

Information sheet product notification to the NVIC

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Nationaal Vergiftigingen Informatie Centrum

Product notification to the NVIC

The National Poisons Information Center (Nationaal Vergiftigingen Informatie Centrum, NVIC) informs medical personnel (physicians, veterinarians, pharmacists a.o.) about symptoms and treatment of acute intoxications. The NVIC information service can be contacted by medical personnel 24 hours per day, throughout the year, via the emergency number +31(0)30 274 8888.

To perform this task adequately the NVIC depends on knowledge of the exact composition and toxicological properties of products to which consumers can be exposed. This information sheet explains how you can notify product information to the NVIC.

European legislation

Article 45 of CLP Regulation (EC) No. 1272/2008 (replaces the Dangerous Preparations Directive 1999/45/EC on June 1st 2015) states that each EU Member State must appoint an authority where information regarding hazardous mixtures must be notified. The appointed authority is responsible for supplying information intended for medical purposes of a curative and preventive nature.

The legal obligation to notify product information also applies for biocidal products (according to the Biocides Regulation (EG) nr. 528/2012, article 73) and plant protection products.

Dutch legislation

In the Netherlands, the NVIC is appointed in the Food and Drug Act ‘Deponering informatie preparaten’ (*Staatsblad 1996, no. 38*) as the competent authority to receive information of hazardous products. If you introduce hazardous products on the Dutch market (both existing and new) you are obliged to notify information to the NVIC. Additionally, you also need to notify changes in trade name and changes in composition. Notification of date of market withdrawal is voluntary. The procedure of product notification is laid down in the Food and Drug Act ‘Warenwetregeling elektronische productnotificatie’ (*Staatscourant Nr. 15507* of 15 Oktober 2009).

The obligation to notify information of hazardous products to the NVIC will be checked within industry by the Netherlands Food and Consumer Product Safety Authority and the Human Environment and Transport Inspectorate.

We would like to ask you to notify information of products not classified as hazardous on a voluntary basis. This is especially appreciated for not classified household products, do-it-yourself products, biocides and plant protection products.

Product information notified to the NVIC will be treated in strict confidence and will not be communicated to third parties. The registration of product information is (still) free of charge.

Required product information quality

On the format of product information the NVIC accepts:

- a Safety Data Sheet (SDS) with
- additional information on the composition of the product (see requirements below).

The SDS and the additional information can either be notified as two separate documents or combined in an improved SDS. You can only notify these documents as pdf-files.

A complete composition (all ingredients without concentration threshold) of the product needs to be notified. There are three possibilities for notification of the ingredient concentration:

- *Optimal requirements*
 - Exact concentrations of all ingredients.
You should be aware that detailed information on the composition is essential to perform an adequate risk assessment in case of an accidental intoxication with a product.



- *Alternative requirements*
 - Exact concentration for ingredients classified for a health hazard according to the CLP Regulation (EC) No. 1272/2008. This corresponds approximately with the hazard classes T⁺, T, C, Xi, Xn according to the Dangerous Preparations Directive 1999/45/EC.
 - Defined concentration ranges (see below) for the other ingredients.
- *Minimum requirements*
 - Defined concentration ranges:
<0,1%, 0,1-1%, 1-5%, 5-10%, 10-20%, 20-30%, 30-50%, 50-75%, 75-100%
 - Alternative: <0,1%, 0,1-1%, 1-5%, 5-10%, 10-15%, 15-30%, 30-60%, 60-100%

The internationally accepted chemical names for the ingredients must be used with the corresponding CAS-numbers. Mentioning EINECS numbers and the hazard classification of each ingredient is optional, but valued.

In exceptional cases products can be notified in groups. For example with paints of different colours and almost the same composition. Please contact the NVIC beforehand.

Notification procedure

For the notification of product information the NVIC has developed a secure website:
www.productnotification.nl

With this secure website you can easily create a product upload list by entering the trade name, a reason for notification (new, mutation, expired) and adding the pdf-files by browsing on your computer. Please find more details on the use of the website in de FAQ part after logging in.

Receiving a user account

To receive a user account you can contact the NVIC by e-mail: productnotificatie@umcutrecht.nl

Please provide the following information:

Contact information (postal/residence address, telephone, fax, contact person) of:

- Company that brings the product to the market (mentioned on the product label).
- Company that notifies the product information (this will often be one and the same company).
- E-mail address on which to receive the account information.

You will receive a login name and a one-time password. After logging in with this one-time password you will be requested to choose your own password. You can then start with the product notification.

If a company notifies product information for several different companies (for example private-label customers) then multiple user accounts must be generated for every combination.

Bulk product notification

For a (first-time) notification of a large number of products the NVIC accepts the product information as pdf-files on CD-ROM/DVD or by E-mail. The files must be accompanied by an overview with information on trade names, reason of notification and accompanying pdf-files in a specific format (csv-file or txt-file). Please contact the NVIC for the requirements on the specific structure and format of this overview.

After this bulk notification you can keep the product information up to date by using the website.

Confirmation of receipt

After notification you will receive a confirmation of receipt by e-mail with an overview of notified product information. You can use this overview as proof of notification when checked by the Netherlands Food and Consumer Product Safety Authority or the Human Environment and Transport Inspectorate.



Important when notifying product information

Trade name

It is important that you mention the complete trade name as present on the label, without abbreviations and if relevant including brand name, product line and variant name. The use of general non-specific names such as 'all-purpose cleaner' or 'wiper fluid' should be avoided.

After exposure the physician will pass down the trade name as mentioned on the label and with this name the product information notified at the NVIC should be found.

Updating product information

By use of the website you can update product information (e.g. a composition change in a product) by selecting 'mutation'. It is important to:

- use the exact same trade name as in earlier notification(s) so the update will be linked to the correct product (you can select the complete trade name from the 'auto-complete list' that appears on input).
- renotify both the SDS and the additional information.

If you have notified incorrect product information you can contact the NVIC to solve this.



Other questions

Notification of Product Information of cosmetic products

Product information of cosmetic products can be notified by use of the Cosmetic Products Notification Portal (CPNP). The CPNP was developed by the European Commission for the implementation of Cosmetics Regulation (EC) No. 1223/2009. For more information, please see: http://ec.europa.eu/consumers/sectors/cosmetics/cpnp/index_en.htm

Use of the NVIC emergency phone number on product labels

The NVIC phone number may *not* be used on product labels because the NVIC only provides information to medical personnel in cases of acute intoxications and not to the general public.

Use of the NVIC emergency telephone number on SDS

According to Regulation (EC) No. 453/2010 (amending REACH Regulation (EG) nr. 1907/2006), it is mandatory to mention the emergency telephone number of the NVIC (030-2748888), as official advisory body responsible for receiving product information, on the SDS. As the NVIC is only available for medical professionals it is necessary to include the sentence: 'Only for the purpose of informing medical personnel in case of acute intoxications' or in Dutch: 'Uitsluitend bestemd om professionele hulpverleners te informeren bij acute vergiftigingen'.

The use of the NVIC emergency telephone number on the SDS is only of use if the product information is notified to the NVIC in accordance with the requirements as described in this document.

Product notification and use of emergency telephone number in EU Member States

For information on the notification procedure and product information requirements in other countries you can contact the 'appointed bodies' in those countries.

For EU Member States you will find an overview at (see paragraph 'Appointed Bodies'):
http://ec.europa.eu/growth/sectors/chemicals/poison-centres/index_en.htm

For information on the use of the emergency telephone number on the SDS in EU Member States:
<http://echa.europa.eu/web/guest/support/helpdesks/national-helpdesks/list-of-national-helpdesks>

Introduction of products on the Dutch market

For specific questions regarding the introduction of products on the Dutch market you can contact the Netherlands Food and Consumer Product Safety Authority, www.nvwa.nl or your own trade organization.

Compilation of the SDS

For questions on the compilation of an SDS you can contact the Netherlands Food and Consumer Product Safety Authority, www.nvwa.nl or your own branch organization.

Contact

For further information you can contact the NVIC by telephone (0031(0)88 755 8561), by postal mail (NVIC, Huispostnummer B.00.118, PO BOX 1, 3508 GA Utrecht, The Netherlands) or E-mail (productnotificatie@umcutrecht.nl).

