



## Online document

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19 July 2022

Further information:

Notification Authority for Chemicals

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# Existing and new substances in Switzerland based on the 1 May 2022 version of the Chemicals Ordinance

### Prepared by:

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- the Chemical Products Division of the Federal Office of Public Health (FOPH)

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### Further information:

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## 1 Introduction

In the Chemicals Act (ChemA; SR 813.1, Art. 6), it is specified that “existing substances” may be placed on the market without the prior consent of the authorities, subject to compliance with the provisions concerning self-regulation.<sup>1</sup>

An existing substance is defined (Art. 2 para. 2 let. f ChemO) as a substance that is registered in accordance with Article 5 of Regulation (EC) No 1907/2006 (REACH Regulation),<sup>2</sup> with the exception of substances that:

1. are placed on the market in larger quantities than those registered in the European Economic Area (EEA), or
2. are registered solely as intermediates,<sup>3</sup> unless they are monomers.

All substances not falling under the definition of existing substances are deemed to be new substances (cf. Art. 4 para. 1 let. a ChemA). In contrast to existing substances, manufacturers<sup>4</sup> of a new substance or their only representative must notify the new substance to the Notification Authority before placing it on the market<sup>5</sup> for the first time:

- a. on its own;
- b. in a preparation; or
- c. in an object from which the new substance may be released under normal or reasonably foreseeable conditions of use.

## 2 Obligation to notify and status: existing and new substances

Under the self-regulation system (Art. 5 ChemO, SR 813.11), manufacturers (including importers) are required to determine the identity of substances themselves. For this purpose, they must collect all accessible information. Here, the ECHA [Guidance for identification and naming of substances under REACH and CLP](#) may be useful.

See also Section 2.2 below.

If the manufacturer now determines that the substance is a new substance, he must notify it in accordance with Art. 24 ChemO before placing it on the market if the substance quantity placed on the

<sup>1</sup> <https://www.anmeldestelle.admin.ch/chem/en/home/themen/pflicht-hersteller/selbstkontrolle.html>

<sup>2</sup> Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, OJ L 396, 30.12.2006, p. 1; last amended by Commission Regulation (EU) 2021/2204, OJ L 446, 14.12.2021, p. 34.

<sup>3</sup> *Intermediate* means a substance manufactured and used solely for chemical processing during which it is transformed into one or more other substances.

<sup>4</sup> In the ChemO (Art. 2 para. 1 let. b), the term *manufacturer* is defined as:

1. any natural or legal person domiciled in Switzerland or with a registered office or branch in Switzerland, who manufactures, extracts or imports substances, preparations or objects in a professional or commercial capacity,
2. also deemed to be a manufacturer is any person who obtains substances, preparations or objects in Switzerland and supplies them on a commercial basis, without altering their composition:
  - under his own name, without specifying the name of the original manufacturer
  - under his own trade name
  - in packaging other than that provided by the original manufacturer
  - for a different intended use, or
  - at a location in whose official language labelling has not been effected by the original manufacturer in accordance with Article 10 paragraph 3 letter b,
3. a person is deemed to be the sole manufacturer if he arranges for the manufacture of a substance, preparation or object in Switzerland by a third party, and if he is domiciled or has a registered office or branch in Switzerland; if he has neither his domicile, a registered office or branch in Switzerland, the third party is the sole manufacturer.

<sup>5</sup> *Placing on the market* means providing for or supplying to third parties and importing for professional or commercial purposes (Art. 4 para. 1 let. i Chemicals Act; ChemA; SR 813.1).

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market exceeds 1 tonne per year and none of the exemptions specified in Art. 26 ChemO are applicable.

<https://www.anmeldestelle.admin.ch/chem/en/home/themen/pflicht-hersteller/stoffe/neuer-stoff/ausnahmen-anmeldepflicht.html>

### 2.1.1 *General exemptions from the obligation to notify*

Substances and groups of substances regulated by specific legislation are excluded from the scope of the ChemO (Art. 1 para. 5 and 6 ChemO). This applies to:

- a. the transport of substances and preparations by road, rail, water, air or pipelines;
- b. the transit of substances and preparations under customs supervision, provided that this does not involve any processing or transformation;
- c. substances and preparations in the form of finished products ready for supply to private and professional users that fall into the following categories:
  1. foodstuffs as defined by Article 4 of the Foodstuffs Act of 20 June 2014,
  2. medicinal products as defined by Article 4 paragraph 1 letter a and medical devices as defined by Article 4 paragraph 1 letter b of the Therapeutic Products Act of 15 December 2000,
  3. animal feedingstuffs as defined by Article 3 paragraph 1 of the Feedstuffs Ordinance of 26 October 2011.
- d. weapons and ammunition as defined by Article 4 paragraphs 1 and 5 of the Weapons Act of 20 June 1997;
- e. substances, preparations and objects which are waste according to Article 7 paragraph 6 of the EPA.
- f. Articles 57, 62 (storage) and 67 (theft, loss, erroneous placing on the market) ChemO apply to imported substances and preparations that are simply relabelled and then exported without alteration. Dangerous substances and preparations that are exported are also governed by the PIC Ordinance of 10 November 2004.

### 2.1.2 *Biocidal products and plant protection products*

New substances that are used exclusively as active substances and co-formulants in plant protection products, or as active substances in biocidal products, are exempt from the notification obligation, as they are already subject to an evaluation procedure and the products to an authorisation procedure.

### 2.1.3 *Cosmetic products*

Only Articles 5–7 (self-regulation, classification) and 81 (review of self-regulation) ChemO apply to cosmetic products within the meaning of Article 53 paragraph 1 of the Ordinance of 16 December 2016 on Foodstuffs and Utility Articles in the form of finished products intended for private or professional users, and only with regard to environmental protection and to classification or assessment in relation to risks to the environment (Art. 1 para. 4 ChemO).

### 2.1.4 *Other cases in which notification is not required*

In addition, notification is not required (Art. 26 para. 1 ChemO) for:

- a. polymers or substances contained as monomer units or chemically bound to the polymer in a concentration of less than 2 per cent by weight;
- b. *repealed*
- c. substances placed on the market in quantities of less than 1 tonne per year;
- d. substances placed on the market by a manufacturer:
  1. exclusively for product and process-orientated research and development purposes,
  2. in quantities not exceeding those required for the specified purpose, and

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3. for a period not exceeding five years; in response to a justified request, the Notification Authority may, in consultation with the assessment authorities, extend this period by an additional five or ten years;
- e. substances used exclusively as raw materials, active ingredients or additives in foodstuffs, therapeutic products and animal feedingstuffs;
- f. substances obtained in Switzerland;
- g. intermediates, provided that they are not monomers;
- h. substances listed in Annex IV or Annex V to the REACH Regulation;
- i. substances already notified and exported by the manufacturer, and re-imported by the same or another manufacturer in the same supply chain who can show that:
  1. the substance being re-imported is the same as the exported substance,
  2. he has been provided with a safety data sheet in accordance with Article 20 for the exported substance, if this is required under Article 19.

## **2.2 How is it to be determined whether a substance on its own or in a preparation is an existing substance?**

If the substance is obtained from the EEA, the importer can request confirmation from the chemical manufacturer in the EU that the substance is registered in the EU with the registration type “Full”<sup>6</sup> or “NONS” and the registration status “Active”, with the registered tonnage band being indicated. It is thus demonstrated that the substance in question is an existing substance.

If a substance is manufactured in Switzerland or obtained from a non-EEA country or via the EU as a transit good, the manufacturer (or importer) must check whether the substance falls under the above-mentioned definition of an existing substance given in the ChemO.

Three criteria must be met:

1. The substance is registered.
2. The substance is not registered exclusively as an intermediate.
3. The substance may not, without being notified, be placed on the market in quantities higher than the tonnage band in which it is registered in the EU.

On the European Chemicals Agency (ECHA) website, a search can be carried out for the registration status of the substance using the CAS number or EC/List number at <https://echa.europa.eu/en/information-on-chemicals/registered-substances> and at <https://echa.europa.eu/en/information-on-chemicals> (see below: “How to search for registered substances on the ECHA website”).

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<sup>6</sup> There are four types of registration: Full registration, Intermediate registration, NONS notification (Notified New Substance, i.e. a substance notified under the previous EU legislation) and NA (not assignable; at the time of publication, only one substance could not be classified).

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## How to search for registered substances on the ECHA website

Under “Substance identity” in the [Registered Substances Factsheets](#) section of the ECHA website, you can search for registered substances either by substance name or by EC/List number or CAS number.

PLATFORM

**REACH - Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation**  
Registered Substances Factsheets  
Substances which have been registered and can be placed on the EEA market by those companies with a valid registration

[ALL SUBSTANCES](#)   [REGISTRANTS/SUPPLIERS](#)   [ABOUT](#)

SEARCH

Substance identity

Substance name:

EC / List number:

CAS number:

Other Numerical Identifiers:

Select

Administrative data

Substance data

Uses and exposure

Clear All   Suchen

Name	EC / List no.	CAS no.	Registration Status	Registration type	Submission type	Total tonnage band	Last Updated	Details
Ethanol	200-578-6	64-17-5	Active	Full		≥ 1 000 000 tonnes	07-03-2022	
Ethanol	200-578-6	64-17-5	No longer Valid	Full		No longer valid	11-01-2016	

Under “Administrative data”, searches can also be performed using a registration number. Under the following conditions, the substance in question is an existing substance:

1. Registration status  
The status is “Active” in at least one case. If the registration status is exclusively “Cease manufacture” and/or “No longer valid”, then the substance is a new substance which must be notified before being placed on the market, unless it falls under the above-mentioned exemptions.
2. Registration type  
As intermediates are exempt from the obligation to notify in Switzerland, the registration type must be “Full” or “NONS”. Otherwise the substance is a new substance which must be notified before being placed on the market, unless it falls under the above-mentioned exemptions.
3. If a registration dossier with the status “Active” exists, but the quantities to be placed on the market in Switzerland are higher than the total tonnage band in the EU, then the substance is a new substance which must be notified before being placed on the market, unless it falls under the above-mentioned exemptions. If the entry under “Total tonnage band” is “Tonnage data confidential”, the registration dossier is to be consulted to determine which tonnage band the usable data correspond to.

An importer can use the safety data sheet to determine whether a substance on its own or in a preparation is registered. In the case of substances, the registration number is shown in Section 1.1 of the safety data sheet, if the substance is registered, and, for preparations, the registration numbers of the constituents are to be found in Section 3.2. However, since – depending on the composition of the preparation – the constituents may not all need to be listed in the safety data sheet, the Swiss importer should request confirmation from the foreign supplier that all the constituents are registered. It must then also be verified that the substance

1. is still registered at least in the tonnage band in which it is to be imported to Switzerland, and

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- is not registered exclusively as an intermediate and is to be used for a different purpose in Switzerland.

This can be checked as described above.

For a number of registered substances, the information on identity is rather limited.

The information on substance identity should first be determined via the link to published registration data (Registered Substances Factsheets). Further information on substance identity can be found by clicking on the Details icon (“View substance registered dossier”).

Last Updated	Details
28-06-2019	
10-12-2019	

Information can then be found under “General information”, “Substance identity” and “Compositions”.

**amyl nitrite\*, mixed isomers**

Substance identity

Identification

Display Name:	"amyl nitrite", mixed isomers
EC Number:	203-770-8
EC Name:	"amyl nitrite", mixed isomers
CAS Number:	463-04-7
Molecular formula:	C5H11NO2
IUPAC Name:	pentyl nitrite

Type of Substance

Composition:	mono-constituent substance
Origin:	organic

Substance Identifiers

Compositions

Boundary Composition(s) open all close all

- "amyl nitrite", mixed isomers	
State Form:	liquid
Constituent 1	

If this does not lead to a clear result, you can contact your supplier, or the Notification Authority for Chemicals.

If a substance is deemed by the manufacturer to be an existing substance, but it cannot be unequivocally matched with the substance registered under REACH, the manufacturer must be able to

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demonstrate the identity in the event of controls by the enforcement authority or queries from the Notification Authority for Chemicals (by means of scientific arguments based on analytical data, or an opinion from the manufacturer or regulatory authority in the EEA).

The Notification Authority for Chemicals may, in individual cases – possibly in consultation with the evaluation authorities – decide whether a substance is to be considered an existing substance, if all available data and sufficient information is provided.

### 2.3 Special cases: monomers and polymers

Exempted from the obligation to notify, under Art. 26 para. 1 let. a ChemO, are polymers<sup>7</sup> or substances contained as monomer units<sup>8</sup> or chemically bound to the polymer in a concentration of less than 2 per cent by weight.

Conversely, substances which are registered exclusively as intermediates are not “existing substances” – with the exception of monomers.<sup>9</sup> Under Art. 26 para. 1 let. g ChemO, intermediates are exempted from the obligation to notify, unless they are monomers.

- Monomers are thus to be notified in cases where they are placed on the market in Switzerland on their own or in the form of a polymer, but are either not registered or registered in a lower tonnage band in the EU.
- Monomers are exempted from the obligation to notify if they are registered in the EU in the same or in a higher tonnage band (registration status “Active”, as “Intermediate”, “Full” or “NONS”).

### 2.4 Tabular overview

	Registration status in the EU	Registration type in the EU	Tonnage band <sup>10</sup> in which the substance is registered in the EU	Substance status in Switzerland
Substance	Active	Full or NONS	EU ≥ CH	Existing substance
Substance (except monomers)	Active	NA or Intermediate	EU ≥ CH or EU < CH	New substance
Substance	Active	Full or NONS	EU < CH	New substance
Substance	Cease manufacture or No longer valid	NA, Intermediate, Full or NONS	EU ≥ CH or EU < CH	New substance
Monomer	Active	Intermediate, Full or NONS	EU ≥ CH	Existing substance
Monomer	Active	NA	EU ≥ CH	New substance
Monomer	Active	NA, Intermediate, Full or NONS	EU < CH	New substance

<sup>7</sup> *Polymer* (Art. 2 para. 2 let. g ChemO) means a substance consisting of molecules characterised by the sequence of one or more types of monomer units and comprising:

1. a simple weight majority of molecules containing at least three monomer units which are covalently bound to at least one other monomer unit or other reactant, and
2. less than a simple weight majority of molecules of the same molecular weight; these molecules must be distributed over a range of molecular weights wherein differences in the molecular weight are primarily attributable to differences in the number of monomer units.

<sup>8</sup> *Monomer unit* (Art. 2 para. 2 let. i ChemO) means the reacted form of a monomer substance in a polymer.

<sup>9</sup> *Monomer* (Art. 2 para. 2 let. h ChemO) means a substance which is capable of forming covalent bonds with a sequence of additional like or unlike molecules under the conditions of the relevant polymer-forming reaction used for the particular process.

<sup>10</sup> The maximum permissible quantity for an existing substance (except monomers) is the upper limit of the highest tonnage band registered in the EU for the substance, with the registration status being required to be “Active” and the registration type “Full” (or “NONS”). For monomers, the registration type may also be “Intermediate”.

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### 3 Transitional provisions

#### 3.1 EINECS substances which become new substances subject to the notification obligation

Transitional provisions for EINECS substances which, under the Amendment of 11 March 2022 to the Chemicals Ordinance (ChemO; SR 813.11), are new substances and become subject to the notification obligation.

To be identified in the portfolio are those EINECS substances which now no longer fall under the definition of an existing substance.

This means that, if the new substance is also to be placed on the market in the future, it must be notified. Here, two types of case are to be distinguished:

1. Tests on vertebrates have to be conducted (Art. 93c para. 2):  
The notifier must submit an advance enquiry (Art. 31 para. 1 and 2) to the Notification Authority by 31 October 2023. He may then continue to place the substance on the market without notification until 30 April 2027. If a justified request is made by the notifier, the Notification Authority may extend this period by a maximum of two years.  
If an advance enquiry concerning a particular substance is received from two or more notifiers, the Notification Authority will inform the notifiers accordingly, so that they can conduct the tests jointly (cf. Art. 31 para. 4).
2. Tests on vertebrates are not necessary, or the manufacturer does not intend to notify the substance (Art. 93c para. 3): In this case, the substance may continue to be placed on the market until 30 April 2024. If a justified request is made by the manufacturer, the Notification Authority may extend this period by a maximum of one year.

#### 3.2 Notified substances which become existing substances

The notifier is not subject to the obligation to provide updated information in accordance with Article 46 and 47. The substance is, however, subject to reporting requirements in accordance with Art. 48 ff.

#### 3.3 Substances no longer registered in the EU

If a substance becomes subject to the notification obligation because it is no longer registered in accordance with REACH, the manufacturer may continue to place it on the market without notification until the end of the calendar year following that in which its registration status changes. The Notification Authority may extend the period by a maximum of two years in response to a justified request (Art. 25 ChemO).

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## Changes to this document

Date	Revision
15.04.2022	Basic version
27.10.2022	Adaptation in chapter 2.2 concerning the identification of a new substance
19.07.2023	Corresponds to the German and French text only.

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