-3(2H)-one (BIT).</p> <p>dry film preservative combinations that require zinc pyrithione.</p>	<p>0,030 %</p> <p>0,040%</p> <p>0,050 %</p>	<p>Verification: Declaration by the applicant and their raw material suppliers.</p>

This Decision is addressed to the Member States.

Done at Brussels,

*For the Commission  
Virginijus Sinkevičius  
Member of the Commission*