

The notification procedure for hazardous substances and mixtures

Hazardous mixtures and substances shall currently be notified in Hungary according to Act No. XXV of 2000 on chemical safety (hereinafter referred as Act) **via the online notification system OSZIR**. Notifications by email or post will not be accepted.

To gain access to the OSZIR system, **registration is required on the webpage: www.antsz.hu** by clicking on ‘OSZIR’ and choosing the option “KB31: Chemical Safety Notification” on registration, allowing you to submit hazardous substance or hazardous mixture notifications to the Hungarian poison centre. The system can be used with your user name and initial password which you receive within a few days of the registration.

It is important to note that, **for the registration, the company name, address, tax number of the company on whose behalf you intend to submit notifications shall be provided**. It is not a requirement for the registered/notifier company to have legal personality in Hungary. Please fill in the registration form according to our attached guide in which you will also find screenshots for your convenience.

It is to be highlighted that in the OSZIR system the term “*partner*” means the notifying company (itself) whose username and password you use to login into the system.

Please note that **notifications can only be initiated/submitted** in the OSZIR system **after the partner/company details have already been given in the submenu “Partner adatok karbantartása”** (Maintenance of partner details) of the menu “*Karbantartás*” (Maintenance). As a first step, please enter and save the company details (addresses, responsible person and contact information) according to the attached guide. We would like to highlight that it is mandatory to provide a telephone number, e-mail and fax number; you will not be able to submit notifications without these.

In accordance with §6 of the Act, companies, which manufacture/produce, import or distribute any kind of hazardous substances or mixtures in Hungary, have the obligation to notify their hazardous chemicals to the National Public Health Center (NPHC) at the beginning of their operation, **unless the same substance or mixture has been notified previously**.

This means that a hazardous substance identified by the same CAS number or a hazardous mixture identified with the same trade name does not need to be notified to the OSZIR system more than once. In case you try to notify a hazardous substance or mixture which has already been notified in our database, the procedure will be terminated and the notification will be deleted from the OSZIR system.

In order to avoid unnecessarily initiated notifications, which have to be terminated, it is advisable (but not mandatory) **to require information** (via ettsz@nnk.gov.hu e-mail address) **before submitting a notification for a "new" product**. Requesting this information is free of charge.

As in Hungary the online database of the hazardous mixtures is based on the trade name of the products, if you request such information from the ETTSZ, please provide the exact trade name of the hazardous mixture as it appears in section 1.1 of the SDS (safety data sheet). In case of substances, the CAS number of the hazardous substance should be provided.

According to §3 of the Act, those substances and mixtures which can be classified in any hazard classes or categories in line with the classification criteria of Regulation No 1272/2008/EC (CLP) are considered to be hazardous. **Only hazardous substances or mixtures have to be notified**. (The indication of any EUH-phrases, in itself, does not imply a hazardous classification.)

In line with §2 (3) of the Act, **the above applies to all hazardous substances and mixtures except for the following:**

- a) Medicinal products, veterinary medicinal products, products and substances considered as medical devices,
- b) Psychotropic substances, narcotics, drug precursors,
- c) Cosmetic products,
- d) Substances and mixtures classified as waste,
- e) Radioactive substances and mixtures,
- f) Food stuffs as defined in Regulation (EC) No 178/2002
- g) Feeding stuffs as defined in Regulation (EC) No 178/2002
- h) Pesticides,
- i) Other hazardous substances and mixtures for which notification, authorization or other administrative procedures are specified by other legislation provided that the requirements of those legislations are in line with this Act.

The telephone number of the Hungarian official advisory body is +36-80-20-11-99. This is a toll free, 24 hours' service maintained by the “*Egészségügyi Toxikológiai Tájékoztató Szolgálat*” (ETTSZ) (“*Health Toxicological Information Service*” (HTIS) in English). **This telephone number has to be included in section 1.4 of every Hungarian safety data sheet** and there is no need to ask any permission for its inclusion. In addition to the above mentioned information the supplier has the opportunity to indicate a reference to its own emergency service(s) in this sub-section, as well.

According to §2 (1) of *Decree No. 1/2009. (I.30) of the Minister of Health on the fees payable for the administrative procedures and services of the National Public Health and Medical Officer Service* **the notification of hazardous substance/mixture is subject to an administration and servicing fee.** The current fee of notification is *9,200 HUF per each substance or mixture* (See V.3. of Annex 1) which **must be present** in our account after deduction of bank charges.

The fee shall be paid to NPHC upon initiating the notification. Please be informed that we can accept transactions in Hungarian Forint (HUF) only. You can use the “*payment order for foreign currency*” in order to initiate the transaction.

We draw your attention that it is possible to pay the administration and servicing fee also by **credit card** not only by bank transfer. Payment by credit card is going to cause no additional cost (bank charges and deductions). In this case you have to choose „*Bankkártyás fizetési mód*” (Payment by credit card) option instead of „*Egyéb fizetési mód*” (Other payment) in our online notification system (OSZIR) when you indicate the new notification.

Please note that the administration and servicing fee is payable for conducting the procedure (regardless of the result of the procedure), so there will be no refund of the fee even if the procedure ends with termination and the notification will be deleted for any reason.

The bank details of the NPHC are as follows:

- Bank account number: 10032000-00290438-00000000
- VAT number: 15598787-2-43
- SWIFT-BIC code: HUSTHUHB
- International bank account number (IBAN): HU55-10032000-00290438-00000000
- Name of Bank: Hungarian State Treasury (MÁK - Magyar Államkincstár)
- Bank address: 1139 Budapest, Váci út 71.

The notification of a hazardous mixture is considered complete, if the Hungarian Safety Data Sheet (SDS) has been attached, the administrative fee has been paid and the certificate has also been attached.

The notification of a hazardous substance must include a draft label in addition to the above mentioned documentation.

It is important to know, that the name of the product in the notification has to be the same as those given in the attached documents.

According to paragraph (1) of §6 of the *Act* the notifier **companies have the obligation to update their previously accepted notifications, if the SDS of the notified product changes**. The update notification is free of charge.

It is important to know that **in Hungary hazardous products are identified by their trade name**. If the trade name of the product notified already in the OSZIR system changes, due to the fact that the trade names of the products have been changed by any reason, new notifications are needed.

Furthermore we would like to call your attention that **a representative in charge with the notification of hazardous mixtures intended to be placed on the Hungarian market acting on behalf of a company shall be able to demonstrate his/her proxy**, if it is not included in the provision register, according to paragraphs (1)-(2) of § 14 of Act No. CL of 2016 *on the General Administrative Order* (Ákr). The proxy shall be included in an authentic instrument or a private document of complete probative value or shall be recorded, and a scanned copy of that document shall be attached to the system. If the proxy does not indicate otherwise, it shall be considered a general one, covering all the declarations and actions relating to the proceedings. The proxy has to be sent to the following address: bejelentes@nnk.gov.hu.

In case of a non-complete request (see above: Hungarian SDS, certificate of payment of the administrative fee, if applicable attachment of a copy of the document about the proxy, draft label, etc.), the authority will order the notifier to amend his notification or make a declaration within a reasonable time given by the authority. Such an order can only be issued once.

If the applicant fails to comply with the request for amending the notification and/or making a declaration within the deadline set, the authority will terminate the procedure. If it is found that the notification has been incorrectly submitted after the order to amend, the procedure will also be terminated.

Once the submission is complete the notification will be confirmed by changing its status into 'registered' ("Nyilvántartásba vett"). The notifications included in the system can be printed out but no separate certificate is needed to be issued to verify the registered status of the notifications. **The accepted notifications are valid without time limit. In case of any deficiency, we will inform the notifier through an official decision which can be found attached in the online system, but we also send it by post.**

Please note that Annex VIII to CLP, harmonising the requirements for notification of hazardous mixtures, require changes to the above-mentioned national legislation on chemical safety. Until the relevant application date of Annex VIII, which is expected on 1 January 2021, notifications shall be made in accordance with the current national legislation (in particular, §6 of the Act and §3 of Decree No. 44/2000 of the Minister of Health). However, in Hungary, submissions can be made voluntarily via the designated ECHA portal, expected to be available from the second half of 2020, after the relevant amendment of the Act has been adopted and the PCN Portal has gone fully operational.

If you have any further question regarding to the notification of hazardous substances and mixtures or biocidal products, do not hesitate to contact us on the following email address: bejelentes@nnk.gov.hu. However, if you have technical problem with the registration or the login to the system, please contact jogosultsag@nnk.gov.hu