

2018 年 4 月 5 日

日本化粧品工業連合会

傘下会員各位

日本化粧品工業連合会

事務局

環状シリコーン化合物（D4、D5、D6）に係る国内外の規制状況について（情報提供）

拝啓 時下ますますご清栄のこととお喜び申し上げます。

さて、化粧品原料として使用される環状シリコーン化合物について、国内及びEUにおいて下記のとおり規制されることとなりましたので御連絡いたします。

このうち、化学物質の審査及び製造等の規制に関する法律（以下「化審法」という。）に基づく国内規制については化粧品への直接の影響はないものと思われませんが、EUの規制には化粧品も対象に含まれています。粧工連では、今後も環状シリコーン化合物に関連する国内外の規制動向について最新情報を収集し、適宜、提供してまいりますので、傘下会員の皆様におかれましても今後の動向に御留意いただきますようお願い申し上げます。

なお、環状シリコーン化合物の名称及び略称は以下のとおりです。

- ・オクタメチルシクロテトラシロキサン（シクロテトラシロキサン：略称D4）
- ・デカメチルシクロペンタシロキサン（シクロペンタシロキサン：略称D5）
- ・ドデカメチルシクロヘキサシロキサン（シクロヘキサシロキサン：略称D6）

敬具

記

1. 国内における規制（化審法）

昨年12月に開催された厚生労働省・経済産業省・環境省3省合同審議会においてD4、D5及びD6について審議され、その結果、D4及びD6の2物質が4月2日付けで化審法に基づく監視化学物質に指定されました。

今般、D4及びD6が監視化学物質に指定されたのは、これらの化学物質が、

- ①自然的作用による化学的变化を生じにくいもの（難分解性）で、かつ、生物の体内に蓄積しやすいもの（高蓄積性）であって、
- ②継続的に摂取される場合、人の健康を損なうおそれ（人への長期毒性）があるか、あるいは、高次捕食動物の生息又は生育に支障を及ぼすおそれ（高次捕食動物への毒性）があるかが明らかでない

とされたことによるものです。また、D5は①には該当するものの、②のおそれがないことが明らかとなったため、監視化学物質には指定されませんでした。

監視化学物質を製造又は輸入した者は、化審法に基づき、毎年度、製造又は輸入数量等の

経済産業大臣への届出が義務付けられ、また、当該物質を譲渡又は提供するとき、相手方に対し監視化学物質である旨を情報提供（SDSへの記載等）するよう努めなければならない等と規定されています。しかしながら、これら化審法の規定は、医薬品、医療機器等の品質、有効性及び安全性の確保等に関する法律に規定する化粧品には適用されないため、D4及びD6を化粧品に使用した場合には、化審法に基づく届出等を行う必要はありません。

2. EUにおける規制（REACH）

水系における生態影響への懸念から欧州化学品規則（REACH: Registration, Evaluation, Authorization and Restriction of Chemicals）により、2020年1月31日からD4及びD5を使用（0.1%以上）した「使用後に水で洗い流される製品*」の販売が禁止されることとなりました（添付参照）。さらに、EU委員会は、欧州化学品庁（ECHA）に対して、環状シリコーン化合物（D4、D5及びD6）のすべての化粧品への使用を同規則により規制することについても検討するよう要請しています。

* (原文) wash-off cosmetic products that, under normal condition of use, are removed with water shortly after application

（以上）

COMMISSION REGULATION (EU) 2018/35**of 10 January 2018****amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards octamethylcyclotetrasiloxane ('D4') and decamethylcyclopentasiloxane ('D5')****(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 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/EC⁽¹⁾, and in particular Article 68(1) thereof,

Whereas:

- (1) On 17 April 2015, the United Kingdom submitted to the European Chemicals Agency ('Agency') a dossier pursuant to Article 69(4) of Regulation (EC) No 1907/2006 ('the Annex XV dossier'⁽²⁾), proposing to restrict octamethylcyclotetrasiloxane (D4) and decamethylcyclopentasiloxane (D5) in cosmetic products that are washed off in normal conditions of use. The dossier demonstrated that action on a Union-wide basis is necessary to address the risks to the environment posed by the use of D4 and D5 when discharged into waste water.
- (2) On 22 April 2015, the Member State Committee, referred to in Article 76(1)(e) of Regulation (EC) No 1907/2006, at the request of the Executive Director of the Agency under Article 77(3)(c) of that Regulation, adopted an opinion that both D4 and D5 fulfil the criteria in Annex XIII to that Regulation for the identification of very persistent (vP) and very bioaccumulative (vB) substances.
- (3) On 10 March 2016, the Agency's Risk Assessment Committee ('RAC') adopted its opinion, concluding that D4 meets the criteria in Annex XIII to Regulation (EC) No 1907/2006 for the identification of a persistent, bioaccumulative and toxic ('PBT') substance and a vPvB substance and that D5 fulfils the criteria for the identification of a vPvB substance. RAC confirmed that the hazard properties of D4 and D5 give rise to specific concerns for the environment when present in cosmetic products that are used or disposed with water. It also concluded that the proposed restriction is a targeted and appropriate Union-wide measure to minimise emissions caused by washed-off products.
- (4) On 9 June 2016, the Agency's Socio-Economic Assessment Committee ('SEAC') adopted its opinion, indicating that the proposed restriction is the most appropriate Union-wide measure to reduce the discharge of D4 and D5 to waste water in terms of its socioeconomic benefits and its socioeconomic costs.
- (5) SEAC recommended a 24-month deferral of application of the restriction, in line with the minimum period of deferral proposed in the Annex XV dossier, to allow stakeholders to take the necessary compliance measures.
- (6) The Agency's Forum for Exchange of Information on Enforcement, referred to in Article 76(1)(f) of Regulation (EC) No 1907/2006, was consulted during the restriction process and its recommendations have been taken into account.
- (7) On 10 August 2016, the Agency submitted to the Commission the opinions of RAC and SEAC⁽³⁾.

⁽¹⁾ OJ L 396, 30.12.2006, p. 1.

⁽²⁾ <https://echa.europa.eu/documents/10162/9a53a4d9-a641-4b7b-ad58-8fec6cf26229>

⁽³⁾ <https://echa.europa.eu/documents/10162/7209f47e-58a0-4fa7-9890-11366f5aa4e9>

- (8) A risk to the environment arises from the presence of D4 and D5 in certain cosmetic products that are washed off with water after application, because of their hazard properties as a PBT and a vPvB substance in the case of D4 and a vPvB substance in the case of D5. The Commission considers that those risks should be addressed on a Union-wide basis. The concentration limit of 0,1 % set by this restriction effectively ensures that all intentional use of D4 and D5 will cease since those substances must be present in wash-off cosmetic products in a much higher concentration to perform their intended function.
- (9) The proposed restriction concerns cosmetic products as defined in Article 2(1)(a) of Regulation (EC) No 1223/2009 of the European Parliament and of the Council ⁽¹⁾. In cosmetic products that are intended to stay in prolonged contact with the skin, the hair or the mucous membranes, D4 and D5 evaporate over time after application and any residue is washed off in the course of normal ablutions. The Annex XV dossier did not cover those products, considering that they did not represent the major source of risk to the environment from D4 and D5, and consequently the risk which they may present to the environment has not yet been assessed by RAC. Therefore, the restriction should apply only to wash-off cosmetic products that, under normal condition of use, are removed with water shortly after application because in these circumstances D4 and D5 are emitted to the aquatic environment before evaporation.
- (10) Stakeholders should be allowed sufficient time to take appropriate measures to comply with the proposed restriction. The new restriction should therefore only apply from a later date.
- (11) Regulation (EC) No 1907/2006 should therefore be amended accordingly.
- (12) The measures provided for in this Regulation are in accordance with the opinion of the Committee established under Article 133 of Regulation (EC) No 1907/2006,

HAS ADOPTED THIS REGULATION:

Article 1

Annex XVII to Regulation (EC) No 1907/2006 is amended in accordance with the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 10 January 2018.

For the Commission
The President
Jean-Claude JUNCKER

⁽¹⁾ Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (OJ L 342, 22.12.2009, p. 59).

ANNEX

In Annex XVII to Regulation (EC) No 1907/2006, the following new entry is added:

<p>'70. Octamethylcyclotetrasiloxane (D4) CAS No 556-67-2 EC No 209-136-7 Decamethylcyclopentasiloxane (D5) CAS No 541-02-6 EC No 208-764-9</p>	<ol style="list-style-type: none">1. Shall not be placed on the market in wash-off cosmetic products in a concentration equal to or greater than 0,1 % by weight of either substance, after 31 January 2020.2. For the purposes of this entry, "wash-off cosmetic products" means cosmetic products as defined in Article 2(1)(a) of Regulation (EC) No 1223/2009 that, under normal conditions of use, are washed off with water after application.'
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