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Guidance on the reporting requirements under Articles 48–54 of the Chemicals Ordinance (ChemO; SR 813.11)

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Contents

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Introduction

The reporting requirements for substances and preparations under Articles 48–54 of the Chemicals Ordinance (ChemO; SR 813.11) were introduced in Switzerland in their current form with the chemicals legislation in 2005 and have since been regularly updated. They arose from the notification requirements for products under the toxic substances legislation.
The reporting of new substances as specified in Art. 26 para. 3 ChemO is described in the "Guidelines for notification, reporting and declaration of new substances in accordance with the Swiss Chemicals Ordinance".[1]
Separate guidance is available for reporting in accordance with the Ordinance on Biocidal Products (OBP; SR 813.12)[2] and the Chemical Risk Reduction Ordinance (ORRChem; SR 814.81).[3]

With the 2018 and 2022 revisions of the ChemO, certain elements of the reporting requirements were aligned with Annex VIII to Regulation (EC) No 1272/2008[4] (CLP Regulation). However, marked differences still remain between the regulations in Switzerland and the EU with regard to the scope of the obligation to report and the requirements concerning reporting.[5]

Reports are submitted to the product register for chemicals (RPC: register des produits chimiques) via an electronic application provided free of charge by the Notification Authority for Chemicals (www.rpc.admin.ch).

This guidance is addressed to those required to submit reports, and to the federal and cantonal employees concerned. It describes in detail the reporting requirements specified in Articles 48–54 ChemO. Use of the electronic application (RPC) is described in a separate document.[6]

1. Purpose of reporting

With regard to the data obtained under the reporting, notification and authorisation requirements, the 1999 Dispatch on the Chemicals Act[7] states: "The product register compiled on the basis of this information may be used not only for medical purposes, but also for purposes of enforcement, primarily in the area of market surveillance." Also mentioned is the use of such data in particular for risk assessments and for prioritisation. In addition, under Art. 18 para. 3 Chemicals Act (ChemA; SR 813.1), reporting requirements may also be specified so as to facilitate the identification of risks and prevention.

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[1] See https://www.anmeldestelle.admin.ch/chem/en/home/themen/pflicht-hersteller/stoffe/neuer-stoff/stoffe-anmeldepflicht-ausgenommen.html

[2] https://www.anmeldestelle.admin.ch/chem/en/home/themen/pflicht-hersteller/zulassung-biozidprodukte.html

[3] https://www.anmeldestelle.admin.ch/chem/en/home/themen/recht-wegleitungen/chemikalienrecht/chemikalien-risikoreduktionsverordnung.html

[4] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006, OJ L 353, 31.12.2008, p. 1; last amended by Commission Regulation (EU) 2017/776, OJ L 116, 5.5.2017, p. 1.

[5] Annex VIII to the CLP Regulation uses the term "notification".

[6] https://www.anmeldestelle.admin.ch/chem/en/home/themen/pflicht-hersteller/chemikalienregister-rpc.html

[7] 99.090; https://www.admin.ch/opc/de/federal-gazette/2000/687.pdf

2. Who is required to submit reports?

Under Art. 48 ChemO, manufacturers are required to submit reports. According to Art. 2 para. 1 let. b ChemO, *manufacturer* means:

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, and,*
2. *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 where the labelling in accordance with Article 10 paragraph 3 letter b has not been applied in the official language by the original manufacturer,*
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.*

In other words, as well as the actual manufacturer, an importer of substances and preparations, a formulator and a repackager are also considered to be manufacturers within the meaning of the ChemO and are thus required to submit reports. Also deemed to be manufacturers are relabellers placing a product on the market under their own name or under their own trade name, and traders taking a product to a part of the country where labelling in the official language has not been applied. In the case of contract manufacturing, the Swiss client is deemed to be the manufacturer.

3. When must a report be submitted?

The deadline specified in Art. 48 ChemO is **3 months after substances and preparations are first placed on the market**[8] in Switzerland (including imports).

4. Which substances and preparations have to be reported?

4.1 Reportable substances and preparations under Art. 48 ChemO

Under Art. 48 para. 1 ChemO, manufacturers must report the following substances and preparations within 3 months after first placing them on the market:

a. *the substances and preparations specified in Article 19, irrespective of whether a safety data sheet has to be compiled for them;*

[8] Under Art. 4 para. 1 let. i Chemicals Act (ChemA; SR 813.1), *placing on the market* means providing for or supplying to third parties and importing for professional or commercial purposes.

b. *nanomaterials, other than those referred to in letter a, which specifically contain biopersistent[9] fibres or tubes exceeding 5 µm in length.*[10]

The substances and preparations specified in Article 19 are as follows:

a. *dangerous substances and preparations* (Article 3 ChemO)*;*
b. *PBT[11] or vPvB[12] substances;*
c. *substances listed in Annex 3 to ChemO[13];*
d. *preparations which are not dangerous within the meaning of Article 3 and contain at least one of the following substances:*
    1. *a substance that is dangerous to health or to the environment in an individual concentration of ≥1.0 per cent by weight (non-gaseous preparations) or ≥0.2 per cent by volume (gaseous preparations),*
    2. *a category 2 carcinogenic substance, a category 1A, 1B or 2 toxic for reproduction substance, a category 1 skin allergen, a category 1 inhalation allergen, a substance having effects on or through lactation, or a PBT or vPvB substance in an individual concentration of ≥0.1 per cent by weight,*
    3. *a substance listed in Annex 3 to ChemO in an individual concentration of ≥0.1 per cent by weight,*
    4. *a substance for which an occupational exposure limit value has been laid down in Directives 2000/39/EC, 2006/15/EC, 2009/161/EU or (EU) 2017/164 or (EU) 2019/1831.*

In the Ordinance, no provision is made for trivial quantities, below which a substance or preparation does not have to be reported, except in the case of intermediates and preparations intended exclusively for professional users. For these two exemptions, a threshold of 100 kg per year is specified.

If a preparation is to be labelled exclusively with one or more EU hazard statements (e.g. EUH208 *Contains <name of sensitising substance>. May produce an allergic reaction*.), then the chemical is not deemed to be dangerous under the Chemicals Ordinance. However, if the preparation contains a substance specified in Art. 19 let. d ChemO above the concentration limit, then the product must be reported and a safety data sheet is to be compiled for professional users.

[9] Biopersistent materials are those with a water solubility of less than 100 mg per litre or with a half-life of 40 days or more in the lungs.

[10] These criteria were derived from the WHO definition of respirable fibres and from the standard definition of high aspect ratio nanomaterials. To be subject to reporting requirements, the material must, however, also meet the definition of a nanomaterial given in Art. 2 para. 2 let. q.

[11] 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.

[12] 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.

[13] List of substances of very high concern (SVHC), taken from the Candidate List of the European Chemicals Agency (ECHA) (Article 59 of the REACH Regulation); https://www.anmeldestelle.admin.ch/chem/en/home/themen/recht-wegleitungen/chemikalienrecht/chemikalienverordnung.html

Notes on substances

Under Art. 26 para. 3 ChemO, new substances that are exempt from notification requirements must be reported (see guidelines on reporting and notifying new substances[14]) if they

- are dangerous within the meaning of Art. 3 ChemO and/or
- have PBT and/or vPvB properties as specified in Art. 4 ChemO.

Intermediates are substances according to the definition given in Art. 2 para. 2 let. j ChemO. Intermediates are exempt from reporting requirements if they

- are placed on the market in quantities less than 100 kg per year,
- are not supplied to third parties, or
- do not leave the manufacturing site.

If they are subject to reporting requirements, they must be specifically declared as intermediates by the manufacturer.
When reported, nanomaterials must be specifically declared as such. A nanomaterial may be a multi-constituent substance or a mono-constituent substance (i.e. with one main constituent present at a concentration of at least 80%). This also applies to preparations containing nanomaterials. For nanomaterials, the Swiss authorities apply, by analogy, the ECHA Guidance “How to prepare registration dossiers that cover nanoforms: best practices”.[15] Also subject to reporting requirements, as well as those nanomaterials classified as dangerous, are those, which contain, by design, biopersistent fibres or tubes exceeding 5 µm in length.

4.2 Exemptions

Provision is made for general exemptions from the obligation to report substances and preparations (Art. 1 para. 5–6 and Art. 54 ChemO). The Ordinance does not apply to:

- *the transport of substances and preparations by road, rail, water, air or pipelines;*
- *the transit of substances and preparations under customs supervision, provided that this does not involve any processing or transformation;*
- *substances and preparations which are placed on the market solely for the purposes of analysis, research or development;*
- *substances which are placed on the market solely for training purposes;*
- *substances and preparations in the form of the following categories of finished products ready for supply to private and professional users:*
    - *foodstuffs as defined by Article 4 of the Foodstuffs Act of 20 June 2014 (FoodA),*
    - *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 (TPA),*
    - *animal feedingstuffs as defined by Article 3 paragraph 1 of the Feedstuffs Ordinance of 26 October 2011 (SR 916.307);*
- *weapons and ammunition as defined by Article 4 paragraphs 1 and 5 of the Weapons Act of 20 June 1997 (WA);*

[14] See https://www.anmeldestelle.admin.ch/chem/en/home/themen/pflicht-hersteller/stoffe/neuer-stoff/stoffe-anmeldepflicht-ausgenommen.html

[15] https://op.europa.eu/en/publication-detail/-/publication/6dc3d254-6c2c-11e7-b2f2-01aa75ed71a1/language-en

- *substances, preparations and objects which are waste according to Article 7 paragraph 6 of the Environmental Protection Act (EPA);*
- cosmetic products (within the meaning of Art. 53 of the Ordinance on Foodstuffs and Utility Articles (SR 817.02);
- products imported for private purposes;
- *substances and preparations to be used exclusively as raw materials for foodstuffs, therapeutic products or animal feedingstuffs;*
- *gas mixtures consisting exclusively of reported gases;*
- gases and gas mixtures that are classified in the "gases under pressure" hazard category;
- chemicals subject to authorisation requirements: plant protection products; biocidal products; substances and fertilisers subject to authorisation and notification requirements; explosives and pyrotechnic devices;
- *preparations not deemed to be dangerous under Article 3 ChemO which are in packages containing no more than 200 ml, if they are manufactured in Switzerland and supplied directly to professional or private users;*
- *preparations placed on the market in quantities of less than 100 kg per year and intended exclusively for professional users;*
- *substances obtained in Switzerland,*
- *preparations obtained in Switzerland and supplied in packaging other than that provided by the original manufacturer, provided that:*
    - *the trade name, composition, the unique formula identifier (UFI)[16] and intended use are unchanged, and*
    - *the name of the original manufacturer is also indicated;*
- *imported substances and preparations that are simply relabelled and then exported without alteration*;
- *intermediates that:*
    1. *are not supplied to third parties,*
    2. *do not leave the manufacturing site, or*
    3. *are placed on the market in quantities less than 100 kg per year;*

  not exempted from reporting requirements (or notification requirements) are intermediates in the form of monomers which are new substances;
- *paints formulated on demand in limited quantities for an individual consumer or professional user at the point of sale by tinting or mixing colours, provided that:*
    1. *the requirements of Article 25 paragraph 8 of the CLP Regulation are complied with, or*
    2. *the potentially hazardous colorants are indicated in the notification of the base colour in the maximum concentration in which they are added; in this case, the product must be labelled with the UFI of the base colour;*
- *concrete, plaster and cement that conform with any of the standard formulas specified in Part D of Annex VIII to the CLP Regulation and that bear the UFI required by the Notification Authority.*

If certain preparations have a UFI, they must be reported even if they fall under an exemption, so that emergency health care can be ensured and Tox Info Suisse does not lose unnecessary time in establishing that no prescription is filed for the UFI. This applies to the following preparations:

[16] Cf. https://www.anmeldestelle.admin.ch/chem/en/home/themen/pflicht-hersteller/selbstkontrolle/kennzeichnung/ufi-eindeutiger-rezepturidentifikator.html

- preparations which are placed on the market solely for the purposes of analysis, research or development;
- preparations used exclusively for foodstuffs, therapeutic products or animal feedingstuffs;
- preparations not deemed to be dangerous under Article 3 which are in packages containing no more than 200 ml, if they are manufactured in Switzerland and supplied directly to professional or private users;
- preparations placed on the market in quantities of less than 100 kg per year and intended exclusively for professional users;
- gas mixtures consisting exclusively of reported gases;

5. What information on substances and preparations has to be reported?

The requirements for reporting of substances and preparations are specified in Art. 49 ChemO and additionally, for the extended report for preparations, in Art. 50 ChemO.
To be included in all reports are:
the name and address of the manufacturer in Switzerland.[17]

In general, substances and already reported preparations can be selected from a list in the RPC. If a substance does not appear in the list, please contact the Notification Authority.

5.1 Specific information on substances

	Legal requirements under Art. 49 para. 1 let. c ChemO	Notes
1	The chemical name in accordance with Article 18 paragraph 2 letters a–d of the CLP Regulation	The product identifier for a substance shall consist of at least the following: a. if the substance is included in Part 3 of Annex VI to the CLP Regulation (list of harmonised classification and labelling), a name and an identification number as given therein, b. if the substance is not included in Part 3 of Annex VI to the CLP Regulation, but appears in the ECHA classification and labelling inventory, a name and an identification number as given therein, c. if the substance is not included in Part 3 of Annex VI nor in the classification and labelling inventory, the number provided by the CAS (hereinafter referred to

[17]To be included, in addition, is the name of the person responsible for placing on the market in the EEA, as specified in Article 17 paragraph 1 letter a of the CLP Regulation, if the manufacturer's name is not mentioned on the labelling. This only applies if, in accordance with Art. 10 para. 3[bis], the substances or preparations:

a. are not intended for distribution to private users; or
b. are supplied to private users, are contained in an inner packaging in portions of no more than 125 ml or g and are marked on the outer packaging with the name, address and telephone number of the manufacturer.

	Legal requirements under Art. 49 para. 1 let. c ChemO	Notes
		as “the CAS number”), together with the name set out in the nomenclature provided by the IUPAC (hereinafter referred to as “the IUPAC Nomenclature”), or the CAS number together with another international chemical name(s); or d. if the CAS number is not available, the name set out in the IUPAC Nomenclature or another international chemical name(s). If in doubt, please contact the Notification Authority, particularly if the substance does not appear in the RPC list.
2	The CAS number	
3	The EC number	
4	The classification and labelling	Hazard class, hazard category and the associated hazard statements (H-phrases) Hazard pictogram, signal word, hazard statements (H-phrases), appropriate precautionary statements (P-phrases) and EUH-phrases
5	The intended uses	The various categories of intended uses are available in a picklist in the RPC.
6	In the case of substances dangerous to the environment: the quantity likely to be placed on the market annually according to one of the following categories: less than 1 tonne, 1–10 tonnes, 10–100 tonnes, more than 100 tonnes	The quantities refer to the quantities imported or placed on the market in Switzerland.
7	In the case of nanomaterials: a. the composition, particle form and mean particle size and, where available, the number size distribution, specific surface area by volume, crystal structure, aggregation status, surface coating and surface functionalisation, and b. the quantity expected to be placed on the market annually according to one of the following categories: less than 1 kilogramme, 1–10 kilogrammes, 10–100 kilogrammes, 100–1000 kilogrammes, 1–10 tonnes, 10–100 tonnes, more than 100 tonnes	
8	An indication of whether the substance is considered to be PBT or vPvB	If a substance is considered to be PBT or vPvB, this property must be indicated in addition to the classification, as it does not necessarily lead to special labelling.
9	The chemical safety report available in the EEA, provided that it can be obtained by the manufacturer with reasonable effort	The chemical safety report contains important information on the hazardous properties, exposure assessment and risk reduction measures. For existing substances, the

	Legal requirements under Art. 49 para. 1 let. c ChemO	Notes
		preparation of such a report may be highly demanding and require considerable resources. If a substance is imported from the EU and a report has been compiled for this substance, the Swiss importer should enquire whether it is possible to obtain the report.

5.2 Specific information on preparations

	Legal requirements under Art. 49 para. 1 let. d ChemO	Notes
1	The trade name	
1a	In the case of preparations classified as dangerous because of the physical or health hazards they pose: the unique formula identifier (UFI)[18]	The UFI allows the composition to be unequivocally determined by Tox Info Suisse[19] in an emergency. Inclusion of a UFI is to become obligatory as follows: • from 1.1.2022: for preparations newly placed on the market from this date which are intended for private users; • from 1.1.2022: for preparations which already have a UFI. This category includes in particular products imported from the EEA. The requirement that products for which a UFI is available must also be reported is designed to ensure that, with the aid of the UFI, Tox Info Suisse can find the formulation in the RPC; • from 1.1.2026: for all other preparations classified as dangerous because of the physical or health hazards they pose. On the ECHA website[20] companies established in the EEA can generate a UFI. For preparations which are imported to Switzerland from the EEA or exported from Switzerland to the EEA, this UFI can also be reported in Switzerland and indicated (or left) on the label.[21] The Swiss Notification Authority has made available an online

[18] While the UFI is only obligatory for preparations classified as dangerous because of the physical or health hazards they pose, the Swiss authorities recommend that, for all preparations, a UFI should be printed on the label and reported, so that the poisons information centre (Tox Info Suisse) can provide appropriate recommendations and unnecessary treatments are avoided.

[19] Tox Info Suisse, as specified in Art. 79 ChemO, is the poisons information centre providing medical advice, round the clock and free of charge, in cases of poisoning or suspected poisoning. http://toxinfo.ch; Tel. 145

[20] https://poisoncentres.echa.europa.eu/ufi-generator

[21] According to the ECHA guidance document, the UFI can also be indicated elsewhere, with the other label elements (see https://echa.europa.eu/documents/10162/17235/guidance_on_annex_viii_to_clp_en.pdf/412c5874-f8ec-cf52-fe1e-2fbe08fe2d11?t=1651484042203).

	Legal requirements under Art. 49 para. 1 let. d ChemO	Notes
		UFI generator for preparations which are only placed on the market in Switzerland.[22]
2	Data relating to the constituents in accordance with the provisions concerning the safety data sheet	All dangerous constituents are to be listed from the specific or generic concentration limits set for the hazard class to which they are assigned (if appropriate, taking the M-factors into consideration and, for PBT and vPvB substances, 0.1%). In order to simplify the reporting of preparations in accordance with Articles 48–54 ChemO, using the RPC, it has no longer been necessary since 1.7.2015 to report the classification of each individual constituent; instead, it is sufficient to indicate the classification and labelling of the preparation as a whole. Listed in the RPC are all EINECS substances and notified substances, as well as all reported preparations. It is recommended that substances should be searched for by CAS or EC number, if possible. If a substance is not listed, please contact the Notification Authority. Data concerning the constituents of a preparation is defined in Section 3 of Annex II to the REACH Regulation, to which reference is made in Annex 2 Number 3 ChemO. In subsection 3.2.4, it is specified that the EC number of each substance concerned is to be given, if available. The substances in the preparation, which have to be indicated on the label, i.e. declared, are to be marked. The substances to be declared are those substances contained in the preparation that contribute to its classification “as regards acute toxicity, skin corrosion or serious eye damage, germ cell mutagenicity, carcinogenicity, reproductive toxicity, respiratory or skin sensitisation, specific target organ toxicity (STOT) or aspiration hazard (Art. 10 para. 1 let. a ChemO in conjunction with Art. 18 para. 3 CLP Regulation). Where that requirement leads to the provision of multiple chemical names, a maximum of four chemical names shall suffice, unless more than four names are needed to reflect the nature and the severity of the hazards (Art. 10 para. 1 let. a ChemO in conjunction with Art. 18 para. 3 CLP Regulation). The chemical names selected shall identify the substances primarily responsible for the major health hazards which have given rise to the classification and the choice of the corresponding hazard statements.”

[22] https://www.anmeldestelle.admin.ch/chem/en/home/themen/pflicht-hersteller/selbstkontrolle/kennzeichnung/ufi-eindeutiger-rezepturidentifikator.html

	Legal requirements under Art. 49 para. 1 let. d ChemO	Notes
3	The classification and labelling	Hazard class, hazard category and the associated hazard statements (H-phrases) Hazard pictogram, signal word, hazard statements (H-phrases), appropriate precautionary statements (P-phrases)
4	The intended uses	The various categories of intended uses are available in a picklist in the RPC.
5	The physical state	
6	In the case of preparations dangerous to the environment: the quantity likely to be placed on the market annually, according to one of the following categories: less than 1 tonne, 1–10 tonnes, 10–100 tonnes, more than 100 tonnes	The quantities refer to the quantities imported or placed on the market in Switzerland.
7	In the case of preparations containing nanomaterials that must be specified in the safety data sheet: the composition of the nanomaterials, their particle form and mean particle size and, where available, the number size distribution, specific surface area by volume, crystal structure, aggregation status, surface coating and surface functionalisation.	

Special form of fulfilment of the obligation to report
To ensure that the submitter only has to contact the Notification Authority once for a given chemical, the obligation to report preparations is deemed to be fulfilled if a request to use an alternative chemical name[23] (Art. 15) has been submitted and the Notification Authority has the information which is required when a report of this kind is submitted (i.e. the information specified in Art. 49 para. 1 let. a, b and d and, if appropriate, in Art. 50).

5.3 Extended report for dangerous preparations sold to private users

In the case of **dangerous** preparations[24] sold to private users, the full composition is to be reported (Art. 50 ChemO), so that in cases of poisoning (particularly in children) Tox Info Suisse can recommend the best possible treatment. *Constituents which are not deemed to be dangerous under Article 3 may be designated by a name that identifies the most important functional groups*. For certain constituents, it is appropriate to indicate the molar mass. Example: aliphatic alcohol, molar mass between 200 and 300.

[23] https://www.anmeldestelle.admin.ch/chem/en/home/themen/pflicht-hersteller/selbstkontrolle/kennzeichnung/chemische-bezeichnung-art-15.html

[24] Dangerous within the meaning of Art. 3, i.e. the preparation is classified as dangerous and to be labelled accordingly.

For pragmatic reasons, it is accepted by the Notification Authority that **non-classified constituents** with a total concentration below 1% are not generally reported. Similar provisions are to be found in Part B Section 3.3 of Annex VIII to the CLP Regulation.

5.4 Concentration ranges applicable to constituents of a preparation

It is desirable that a specific concentration should be reported for each constituent. If necessary, however, concentration ranges may be indicated. The ChemO does not contain any provisions concerning the concentration ranges that may be submitted when the constituents of a preparation are reported. In the interests of harmonisation of data requirements with the EU, the Swiss authorities recommend application of the rules given in Part B Section 3.4 of Annex VIII to the CLP Regulation:

Note: The highest concentration within each range determines the classification of the preparation.

Concentration ranges applicable to hazardous components of major concern for emergency health response[25]

Concentration range of the hazardous component contained in the mixture (%)	Maximum width of the concentration range to be used in the submission
≥ 25 – < 100	5 % units
≥ 10 – < 25	3 % units
≥ 1 – < 10	1 % units
≥ 0,1 – < 1	0,3 % units
> 0 – < 0,1	0,1 % units

Concentration ranges applicable to other hazardous components and components not classified as hazardous.

Concentration range of the component contained in the mixture (%)	Maximum width of the concentration range to be used in the submission
≥ 25 – < 100	20 % units
≥ 10 – < 25	10 % units
≥ 1 – < 10	3 % units
> 0 – < 1	1 % units

[25] Of major concern for emergency health response are substances classified as follows:

- Acute toxicity, Category 1, 2 or 3,
- Specific target organ toxicity – Single exposure, Category 1 or 2,
- Specific target organ toxicity – Repeated exposure, Category 1 or 2,
- Skin corrosion, category 1, 1A, 1B or 1C,
- Serious eye damage, Category 1.

5.5 Colorants and perfumes

For perfumes and fragrances with a total concentration not exceeding 5% by weight and for colorants with a total concentration not exceeding 25% by weight, generic product identifiers may be indicated in the RPC:

- perfume (PAID : 380880-21)
- colorant (PAID : 807554-11)

Substances of very high concern included in Annex 3 ChemO are, however, to be indicated separately. These are to be found in Section 3.2 of the safety data sheet of the fragrance or colorant. Unlike in the EU, this provision is applicable in Switzerland not only for colouring agents, but also for colorants. Colorants are defined as substances and preparations that primarily contain colouring agents, colour pigments and effect-producing pigments which are added solely for the purpose of colouring or producing effects (Art. 2 para. 2 let. r ChemO). The Swiss authorities recommend that a safety data sheet should be submitted for the colouring agents and fragrances, with fragrances not classified as dangerous being indicated if possible.

5.6 Identical preparations containing different colorants and fragrances

The ChemO does not contain any provisions for the notification of a preparation indicating several color shades or fragrances (in the sense of a group reporting). Furthermore, the RPC is not designed to potentially represent several compositions within one report.
However, since the management and administration of products that have a color or fragrance palette and differ only by colorants or fragrances can be very time-consuming, the Notification Authority accepts the pragmatic form of group reporting under the following conditions in the interest of proportionality:

- ToxInfo Suisse can quickly and easily identify the preparation and its ingredients based on the message in the RPC;
- The main identifier is identical, except for the color/fragrance information;
- The complete main identifier including all color/fragrance information is listed in the report (if necessary, under additional trade names, e.g., product red, product blue, etc.);
- The products of the different color shades or fragrances must not differ in classification and labelling or contain additional substances which may lead to further regulatory obligations;
- The compositions of the products must be identical, except for colorants, which may be a maximum of 25%, or fragrances, which may be a maximum of 5%, i.e., when the reported concentration or concentration range is the same for each ingredient; and
- All other data for reporting (Art. 49 and 50 ChemO) are identical.

The submission of a safety data sheet for each color shade or fragrance note in the RPC (under Documents) is recommended.

Regarding the UFI, the Notification Authority will accept a report and a UFI provided that all necessary requirements are fulfilled (cf. point 3.2.3 of Part B of Annex VII EU CLP Regulation).[26]

5.7 Paints formulated on demand (bespoke paints)

Exempted from the reporting requirements are paints formulated on demand (bespoke paints) in limited quantities for an individual consumer or professional user at the point of sale by tinting or mixing colours, provided that:

- the UFIs of the added colorants subject to UFI requirements are indicated on the label of the base colour, if they constitute more than 0.1% of the final product; if the concentration exceeds 5%, they are also to be listed as a constituent (this corresponds to Art. 25 para. 8 of the CLP Regulation); or
- the colorants are indicated in the notification of the base colour in the maximum concentration in which they are added; in this case, the paint may be sold with the label of the base colour.

5.8 Concrete, plaster and cement

Concrete, plaster and cement are exempted from the reporting requirements if the following two conditions are met:

1. they conform with any of the standard formulas specified in Part D of Annex VIII to the CLP Regulation and
2. they bear the UFI required by the Notification Authority.

All the standard formulas specified in Part D of Annex VIII to the CLP Regulation have been recorded in the RPC by the Notification Authority:

1. Cement standard formula – 1 to 20 with EU UFIs kindly provided by an association in the EU. This is designed to ensure that the UFI does not need to be changed if a border is crossed from or into a neighbouring country.
   In the RPC (www.rpc.admin.ch), search for: “Cement standard formula – 1” to 20
2. Concrete standard formulas 1 and 2: in the RPC, “Ready mixed concrete standard formula 1” and “Ready mixed concrete standard formula 2”, The UFIs have been kindly provided by an association in the EU.
   Mortars that comply with the concrete standard formulations can also benefit from the exemption, provided that the product is equipped with the corresponding UFI specified by the Notification Authority.
3. Gypsum binder standard formula: in the RPC, “Gypsum binder standard formula”
   It was not possible to obtain an EU UFI for gypsum. Therefore, it is a Swiss UFI that may only be used in Switzerland.[27]

With regard to preparations that have been already reported to the Chemicals Product Register (RPC) and that comply with the standard formulations, either

- add the UFI specified by the notification authority for chemicals to the reporting, or

[26] Further Information from 5.3.3 in general. Point 5.4 for perfume under https://echa.europa.eu/documents/10162/13643/guidance_on_annex_viii_to_clp_de.pdf/1a231979-2ba0-a1b5-d25e-4310e3650176

[27] Cf. https://www.anmeldestelle.admin.ch/chem/en/home/themen/pflicht-hersteller/selbstkontrolle/kennzeichnung/ufi-eindeutiger-rezepturidentifikator.html

- - contact the Notification Authority at cheminfo@bag.admin.ch to have the reporting cancelled. Other UFIs that have already been generated for the preparation would no longer be marketable.

6. In what format are reports to be submitted?

In Switzerland, electronic reports can be submitted manually via www.rpc.admin.ch. Also now available is a mass registration interface.[28]

7. When does a report need to be updated or a new UFI generated?

Art. 52 ChemO indicates when a report in the RPC is to be updated:

1. **Modifications to the information** referred to in Section 5 of this guidance (i.e. the information specified in Art. 49 and 50) must be reported within three months. An existing submission must always be updated if there is any change in the classification or labelling. If this is not the case, for variations of the concentration of components requiring a submission update, the provisions of Part B Section 4 of Annex VIII to the CLP Regulation can serve as a guide. If an update of the recipe is necessary according to these specifications, a new UFI must also be generated, indicated in the existing report and affixed to the product.:

Variations of the concentration of components requiring a submission update

Exact concentration of the component contained in the mixture (%)	Variations (±) of the initial component concentration requiring a submission update
> 25 – ≤ 100	5 %
> 10 – ≤ 25	10 %
> 2,5 – ≤ 10	20 %
≤ 2,5	30 %

2. If the **quantity of substances and preparations dangerous to the environment** actually supplied in a year falls outside the reported category of quantities placed on the market, the quantity placed on the market in the previous year must be reported by 31 March of the following year in accordance with the categories specified in Article 49 paragraph 1 letter c number 6 and letter d number 6.

[28] Information on the mass registration interface: https://www.anmeldestelle.admin.ch/chem/en/home/themen/pflicht-hersteller/chemikalienregister-rpc/massenmeldetool.html

List of amendments

Version	Date	Content
1.0	04.06.2019	Original version
1.1	19.05.2020	Clarification in Section 4.1 Reportable substances and preparations under Art. 48 ChemO
1.2	15.12.2020	Updates concerning the UFI in Section 5.2
2.0	01.05.2022	Amendments in connection with the revision of the ChemO
2.1	03.06.2022	Actualisation of links and references
2.2	03.10.2022	Addition of PAID under 5.5; New chapter 5.6
2.3	12.12.2022	Addition in chapter 4.2 Exceptions Clarification in chapter 5.8
2.4	04.04.2023	Amendments in chapter 5.8: moratar and procedure for preparations already reported
2.5	03.02.2025	Clarification concerning the quantities in Chapter 5.1 and 5.2, Section 6, and addition of the UFIs in Chapter 7

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