

Guidelines

Reporting and notifying new substances in the Product Register for Chemicals (RPC)

www.rpc.admin.ch

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Version: 17.8.2022

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1. Introduction

The manufacturer¹ of new substances who places them on the market in Switzerland in quantities of 1 tonne or more per year must notify the new substance before **placing it on the market for the first time** in Switzerland (Art. 26 ChemO)

The manufacturers of new substances that, in accordance with Art. 26 ChemO para. 1 let. ac, are exempted from the obligation to notify, shall, independently of whether a safety data sheet must be compiled for them, report them to the Notification Authority for Chemicals within three months after first placing them on the market (Art. 48, Art. 19 ChemO).

The notification as well as the report must be submitted in an electronic format. (Art. 27 para. 1 and Art. 51 ChemO). Notifications may be submitted, reports must be submitted via the RPC portal (www.rpc.admin.ch).

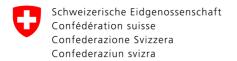
2. Requirements for the submission via RPC

- 1. Personal user account in the RPC
- 2. Linkage of the user account with the reporting company
- 3. Review of whether a notification or reporting obligation exists (self-regulation)

3. Resources

1. Safety data sheet for the substance

¹ A manufacturer means any person who manufactures, extracts or imports substances, preparations or objects in a professional or commercial capacity. Art. 2 para. 1 let. b no. 1 ChemO (SR 813.11)



2. Introductory course: Reporting in the public product register for new reporters but not obligatory. (See the links at the end of this document)

4. Reporting acc. Art. 48/Notification acc. Art. 24

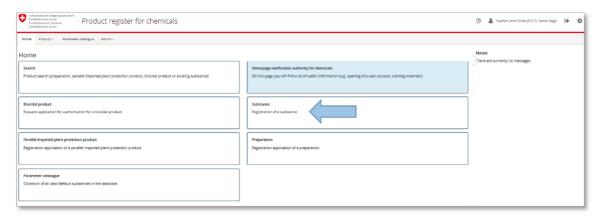


Fig. 1

After having logged in click on the button Substance to reach substance reporting

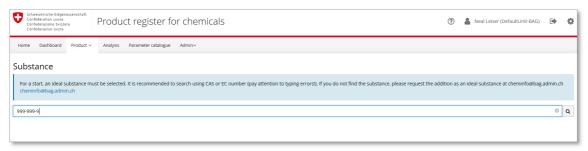


Fig. 2

Search for the substance by entering a number (EC/List number/CAS/PAID) in our database. Text searches are also supported.

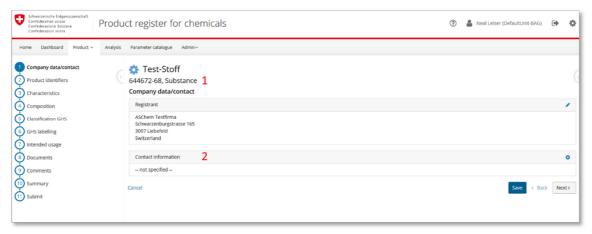


Fig. 3

- 1) The CPID is generated as soon as you save for the first time.
- 2) Key in contact information and correspondence language.

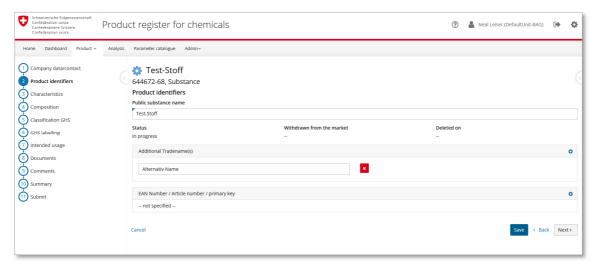


Fig. 4

The report of new substances or their entries in the Product Register for Chemicals are not public and cannot be found in a search by third parties.

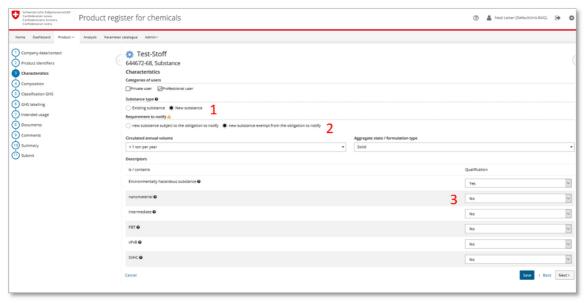


Fig. 5



Fig. 6

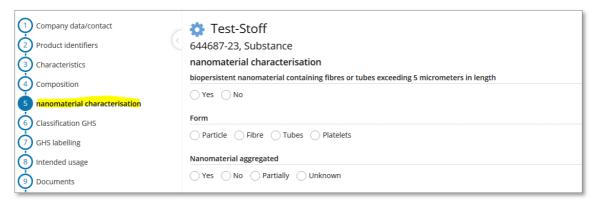


Fig. 7

Fig. 5, 6 and 7

- 1) Choose the substance type New Substance
- 2.1) When reporting acc. to Art. 48 (<1tpa) choose New substance subject to the obligation to notify.
- 2.2) When notifying acc. to Art. 24 (>1tpa) choose **New substance exempt from the obligation to notify**; additional fields will then appear for completion (Fig. 6):
 - Art. 29 ChemO new notifier: You refer to the notification by another notifier, and in the case that the data protection period acc. to Art 30 ChemO has not expired, you provide a letter of access (documents).
 - Sole representative: The supplier based abroad can designate you as the sole representative (a list of all importers and quantities of substances has to be submitted). The importer informs the sole representative annually of the imported quantities.
 - Additional information: You update your notification, for example on exceeding a threshold (Art. 47 ChemO).
- 3) By choosing the **descriptor Nanomaterials** you will be required to furnish additional data (Art. 49 let. c no. 7 ChemO). The **Wizzard-Step (5) Characterisation of Nanomaterials** will be inserted. (see Fig. 7)

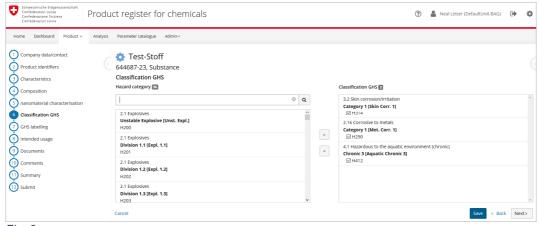


Fig. 8

No harmonised minimum classification is given. The classification acc. to CLP EC 1272/2008 has to be keyed in by you. Help for this may be for example the safety data sheet Section 2 for the substance or Section 3 of the SDS of the preparation, in which the substance in question is comprised.

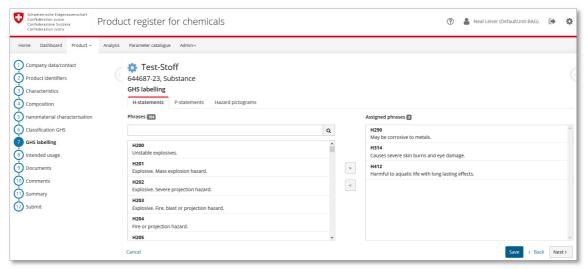


Fig. 9

The labelling acc. to CLP EC 1272/2008 is not taken over from the classification (**Wizzard-Step Classification**). Please key it in here as well.

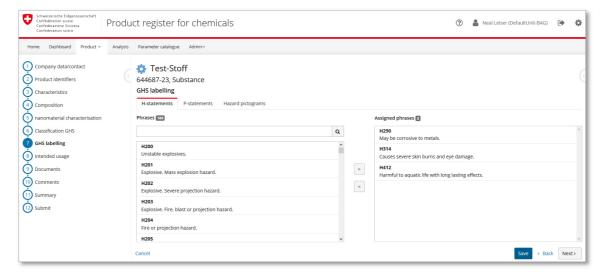


Fig. 10

Reporting acc. to Art. 48 ChemO does not require any additional documents. However, you may upload any additional documentation here (e.g. SDS). For a notification acc. to Art. 24 ChemO there are minimum requirements for documentation and files to be submitted, in particular an IUCLID export file that has to be uploaded under "Documents". Please consult the guidelines in chapters 5 and 6 of (Guidelines for notification, reporting and declaration of new substances in accordance with the Swiss ChemO).

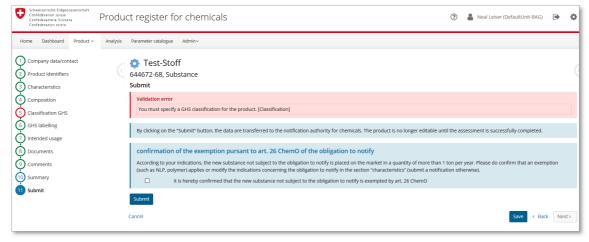


Fig. 11

On reaching this step a validation is carried out and any inconsistences will be shown. When all errors have been eliminated enter the dataset by clicking the button **Submit**.

5. What happens after the reporting/notification?

Reporting: If the automatic validation has not found any error then the **entered** dataset is shown as **Qualified** and the reporting is thus terminated.

Notification: The dataset is given the status *under examination*. The submitted documents are subjected to an initial examination. If everything is complete then a written confirmation of receipt will be sent to the notifier and the dossier transmitted from the notification authority for chemicals to the assessment authorities for the scientific examination. The authorities have a period of 60 days in which to review the application (Art. 40 ChemO). The period begins on the day after the complete technical dossier is received by the notification authority for chemicals (taking into account any standstill period according to Art. 22a of the Administrative Procedure Act, APA, SR 172.021). It ends at the end of the last day of the period.

At the end of the assessment the notification authority for chemicals makes a ruling and sends an invoice to the manufacturer (or sole representative).

If within the period the notification authority for chemicals has not adopted the notification or has not issued any material response to the notification then the substance may be placed on the market after the expiry of the period (Art. 40 let. b ChemO).

4. FAQ

How do I know whether my substance is subject to obligatory notification or not?

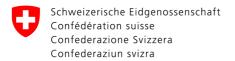
According to article 4, paragraph 1, letter a of ChemA, new substances are defined as those which are not existing substances.

An existing substance is a substance registered under Article 5 REACH, with the exception of substances that:

- are placed on the market in higher quantities than those registered in the European Economic Area (EEA); or
- are registered exclusively as intermediates, insofar as they are not monomers; (art. 2 par. 2 let. f ChemO).

If you now determine that the substance is a new substance, you have to notify it according to Art. 24 ChemO prior to placing it on the market if the amount of substance placed on the market is more than 1 tonne per year and no exemption pursuant to Art. 26 ChemO applies. If an exemption pursuant to Art. 26 ChemO can be validated, the new substance has then to be reported according to Art. 48 ChemO within 3 months after the first placement on the market.

See also under the links: <u>"How do I recognise a new substance?"</u> and <u>"General map of obligations for substances"</u> and <u>Guidelines for notification, reporting and declaration</u> of new substances in accordance with the Swiss Chemicals Ordinance



Is the notification subject to a fee?

Yes. The fees are specified in the Chemicals Fees Ordinance (ChemFO, SR 813.153.1) and depend essentially on the quantity placed on the Swiss market. An overview of the currently applied fees can be found in the <u>Guidelines for notification, reporting and declaration of new substances in accordance with the Swiss ChemO</u> (see links). Invoicing is made after a notification has been accepted.

Is the reporting subject to a fee?

No.

I obtain my substance from a trader in Switzerland. Am I subject to the obligation to notify or reporting?

No. The trader who places the substance on the market has to fulfil the obligation to notify or reporting. According to Art. 4 para. 1 let. i of the Chemicals Act (ChemA, SR 813.1), placing on the market is "providing for or supplying to third parties and importing for professional or commercial purposes".

I am placing the new substance not as such on the market but rather in a preparation that I have already notified in the Product Register Chemicals. Must I then separately notify this new substance?

Yes. cf. Art. 24 para. 1 ChemO.

New substances exempted from the notification requirement, on the other hand, are only subject to reporting under Art. 26 para. 3 ChemO if they

- are placed on the market as such and
- are classified as hazardous, PBT² or vPvB³

5. Links

Opening a user account

https://www.anmeldestelle.admin.ch/chem/en/home/themen/pflicht-hersteller/chemikalienregister-rpc/eroeffnung-benutzerkonto.html

- Introductory course: Reporting in the public product register for new reporters

 https://www.anmeldestelle.admin.ch/chem/en/home/aktuelle/kurse.html
- How do I recognize a new substance?

https://www.anmeldestelle.admin.ch/chem/en/home/themen/pflicht-hersteller/stoffe/neuer-stoff/neue-stoffe-kurz-erklaert/erkenne-einen-neuen-stoff.html

Guidelines for notification, reporting and declaration of new substances in accordance with the Swiss Chemicals Ordinance

https://www.anmeldestelle.admin.ch/dam/chem/en/dokumente/wegleitung-

 $^{^2}$ Substances are considered persistent, bioaccumulative and toxic (PBT) if they fulfil the criteria defined in Sections 1.1.1–1.1.3 of Annex XIII to the REACH Regulation.

³ Substances are considered very persistent and very bioaccumulative (vPvB) if they fulfil the criteria defined in Sections 1.2.1 and 1.2.2 of Annex XIII to the REACH Regulation.

anmeldungen-meldungen-mitteilungen-neuer-stoffe-chemv-schweiz.pdf.download.pdf/Wegleitung_NS_EN.pdf

General map of obligations for substances



https://www.anmeldestelle.admin.ch/dam/chem/en/dokumente/uebersicht-der-pflichten-bei-stoffen.pdf.download.pdf/Uebersicht_der_Pflichten_bei_Stoffen_E.pdf