Preservatives: Cosmetics Regulation Update

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www.ctpa.org.uk
Agenda

- Current status of Annex V
- Regulatory timescales
  - Claims
    - e.g.
      - ‘free from’
      - use of multifunctions
## Annex V Preservative Entries

<table>
<thead>
<tr>
<th></th>
<th>Preservatives/Ingredients</th>
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<tbody>
<tr>
<td>1</td>
<td>Benzoic acid &amp; Na salt</td>
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<td>1a</td>
<td>Other salts of benzoic acid</td>
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<tr>
<td>2</td>
<td>Propionic acid &amp; salts</td>
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<td>3</td>
<td>Salicylic acid &amp; salts</td>
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<td>4</td>
<td>Sorbic acid; Ca, Na, K sorbates</td>
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<td>5</td>
<td>Formaldehyde &amp; paraformaldehyde</td>
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<td>7</td>
<td>o-Phenylphenol and o-phenylphenates</td>
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<td>8</td>
<td>Zinc pyrithione</td>
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<td>9</td>
<td>Inorganic sulphites and H-sulphites</td>
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<td>11</td>
<td>Chlorobutanol</td>
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<td>12</td>
<td>4-Hydroxybenzoic acid, salts and esters</td>
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<tr>
<td>13</td>
<td>Dehydroacetic acid &amp; Na dehydroacetate</td>
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<td>14</td>
<td>Formic acid &amp; Na formate</td>
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<td>15</td>
<td>Dibromohexamidine isethionate</td>
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<td>16</td>
<td>Thiomersal</td>
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<td>17</td>
<td>Phenylmercuric salts</td>
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<td>18</td>
<td>Undecylenic acid &amp; undecylates</td>
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<td>19</td>
<td>Hexetidine</td>
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<td>20</td>
<td>5-Bromo-5-nitro-1,3-dioxane</td>
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<td>21</td>
<td>*Bronopol</td>
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<tr>
<td>22</td>
<td>Dichlorobenzyl alcohol</td>
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<td>23</td>
<td>Triclocarban</td>
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<td>Chlorocresol</td>
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<td>26</td>
<td>Chloroxylenol</td>
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<td>27</td>
<td>Imidazolidinyl urea*</td>
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<td>28</td>
<td>Polyaminopropyl biguanide</td>
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<td>29</td>
<td>Phenoxyethanol</td>
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<td>30</td>
<td>Methenamine</td>
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<td>31</td>
<td>Quaternium-15</td>
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<td>Climbazole</td>
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<td>33</td>
<td>DMDM Hydantoin*</td>
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<td>34</td>
<td>Benzyl alcohol</td>
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<td>Piroctone Olamine</td>
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<td>Bromochlorophene</td>
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<td>o-Cymen-5-ol</td>
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<td>MCI/MI blend</td>
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<td>Chlorophene</td>
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<td>Chloracetamide</td>
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<td>Chlorhexidine</td>
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<td>Phenoxyisopropanol</td>
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<td>44</td>
<td>Alkyl trimethyl ammonium Br &amp; Cl</td>
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<td>45</td>
<td>Dimethyl oxazolidine</td>
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<td>46</td>
<td>Diazolidinyl urea*</td>
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<td>Hexamidine</td>
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<td>Glutaral</td>
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<td>49</td>
<td>7-Ethylbicyclooxazolidine</td>
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<td>Chlorophenesin</td>
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<tr>
<td>51</td>
<td>Sodium hydroxymethylglycinate*</td>
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<tr>
<td>52</td>
<td>Silver chloride</td>
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<tr>
<td>53</td>
<td>Benzethonium chloride</td>
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<td>54</td>
<td>Benzalkonium Cl, Br &amp; saccharinate</td>
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<td>55</td>
<td>Benzylhemiformal</td>
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<td>56</td>
<td>IPBC</td>
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<td>57</td>
<td>MI</td>
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<tr>
<td>58</td>
<td>Ethyl Lauroyl Arginate HCl</td>
</tr>
<tr>
<td>59</td>
<td>Citric acid (and) silver citrate - Newly added</td>
</tr>
</tbody>
</table>

**Key:**
- Widely used
- * HCHO releaser
- Not/rarely used
- Legislation pending/new restriction/ingredient under review
Related Legislation

Horizontal link with CLP Regulation/CMR classification
- Formaldehyde
- Salicylic acid
- Polyaminopropyl biguanide (PHMB)
- Formaldehyde releasers
- Zinc pyrithione
- Quaternium-15

Hazard vs. Risk
Future Concerns

- Decreasing palette of available preservatives
- Bad science
- Hazard approach
- Scares & rumours
Industry Actions

- Technical consortia to defend uses

- Cosmetics Europe Expert Team Product Preservation & strategy
  - Review available data
  - Use & exposure survey

- Commission workshops

- New preservatives? ...animal testing ban!
Industry Use Survey

Objective

- Identify cosmetic product types and the concentrations used
- Identify instances where preservative ingredients are not used and why
- Identify which product types have limited flexibility on the use of preservatives
- Real time data for use in discussions
- Confidential database that can be updated
- Input for ongoing dossiers – e.g. salicylic acid & salts

Scope

- All cosmetic manufacturers
- Europe (geographical region)
Educating Consumers & Stakeholders

Preservatives in the EU

What are preservatives?

A preservative is a natural or synthetic ingredient that is added to products to prevent them from spoiling. Preservatives ensure that cosmetics and personal care products, as well as pharmaceuticals and foods, remain safe during their period of use by consumers.

Preservatives must undergo rigorous evaluation, including safety assessments and quality testing, to ensure that they are safe for use.

Why do we need them?

Without preservatives, cosmetic products, just like food, can become contaminated, leading to product spoilage.

Microbial contamination of products, especially those used around the eyes and on the skin, can cause irritation or infections. Preservatives help prevent such problems.

What is the European Commission doing about them?

- It ensures an updated list of scientifically evaluated safe preservatives for use in cosmetic products on the EU market.
- It supports and guides national authorities to monitor products already on the EU market.
- It encourages scientific research and innovation so that new and more-efficient preservatives for cosmetic products are discovered.

Advice

Preservatives are ingredients that protect products against the growth of bacteria, yeasts, and fungi. They are essential and used in a variety of products.

Some preservatives used in cosmetics can be found in nature, while others are synthetic.

Without preservatives, cosmetic products could become contaminated, spoil easily, and possibly harm you.

Bacterial growth in cosmetics

With preservatives

Without preservatives

Home

- Antiperspirants & deodorants
- Baby care
- Fragrance
- Hair colors and haircare
- Make-up
- Male grooming
- Makeup
- Skincare
- Sunscreens

What’s in my cosmetic?

Preservatives - in depth

1. Preservatives in the product

- Preservatives may be added to a product to prevent its contamination by microorganisms.
- The type of preservative used depends on the type of product.
- Some preservatives may be used in multiple product types.

2. Preservatives in the market

- Not all preservatives are the same.
- Some preservatives are more effective at inhibiting the growth of certain types of microorganisms.
- Some preservatives are more irritating to the skin than others.

3. Preservatives in the eye

- The eye is a sensitive organ, and preservatives can be irritating.
- The type of preservative used in eye products may vary depending on the product type.

4. Preservatives in personal care

- Personal care products often contain preservatives to prevent contamination.
- The type of preservative used may vary depending on the product type.

5. Preservatives in food

- Food products often contain preservatives to prevent spoilage.
- The type of preservative used may vary depending on the food type.

6. Preservatives in pharmaceuticals

- Pharmaceutical products often contain preservatives to prevent contamination.
- The type of preservative used may vary depending on the pharmaceutical type.

7. Preservatives in cosmetics

- Cosmetic products often contain preservatives to prevent spoilage.
- The type of preservative used may vary depending on the cosmetic type.

8. Preservatives in other products

- Other products, such as household cleaning products, may also contain preservatives.
- The type of preservative used may vary depending on the product type.

Why is it important to have a wide array of preservative ingredients?

- Not all preservatives are the same. Some are better at inhibiting the growth of bacteria, while others are better at inhibiting the growth of yeast.
- It is important to have a variety of preservatives to ensure that products remain safe and effective.

Government agencies can take action if they have evidence that a preservative ingredient is unsafe as used in cosmetics.

Some preservatives used in cosmetics can be found in nature, while others are synthetic.

Not all preservatives work in the same way. Because there are many types of cosmetic products, a variety of preservatives are necessary to protect them against spoilage.
Agenda

- Current status of Annex V
- Regulatory timescales
- Claims
  - e.g. ‘free from’
Removing/Amending Preservative Entries

Ingredient concern + SCCS review

CMR substance (+ SCCS review)

Adaptation to Technical Progress (Publication in Official Journal of EU)

or

Automatic prohibition (CMRs)*

* Ongoing EU discussions
Transition Periods

- Begins 20 days after the regulation is published in the Official Journal of the European Union.
- Ingredients added to a positive list (e.g. new preservatives) do not require a transition period.
- Usually there are 2 different lengths of time given:

*Placing on the market*

The first time a cosmetic is made available on the Community market.

*Making available on the market*

Any supply of a cosmetic product for distribution, consumption or use on the Community market in the course of a commercial activity, whether in return for payment or free of charge.
Transition Periods – an example

Methylisothiazolinone (MI)

- Preservative listed in entry 57, Annex V

- December 2013: Recommendation by Cosmetics Europe to discontinue MI in leave-on products

- Following SCCS opinion, MI banned in leave-on products since 12 Feb 2017.

- Restriction for rinse-off products changed from 100ppm to 15ppm
  - Published in OJ - 7 July 2017
  - From **27 January 2018** – maximum 15ppm in rinse-off products placed on market
  - From **27 April 2018** – maximum 15ppm in rinse-off products made available to consumer
2013 - British Association of Dermatologists report increase in allergy to MI and MCI

MI/MCI blend already undergoing legislative change

Industry voluntarily removes MI from leave-on skincare

Catalyst for future dialogue between industry and dermatologists

CTPA and BSCA Working Group
  • MI
  • Gel cured artificial nails
  • Help note for dermatologists (ingredient listing)
  • Patch test guidelines for companies
Guidance for Consumers

KEY POINTS

If you believe you have had a reaction to a cosmetic product:

- Stop using the suspected product(s) and wash off any remaining product that you may have applied.
- Discuss with your healthcare professional
- Contact the company

www.thefactsabout.co.uk/allergies
Agenda

- Current status of Annex V
- Regulatory timescales
- Claims
  - e.g. ‘free from’
Cosmetics Regulation (EC) 1223/2009
Article 20

…[claims] shall not imply products have characteristics or functions which they do not have.

…Commission shall establish an action plan regarding claims used and fix priorities for determining common criteria justifying the use of a claim.

…Commission…shall adopt a list of common criteria for claims which may be used in respect of cosmetic products…
Article 20 Scope

- text
- names
- trade marks
- pictures
- figurative or other signs

- labelling
- making available on the market
- advertising
Article 20: Common Criteria

- Commission Regulation (EU) No 655/2013 lays down common criteria for the justification of claims used in relation to cosmetic products and Guidelines.

- Establishes who is responsible for compliance with Article 20:
  - Responsible Person
  - Distributor

- Not aimed at defining and specifying the wording that can be used.

- Encouraging a common approach across the EU.
Article 20: Common Criteria + Guidance

1. Legal compliance
2. Truthfulness
3. Evidential support
4. Honesty
5. Fairness
6. Informed decision-making
Article 20: Additional Technical Guidance

Agreed by the Sub-Working Group on Claims (3rd July, 2017)

Foreword by European Commission:

- Collection of best practice – a ‘tool’
- Case-by-case application
- National competent authorities and courts
- Not legally binding/not official EC position
- Only the European Court of Justice can give authoritative interpretation
- Work in progress/subject to modifications

Focus on ‘free-from’ and hypoallergenic claims
Annex III – ‘Free-from’ claims

Looks at how the six Common Criteria apply to such claims

n.b. ‘Free-from’ includes claims with a similar meaning

Legal Compliance:

• Not permitted for prohibited ingredients

• e.g. The claim ‘free from Corticosteroids’ is not allowed as Corticosteroids are banned by EU cosmetics legislation
Annex III – ‘Free-from’ claims

Truthfulness:

• In relation to functional groups of ingredients (e.g. colorants, preservatives), there should be no ingredient of that group present.

• If a specific ingredient is referred to, it must not be present or released.

• e.g. ‘free from formaldehyde’ is not allowed if the product contains a formaldehyde-releasing ingredient (such as Diazolidinyl Urea).
Annex III – ‘Free-from’ claims

Evidential support:

• The absence of the specific ingredient or ingredients should be demonstrated by adequate and verifiable evidence

• Annex II of this document covers best practices applying to experimental studies and should be consulted for advice
Annex III – ‘Free-from’ claims

Honesty (i):

- ‘Free from’ claims should not be allowed when they refer to an ingredient which is typically not used in the particular kind of cosmetic product

  - e.g. Fine fragrances usually contain such a high amount of alcohol that the additional use of preservatives is not necessary. It would be dishonest to highlight that a certain fine fragrance does not contain any preservative
Annex III – ‘Free-from’ claims

Honesty (ii):

• ‘Free from’ claims should not be allowed when they imply guaranteed properties of the product, based on the absence of an ingredient, which cannot be given

• e.g. The claim ‘free from allergenic/sensitizing substances’ is not allowed.
  − A complete absence of the risk of an allergic reaction cannot be guaranteed and the product should not give the impression that it does
Annex III – ‘Free-from’ claims

Honesty (iii):

• ‘Free from’ claims addressing functional groups of ingredients should not be allowed if the product contains ingredients with multiple functions and among these is the function that the product is claimed to be free from.

• Exceptions may be possible (e.g. based on challenge test results of the formula without the particular ingredient)
Annex III – ‘Free-from’ claims

Honesty (iv):

- e.g. The claim ‘free from preservatives’ should not be made when the product contains an ingredient showing a protective effect against micro-organisms and which is not included in Annex V of the CPR 1223/2009.

- If the responsible person has evidence that the particular ingredient or combination of ingredients does not contribute to product protection, it might be appropriate to use the claim.
Annex III – ‘Free-from’ claims

Honesty (v):

- e.g. The claim ‘free from perfume’ should not be used when a product contains an ingredient which exerts a perfuming function in the product, regardless of its other possible functions in the product.
Annex III – ‘Free-from’ claims

Fairness (i):

• ‘Free from’ claims should not be allowed when they imply a denigrating message, notably when they are mainly based on a presumed negative perception on the safety of the ingredient or group of ingredients.

• e.g. Certain parabens are safe when used in accordance with the CPR. Considering the fact that all cosmetic products must be safe, the claim ‘free from parabens’ should not be accepted, because it is denigrating the entire group of parabens.
Annex III – ‘Free-from’ claims

**Fairness (ii):**

- e.g. Phenoxyethanol and triclosan are safe when used according to the CPR. Hence the claim ‘free from’ these substances should not be accepted because it is denigrating authorised substances
Annex III – ‘Free-from’ claims

**Informed decision-making:**

- ‘Free from’ claims should be permitted when they allow an informed choice to a specific target group or groups of end users.
- The following claims should be permitted if they also comply with the other common criteria:
  - ‘free from alcohol’ in a mouthwash intended as a family product.
  - ‘free from animal-derived ingredients’ in products intended for vegans.
  - ‘free from acetone’ in nail polish for users wishing to avoid its particular smell.
Annex III – ‘Free-from’ claims

Summary:

‘Free-from’ claims are **not all prohibited** – some may be acceptable
Some Member States may take particular interest in these claims
Decisions will be taken nationally on a case-by-case basis
(competent authority – national courts – ECJ)
Compliance will be expected
Enforcement likely from **1 July 2019**
Consumer Protection Law

The UK Consumer Protection from Unfair Trading Regulations 2008

Protect the consumer from unfair commercial practices such as:

- misleading actions
- misleading omissions
- aggressive commercial practices
- and unfair practices listed in Schedule 1

Misleading actions and omissions can be given:

- verbally
- in writing
- by illustration
- by implication
Consumer Protection Law

Misleading actions include…

- Benefits of the product
- Risks of the product
- Composition of the product
- The method and date of manufacture of the product
- Usage of the product
- Quantity of the product
- Specification of the product
- Geographical or commercial origin of the product
- Results to be expected from use of the product
Consumer Trends

How do consumers perceive the term ‘natural’?

>50% of EU consumers connect ‘natural’ with ‘preservative-free’!*

What does this really mean for preservatives and industry?

* GlobalData 2016 Q4 Global Consumer Survey
Multifunctional Ingredients

Article 2 defines preservatives as...

(1) …substances which are exclusively or mainly intended to inhibit the development of micro-organisms in the cosmetic product.

Therefore, any substance which has only one function (to inhibit microbial growth) must be on Annex V.

True multifunctionals – must have a clear ‘other’ purpose for inclusion in the formulation (visible in the PIF)

Example - alcohol
‘Micro’ Claims

- Microbiome
- Probiotic

Remember:
- all claims must be substantiated
- microbial quality of the product must be assured
What will Brexit mean for Annex V?

Cosmetic, Toiletry and Perfumery Association

www.ctpa.org.uk
Cosmetics Regulation Assessment

- Market Surveillance and Administrative Co-operation
- Responsible Person (RP)
- Role and Responsibilities (e.g. cross border distributors)
- Product Information Files (PIF)
- Safety Assessor Qualification
- Notification and Labelling Changes
- The ‘Repeal Bill’ – converting EU law to the UK
- Future ingredient management??
Cosmetics industry visibility

Working with UK Government

Acting at EU, MS and global level

Supporting Members

CTPA Involvement

Getting the Best from Exiting the EU
11 April 2017

Cosmetics Industry 3 Key Asks

Remain in the Customs Union until a Free Trade Agreement with the EU is reached
A tariff-free market for the export / import of products, raw materials and commodities will be vital to safeguard an efficient supply chain.

Provide a clear and reasonable phased implementation for changes to UK/EU trade from leaving the EU to signing a full Free Trade Agreement
A reasonable phased implementation will minimise impact on business continuity and provide financial stability for companies.

Avoid additional administrative trade barriers by securing Administrative Cooperation with EU Competent Authorities for cosmetics after the UK has left the EU
A specific agreement for cosmetics will allow UK companies to maintain easy trade with the EU.
BREXIT - what you need to know

Following the outcome of the Referendum on the United Kingdom’s status in the European Union, CTPA would like to reassure its members, the cosmetics industry at large and of course our millions of customers that the UK decision to leave the EU does not alter the strict safety laws that govern our cosmetic products.

The UK as of now is still a full member of the EU and the current legal structure will stay unchanged for the time being – indeed, the process of transitioning will take years. For our cosmetics sector, it means that all existing laws, regulations and guidelines remain in place exactly as they did before the vote – nothing changes. In particular, it means that all of the cosmetics sold in the UK must continue to comply fully with the European Cosmetic Products Regulation, including requirements relating to safety, labelling and the ban on animal testing. Consumers may have concerns about the ban on animal testing, but we would like to stress that the UK cosmetics industry voluntarily abandoned animal testing seven years ahead of the EU wide ban, so you can be assured this is not going to change.

The European Cosmetic Products Regulation is seen globally as a success and many other jurisdictions across the world look to it for inspiration. It will remain a passport for trade.

CTPA Latest Position Papers

- 11 April 2017 - CTPA Getting the Best from Exiting the EU
- 5 October 2016 - CTPA Tackles Brexit - Implications for the Cosmetics Industry

www.ctpa.org.uk/brexit
Thank you for your attention!