

**EXPLANATORY MEMORANDUM FOR EUROPEAN UNION
LEGISLATION/DOCUMENTS WITHIN THE SCOPE OF THE UK/EU
WITHDRAWAL AGREEMENT AND THE WINDSOR FRAMEWORK**

COM (2026)15

COMMISSION REGULATION (EU) 2026/78 of 12 January 2026 amending Regulation (EC) No 1223/2009 of the European Parliament and of the Council as regards the use in cosmetic products of certain substances classified as carcinogenic, mutagenic or toxic for reproduction

Submitted by Department for Business and Trade, 16 February 2026

SUBJECT MATTER

1. Commission Regulation (EU) 2026/78 amends Annexes II, III, IV and V to Regulation (EC) No 1223/2009 of the European Parliament and of the Council (EU Cosmetic Regulation) which applies to cosmetic products placed on the EU market. The Annexes to the Regulation set restrictions on the ingredients that can be used in cosmetic products.
2. As the EU Cosmetic Regulation applies under Annex 2 to the Windsor Framework, these updates to the technical annexes will also apply to cosmetic products placed on the market in Northern Ireland.
3. Article 15 of the EU Cosmetic Regulation contains provisions regarding the use of substances that have been classified as carcinogenic, mutagenic or toxic for reproduction (CMR) category 1A, 1B or 2 under Regulation (EC) No 1272/2008 and have been revised or added to the list of harmonised classification and labelling of hazardous substances in Table 3 of Annex VI of that Regulation. The amendments to Commission Regulation (EU) 2026/78 concern a set of substances with this CMR classification and result in these substances either being prohibited for use in cosmetics or restrictions being placed on their use.
4. Following their classification as CMRs, these substances are prohibited for use in cosmetics products. This is regardless of any previous regulatory restrictions or conditions for use that applied under the EU Cosmetic Regulation prior to their classification as CMRs, or whether those chemicals are currently being used in cosmetic products. However, an exemption may be granted following an application by industry, which includes evidence sufficient to demonstrate the safety of the substances as a cosmetic. Industry is able to submit an exemption application for any of the substances classified as CMRs. If an application is not submitted, this is because industry has chosen not to defend the use of the chemical in cosmetic products.

5. The EU received an exemption application for three of the specific substances classified as CMRs. Following subsequent assessment by the Scientific Committee on Consumer Safety (SCCS), the three substances – Silver, Hexyl Salicylate, and O-Phenylphenol were considered safe for use in cosmetics under the following restrictions, which are being introduced through updates to Annexes III, IV and V to the EU Cosmetic Regulation:
 - **Silver** - maximum concentration between 0.05%- 0.2% depending on particle size and product type.
 - **Hexyl salicylate** - maximum concentration between 0.001%-2 % depending on product type, with some additional restrictions for products intended for use by children under the age of three years.
 - **O-Phenylphenol** - maximum concentration between 0.15%-0.2% depending on product type, with additional requirements for warnings regarding avoiding contact with eyes.
6. All other substances classified as CMRs are being added to Annex II of the EU Cosmetic Regulation and will not be permitted for use as ingredients in cosmetic products.
7. This Regulation, amending the annexes of the EU Cosmetic Regulation, will have legal effect from 12 May 2026 in Northern Ireland (and all EU member states).

SCRUTINY HISTORY

8. Multiple Explanatory Memorandums have been produced regarding earlier amendments to the EU Cosmetic Regulation. However, the specific changes now proposed have not been considered before.

MINISTERIAL RESPONSIBILITY

9. The Secretary of State for the Department for Business and Trade has responsibility for product safety policy, including cosmetics.

INTEREST OF THE DEVOLVED GOVERNMENTS (DGs)

10. The Devolved Governments have been consulted on this Explanatory Memorandum. This is a substantially reserved matter which the UK Government will continue to discuss with devolved counterparts as needed.
11. The amendments to the EU Cosmetic Regulation will apply directly in all EU member states, and in Northern Ireland under the terms of the Windsor Framework, subject to the relevant democratic scrutiny processes. The Northern Ireland Executive Office has been contacted as part of the

preparation of this explanatory memorandum and did not raise any concerns. The Department of Business and Trade will continue to see to engage with the Devolved Governments regarding this matter.

LEGAL AND PROCEDURAL ISSUES

12. This Regulation applies to Northern Ireland, as part of the EU Cosmetic Regulation, as per the terms of the Windsor Framework. The changes will have legal effect in relation to goods placed on the Northern Ireland market from 12 May 2026.
13. The Regulation has been adopted in accordance with relevant regulatory and scrutiny procedures.

POLICY AND LEGAL IMPLICATIONS

14. These changes will apply to cosmetics placed on the Northern Ireland market after the Regulation enters into force on 12 May 2026. Under the Windsor Framework, relevant products placed on the Northern Ireland market need to be compliant with the Regulation when placed on the market for the first time.
15. The EU Cosmetic Regulation does not apply to products placed on the GB market. Cosmetics that are placed on the market in Northern Ireland, in accordance with the applicable rules, can be sold in GB market through the provisions in place for Northern Ireland's unfettered access to the rest of the UK. Given UK cosmetic products are generally also traded into the EU, we do not expect an impact on the movement of cosmetics products from GB into Northern Ireland as a result of this Regulation.
16. GB legislation has already been amended to make equivalent changes to domestic legislation concerning most of the substances included in the EU amendment. The remaining substances are currently being assessed regarding their use in GB (as set out below in paragraphs 19-21).
17. The UK's decisions on the safe use of chemicals in cosmetic products are informed by independent scientific assessment of the available safety data and other scientific evidence on these chemicals when used in cosmetics. In addition to the scientific advice, the Government also considers impacts on the UK internal market before making changes to the GB Cosmetic Regulation.
18. The Health and Safety Executive (HSE) which leads on the classification and labelling of chemical substances and mixtures, considers the mandatory classification and labelling of substances in GB under the GB CLP Regulation in response to any changes proposed by the EU, including substances to be classified as CMR. HSE updates the GB Mandatory Classification and Labelling List (GB MCL List) accordingly following a Ministerial decision with

the consent of Ministers in the Devolved Governments in Scotland and Wales only.

19. These GB mandatory classification and labelling changes for substances classified as CMR which are added to the GB MCL List are then reflected under the GB Cosmetic Regulation. HSE's mandatory classification of CMR substances generally tends to be in alignment with the EU's harmonised classifications for substances classified as CMR that have been added to the list of harmonised classification and labelling of hazardous substances in Table 3 of Annex VI of Regulation (EC) No 1272/2008.
20. The substances listed in the EU amending instrument have also been classified as CMRs under GB CLP and have been added to the GB MCL. The substances that were not subject to an exemption application are also included in recent GB regulatory amendments to the GB Cosmetic Regulation, made by way of The Cosmetic Products Regulation (EC) No 1223/2009 (Restriction of Chemical Substances) (Amendment and Transitional Provisions) Regulations 2026 (SI 2026/23) and The Cosmetic Products Regulation (EC) No 1223/2009 (Restriction of Chemical Substances) (Amendment and Transitional Provisions) (No. 2) Regulations 2026 (laid before Parliament on 15 January 2026 and 9 February 2026 respectively). These SIs have the effect of prohibiting use of the substances that have not been subject to an exemption application, in line with the amendments made by the EU.
21. Regarding the regulatory status of hexyl salicylate in GB, Government also received an exemption application from industry. Following assessment of the application by the Scientific Advisory Group on Chemical Safety (SAG-CS) it was concluded that hexyl salicylate can be safely used in cosmetics (subject to specific restrictions). The amendment to introduce these restrictions was made to the UK Cosmetic Regulation as part the Cosmetic Products Regulation (EC) No 1223/2009 (Restriction of Chemical Substances) (Amendment and Transitional Provisions) (No. 2) Regulations 2026.
22. Additionally, the Office for Product Safety and Standards (OPSS) issued a call for data which closed in June 2025, on the safety of multiple cosmetic ingredients including silver. Decisions regarding the use of silver in cosmetics will be informed by the data received. This data will be assessed by SAG-CS, whose opinions will inform Government's decision on whether to amend legislation. Both silver and O-Phenylphenol have been prioritised for SAG-CS assessment. Government will act as quickly as possible after SAG-CS has concluded their assessment to ensure that GB regulations continue to reflect the most up to date scientific advice on the safe use of chemicals in cosmetic products.

CONSULTATION

23. There has been no consultation on this change in relation to Northern Ireland. As noted, OPSS has previously issued a call for data on the safety of multiple

cosmetic ingredients including silver. The Government has already decided to provide a similar restriction rather than ban on hexyl salicylate in Great Britain. Silver and O-Phenylphenol have been prioritised for SAG-CS consideration, which will inform government's decision on these chemicals. Government publishes the SAG-CS opinions and engages further with industry and other stakeholders to inform final decisions on any regulatory changes. In accordance with the Windsor Framework, the changes made by this Regulation will be automatically applicable in Northern Ireland.

FINANCIAL IMPLICATIONS

20. There is no data available on the financial implications of these changes

MINISTERIAL NAME AND SIGNATURE

A handwritten signature in blue ink that reads "Kate Dearden".

Kate Dearden MP
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Department for Business and Trade