

# Validation rules for poison centres notifications

Version 3.0  
May 2020

## Table of Contents

<b>1. INTRODUCTION .....</b>	<b>3</b>
<b>2. VALIDATION RULES .....</b>	<b>3</b>
2.1 List of PCN Validation rules in IUCLID .....	3
2.2 List of PCN Validation rules in ECHA Submission Portal.....	9
<b>3. KNOWN ISSUES .....</b>	<b>12</b>
3.1 Validation report links.....	12
<b>4. CHANGES TO THIS DOCUMENT .....</b>	<b>12</b>

### Legal notice


This document aims to assist users in complying with their obligations under the CLP Regulation. However, users are reminded that the text of the CLP Regulation is the only authentic legal reference and that the information in this document does not constitute legal advice. Usage of the information remains under the sole responsibility of the user. The European Chemicals Agency does not accept any liability with regard to the use that may be made of the information contained in this document.

## 1. Introduction

This document provides short descriptions of the validation rules in IUCLID and in ECHA Submission portal, which are relevant for poison centres notifications (PCNs).

## 2. Validation rules

Current PCN submission types include standard submissions (**S**), limited submissions (industrial use only) (**L**) and non-hazardous submissions (voluntary submissions) (**N**). A rule can be relevant for the specific submission type or for the **all** the above mentioned submission types. This is indicated in the third column.

 'Group notifications' are not included in October 2019 release of IUCLID and ECHA Submission portal.

### 2.1 List of PCN validation rules in IUCLID

A business rule (**BR**) failure leads to the failure of the submission. A quality rule (**QLT**) warns or reminds the notifier of common shortcomings and inconsistencies. Quality rules will not lead to the failure of the submission, but can result in further clarification requests from Member state(s) at a later stage.

\*new rule or rule modified since previous IUCLID release

Rule number	Short description of the rule	Type
-------------	-------------------------------	------

#### LEGAL ENTITY – IDENTIFICATION OF THE SUBMITTER

<b>BR608*</b>	<b>Legal entity</b> (Duty holder) must be provided in 'Mixture identity and legal submitter' record in the field 'Legal entity owner'.	All
<b>BR519</b>	The contact details of the legal entity must include: <ul style="list-style-type: none"> <li>• address 1</li> <li>• town</li> <li>• country</li> <li>• phone</li> <li>• email</li> <li>• postal code.</li> </ul>	All
<b>BR522</b>	Email address must be in email format.	All

#### DOSSIER HEADER

<b>BR553</b>	The <b>PCN number</b> must be indicated and it must be in UUID format. The UUID format is described in <a href="https://tools.ietf.org/html/rfc4122">https://tools.ietf.org/html/rfc4122</a>	All
<b>BR554</b>	At least one ' <b>Country (market placement)</b> ' must be selected.	All

<b>BR558</b>	Each country mentioned as ' <b>Country (market placement)</b> ' must have at least one corresponding 'Product information' record.	All
<b>BR559</b>	At least one ' <b>Language</b> ' must be selected.	All
<b>BR561</b>	Either 'The submission is an initial notification', 'The submission is a new notification after a significant change in composition' or 'The submission is an update' must be selected.	All
<b>BR562</b>	If 'The submission is a new notification after a significant change of composition' is selected, 'CLP related PCN number' must be provided in the 'Unique formula identifiers (UFI) and other identifiers' section.	All
<b>BR543</b>	If 'The submissions is an update' is selected, 'Reason for updating' must be reported.	All

#### CONTACT PERSON

<b>BR552</b>	An emergency contact must be provided in the 'Contact person' section for each country indicated in the dossier header.	L
<b>BR523</b>	The contact details of the emergency contact must include : <ul style="list-style-type: none"> <li>• last name</li> <li>• organisation</li> <li>• phone</li> <li>• email</li> <li>• country.</li> </ul> <p>Please note that if "Last name" is not available or not relevant, a more generic name can be used instead (e.g. Helpdesk, Support)</p>	L

#### pH

<b>BR512</b>	Exactly one 'pH' record must be provided.	S, L
<b>BR545</b>	Either 'pH not relevant' must be selected or a pH value must be reported (one value or range).	S, L
<b>BR524</b>	Allowed pH values: $-3 \leq \text{pH} \leq 15$	All
<b>BR615</b>	Allowed pH qualifiers: one value cannot have qualifiers, range cannot have 'c.a.'.	All
<b>QLT504</b>	pH value must be indicated as an integer or specified to one decimal.	All
<b>QLT501</b>	Maximum pH value range width is 1 unit (when $\text{pH} \leq 3$ or $\geq 10$ ).	All
<b>QLT510</b>	Maximum pH value range width is 3 units (when $3 < \text{pH} < 10$ ).	All
<b>BR585</b>	If pH is relevant, 'Solution concentration' must be provided.	All

#### TOXICOLOGICAL INFORMATION

<b>BR515</b>	Exactly one 'Toxicological information' record must be provided.	S, L
--------------	--	------

<b>BR538</b>	Toxicological information must be provided (at least 200 characters) in 'Toxicological information (section 11 of SDS)' field(s) in all relevant languages.	S, L
--------------	---	------

#### MIXTURE COMPOSITION

<b>BR509</b>	Exactly one 'Mixture composition' record must be provided.	All
<b>BR521</b>	At least one 'Mixture' (MiM) or 'Substance' component must be provided in 'Mixture composition' (MainMixture).	All
<b>BR551</b>	'Reference substance' datasets cannot be linked from 'Mixture composition' (MainMixture). Only 'Mixture' (MiM) and 'Substance' datasets can be linked from 'Mixture composition' (MainMixture).	All

#### MIXTURE COMPONENTS (MiM)

<b>BR527*</b>	For identifying the MiM, it is mandatory to provide either: a) UFI b) Available component(s): - If MiM is hazardous 'Supplier' record and available components (at least one Substance). - If MiM is non-hazardous, then providing the 'Supplier' record is enough. Components identified using the Generic Product Identifier (GPI) are an exception.	All
<b>BR578</b>	There cannot be more than one UFI per MiM.	All
<b>BR606*</b>	If the MiM is identified with providing the available component(s) of the composition, then the legal entity in the 'Suppliers' record must include the contact details: <ul style="list-style-type: none"> <li>• legal entity name</li> <li>• phone</li> <li>• email.</li> </ul>	All
<b>BR624*</b>	If the MiM is identified with providing the available component(s) of the composition, then the legal entity in the 'Suppliers' record must be different than the Submitting Legal entity (Submitting legal entity is reported in 'Mixture identity and legal submitter' record in the field 'Legal entity owner'.)	All
<b>BR577</b>	'Reference substance' datasets and 'Mixture' datasets cannot be linked from 'Mixture' (MiM). Only 'Substance' datasets can be linked from 'Mixture' (MiM).	All

#### SUBSTANCE COMPONENTS (SiM)

<b>BR539</b>	Substance components must have linked 'reference substance' datasets. Components identified using the Generic Product Identifier (GPI) are an exception.	All
<b>BR540</b>	'Reference substance' must have at least one of the following identifiers: EC number, CAS number, IUPAC name, INCI or colour index name. (International chemical name should be reported in the IUPAC name field.)	All
<b>QLT509</b>	If no EC number, CAS number or IUPAC name is provided for the 'reference substance', then notifier is reminded that more identifiers could be provided.	All

<b>BR525</b>	EC number format must be correct.	All
<b>BR526</b>	CAS number format must be correct.  The CAS number format is described in: <a href="https://www.cas.org/support/documentation/chemical-substances/checkdig">https://www.cas.org/support/documentation/chemical-substances/checkdig</a> .	All
<b>QLT592*</b>	Repeating the same 'reference substance' not allowed unless the related classification is different.	All

Substance or mixture components identified using the Generic Product Identifier (GPI)		
<b>BR583*</b>	If the component is indicated using the GPI, 'Function' must be 'Colourant, or 'Perfume'.	All
<b>BR605</b>	GPI cannot be classified for human hazard.	All
<b>BR604</b>	GPI type 'Perfume' can only be used once.	All
<b>BR617</b>	GPI type 'Colourant' can only be used once.	All
<b>BR602</b>	The concentration of the GPI type component 'Colourant' must not exceed 25 %.	All
<b>BR603*</b>	The concentration of the GPI type component 'Perfume' must not exceed 5 %.	All

Components concentrations		
<b>BR590*</b>	Components must have concentrations (value and unit). Components described in provision B.3.4.2 of Annex VIII are an exception.	All
<b>BR581</b>	Either 'Typical concentration' (exact concentration) or 'Concentration range' must be provided, not both.	All
<b>BR607*</b>	Report only components which are present in the mixture; <ul style="list-style-type: none"> <li>- Components which 'Typical concentration' (exact concentration) is 0% are not allowed.</li> <li>- Components which lower concentration range value is <b>exactly</b> 0% are not allowed. Therefore, lower concentration range values which are reported with qualifier =&gt; to be 0% are not allowed. Please note that concentration ranges where lower value is indicated to be <b>above</b> 0% are allowed. To this end indicate the concentration value with qualifier &gt;.</li> </ul> <p>Negative values are not allowed as concentration values.</p>	All
<b>QLT502</b>	If the concentration is above 1 %, the recommended number of decimals is one.	All
<b>QLT505</b>	If the concentration value is 0.1-1 %, the recommended number of decimals is two.	All
<b>BR518</b>	Allowed concentration ranges for hazardous components of major concern must be in accordance with Annex VIII to the CLP Regulation, Table 1 of Part B.	S, N
<b>BR588</b>	Allowed concentration ranges for other hazardous components and components not classified as hazardous must be in accordance with Annex VIII to the CLP Regulation, Table 2 of Part B.	S, N

<b>BR556</b>	Total concentration of the mixture is too low (below 70 %). If the reported concentration is lower than 70 %, the dossier cannot be accepted.	S, N
<b>QLT506</b>	Total concentration of the mixture is too low (70-90 %). If the reported concentration is lower than 90 %, the notifier is warned that the full composition is currently not included.	S, N
<b>BR593</b>	Total concentration of the mixture exceeds 100%. If the reported concentration is higher than 105 %, the dossier cannot be accepted.	all
<b>BR591</b>	Units provided for concentrations must be consistent.	All
<b>BR541</b>	Allowed units for concentrations: v/v % and w/w %.	All
<b>BR548</b>	Allowed qualifiers for concentrations: - 'Typical concentration' cannot have qualifiers - 'Concentration range' 'c.a.' not allowed.	All
<b>BR625*</b>	If 'Concentration range' is provided then qualifiers must be included.	All

#### UNIQUE FORMULA IDENTIFIER (UFI) AND OTHER IDENTIFIERS

<b>BR516</b>	'Unique formula identifiers (UFI) and other identifiers' record must be provided.	S, L
<b>BR528</b>	UFI is mandatory. At least one entry with the regulatory programme type 'CLP unique formula identifier (UFI)' and the appropriate UFI value in the field 'Id' must be included.	S, L
<b>QLT508</b>	UFI should be provided. At least one entry with the regulatory programme type 'CLP unique formula identifier (UFI)' and the appropriate UFI value in the field 'Id' must be included.	N
<b>BR549</b>	UFI number format must be correct. The UFI format is specified in the UFI Developers Manual: <a href="https://poisoncentres.echa.europa.eu/ufi-generator">https://poisoncentres.echa.europa.eu/ufi-generator</a> .	All
<b>BR563</b>	'CLP related PCN number' not allowed for initial submissions.	All
<b>BR562</b>	'CLP related PCN number' is mandatory for 'After significant composition change' notifications.	All
<b>BR609</b>	Submission cannot have more than one 'CLP related PCN number' reported.	All
<b>BR557</b>	'PCN number' reported in dossier header cannot be same as 'CLP related PCN number'.	All
<b>BR584</b>	'Unique formula identifiers (UFI) and other identifiers' record must be included in 'Product information' record.	S, L

#### CLASSIFICATION AND LABELLING

<b>BR513</b>	Exactly one 'Classification and labelling information' record must be provided in 'Mixture information' (MainMixture).	All
<b>BR510</b>	Exactly one 'Classification and labelling information' record must be provided for each 'Mixture' component (MiM).	All

<b>BR612</b>	Exactly one 'Classification and labelling information' record must be provided for each 'Substance' component.	All
<b>QLT507</b>	Voluntary submissions cannot be classified for health or physical hazards. An exception can be made if classification is only regarding explosive or gases under pressure hazards.	N
<b>BR546*</b>	In 'Mixture information' (MainMixture): Either ' <b>Not classified</b> ' must be selected or at least one selection in ' <b>Hazard categories and statements</b> ' must be made.	All
<b>BR613*</b>	In 'Mixture information' (MainMixture): 'Classifications' must be complete: If 'Hazard category' is selected then also the adjacent 'Hazard statement' must be selected.	All

<b>PRODUCT INFORMATION</b>		
<b>BR517</b>	At least one 'Product details' record must be provided.	All
<b>BR508</b>	'Trade name' must be provided.	All
<b>BR531</b>	Each 'Product details' record must have at least one linked UFI number.	S, L
<b>BR532</b>	Market placement 'Country' is mandatory.	All
<b>BR610</b>	Each country indicated in the 'Product information' record must be also indicated as a market placement country in the dossier header.	All
<b>BR514</b>	'Colour and physical state' record is mandatory.	S, L
<b>BR529</b>	'Physical state' must be indicated.	S, L
<b>BR547</b>	'Physical state' must be same in all 'Colour and physical state' records.	S, L
<b>BR530</b>	'Colour' must be indicated.	S, L
<b>BR542</b>	Either 'Packaging document' must be linked or 'Product not packaged' must be selected. Exception if use type is only 'Industrial'.	S
<b>BR536</b>	'Type of packaging in contact with the product (container type)' must be indicated.	S, L
<b>BR537</b>	'Size of packaging in contact with the product (container size)' must be indicated.	S, L
<b>BR535</b>	At least one 'Use type' must be indicated.	S, L
<b>BR587</b>	For limited submissions, 'Use type' can only be 'Industrial'. 'Professional' and 'Consumer' are not allowed.	L
<b>BR534</b>	'Main intended use' must be indicated.	S, L
<b>QLT503</b>	Up to three 'Secondary uses' allowed.	S, L
<b>BR589</b>	Biocides or plant production products cannot be selected as 'Secondary uses' unless also declared in 'Main intended use'.	All



## 2.2 List of PCN validation rules in ECHA Submission portal

Rules marked in blue (**BR**) lead to the failure of the submission. Rules marked in orange (**BR**) warn or remind the notifier of common shortcomings and inconsistencies. These warnings will not lead to the failure of the submission, but can result in further clarification requests from Member state(s) at a later stage.

GENERAL RULES		
<b>[BR564]</b>	The exactly same dossier cannot be submitted again.	All
<b>[BR565]</b>	ECHA Submission portal currently only accepts dossiers of which the submission type is 'CLP Poison centres notification'.	All
<b>[BR619]</b>	'Group submissions' are not allowed.	G
<b>[BR573]</b>	'Mixture name' should remain same in update dossier.	All

DOSSIER HEADER		
<b>[BR570]*</b>	Submitter legal entity in 'ECHA Submission portal' must be same as the legal entity included in the 'Mixture identity and legal submitter' record in the field 'Legal entity owner'.	All
<b>[BR567]</b>	A new 'PCN number' should be provided for initial notifications and significant change of composition notifications.	All
<b>[BR568]</b>	An existing 'PCN number' should be used in updates notified by the same legal entity.	All
<b>[BR576]</b>	In case of updates, the dossier creation date should be greater than the previously submitted notifications creation date.	All
<b>[BR623]*</b>	Removing market placement countries is not allowed.	All
<b>[QLT513]*</b>	Notice that update has more market placement countries than the previous successful notification.	All
<b>[BR574]</b>	Any changes to the notification should be reported as an 'update' and not as a new 'initial' submission.  Therefore new 'initial' submissions: (i) for products having the same trade name (ii) made by the same company (iii) targeted at the same market area/country and (iv) and belong to the same product category are not allowed.	All

<b>[QLT514]*</b>	<p>Any changes to the notification should be reported as 'update' and not as a new 'initial' submission.</p> <p>Therefore new 'initial' submissions:</p> <p>(i) for products having the same UFI</p> <p>(ii) made by the same company</p> <p>(iii) where concentration:</p> <ul style="list-style-type: none"> <li>• Ranges have not changed beyond the initial submissions concentration ranges</li> <li>• Typical (exact) concentrations have not changed beyond the allowed limits (accordance with Annex VIII to the CLP Regulation, Table 3 of Part B.)</li> <li>• Components have not been altered (added or deleted)</li> </ul> <p>are not allowed.</p>	All
<b>[BR620]</b>	'New submission after significant change of composition' is not allowed if there is no change in the composition from the previous notification. Therefore, submissions where there is no change in composition should be reported as an 'update' not as a 'New submission after significant change in composition'.	All

Components concentrations		
<b>[BR601]</b>	Same concentration units must be used across updates.	All
<b>[BR598]</b>	Adding, replacing or removing components in updates is not allowed.	All
<b>[BR597]</b>	Change of concentration ranges beyond limits in updates (as indicated in Annex VIII to the CLP Regulation, Table 1 and 2 of Part B) is not allowed.	All
<b>[BR599]</b>	Change of typical concentrations beyond limits in updates (as indicated in Annex VIII to the CLP Regulation, Table 3 of Part B) is not allowed.	All

UNIQUE FORMULA IDENTIFIER (UFI) AND OTHER IDENTIFIERS		
<b>[BR569]</b>	'CLP related PCN number' should refer to existing PCN number from the same legal entity notified by a succeeded submission.	All
<b>[BR611]</b>	'CLP related PCN number' indicated in the case of a significant change of composition must be retained across updates.	All
<b>[BR618]*</b>	One UFI cannot correspond to more than one PCN number submitted in the same market placement country.	All
<b>[BR572]</b>	UFI(s) can be added but never removed in updates.	All
<b>[BR571]</b>	UFI(s) which have been notified by another legal entity are not allowed unless there is a valid reason (e.g. you are successor of that legal entity, you are a toll formulator's customer and you act with an agreement on the re-use of the UFI, same UFI is used by different subsidiaries companies etc.).	All
<b>[QLT515]*</b>	The UFI used to identify the MiM component should have been notified by a valid submission (e.g. by the Supplier of this component) in the relevant market placement countries.	All

<b>[BR596]</b>	A MiM component identified by UFI, which has been notified for only Industrial use, cannot be used in other cases (Professional/Consumer use).	All
----------------	--	-----

## PRODUCT INFORMATION

<b>[BR575]</b>	'Trade names' can be added, but not removed in updates.	All
----------------	---	-----

## 3. Known issues

### 3.1 Validation report links

When validating Poison Centers notifications, the links from validation failures to the corresponding dossier/dataset sections do not work correctly in all occasions. The behavior will be improved in a subsequent IUCLID releases.

## 4. Changes to this document

Version	Changes
1.0	April 2019 First version
2.0	October 2019 <ul style="list-style-type: none"> <li>Rules embedded in 'ECHA Submission portal' added to this document.</li> <li><b>BR540</b> It was clarified that 'International chemical name' should be reported in IUPAC name field.</li> <li><b>BR542</b> It was clarified that if use type is only 'Industrial use' then they excluded from the requirement to provide Packaging record.</li> <li><b>BR557</b> 'PCN number' cannot be same as 'CLP related PCN number' rule was added</li> <li>Known issues: "Regarding BR608: Legal entity information must be included from 'Advanced settings'" was removed</li> </ul>
2.1	January 2020 <ul style="list-style-type: none"> <li><b>QLT510</b> wording: 'Minimum pH value range width is 3 units (when pH 3 &lt; pH &lt;10)' changed to 'Maximum pH value range width is 3 units (when pH 3 &lt; pH &lt;10).'</li> <li><b>BR589</b> wording: 'Biocides or plant production <b>products</b> cannot be selected as 'Secondary uses' unless also declared in 'Main intended use'.' Changed to 'Biocides or plant <b>protection</b> products cannot be selected as 'Secondary uses' unless also declared in 'Main intended use'.'</li> <li><b>BR573</b> changed to be warning <b>BR573</b></li> </ul>
3.0 (Draft to WG only)	May 2020 <b>Legal entity:</b> <ul style="list-style-type: none"> <li><b>BR608</b> MODIFIED: requirement to provide Legal entity in both 'dossier header' and in 'Mixture identity and legal submitter' record changed to requirement to provide the legal entity just in ' Mixture identity and legal submitter' record</li> <li><b>BR520</b> DEACTIVATED requirement to provide same legal entity in 'Dossier header' and in 'Mixture' deleted</li> </ul>

- **[BR570]** MODIFIED Legal entity in the 'Mixture identity and legal submitter' must be the same as the Submitting Legal entity in ECHA Submission portal was changed to Legal entity in the 'Mixture identity and legal submitter' must be the same as the Submitting Legal entity in ECHA Submission portal

#### **MiM:**

- **BR527** MODIFIED 'MiM identified with SDS' changed to 'MiM identified with available Substance(s)' and Supplier record
- **BR579** DEACTIVATED 'If the MiM is identified using a Safety data sheet (SDS), the 'Suppliers' record is mandatory.' (rule was merged to BR527)
- **BR606** MODIFIED 'MiM identified with SDS' changed to 'MiM identified with available Substance(s)'
- **BR624** NEW If MiM is identified with available substances then the Supplier (Legal entity reported in 'MiM Supplier record field 'Name') must be different from the duty holder (legal entity reported ' Mixture identity and legal submitter')
- **QLT512** DEACTIVATED 'MiM identified with SDS should be used as last resort'

#### **Substance:**

- Rule type changed from 'failure' to 'warning': **BR592** changed to **QLT592**

#### **Fragrance related changes:**

- **BR583** MODIFIED reference to Fragrance removed
- **BR616** DEACTIVATED Rule regarding 'GPI type Fragrance can be reported once'
- **BR603** MODIFIED reference to Fragrance removed
- **BR590** MODIFIED in exception regarding Fragrances removed

#### **Concentration:**

- **BR607** MODIFIED 'Only positive values are allowed rule is modified' to also check that lower concentration range cannot be reported to be exactly zero.
- **BR625** NEW Qualifiers are mandatory if concentration range is reported

#### **C&L**

- **BR546** NEW Either 'Not classified' must be ticked or at least one selection in 'Hazard categories and statements' must be made.
- **BR613** NEW If 'Hazard category' is selected then also the adjacent 'Hazard statement' must be selected

#### **[Dossier header]:**

- **[BR600]** DEACTIVATED Changing 'Market placement countries' is not allowed.
- **[BR623]** NEW Removing 'Market placement countries' not allowed.
- **[QLT513]** NEW Notice that update has more 'Market placement countries'
- **[QLT514]** NEW Dossier must be 'update' and not new 'initial' if there is already 'initial' notification for the same Legal entity, UFI and composition

#### **[UFI]**

- **[BR618]** MODIFIED 'One UFI cannot correspond to more than one UFI' is modified to 'One UFI cannot correspond to more than one UFI in the same market placement country'.
- **[BR566]** DEACTIVATED 'The UFI used to identify the MiM component should have been notified by a valid submission (e.g. by the Supplier of this component).'
- **[QLT515]** NEW 'The UFI used to identify the MiM component should have been notified by a valid submission (e.g. by the Supplier of this component)' in the relevant market placement countries.'