

Internal Market, Industry, Entrepreneurship and SMEs

Guide to Using



Cosmetic Products Notification Portal

For Responsible Persons and Distributors

Last Update: 24/05/2017

INTENDED AUDIENCE

This manual is intended for users identified as 'Responsible Persons' or 'Distributors' in the meaning below.

It explains the main functions of CPNP.

- Cosmetic industry responsible persons and users acting on their behalf referred to in this User Manual as 'Responsible Persons';
- Distributors who make available in a Member State a cosmetic product already
 placed on the market in another Member State and translate, on their own initiative,
 any element of the labelling of that product in order to comply with national law referred to in this User Manual as 'Distributors'.

Readers are kindly invited to report any remark on this User Manual to:

grow-cpnp@ec.europa.eu

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Overview

Introduction

What is the Cosmetic Products Notification Portal (CPNP)?

CPNP is the free of charge online notification system created for the implementation of Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products¹.

(1) OJ L342, 22.12.2009, p.59.

Important

It is important to note that the fact that a product has been successfully notified through CPNP does not necessarily mean that the product in question fulfills all the requirements of the Regulation (EC) N° 1223/2009 of the European Parliament and of the Council on cosmetic products.

What information needs to be entered into CPNP?

Article 13 of Regulation (EC) N° 1223/2009 lists the information that the responsible persons and, under certain circumstances, the distributors of cosmetic products shall notify through CPNP about the products they place or make available on the European market.

What CPNP does with the information entered?

CPNP makes some of this information available electronically to the Competent Authorities (for the purposes of market surveillance, market analysis, evaluation and consumer information) and to the Poison Centres, or similar bodies established by Member States (for the purposes of medical treatment).

When does information have to be entered into CPNP?

The use of CPNP is mandatory since 11 July 2013.

Regulation (EC) No 1223/2009 (Article 13) requires that, **prior to placing cosmetic products in the EU market**, the responsible persons and, under certain circumstances, the distributors of cosmetic products submit some information about these products through the CPNP.

Key Terms

Some key terms used in this User Manual are reproduced here for ease of reference:

CMR substances

Substances classified as carcinogenic, mutagenic or toxic for reproduction pursuant to Regulation (EC) No 1272/2008¹.

(Single or multiple) Component product

Single component products

A 'single component product' is a product that is composed of one single element. Examples: a single jar of moisturising cream, a single bottle of shampoo, a lipstick tube, a single bottle of aftershave, etc.

Multi-component products

A 'multi-component product' is a product composed of several components that are not marketed separately. Examples: hair dye sets, skin peeling kits, permanent styling products, anti-age/revitalizing kits, etc.

Please not that the distinction between single and multi component products has nothing to do with the fact that the product has only one or several ingredients/substances in its composition!

A notification that relates to multi-component products will be different from that of a single component product.

Sets do not need to be notified as multi-component products provided that all components that compose this set have been notified individually.

Contact person

For each cosmetic product notified, the Responsible Person shall indicate the contact details of a physical person to contact in the case of necessity.

CosIng

It is a European Commission database that contains information on cosmetic substances and ingredients².

¹ OJ L353, 31.12.2008, p.1

http://ec.europa.eu/growth/tools-databases/cosing/

Cosmetic product

'Cosmetic product' means any substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours.

Delegate for nanomaterials

Article 16 of Regulation (EC) No 1223 on cosmetic products requires that, in addition to the notification under Article 13, cosmetic products containing nanomaterials shall be notified to the Commission by the Responsible Person 6 months prior to being placed on the market. However, the provisions of Article 16 do not apply to nanomaterials used as colorants, preservatives or UV-filters regulated under Article 14, unless expressly specified. To do so the Responsible Person can mandate a *Delegate for nanomaterials*.

Delegates for nanomaterials are restricted to Art. 16; they cannot notify products as part of Art. 13!

The role of the Delegate is to enter certain data only for the nanomaterials notification.

Distributor

'Distributor' means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a cosmetic product available on the Community market.

EU Login

EU Login (formerly known as 'ECAS') is the European Commission Authentication Service with which people can access different applications and services offered by the European Commission.

Frame formulation

'Frame formulation' means a formulation which lists the category or function of ingredients and their maximum concentration in the cosmetic product or gives relevant quantitative and qualitative information whenever a cosmetic product is not covered or only partially covered by such a formulation.

Importer

'Importer' means any natural or legal person established within the Community, who places a cosmetic product from a third country on the Community market.

Local administrator

A local administrator is a person who may manage the access requests to the organisation to which he/she is linked, and as well the details of the organisation. These grants are only applicable to local administrators. It is a role in SAAS. The first user creating an organisation in SAAS for requesting access to CPNP must be the local administrator of this organisation.

Making available on the market

'Making available on the market' means 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.

Nanomaterial

'Nanomaterial' means an insoluble or biopersistant and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nm.

Organisation

An organisation means either a 'Responsible Person' (or its sub-contractors/organisations) or a 'Distributor'.

Article 19.1 of the Cosmetics Regulation states: "...cosmetic products shall be made available on the market only where the container and packaging of cosmetic products bear the following information in indelible, easily legible and visible lettering: (a) the name or registered name and the address of the responsible person...".

Please note that when you create an organisation with Responsible Person profile in SAAS, this must correspond to the Responsible Person details visible on the labelling!

Placing on the market

'Placing on the market' means the first making available of a cosmetic product on the Community market.

Product name

The product name must be detailed enough to enable the specific identification of the cosmetic product.

It should include the trade mark/brand, the product line and the specific name of the product as they appear on the packaging. The complete name should also include the function unless it is part of the specific name of the product.

See also information under 'Organisation'.

Responsible Person (RP)

Only cosmetic products for which a legal or natural person is designated within the EU as a 'responsible person' can be placed on the EU market. The Responsible Person shall ensure compliance with the obligations set out in Regulation (EC) No 1223/2009.

For a <u>cosmetic product</u> manufactured within the Community, and not subsequently exported and imported back into the Community, the manufacturer established within the Community shall be the responsible person.

The manufacturer may designate, by written mandate, a person established within the Community as the responsible person who shall accept in writing.

Where, for a cosmetic product manufactured within the Community, and not subsequently exported and imported back into the Community, the manufacturer is established outside the Community, he shall designate, by written mandate, a person established within the Community as the responsible person who shall accept in writing.

For an imported cosmetic product, each importer shall be the responsible person for the specific cosmetic product he places on the market.

The importer may, by written mandate, designate a person established within the Community as the responsible person who shall accept in writing.

The distributor shall be the responsible person where he places a cosmetic product on the market under his name or trademark or modifies a product already placed on the market in such a way that compliance with the applicable requirements may be affected.

The translation of information relating to a cosmetic product already placed on the market shall not be considered as a modification of that product of such a nature that compliance with the applicable requirements of this Regulation may be affected.

SAAS

The SAAS (**SAnte A**uthorisation **S**ystem) provides users with a profile and access rights for a specific European Commission application. This application manages specifically the access rights.

The name or registered name and the address of the Responsible Person shall be in the cosmetic products labelling.

Shade

Individual colour, fragrance or strength variant of a cosmetic product.

For example:

- the different color names of the same lipstick (e.g. 'Pure rouge', 'Ruby', 'Vermeil', etc.)
- the different scents of the same body lotion (e.g. 'Bali mango', 'Hawai coconut', 'Fiji passion fruit', etc.)
- the different strengths of a fixing spray (e.g. 'Soft', 'Strong', 'Extra Strong', etc.)

Getting Started

System Requirements

The following items are required in order to connect to CPNP:

- An Internet connection;
- A computer screen resolution of at least 1024 X 768 pixels.

CPNP is optimized for use with recent versions of Microsoft Internet Explorer, Mozilla Firefox or Google Chrome (JavaScript and cookies enabled).

Registration

In order to access CPNP, the user needs a user login, a password, an organisation, a role and a profile.

Two systems are needed:

- EU Login. The European Commission Authentication Service (formerly known as 'ECAS') with which people can access different applications and services offered by the European Commission.
- The SAnte Authorisation System (SAAS). This system provides the user with an organisation, a role and a profile for having the access rights for a specific European Commission application, in this case CPNP.

Starting CPNP

To start CPNP, just type the following URL in the address bar of your browser: https://webgate.ec.europa.eu/cpnp

The first time you will connect to CPNP, you will see the following tutorial:



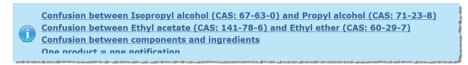
- This tutorial allows learning how to use the EU Login and SAAS authentication systems, and how to and access CPNP. You can skip it by clicking Skip the tutorial
- Select the **Do not show again** check box if you do not wish to see this tutorial again when connecting to CPNP. In this case, the tutorial will remain accessible only *via* the useful links menu as long as you do not delete your cookies.

Meeting the Interface

The CPNP Home Page

Depending on your user profile (i.e. Responsible Person or Distributor), the home page and subsequent screens may slightly differ. This is detailed throughout this user manual.

On the CPNP home page you may occasionally notice an information box. It is used to announce any new information concerning the application (e.g. new features available, tips, guidance, maintenance interventions).



Interface Components

The following menus may be displayed on the home page, depending on the user profile:



Menu bar

The menu bar contains the following menus: Home, Products, Distribution, Nanomaterials, Contact persons, Admin and Useful links.



Use this menu to go back to the home page.

Products

The Products menu contains the following menu options i.e.

My notifications

This menu option displays an overview of all products (i.e. Draft and Notified) which are specifically attached to your RP/organisation.

Notify a product

This menu option allows the Responsible Persons to create notifications for single or multiple component products.

Simple search

This menu option allows you to search for products or components, using keywords.

Advanced search

This menu option allows you to search for products or components on the basis of several criteria.

Distribution

The **Distribution** menu is available for Reponsible Person and Distributors. If you are a Distributor, using this menu will allow you to enter distribution notifications and to search for notifications that you have already entered in the system.

Contact persons

The **Contact persons** menu is available for Responsible Persons only. If you are a Responsible Person, using this menu will allow you to manage (create, modify, delete) and search for the contact details of all contact persons associated to your organisation. For details, please refer to 'Managing Contact Persons', p. 45.

Nanomaterials

The **Nanomaterials** menu is used to notify nanomaterials. Regulation (EC) No 1223/2009, Article 16, requires that, in addition to the notification under Article 13, cosmetic products containing nanomaterials shall be notified to the Commission by the Responsible Person by electronic means six months prior to being placed on the market. Please note that this specific module will not be described in this manual but in another dedicated manual that can be consulted from the **Useful links > ART. 16** menu.

Admin

The Copy your products to another Responsible Person option in this menu can be used, if required, to transfer your products to another Responsible Person (for example in case of merger or Responsible Person change of name). A copy of the selected products will be saved, in DRAFT, under the new designated Responsible Person. Please note that all the information is copied, except the packaging and labelling information, as well as the contact person details.

And an additional **Move products** option will be available in the Admin menu as well, for users belonging to an organisation with sub-organisations. This options is used to move products from a main organisation or from one of its sub-organisations to another one of the sub-organisations or to the main organisation.

Useful links

This menu provides links to the Tutorial, the Frequently Asked Questions (FAQ), Q&A on nanomaterials, documentation about Article 13 (i.e. user manual, frame formulations, Cat./Frames/Triggered questions + an instruction package for using the upload webservice) and Article 16, external links (SAAS, CosIng), Regulation (EC) No 1223/2009 on cosmetic products, release notes.

Top link bar

The top link bar provides quick access links to the following: **Privacy Statement**, **Contact**, **Profile** and **Logout**.

Privacy Statement

This hyperlink opens the CPNP privacy statement.

Contact

Use this hyperlink to send an email to the CPNP functional mailbox.

Profile

Use this hyperlink to check your CPNP profile, including your name, email adddress, language, postal address; the ID, name, contact email address, profile and any other known information about your organisation.

Logout

Use this link to log out of the system.

Language selection box

Use the language selection box at the top right of each page to change the interface language.

Note:

The CPNP interface and this User Manual are originally in English. In case of doubt, please use the English version as reference and do not hesitate to report to grow-cpnp@ec.europa.eu any inconsistency you would find in any other language.

Using CPNP

Responsible Persons – Managing Notifications Pursuant to Articles 13(1) And 13(2)

Notifying Products

As per Article 13(1) of Regulation (EC) No 1223/2009, Responsible Persons are required to submit a number of information to the CPNP prior to placing any cosmetic product on the EU market; as per Article 13(b), the Responsible Person is further obliged, when the cosmetic product is placed on the market, to notify to the CPNP the original labelling, and, where reasonably legible, provide a photograph of the corresponding packaging.

These two requirements are accommodated for Responsible Persons through the **Notify a product** option in the **Products** menu.

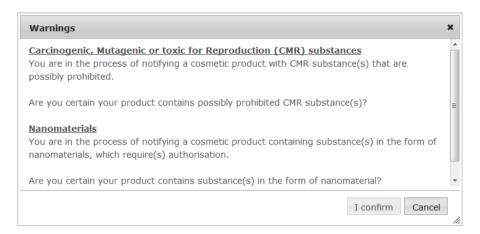
• To notify a product

1. In the Products menu, select Notify a product.

Result: The Add a new product start page prompts you to select the type of product that you wish to notify:



- 2. Select the type of product that you want to notify.
- 3. Complete the product detail page with all information you have about the product (for details about each tab/field, see the following pages).
- 4. To save the notification as draft (i.e. if it does not contain all mandatory information), click Save as draft and answer the confirmation message (only if you have specified that the product contains CMR susbstances and/or nanomaterials see 'Product details' tab, p.17'):



Please note that at least a product/component name and the corresponding language must be filled (as indicated by "**").

Or,

When the information on the notification is complete and all mandatory fields (indicated by a "*" have been filled in), click **Notify**. The information will then be made available to Competent Authorities and Poison Centres. Please note that it will no longer be possible to delete the notification by that time. Only updates will be possible.

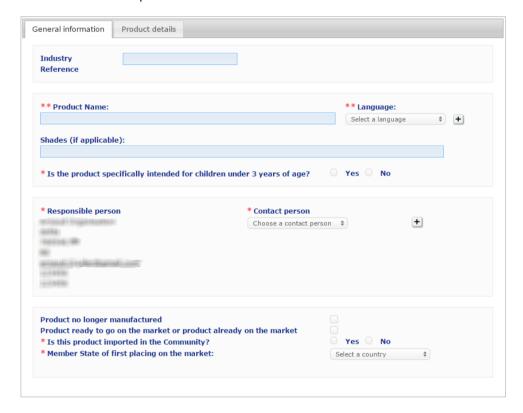
I. Notifying a single component product



A single component product refers to a product that is composed of one single element (e.g. a single bottle of shampoo).

'General information' tab

The **General information** tab allows the Responsible Person to enter the following information about the product:



Industry Reference

The reference given to the product by the industry (only for industry's internal use).

Product Name



The product name is a crucial element of the notification since it will be often used by Competent Authorities or by Poison Centres to search for a product in the CPNP.

Important

The product name must be detailed enough to enable the specific identification of the cosmetic product. It should include the **trade mark/brand**, the **product line** and the **specific name** of the product as they appear on the product. The complete name should include the **function** unless it is part of the specific name of the product.

Examples:

- 1. Trade Mark / Brand
- 2. Product Line
- 3. Specific name (function included)

The complete name of the product is:

Trade Mark / Brand + Product Line + specific name (function included), e.g.:

- Niveo / Repair & Shine smoothing cream
- Niveo / Repair & Shine smoothing shampoo silk
- Elisa / Erden Five Minutes Cream Intensive lip repair balm
- Chenal / Hydra Star Serum Hydratant Repulpant Intense
- Yves St Vincent / Opium Bleu Eau de parfum

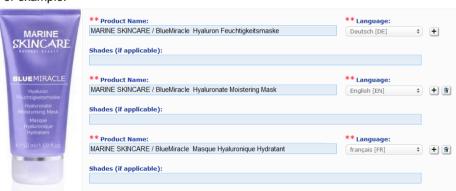
Language



When the product is made available on the market with a name translated in different languages, each of these names has to be mentioned in the notification together with the corresponding language (selected *via* the selection box).

The + next to the language selection box allows the Responsible Person to add product name translation(s) and to select the corresponding language(s).

For example:



<u>Disclaimer</u>: The product illustrated here is not a real product; the name and all its markings have been invented for

the sole purpose of

clarification.

Should you need to delete a product name translation, just click next to the corresponding language.

If the product name is the same in <u>all languages</u>, you can indicate this name only once and select 'Multilingual' in the selection box. Please note, however, that 'Multilingual' cannot be used if the product name is the same in <u>some</u> languages, but different in others. In this case, all linguistic versions of the product name have to be entered individually in the system. Even when the name is the same for some languages, it has to be repeated indicating for each one the corresponding language.

Shades (if applicable)

To avoid unnecessary notifications, you can notify the different shades of a product (e.g. different shades of a lipstick) into one single notification. This can be done **only if all** these shades are fully covered by the information contained in the notification.

The different shades shall be indicated in the shades field and shall be clearly separated by a " / " preceded and followed by a white space.

The Shades field is limited to 2000 characters for reasons of lisibility.

The translations of these shades in the different languages have to be indicated in the shades field just below the corresponding linguistic version of the product name.

Please note that when some shades of a cosmetic product are not fully covered by the information contained in the notification (e.g. different composition information), they must be notified separately.

Is the product specifically intended for children under 3 years of age? Please select **Yes** or **No** to specify here whether the product is <u>specifically</u> intended for children under 3 years of age.

Responsible person

The notification shall contain at least the name and the address of the Responsible Person. This information appears on the left part of the screen under 'Responsible person' and is automatically retrieved from SAAS on the basis of the login of the user.

Important

When the Responsible Person needs to update or correct its details, this has to be done in SAAS. Access to SAAS is available from the 'profile' item located at the top right of the CPNP screen. Only local administrators can modify the Responsible Person details. Never change the name or country in SAAS; this would lead to the creation of a new Organisation and would imply new product nofitication!!

Contact person

For each notification, the Responsible Person has to indicate the contact details of a contact person i.e. a physical person to contact in case of necessity.

Pull down the selection box to see the list of all the contact persons that are currently linked to the Responsible Person, and then select the desired contact person.

If the desired contact person does not appear in the selection box, you can add it. The person will then become available for linking to this notification and to future notifications.

To do so:

- 1. Click the + Add contact icon.
- 2. Enter he contact person's details on the *Add contact person* page i.e. first and last name, phone, postal address, email address, etc.

(Please note that all mandatory fields are indicated by a *).

3. Click Add at the bottom of the page to add the new contact person to the notification.



Result: The new contact person is automatically selected for this notification. At the same time, an e-mail is sent to this contact person, with information on data protection.

Important

All telephone and fax numbers in CPNP need to include the international country calling code. For example: +32 2 296 93 62.

Please note that contact persons are further managed in the dedicated Contact persons menu (available for Responsible Persons only):



Every contact person that you create / modify on a notification is immediately added to / modified in the Contact persons modules, and vice versa. For details, please refer to 'Managing Contact Persons', p. 45.

Product no longer manufactured

Check this box if the product is no longer manufactured.

Product ready to go on the market or already on the market Check the 'Product ready to go on the market or already on the market' box if the product is ready to go on the market or already on the market.

Please note that you will not be abe to notify the product if you select this box without providing any information about its original labelling and packaging in the 'Orginial labelling & original packaging' accordion of the 'Product details' tab.

Important

To fulfil its legal obligations, the Responsible Person has to notify once the original labelling, and, where reasonably legible, a photograph of the corresponding packaging at the latest when the product is placed on the market.

Is the product imported in the Community?

Select the appropriate option button to indicate whether the product is imported in the European Community. If you select **Yes**, an additional **Country of origin** selection boxes will appear to select i) the country of origin and ii) the end date of responsibility:



Please note that there may be rare cases where the same product is imported from several countries. In such cases, please make one notification per country of origin and mention the country of origin into brackets in the product name.

Examples: Trade Mark / Brand Repair & Shine smoothing cream (United States)
Trade Mark / Brand Repair & Shine smoothing cream (China)

There may also be rare cases where the same product is both imported and not imported. In such cases, please make 2 different notifications, *i.e.* one notification for the imported version of the product (specifying the country of origin into brackets in the product name) and another notification for the non-imported version of the product.

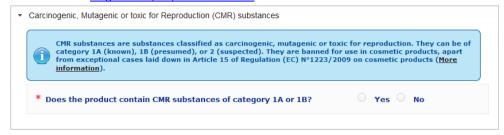
Member State of first placing on the market

Pull down the selection box to select the Member State of first placing on the market.

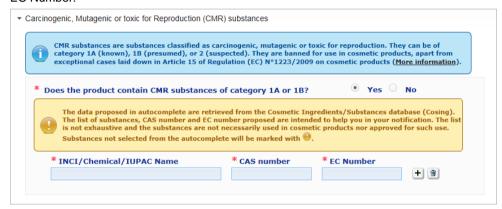
'Product details' tab

The Product details tab contains 4 different sections:

Carcinogenic, Mutagenic or toxic for Reproduction (CMR) substances Use this section to specify whether the product contains substances classified as carcinogenic, mutagenic or toxic for reproduction (CMR), of category 1A or 1B, under Part 3 of Annex VI to Regulation (EC) No 1272/2008.

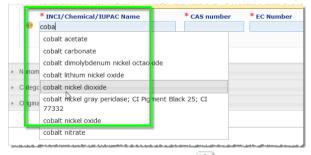


If the product does contain such substances, and you answered **Yes** to the question, you will then be prompted to identify each of these based on their INCI/Chemical/IUPAC, CAS or EC Number:



To help you enter this information, the Names, CAS and EC numbers can be retrieved from CosIng, when available. To do so, proceed as follows:

- Type the first characters or digits of the searched INCI/Chemical/IUPAC, CAS or EC Number in the related input box.
- 2. Select the appropriate substance in the list of matching substances:



3. To add more substances, click the + and proceed likewise.



Important

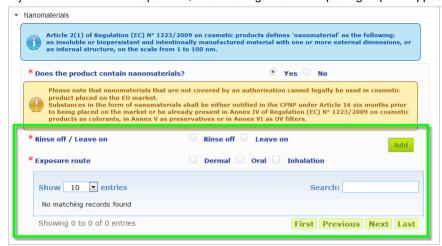
Please note that the list of ingredients retrieved from CosIng cannot be filtered to include only CMRs 1A or 1B. Please note as well, that the list of ingredients retrieved from CosIng may include ingredients which are not intended for use in cosmetic products! You remain responsible for checking the completeness and the exactness of the information provided, and for changing it where necessary.

Nanomaterials

Use this section to specify whether the product contains substances classified as nanomaterials under Article 2(1) of Regulation (EC) No 1223/2009 on cosmetic products.



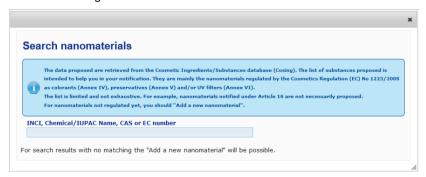
If you answer **Yes** to this question, the following additional option group will appear:



CPNP will first ask you to answer two questions on the exposure conditions:

- Is the product a rinse off or a leave on product?
- What is the exposure route (dermal, oral and/or inhalation)?
- ♦ To add a nanomaterial to the notification
 - 1. Click Add.

Result: A pop up page will appear for you to search for the nanomaterial into CosIng:



To help you enter this information, the INCI, IUPAC, INN, CAS or EC Number can be retrieved from CosIng, when available.

To do so:

 type at least the first 2 characters or digits of the searched INCI, IUPAC, INN, CAS or EC Number in the input box. All matching items will show from CosIng,

Important

Please note that the list of nanomaterials from CosIng may include ingredients which are not intended for use in cosmetic products! You remain responsible for checking the completeness and exactness of the information provided, and for changing it where necessary. The CosIng search feature will look for nanomaterials and nanomaterials under Art.16.

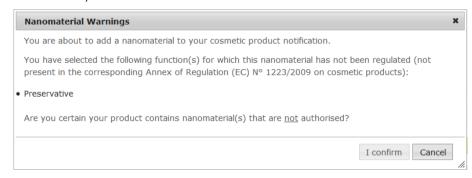
- click the next to the desired item in the search results table:



- check the information about the selected item and the click Add:

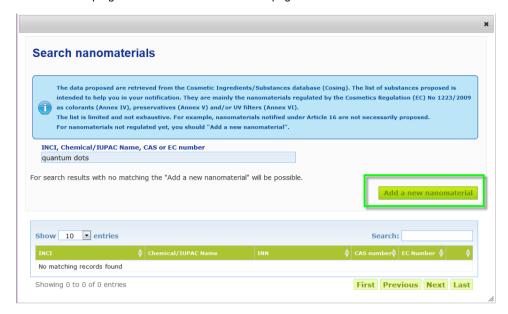


Please note that the information about the 'Colorant', 'Preservative' and/or 'UV Filter' functions is automatically retrieved from CosIng; the 'Other' option is automatically retrieved from Article 16 of CPNP (Nanomaterials → Notify a nanomaterial). At least one function is mandatory; a popup will show if you add some functions (e.g. 'Preservative'):

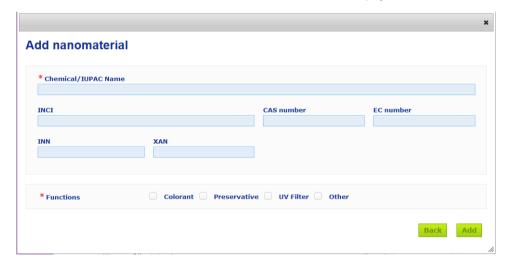


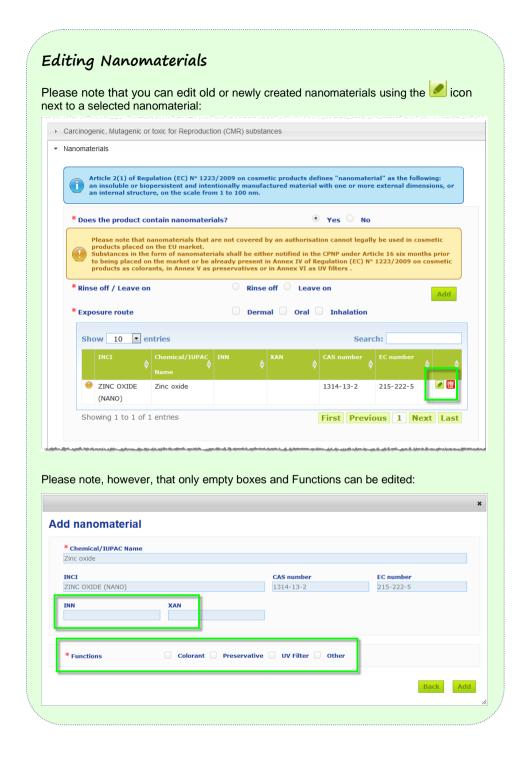
Or,

If the searched nanomaterial is not found, you can add it using the **Add new nanomaterial** button at the top right of the *Search nanomaterials* page:



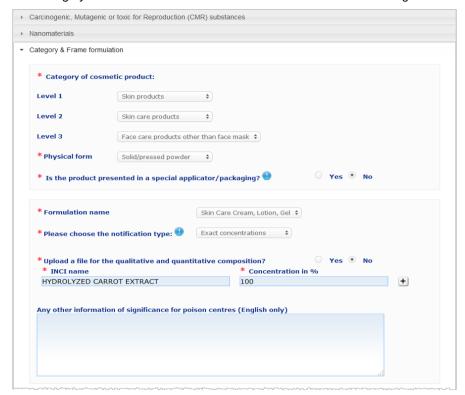
You will then be able to enter all details of the nanomaterial on a new page:





Category & Frame formulation

The Category & Frame formulation accordion is used to enter the following information:



Category of cosmetic product

You have to select here 3 category levels, starting by the Level 1, followed subsequently by Levels 2 and 3:



Important

In some rare cases, products may have several 'functions' that may make them fall under different categories. In these cases, it is the primary function that has to be considered for the categorisation of the cosmetic product.

The choice of a category at Level 1 determines the categories available at Level 2; the choice of a category at Level 2 will determine the categories available at Level 3.

All existing categories are available under the useful links tab of CPNP.

Physical form

Pull down the selection box to select the physical form of the product. **Note**: 'Liquid' includes formulations (e.g. solution or milks) with low

Note: 'Liquid' includes formulations (e.g. solution or milks) with low viscosity, typically below 10.000 cp



Is the product presented in

Select **Yes** or **No** to indicate whether the product is presented in a typical non-pressurised cosmetic packaging (*e.g.* bottle, jar, or sachet) or rather in a special applicator or packaging. This information might allow Poison

a special applicator/p ackaging?

Centres to modulate their risk assessment in case of emergency medical treatment.

You can view the possible choices in terms of special applicators and packaging by clicking the ①.

If you answer **Yes**, select the appropriate applicator/packaging from the selection list:



If you select **Other** in the selection list, you will be invited to suggest an applicator / packaging denomination (preferably in English). All applicator / packaging suggested names will be taken into consideration by the CPNP maintenance group in order to create new applicator/packaging names, or update the existing ones, where necessary:



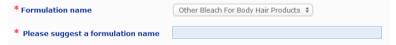
Formulation name

Please note that the **Formulation name** selection box is enabled only after you select category levels in the **Category of cosmetic product** section above. Depending on the levels selected, you will be offered a corresponding list of possible formulation names for selection. Pull down the selection box and select the appropriate formulation name. The formulation name provides a more detailed product categorisation, which is made available to poison centers only.

Important

Choosing a formulation name does not mean that you will be notifying his product using a predefined frame formulation. After having selected a formulation name you will still have the choice to notify using a predefined frame formulation, an exact concentration declaration or a concentration ranges declaration.

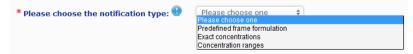
If you select **Other**, you will be invited to suggest a formulation name (preferably in English). All suggested names will be taken into consideration by the CPNP maintenance group in order to create new formulation names, or update those existing, where necessary.



Shouldn't you have any suggestion for any formulation name, you can then simply repeat the name selected for the Level 3 category.

Please choose the notification type

In the majority of the cases, the selection box will offer 3 options, *i.e.*Predefined frame formulation, Exact concentrations or Concentration ranges.

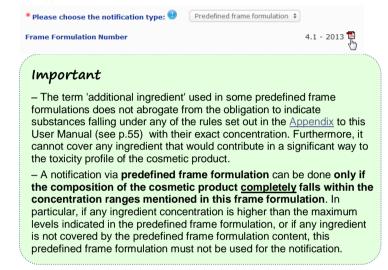


In some cases, depending on the categories of cosmetic products selected, there may be no existing predefined frame formulation. In such cases, only two options will be available, i.e. 'Exact concentrations' or 'Concentration ranges'.

Predefined frame formulation

A set of predefined frame formulations have been elaborated by an expert group composed of representatives from Poison Centres, Competent Authorities, industry trade associations and Commission' services. These are available for consultation in a separate document.

If you select **Predefined frame formulation** in the 'Please choose the notification type' selection list, CPNP will automatically propose the corresponding predefined frame formulation on the basis of the category and formulation name that you selected. This predefined frame formulation will be linked to the notification as a PDF document. Please check the relevance of the selected predefined frame formulation for the product being notified by clicking the little



Depending on the product categories, the physical form and the formulation name selected, additional information will be asked by CPNP on specific ingredients of concern and/or the pH value of the product.

The rules that CPNP applies have been elaborated by an expert group composed of representatives from poison centres, competent authorities, industry trade associations and Commission' services and are available for consultation in the Appendix to this User Manual (see p.55). The links between the categories of cosmetic products and the rules triggered by CPNP are available under the useful links tab of CPNP.

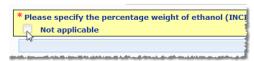
The following first question will be asked:



Please carefully go through the whole list of ingredients by clicking on each of the + to expand each section.

Either select **Yes**, **see below**, check the box of the relevant ingredient(s) and indicate its (their) concentration(s) in the product, or select **No** as appropriate.

For the other questions, you will usually have the choice between answering the question in the dedicated field(s) or selecting the **Not applicable** check box:



To facilitate the entry of names of ingredients, a link is made to **CosIng** to retrieve the information. You can also enter an ingredient name if the appropriate one is not included in CosIng.

Important

In the case of **ethanol and/or isopropanol**, 'Not applicable' means that these ingredients are **not present in the product**!

In the case of all other ingredients of concern, it means that the ingredient is either not present in the product, or is present in the product but under the concentration of concern (according to the rules set out in the <u>Appendix</u> to this User Manual (see p.55)).

All ingredient names shall be expressed using **INCI names**, when available.

Where the information on pH is required and the pH could not be measured in the product directly, but through an aqueous solution, extract or dispersion (e.g. for solid formulations), the user should mention this in the field dedicated to "Any other information of significance for poison centres" using the expression "pH (aqueous extract/solution/dispersion)" in English only.

All ingredient quantities shall be expressed using **% w/w**. The symbol **% w/w shall not be indicate**d in the answering field.

Please use the English notation for numbers, for example: 0.3, and NOT 0,3.

For ethanol and/or isopropanol, an updated notification is required when the content of either ingredient or the sum of both ingredients changes by more than 5, if the value declared previously is <30%, or by more than 10, if the value declared previously is $\geq 30\%$

For all other ingredients of concern, an updated notification is required when the concentration of the ingredient changes by more than 20% of the value previously declared (see Appendix to this User Manual (see p.55) for further details).

An updated notification is also required when the product does not fall anymore in the predefined frame formulation, when a new ingredient of concern enters in the composition of the product or when an ingredient of concern no longer enters the composition of the product.

In the lower text box, please also mention any other information on the product that would be of significance for Poison Centres (using English only). Such additional information refers in particular to additional information to identify the product or assess its risk in a poisoning scenario (e.g. colour, taste, smell, other information to help poison centers in the assessment of a case):

Any other information of significance for poison centres (English only)				

Exact concentrations

If you select **Exact concentrations** in the 'Please choose the notification type' selection box, you will be asked whether you want to upload a file for the qualitative and quantitative composition:



 If you answer Yes, you will be asked to attach the corresponding file. Please note that only PDFs are allowed.

Important

No hand-written document is allowed.

Only clear and legible electronic PDF text format documents are allowed

In order to facilitate poison centres reading in emergency situations, it is recommended that the exact concentration document starts by mentioning the ingredients of concerns and their concentration (according to the rules set out in the Appendix to this User Manual (see p.55)) and then lists all other ingredients by decreasing order of their concentration in the product.

All ingredient names shall be expressed using INCI names, when available.

All ingredient quantities shall be expressed using % w/w.

Please use the English notation for numbers. For example: 0.3, and NOT 0.3.

Where the information on pH is required and the pH could not be measured in the product directly, but through an aqueous solution, extract or dispersion (e.g. for solid formulations), the user should mention this in the field dedicated to "Any other information of significance for Poison Centres" using the expression "pH (aqueous extract/solution/dispersion)" in English only.

For ethanol and/or isopropanol, an updated notification is required when the content of either ingredient or the sum of both ingredients changes by more than 5, if the value declared previously is <30%, or by more than 10, if the value declared previously is $\geq 30\%$.

For the other ingredients, an updated notification is required when the concentration of an ingredient changes by more than 20% of the value declared previously, when a new ingredient enters in the composition of the product or when an ingredient no longer enters the composition of the product.

 If you answer No, you have to enter the ingredients one by one.

To facilitate the entry of names of ingredients, a link is made to **CosIng** to retrieve the information. You can also enter an ingredient if its name is not included in CosIng. Here too, it is recommended that you start by mentioning the ingredients of concern, and their concentration (according to the rules set out in the Appendix to this User Manual (see p.55)) and then lists all other ingredients by decreasing order of concentration in the product.

Important

All ingredient names shall be expressed using $\ensuremath{\text{INCI}}$ names, when available.

All ingredient quantities shall be expressed using % w/w.

The symbol % w/w shall not be indicated in the answering field. Please use the **English notation for numbers**. For example: 0.3, and NOT 0,3.

In the lower text box, please also mention any other information on the product that would be of significance for Poison Centres (using English only). Such additional information refers in particular to additional information to identify the product or assess its risk in a poisoning scenario (e.g. colour, taste, smell, other information to help poison centers in the assessment of a case):

Any other information of significance for poison centres (English only)

Concentration ranges

If you select **Concentration ranges** in the 'Please choose the notification type' selection box, you will be asked whether you want to upload a file for the qualitative and quantitative composition.



 If you answer Yes, you will be asked to attach the corresponding file. Please note that only PDFs are allowed.

Important

No hand-written document is allowed.

Only clear and legible electronic PDF text format documents are allowed. For ingredients that are not of special concern **only the following concentration ranges are allowed**:

- ≤ 0.1%
- > 0.1% ≤1%
- > 1% ≤ 5%
- > 5% ≤ 10%
- > 10% ≤ 25%
- > 25% ≤ 50%
- > 50% ≤ 75% > 75% - ≤ 100%

In order to facilitate poison centres reading in emergency situations, it is recommended that the exact concentration document starts by mentioning the ingredients of concerns and their concentration (according to the rules set out in the Appendix to this User Manual (see p.55)) and then lists all other ingredients by decreasing order of their concentration in the product.

Where the information on pH is required and the pH could not be measured in the product directly, but through an aqueous solution, extract or dispersion (e.g. for solid formulations), the user should mention this in the field dedicated to "Any other information of significance for Poison Centres" using the expression "pH (aqueous extract/solution/dispersion)" in English only.

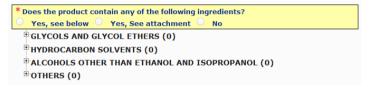
For ethanol and/or isopropanol, an updated notification is required when the content of either ingredient or the sum of both ingredients changes by more than 5, if the value declared previously is <30%, or by more than 10, if the value declared previously is \geq 30%.

For all other ingredients of concern, an updated notification is required when the concentration of an ingredient changes by more than 20% of the value previously declared (see Appendix to this User Manual (see p.55) for further details).

An updated notification is also required when an ingredient falls in a concentration range different from the one previously declared, when a new ingredient of concern enters in the composition of the product or when an ingredient of concern no longer enters the composition of the product.

As for predefined frame formulations, depending on the product categories, the physical form and the formulation name selected, additional information will be asked by CPNP on specific ingredients of concern and/or the pH value of the product. The rules that CPNP applies have been elaborated by an expert group composed of representatives from poison centres, competent authorities, industry trade associations and Commission' services and are available for consultation in the Appendix to this User Manual (see p.55). The links between the categories of cosmetic products and the rules triggered by the CPNP are available under the useful links tab of CPNP.

The following first question will be asked:



Please carefully go through the whole list of ingredients by clicking on each of +.

Either select **Yes**, **see below**, check the box of the relevant ingredient(s) and indicate its (their) concentration(s) in the product, or select **No** as appropriate.

For the other questions, you will usually have the choice between answering the question in the dedicated field(s) or selecting the **Not applicable** or **See attachment** check box(es):



Important

In the case of **ethanol and/or isopropanol**, 'Not applicable' means that these ingredients are **not present in the product**!

In the case of all other ingredients of concern, it means that the ingredient is either not present in the product, or is present in the product but under the concentration of concern (according to the rules set out in the Appendix to this User Manual (see p.55)).

'See attachment' can be used to answer a specific question only when the information requested on the ingredient of concern is provided in the qualitative and quantitative composition document attached.

All ingredient names shall be expressed using **INCI names**, when available.

The quantities of all ingredient of concern shall be expressed using **% w/w**. The symbol **% w/w shall not be indicated** in the answering field.

Please use the **English notation for numbers**, for example: 0.3, and NOT 0.3.

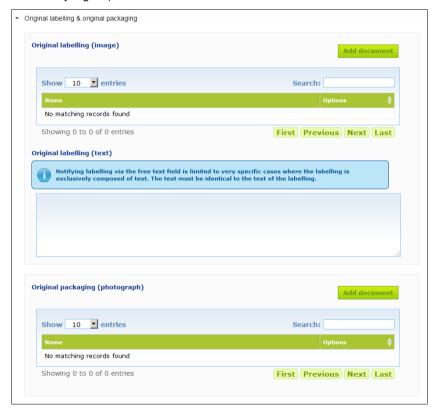
 If you answer No, you will be asked to enter the ingredients and the corresponding concentration ranges one by one by decreasing order of concentration in the product. To facilitate the entry of names of ingredients, a link is made to CosIng to retrieve the information. You can also enter an ingredient if the name is not included in CosIng:



In the lower text box, please also mention any other information on the product that would be of significance for Poison Centres (using English only). Such additional information refers in particular to additional information to identify the product or assess its risk in a poisoning scenario (e.g. colour, taste, smell, other information to help poison centers in the assessment of a case).

Original labelling & original packaging

Use this section to attach the **original labelling** and a **photograph** of the original packaging (where reasonably legible).



Only PDF, JPG or JPEG format are accepted.

Please note that 'Original' means the one corresponding to the first placing on the market in the EU. The submission of the original labelling and of a photograph of the original packaging (where reasonably legible) is mandatory at the latest when the product is placed on the market.

Various situations may occur:

Example 1:

A single component product without any secondary packaging (e.g. a standalone bottle of shampoo)

 \rightarrow The original labelling of the bottle and, if reasonably legible, the photograph of the bottle shall be submitted.

Example 2:

A single component product with a secondary packaging (e.g. a bottle of shampoo in a box)

- \rightarrow The original labelling of the box (outer packaging) and, if reasonably legible, the photograph of the box shall be submitted.
- ightarrow Optionally, the original labelling and the photograph of the bottle can also be submitted. Example 3:

A multi-component product (e.g. a set composed of three bottles)

- → The original labelling of the set and, if reasonably legible, the photograph of the set shall be submitted
- \rightarrow Optionally, the original labelling of each bottle and the photograph of each bottle can also be added to the notification at the component level.

Important

The labelling shall include any text, symbols, pictures etc. (e.g. art work). It shall cover notably all the mandatory elements mentioned in Article 19 of Regulation (EC) N°1223/2009. In cases where, in accordance with Article 19(2), some mandatory information is mentioned on an enclosed or attached leaflet, label, tag or card, this leaflet, label, tag or card shall also be included in the notification.

If the notification covers several pack sizes or shades, the most legible original labelling & original packaging are to be attached to the notification, usually the biggest pack size.

- ◆ To add an image of the original labelling or a photograph of the original packaging:
- 1. Click Add document

Result: A pop up will appear where the documents can be uploaded.

- 2. Click Browse in the Add Document pop up and select the document in the folder structure.
- Click Save
- 4. If necessary, use the + to upload additional documents.

Important

The **size** of all attached documents (labelling, photograph of the packaging, composition document) cannot exceed **2 MB**.

The labelling can also be submitted by using the free text box. This is however limited to the very specific cases where the **labelling** is <u>exclusively</u> composed of text.

Original labelling (text) Notifying labelling via the free text field is limited to very specific cases where the labelling is exclusively composed of text. The text must be identical to the text of the labelling.

II. Notifying a multi-component product



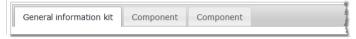
A multi-component product refers to a collection of components sold as set and intended to be used as a mix or sequentially (e.g. hair colouring kit, skin peeling kit, permanent styling product, etc.).

A notification that relates to products composed of several components (e.g. hair dye sets, make-up sets) that are not marketed separately will be different from that of a single component product.

Important

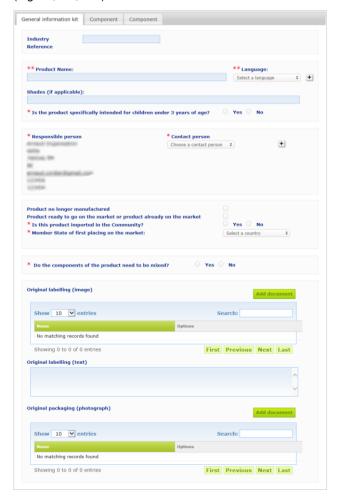
- The notion of single or multi component product has nothing to do with the fact that the product contains several ingredients/substances in its composition!!
- Please note that sets do not need to be notified as multi-component products provided that all components that compose this set have been notified individually.

A multi-component notification page is composed of 3 different tabs i.e. 1 General information kit and 2 Component tabs:



'General information kit' tab

The **General information kit** tab allows the Responsible Person to enter some general information about the product (e.g. kit, set, etc.).



Except for the group of questions in the block starting with **Do the components of the product need to be mixed?**, the information to be entered in the **General information kit** tab is identical to the information requested in the **General information** tab of a single component product. So, for a description of the common fields, please refer to 'I. Notify a single component product', 'General information tab', p. 13).

The additional, multi-component product-specific questions are grouped in the block starting with **Do the components** of the product need to be mixed?

* Do the components of the product need to be mixed?	O Yes O No
If you answer Yes to this question, you will be asked w	hether the product is a h
* Do the components of the product need to be mixed? * Is the product a hair dye	• Yes O No Yes O No
If you answer No to the question about hair dye, you w	vill be asked whether the
 * Do the components of the product need to be mixed? * Is the product a hair dye * Is the pH lower than 3 or higher than 10 	• Yes • No • Yes • No • Yes • No
If you answer Yes to the question about the pH, you w exceed 1 pH unit.	ill be prompted to specify
 Do the components of the product need to be mixed? Is the product a hair dye Is the pH lower than 3 or higher than 10 Please indicate the pH (min and max values) 	Yes No Yes No Yes No No

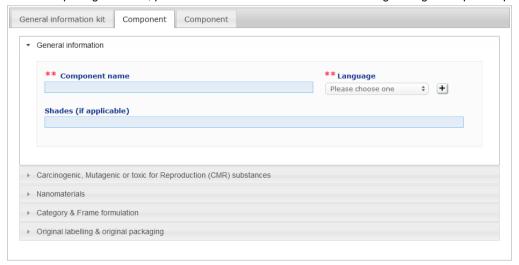
If you indicate that the product is a hair dye, CPNP will directly ask the pH range. The pH range cannot exceed 1 pH unit.



'Component' tabs

The first question is this:

The '**Component'** tabs allow you to provide information about each of the components separately (for guidelines about completing each tab, please refer to the same information relating to single component products p. <u>13</u>).



Except for the **Component name(s)** in one or more languages, the information to be entered in the **Component** tabs of a multi-component product is similar to the information requested in the **General information** tab of a single component product. So, for a description of the common fields, please refer to 'I. Notify a single component product', 'General information tab', p. 13).

Important

The **component name is a crucial element** of the notification, as it might be used by competent authorities or by poison centres to search for a specific component in the database.

Example:



The Marine HAIRCARE* kit contains 3 components:

- Component 1 Name (EN): HairShock Revitalising Mousse
- Component 2 Name (EN): HairShock Restructuring Fluid
- Component 3 Name (EN): HairShock Volumising Cream

(*)Disclaimer:

The product illustrated here is not a real product; the name and all its markings have been invented for the sole purpose of clarification.

The component name must be detailed enough to enable its specific identification.

Only in cases where the component has no name (e.g. certain make-up set components) the component name shall be understood as the description of the component that enables its specific identification.

By default 2 Component tabs are displayed, but additional ones can be added to the notification if necessary using the **Add component** button.

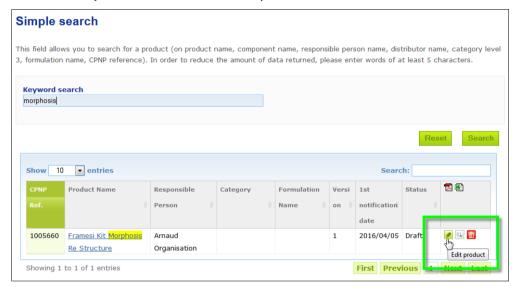
Editing Products

The **Edit product** option is available for Responsible Persons only. As Responsible Person, you can edit a notification that you have previously entered in the system.

• To edit a notification:

- 1. Perform a Simple or an Advanced Search to look for the desired product (see 'Using the Search Tools', p.51).
- 2. Either:

Click **Edit product** next to the desired product in the search result list:



Or:

Click on the desired product hyperlink in the 'Product Name' column of the search result list.

Or:

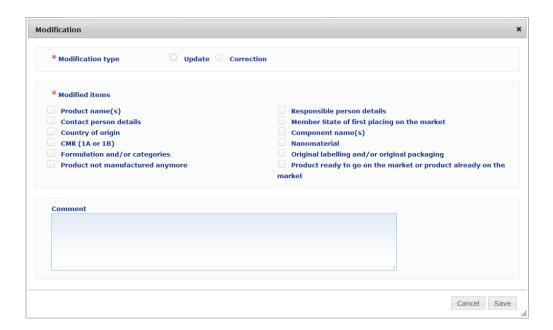
Click the View product next to the desired product in the search result list, and then click Edit on the product detail page.

3. Make the required changes and save.

Important

Where any of the information set out in paragraphs 1, 3 and 4 of Article 13 of Regulation 1223/2009 changes, the responsible person or the distributor shall update its notification **without delay**.

Once the change(s) made, the system will ask you to specify which type of modification you have made (update or correction) and which specific information was modified:



Important

It is important to make a **clear distinction between an update and a correction**. It is particularly important to make this distinction when it concerns the formulation.

An '**update**' of the formulation means a change of previously valid information. The original data are related to the older product formulation while the updated dataset relates to the <u>new</u> formulation. Poisons centre must evaluate both formulations in case they cannot reliably decide which formulation version is involved in an exposure case.

A '**correction**' of the formulation means change of <u>erroneous or incomplete</u> product information without changing the (real world) formula. Poisons centre need only evaluate the corrected dataset.

As a Responsible Person, you have the possibility to add some comments (in English only) in the lower free text box if you wish to provide further details on the modification that you made.

Click **Save** to notify the changes in the system. They will then be made available to Competent Authorities and Poison Centres.

Important

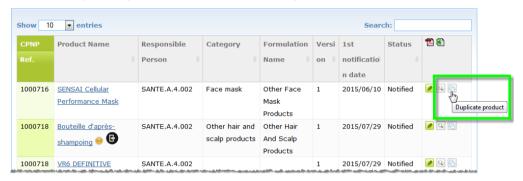
Only an update (not a correction) of the formulation and/or category will create a <u>new</u> version of a notification. All other changes will simply result in a new timestamp of the same version of the notification.

Duplicating Products

The **Duplicate product** option allows Responsible Persons only to duplicate products that they have notified. This may be useful when very similar products have to be notified separately i.e. you will not have to enter the same information again.

• To duplicate a product:

- Perform a Simple or an Advanced Search to look for the desired notified product (see '<u>Using the Search Tools'</u>, p.51).
- 2. Either:
 Click Duplicate product next to the desired product in the search result list:



Or:

Click on the desired product hyperlink in the 'Product Name' column of the search result list, and then click the **Duplicate product** button at the top or bottom of the product page

Or:

Click the View product next to the desired product in the search result list, and then click the **Duplicate product** button at the top or bottom of the product page.

Result: The duplicated product is displayed. CPNP duplicates all data except the answers to questions relating to ingredients of concern, attached labelling (and packaging where appropriate) and the Product ready to go on the market or already on the market checkbox.

3. Click Save as draft and make the required adjustments to the duplicated product.

Copying Products To Another Organisation

The Copy your products to another Responsible Person option in the Admin menu is used to copy a selection of your products to another Responsible Person (in case of merger, for instance). The selected products will then be copied to the designated Responsible Person's user interface, with new CPNP Product References, a DRAFT status and a special icon showing that they are coming from another Responsible Person. The recipient Responsible Person will then be able to edit these products with its own information. (All information is copied from the source, except for packaging and labelling information, and contact person details).

In your own interface, the original products will remain unaffected; there will be just another special icon indicating that they have been copied to another Responsible Person.

To copy products

- In the Admin menu, select Copy your products to another Responsible Persons.
- 2. In the **Search** box, enter either the unique ID of the Responsible Person to which you wish to copy products or the first letters of its name.

Result: A list of matching organisations is displayed:



3. Click on the desired organisation in the list to select it.

Result: The full name and address of selected organisation will show:



4. In the lower table, select the check boxes for each product to be copied:



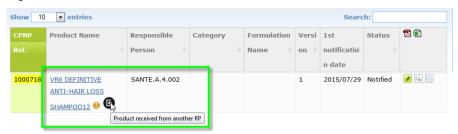
 Should you wish to copy products that you did already copy to another organisation in the past, please select the **Including products previously copied to another Responsible Person** check box. This will instantly refresh the lower list to include such products as well.

About Responsible Person IDs:

Every Responsible
Person is uniquely
identified by a systemassigned ID in CPNP.
This ID is part of a
Responsible Person's
profile and can be
consulted using the
Profile hyperlink in the
Top link bar (see p.10)

- 6. Click Copy products.
- 7. Answer the confirmation message.

Result: The selected products are immediately made available to the recipient Responsible Person in his CPNP user interface. A special icon (i.e. door with arrow pointing inside) appears next to those products to indicate that they come from another organisation:



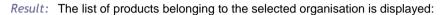
Simultaneously, another special icon is displayed next the products that you have copied to another organisation: (i.e. door with arrow pointing outside).

Moving Products To a Sub-organisation

The **Move products** option in the Admin menu is used to move one or more products from your organisation or one of its sub-organisations to another one of your sub-organisations or to your main organsiation. The selected products will then show as DRAFT in the designated Responsible Person's user interface, with the same CPNP Product References. Please note that all the information is copied, except for packaging and labelling information, and contact person details.

To move products

- 1. In the Admin menu, select Move products.
- 2. Pull down the **Choose the sub-organisation (FROM)** selection box and select the source organisation which currently owns the product(s).





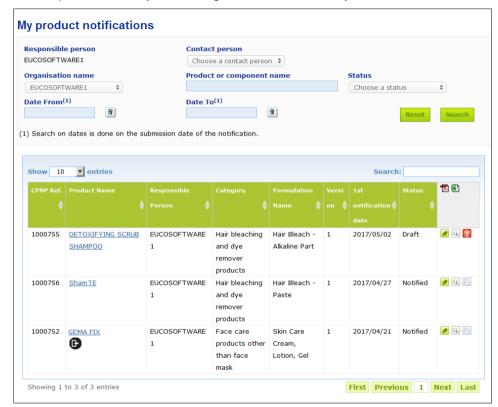
- In the right-most column of the list, select the check boxes for each product to be moved.
- 4. Pull down the **Choose the sub-organisation (TO)** selection box and select the organisation to which you wish to move the selected products.
- 5. Click Move products.

Result: The selected products are immediately made available to the recipient suborganisation.

Ensuring Follow-up Of Product Notifications

The **My notifications** option in the Products menu provides quick overviews of an RP's products for easy follow-up and management purposes.

- To consult your product notifications
 - 1. In the Products menu, select My notifications.
 - 2. By default, the *My product notifications* page displays a list of all Draft as well as Nofiied products from your RP/organisation, ordered by last modification date:



3. You can use the filter options in the upper section of the page to focus only on Draft or Notified products, products entered during a certain period, with a certain contact person, etc.

Viewing Product Details

To view the details of a product from a search result page, either click the desired *Product Name* hyperlink (this will open the product detail page in edit mode), or click the View Product.

In View mode, the <u>upper</u> section of a product detail page provides the product header. It contains the following information:

Product name: THE PRECISION LIQUID LINER

Product name (interface language): THE PRECISION LIQUID LINER

Responsible Person name: SANCO.A.4.002

CPNP Reference: 1000723

Date first notification: 07/12/2015 15:27:42

Current version: 1

Previous version(s): N/A

- product name;
- product name in the interface language;
- · responsible person name;
- CPNP reference i.e. the reference given by CPNP to the product;
- current version number (indicating the formula version, not the dataset version, see below);
- date of the first notification;
- previous version(s) of the product (if any).

The <u>lower</u> section of a product page depends on whether the product is a single or multi-component product.

Single-component products

The information available in the lowser section of a single-component product is organised in the following tabs:



General information

The 'General information' tab displays some general information on the product, e.g.:

- the CPNP reference;
- the industry reference (for industry's internal use);
- the version of the notification:
- the last modification date and time stamp;
- the product name(s), shades (if applicable) and corresponding language(s), given by the responsible person and by the distributors;
- the information on whether the product is specifically intended for children under 3 years of age;
- the responsible person details (at least name and address);
- the contact person details;
- the information on whether the product is ready to go on the market or already on the market;
- whether the product was imported in the Community (and if so, the country of origin):
- the Member State of first placing on the market.

Product details

The 'Product details' tab displays information on:

- the category of the product;
- the physical form of the product;
- the special applicator or packaging (if applicable);
- information on the pH of the product (if applicable);
- the **notification type** (*i.e.* predefined frame formulations, exact concentrations or concentration ranges):
- the information on ingredients of concern contained in the product (name and quantity % w/w).
 (Note: where 'not applicable' is indicated, the meaning is indicated in the right

column, i.e. **either** it means that the ingredient is **'not present'** in the product (in this case 0% w/w is indicated) or is present in the product but under the concentration of concern (in this case the concentration of concern is indicated));

- the **formulation name** (and formulation number in case of predefined frame formulation);
- a hyperlink to the **composition** of the product (predefined frame formulation, exact composition or composition with ranges);
- information on CMR substances of category 1A or 1B present in the product;
- information on substances in the form of nanomaterials present in the product;
- the original packaging of the product (accessible by clicking on);
- the **original labelling** of the product (accessible by clicking on);
- the original labeling of the product (text only).

Versions

If multiple versions exist for the same product, the 'Versions' tab indicates into brackets the number of versions available and displays information on these different versions of the notification (period of validity, type of change (update or correction) and reason for change.

The following buttons are available at the top and bottom right of each tab:

- Duplicate product allows you to duplicate the active notified product (see 'Duplicating Products', p. 36).
- Edit (available if you opened the product page with the View product icon) allows you modify the information about the product (see 'Editing Products', p.34).
- PDF allows you to create a PDF document for the notification.
- Back allows you to go back to the search screen.

Multi-component Products

The information available in the lower section of a multicomponent product is organised in the following tabs:



General information

The 'General information' tab displays some general information on the product, e.g.:

- CPNP reference i.e. the reference given by CPNP to the product;
- the industry reference i.e. the reference given by the industry to the product (for industry internal use);
- the version of the notification;
- the last modification date and time stamp;
- the product name(s), shades (if applicable) and corresponding language(s), given by the responsible person and by the distributors;
- the information on whether the product is specifically intended for children under
 3 years of age;
- the responsible person details (at least name and address);
- the contact person details;
- the information on whether the product is ready to go on the market or already on the market;
- if the product imported in the Community (and if yes, the country of origin);
- the Member State of first placing on the market;
- the pH of the mixed product (if appropriate)
- the **original packaging** of the product (accessible by clicking on);
- the **original labelling** of the product (accessible by clicking on):
- the original labeling of the product (text only)

Component

Each 'Component' tab(s) display(s) information on:

- the component name(s), shades (if applicable) and corresponding language(s), given by the responsible person and by the distributors, if any;
- the category of the component;
- the physical form of the component;
- the special applicator or packaging (if applicable);
- the notification type (i.e. predefined frame formulations, exact concentrations or concentration ranges);
- the information on ingredients of concern contained in the component (name and quantity % w/w). (Note: Where 'not applicable' is indicated, the meaning is indicated in the right column, i.e. either it means that the ingredient is 'not present' in the product (in this case 0% w/w is indicated) or is present in the product but under the concentration of concern (in this case the concentration of concern is indicated));
- a hyperlink to the **composition** of the component (predefined frame formulation, exact composition or composition with ranges);
- the formulation name of the component;

- information on CMR substances of category 1A or 1B present in the component;
- information on substances in the form of nanomaterials present in the component;
- · other information of significance for poison centres;
- optionally, the **original packaging** of the component (accessible by clicking on):
- optionally, the **original labelling** of the component (accessible by clicking on);
- optionally, the original labeling of the component (text only)

Versions

If multiple versions exist for the same product, the 'Versions' tab indicates into brackets the number of versions and displays information on these different versions of the notification (dates of validity, type of change (update or correction) and reason for change.

The following buttons are available at the bottom right:

- Duplicate product
 allows you to duplicate the active notification (see <u>Duplicating</u>
 Products', p. 36).
- (available if you opened the product page with the View product icon) allows you modify the information about the product (see 'Editing Products', p.34).
- PDF allows you to create a PDF document for the notification.
- Back allows you to go back to the search screen.

Managing Contact Persons

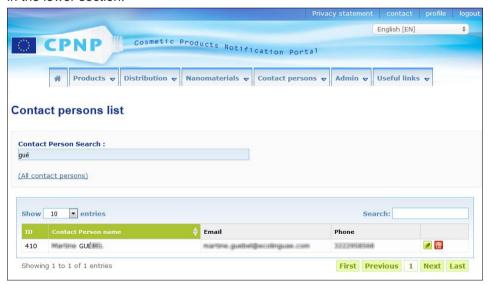
The **Contact persons** menu is available for <u>Responsible Persons **only**</u>. It is used to manage (i.e. create, edit, delete) all contact person associated to/that can be associated to notifications.



Every contact person that a user creates / modifies on a notification is immediately added to / modified in the Contact persons module, and vice versa. Every new Contact person is automatically allocated by a unique ID and is described by its name, postal address, phone and fax numbers and email address.

To consult the Contact persons details:

- From the Contact persons menu, select List.
- To look for a specific person, enter the first few characters (i.e. min.3 characters) of its name or surname in the search box. All matches will be listed in the lower section:



Or,

Select the Add contact persons hyperlink to display the list in full.

3. To edit a person in the list, click next to the person, make the appropriate changes, and then click **Save**.

Or

To delete a person, click and answer the confirmation message. (Please note that a Contact person can not be deleted if it is already used in connection with an existing notification. CPNP checks this when you save.)

• To add a new Contact person:

1. From the Contact persons menu, select New contact person.

Result: The Add contact person page opens:



- 2. Enter all required information about the new Contact person.
- 3. Click Save.

Result: The new Contact person is immediately available for use in notifications; simultanesouly, he/she will receive an e-mail with information on data protection.

Distributors Entering/Viewing/Editing Notifications (Article 13(3))

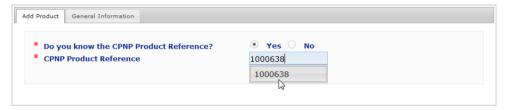
A Distributor who makes available in a Member State a cosmetic product already marketed in another Member State and, for that purpose, translates, at his initiative, any element of labelling in order to comply with national law is obliged to notify this in CPNP after finding the Responsible Person who first notified the product. All this information is managed in the dedicated Distribution menu.

Entering New Notifications Pursuant To Article 13(3)

- To enter a distribution notification, proceed as follows:
 - 1. Select Notify a product in the Distribution tab:



- 2. Select **Yes** or **No** to indicate whether you know the unique CPNP reference of the product that you wish to notify.
- 3. If you have selected 'Yes', enter the CPNP Product Reference in the next input box, and then select it in the list of matching Product References found in CPNP:



Or,

If you do not know the CPNP Product Reference and you have selected 'No' above:

 Enter (the first characters of the) name of the Responsible Person for the product that you want to distribute.

Result: Based on this information, CPNP will display a limited list of results of matching Responsible Person's name:



Select the Responsible Person from the list of matching results.

 Enter at least 5 characters of the searched product in the Product name in the Member State of dispatch box.

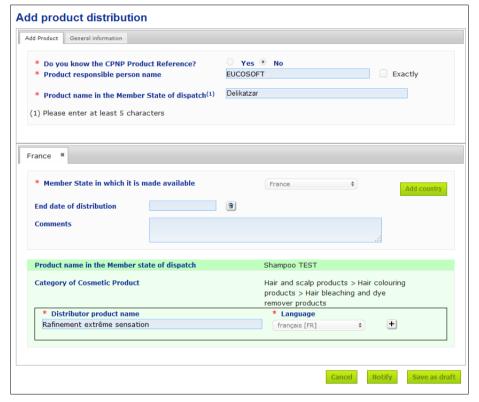
(The Member State of the dispatch is the country where the product was brought on the market by the Responsible Person).

Result: Based on this information, a limited list of matching product names is displayed.

- Select the desired product in the list of the proposed results.
- 4. Select the **Member State in which it is made available**. (The Member State where the product is made available is the Member State where you are bringing the product on the market).



- 5. Specify an End date of distribution if required.
- 6. In the **Comments** box, enter any comments or remarks about the distribution if necessary.
- 7. In the **Distributor product name** box, enter the name of the product as given by the distribtor in the selected country, in the specified language. (The same product in the same country can be distributed under different names in different languages):



- 8. If the product is distributed in more than one country, the system foresees a tab per country: click the **Add country** button to enter the translations per country.
- To save the notification as draft, click Save as draft.Or.

When the information on the distribution notification is complete, click **Notify** and confirm. The information will then be made available to Competent Authorities and Poison Centres. It will be linked to the original notification of the product being distributed. Please note that it will no longer be possible to delete the notification by that time. Only updates will be possible.

Consulting Notifications Pursuant To Article 13(3)



Using the dedicated **My notifications** option in the **Distribution** menu, Distributors can look for products/notifications based on any combination of the following criteria: Responsible Person name, CPNP Product reference, Member State in which the product is made available by the Distributor and/or Status of the related notification (i.e. 'Draft' or 'Notified):



Editing Notifications Pursuant To Article 13(3)

Once a search for notifications pursuant to Article 13(3) has been performed, click next to the notification that you wish to edit, update or correct, make your changes and then click **Save**.

Replying to CA/PIC Comments

Using the CAs/PICs Comments tab on a product notification page, national Competent Authorities and Poison Centres can raise points / initiate discussions with a responsible person in case they need any clarifications or have any queries or comments about the product at hand. Competent Authorities/Poison Centers can only see the discussions that they have personally initiated, as well as the feedback to these, given by the responsible person. Responsible Persons, on the other hand, are expected to provide feedback to any such comments left by national Competent Authorities and/or Poison Centres on the notifications that they are in charge of.

To reply to a comment:

 Either click the link in the comment received notification that you have received by email.

Or,

Perform a search and open the commented product to which you wish to reply.

- 2. Select the CAs/PICs Comments tab.
- 3. Click Reply next to the desired comment.
- 4. Type your reply in the Your Reply to (...) box.
- 5. Click Send.

Result: Your reply is added to the CAs/PICs Comments tab; simultaneously, an email is sent to Competent Authority or to the PIC who posted the comment.

Using the Search Tools

The **Products** menu offers 2 search options for finding products, organisations and notifications i.e.

- Simple search
- Advanced search

In addition to these standard product/notification search features, a dedicated Search option is available in the **Distribution** menu to look for a product/notification based on: i) the Product Name in the Member State where the Distributor made it available, ii) the Member State where the product is made available by the Distributor and/or iii) the status of the notification (i.e. 'Draft' or 'Notified).

Simple Search

The **Simple search** option in the **Products** menu allows you to quickly search for a notification using key words. To reduce the amount of data returned at least five characters must be entered and the number of results is limited to 100.



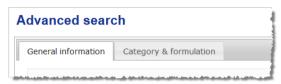
As a Responsible Person, you can find only notifications that you (or users acting on your behalf) have entered into the system. A Responsible Person with several users acting on his/her behalf can find any notifications entered by these users. A Responsible Person can search for draft and submitted notifications.

The Simple search searches on product names (including Distributed Product names), component names, responsible person names, distributor names, CPNP references, etc.

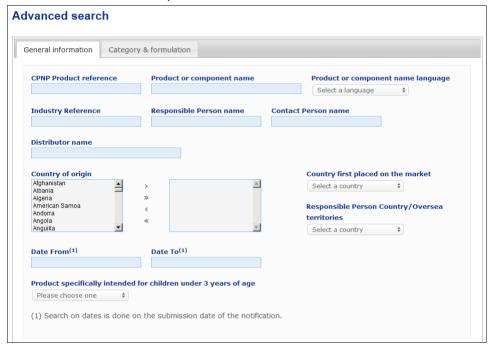
Advanced Search

The **Advanced search** option in the **Products** menu allows you to search products within CPNP by combining multiple search criteria.

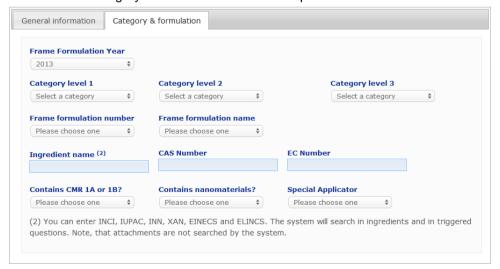
The Advanced search criteria are organized on two different tabs i.e. **General information** and **Category & formulation**:



• The **General information** tab allows you to search on the following general information criteria about the product:



• The Category & formulation tab allows you to search on the following criteria related to the category and the formulation of the product:



When multiple versions exist for a notification, any previous (i.e. historic) versions will show on a row with a grey background, and the word '**Old'** will appear in the Version'

column. The current version of a notification, on the other hand, is always displayed with a white background.

At the bottom right of each search, the Reset and Search buttons are available to either reset the search criteria or launch the search based on the criteria that you have entered.

Consulting Notifications

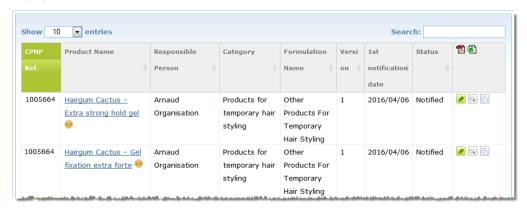
Once a simple search or an advanced search has been performed, CPNP will display a list of matching notifications:



When more than 10 results are found, they are distributed over a number of pages. Use the page browse button at the bottom of each page to quickly navigate from one page to another:



Please note that a product can appear on several lines with the same CPNP Ref. These are products for which the Name has been supplied in more than one language. In the example below, the same hair product appears in English and French:



Please note as well that the 'Category' column shows level-3 categories only.

Different symbols may appear for some notifications in the **Product Name** column. These include:

SYMBOL	MEANING
•	The original labelling of the product (and the photograph of the packaging, if reasonably legible) has not yet been notified. The product has therefore not yet been placed on the market.
Q	Some comments are available about the notification
B	The product has been transferred to another Responsible Person
E	The product received from another Responsible Person

You can further customise the number of results that you want to see on each page using the **Show** selection box at the top right of the page:



Two icons, i.e. and and available at the top right of the result table for exporting the list in PDF or XLS format.

Appendix

Rules On Specific Ingredients Of Concern And/Or pH Values

Rule 1 – Ethanol and/or isopropanol

The percentage weights (w/w) of ethanol and/or isopropanol must be specified for all products.

An updated notification is required when the content of either ingredient or the sum of both ingredients changes by more than:

- 5 if the value declared previously is < 30%
 Examples: A change from 20% of ethanol to 26% ethanol constitutes a change of 6 in the ethanol content in the formulation and therefore requires an updated notification.
 - A change from 20% of ethanol and 20% isopropanol to 23 % of ethanol and 24 % of isopropanol constitutes a change of 7 of the sum of ethanol and isopropanol in the formulation and therefore requires an updated notification.
- 10 if the value declared previously is ≥ 30%
 If ethanol or isopropanol are not present in the cosmetic product, then 'not applicable' must be checked.

Notes:

- declarations of percentage weights may be rounded to the nearest whole number
- if the percentage weight is below 1%, it can be specified as 1%.

Rule 2 – Antidandruff products

The INCI name and the concentration of the antidandruff agent(s) must be specified.

An updated notification is required when the concentration of the antidandruff agent changes by more than 20% of the value declared previously.

Rule 3 – Anti-hair loss products

The INCI name and the concentration of the anti-hair loss agent(s) must be specified.

An updated notification is required when the concentration of the anti-hair loss agent changes by more than 20% of the value declared previously.

Rule 4 – Skin lightening products containing anti-pigmenting and/or depigmenting agent(s)

The INCI name and the concentration of anti-pigmenting and depigmenting agent(s) must be specified.

An updated notification is required when the concentration of at least one agent changes by more than 20% of the value declared previously.

If anti-pigmenting and depigmenting agent(s) are not present in the cosmetic product, then 'not applicable' must be checked.

Rule 5 – Chemical exfoliation products containing chemical exfoliating agent(s) (e.g. lactic acid, glycolic acid, salicylic acid)

The INCI name and the concentration of chemical exfoliating agent(s) must be specified.

An updated notification is required when the concentration changes by more than 20% of the value declared previously.

Rule 6 – Products containing vitamin A and derivatives (e.g. retinol, retinyl esters)

The exact content of vitamin A or any of its derivatives must be specified if the level exceeds 0.20 % (calculated as retinol) or if the amount exceeds 0.09 grams (calculated as retinol) for the whole product.

An updated notification is required when the concentration of vitamin A or derivatives changes by more than 20% of the value declared previously.

If the level of vitamin A or any of its derivatives does not exceed 0.20% (calculated as retinol) or if the amount does not exceed 0.09 grams (calculated as retinol) or if vitamin A or any of its derivatives are not present in the product, then 'not applicable' must be checked.

Rule 7 – Products containing xanthine derivatives (e.g. caffeine, theophylline, theobromine, plant extracts containing xanthine derivatives e.g. Paulinia cupana (guarana) extracts/powders)

Should a product contain more than 0.5% xanthine derivatives, the INCI name and the concentration of the derivative(s) must be specified.

An updated notification is required when the concentration changes by more than 20% of the value declared previously.

If xanthine derivatives are not present or present below 0.5% in the cosmetic product, then 'not applicable' must be checked.

Rule 8 – Products containing cationic surfactants with three or four chains or groups with a length shorter than C12 (including straight, branched, cyclic or aromatic groups)

The INCI name and the concentration of these cationic surfactants must be specified if the surfactant is used for non preservative purpose.

An updated notification is required when the concentration changes by more than 20% of the value declared previously.

Typical examples for cationic surfactants covered by this rule are:

- behenalkonium chloride
- behentrimonium chloride
- · cetrimonium chloride
- dodecylbenzyltrimonium chloride

If cationic surfactants are not present in the product, then 'not applicable' must be checked.

Rule 9 – Products containing propellants

The INCI name and the concentration of each propellant must be specified.

An updated notification is required when either of these concentrations changes by more than 20% of the value declared previously.

If propellants are not present in the product, then 'not applicable' must be checked.

This rule concerns aerosol spray products and any other product which are presented in aerosol spray.

Other products may be presented in pressurized packaging but do not create aerosol sprays upon application. This needs to be indicated as 'pressurised container – non spray product' in the field for 'special applicator'. In this case an applicable Frame Formulation can be chosen for the product, even if it does not specifically mention propellants.

Rule 10 – Products containing or releasing hydrogen peroxide

The concentration of hydrogen peroxide and/or the INCI name and concentration of the compounds releasing hydrogen peroxide must be specified.

An updated notification is required when the concentration changes by more than 20% of the value declared previously.

If hydrogen peroxide and compounds releasing hydrogen peroxide are not present in the product, then 'not applicable' must be checked.

This rule concerns hair colorant products, hair bleach products, permanent wave products, and hair straighteners.

Rule 11 – Products containing reducing agents

The INCI name and the concentration of each reducing agent must be specified.

An updated notification is required when either of these concentrations changes by more than 20% of the value declared previously.

This rule concerns depilatories, hair dyes, dye removers and permanent wave products.

Examples for reducing agents typically used are:

- thioglycerin,
- thioglycolic acid and its salts (ammonium thioglycolate, ethanolamine thioglycolate)
- ammonium thiolactate
- cysteine HCI
- sodium sulfite
- sodium metabisulfite
- sodium hydroxymethane sulfonate
- sodium hydrosulfite
- alkaline and earth alkaline sulphides

If reducing agent(s) are not present in the product, then 'not applicable' must be checked.

Rule 12 – Products containing persulfates

The INCI name and the concentration of each persulfate must be specified.

An updated notification is required when either of these concentrations changes by more than 20% of the value declared previously.

If persulfate(s) are not present in the product, then 'not applicable' must be checked.

Rule 13 – Products containing hair straightening agents

The INCI name and the concentration of straightening agents must be specified.

An updated notification is required when either of these concentrations changes by more than 20% of the value declared previously.

Examples of straightening agents typically used include:

- sodium hydroxide, potassium hydroxide, lithium hydroxide
- potassium citrate
- calcium hydroxide
- guanidine carbonate
- reducing agents :
- · ammonium thioglycolate
- ammonium thiolactate
- cysteine HCI
- ethanolamine thioglycolate

Rule 14 – Bath salts/cubes containing inorganic sodium salts

The total concentration of sodium salts must be specified.

An updated notification is required when the total concentration of inorganic sodium salts changes by more than 20% of the value declared previously.

Rule 15 – Toothpastes and mouthwashes containing Fluoride compounds

The concentration of fluoride compounds (calculated as Fluorine), must be specified.

An updated notification is required when the fluorine concentration changes by more than 20% of the value declared previously.

If fluoride compounds are not present in the product, then 'not applicable' must be checked.

Rule 16 – Products with a pH lower than 3 or higher than 10, and pH of hair coloring products

The pH of <u>single-component products or individual component (except for hair</u> dyes) must be specified in the pH field if it is lower than 3 or higher than 10.

In the case of **multiple component products (except for hair dyes)** that are mixed prior to use, the pH of the mixed product must be specified in the respective pH field if it is lower than 3 or higher than 10.

It is acknowledged that different mixing ratios of components (e.g. to achieve different strengths) can lead to pH variations. In case the exact pH cannot be determined for the mixed product then the pH can be expressed in range form of no more than one unit (e.g. 9.5 – 10.5).

For the case of **single-component or multi-component hair dyes**, the pH must always be indicated, even if it is within the range of pH 3 to pH 10.

However given pH variations between color shades of the same product, the indication of an exact pH may not be relevant. For these products, the pH of the components and the mixed products can be expressed in range form of no more than one unit (e.g. 8.5 - 9.5)

In all cases above, an updated notification is required when the pH declared previously changes by more than 0.5.

For any product or component with a pH higher than 10, the INCI name and concentration of each alkaline agent, and – if applicable – ammonium hydroxide liberator must be specified.

An updated notification is required when either of these concentrations changes by more than 20% of the value declared previously.

Examples for alkaline agents typically used are:

- sodium/potassium hydroxide
- sodium/potassium carbonate
- sodium/potassium metasilicate
- calcium oxide
- · ammonium hydroxide
- ethanolamine
- · a typical ammonium hydroxide liberator is
- ammonium chloride

Rule 17 – Products containing essential oils, camphor, menthol or eucalyptol

Except for perfume and some limited other product categories, when a manufacturer introduces in a formula essential oils, camphor, menthol or eucalyptol with a total level higher than 0.5%, the total level concentration must be indicated.

If essential oils, camphor, menthol or eucalyptol are not present in the product or if the total level of essential oils, camphor, menthol and eucalyptol does not exceed 0.5%, then 'not applicable' must be checked.

For each individual essential oil and camphor, menthol or eucalyptol with a level higher than 0.5% (0.15 % in case of camphor), the manufacturer must state the name and quantity of this essential oil/essential oil derivative.

If no individual essential oil, camphor, menthol or eucalyptol are present with a level higher than 0.5% (0.15 % in case of camphor), then 'not applicable' must be checked.

An updated notification is required when the concentration changes by more than 20% of the value declared previously.

Rule 18 - Other Ingredients

In addition to the rules above, a number of substances have been identified by European Poison Control Centres as posing a particular concern with regard to an acute poisoning emergency.

The concentration, above the indicated threshold, of any of these ingredients in a formulation must be specified. If no threshold is indicated, the concentration must always be specified.

An updated notification is required when the concentration changes by more than 20% of the value declared previously:

Glycols and Glycol ethers

BUTETH-2 ACETATE (above 1%)

BUTOXYDIGLYCOL (above 1%)

BUTOXYETHANOL (above 1%)

BUTOXYETHYL ACETATE (above 1%)

DIETHOXYDIGLYCOL (above 1%)

DIPROPYLENE GLYCOL (above 10%)

DIPROPYLENE GLYCOL DIMETHYL ETHER (above 10%)

DIPROPYLENE GLYCOL ISOBORNYL ETHER (above 10%)

ETHOXYDIGLYCOL (above 1%)

ETHOXYDIGLYCOL ACETATE (above 1%)

GLYCOL (above 1%)

GLYCOL ETHERS (not polymers) (above 1%)

METHOXYISOPROPANOL (above 10%)

METHOXYISOPROPYL ACETATE (above 10%)

PPG-2 METHYL ETHER (above 10%)

PPG-2 METHYL ETHER ACETATE (above 10%)

PROPYLENE GLYCOL (above 10%)

PROPYLENE GLYCOL BUTYL ETHER (above 10%)

Hydrocarbons solvents

CYCLOHEXANE (above 5%)

HYDROGENATED DIDODECENE (above 5%)

ISOPENTANE (above 5%)

PENTANE (above 5%)

TOLUENE (above 5%)

TURPENTINE (above 5%)

Alcohols other than ethanol and isopropanol

BENZYL ALCOHOL (above 1%)

FURFURYL ALCOHOL (above 1%)

HEXYL ALCOHOL (above 5%)

N-BUTYL ALCOHOL (above 1%)

PROPYL ALCOHOL (above 1%)

T-BUTYL ALCOHOL (above 1%)

Others

ACETONE (above 5%)

BENZYL BENZOATE (above 1%)

BRUCINE SULFATE

BUTYL ACETATE (above 1%)

BUTYROLACTONE (above 0,1%)

BUTOXYETHYL ACETATE (above 1%)

CHLOROPLATINIC ACID (above 0,1%)

COPPER SULFATE (above 0,1%)

CYCLOHEXANONE (above 5%)

DIMETHYLTOLYLAMINE (above 0,1%)

ETHYL ACETATE (above 1%)

ETHYL ETHER (above 5%)

FORMALDEHYDE (above 0,2%)

HYDROXYLAMINE HCL: HYDROXYLAMINE SULFATE (above 1%)

M-CRESOL, O-CRESOL, P-CRESOL, MIXED CRESOLS (above 0,1%)

MEK (above 5%)

METHYL ACETATE (above 0,1%)

METHYL PYRROLIDONE (above 5%)

MIBK (above 5%)

POTASSIUM CHLORATE (above 0,1%)

SODIUM CHLORATE (above 0,1%)

TRIETHYL PHOSPHATE (above 0,1%)

The user should also notify in the dedicated field any other information on the product that would be of significance for Poison Centres or similar bodies, where such centres or bodies have been established by Member States (using English only).

Note: Frame formulations mentioning "AQUA" also cover products in which water is not added as such as an ingredient but through carry-over from aqueous plant extracts, fruit juices, etc.

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