THE EUROPEAN DIRECTORATE FOR THE QUALITY OF MEDICINES & HEALTHCARE (EDQM)

edqm

European Directorate for the Quality of Medicines & HealthCare | Direction européenne de la qualité du médicament & soins de santé

COUNCIL OF EUROPE

CONSEIL DE L'EUROPE

European Pharmacopoeia Reference Standards

Handling, dispatch, where to find useful information and other practicalities

European Pharmacopoeia training webinars

Strasbourg, 6 December 2024

Dr Maryline Clauzel

Head of Operations Division – Supply Chain Department

Topics

- Before ordering 
- Ordering 
- Labelling 
- What is expected from users 
- Proving validity 
- Shipping & Storing 
- Safety 
- Other sources of information & FAQ 

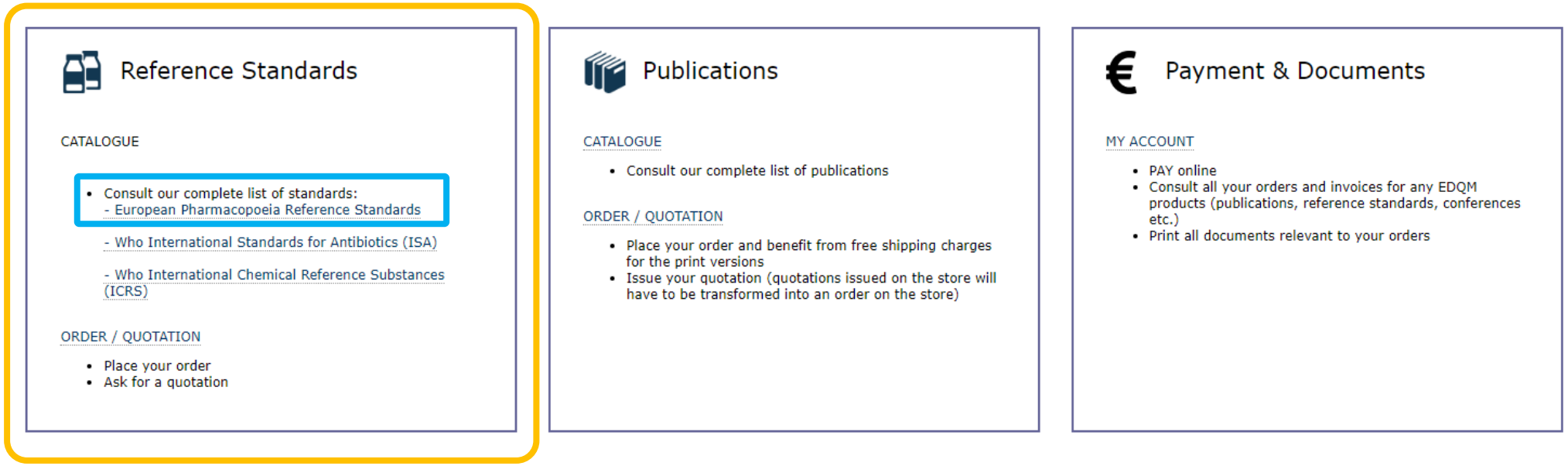
Before ordering

Online Catalogue – Where to find it

Consult the online catalogue.

⚠ Specific catalogue for Ph. Eur. / ISA and ICRS (WHO)

https://store.edqm.eu/index.html



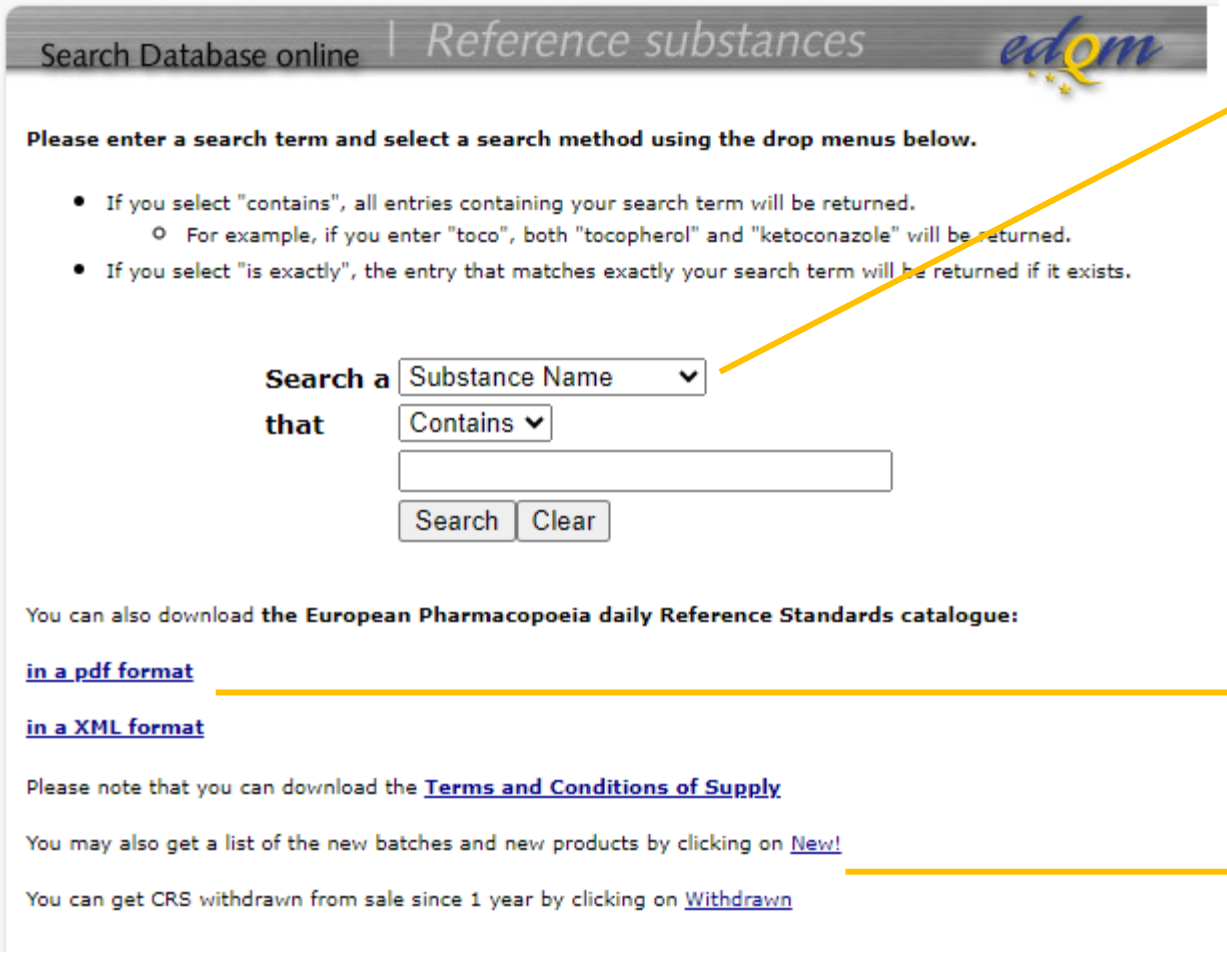
Online Catalogue – Where to find it

Available online

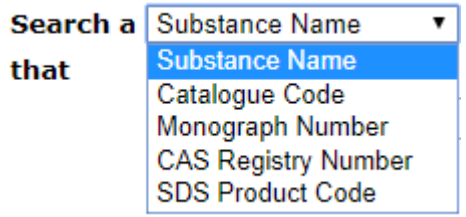
Updated daily - English only.

For searching database: https://crs.edqm.eu

Search Database



Several possibilities to search for a RS:



Possibility to print the entire catalogue (interface with IT system in xml)

See next slide

Prepare for customs and reception in your laboratory

Catalogue Code	Y0001984
Name	Codeine for system suitability - * narc CRS
Current batch number	2
Unit quantity per vial	10 mg
Number of vials per sales unit	1
Used in monograph(s)	0074, 0075, 0076, 1412
Assigned content	See leaflet
Additional information	An original import permit is required to apply for an export licence from the French authorities (allow 2-3 weeks). Your permit must be valid for at least 3 months. Please state on your purchase order your preferred airport. You should apply for your import permit, per vial: - 9,19 mg of codeine monohydrate - 0,019 mg of thebaine - 0,031mg of norcodeine
Leaflet	click to download the leaflet
Chemical hazard	Click to download Safety Data Sheet
Biological hazard	none identified
SDS Product Code	201600233
CAS Registry Number	N/A
Presentation	
Origin	click to download Origin Of Goods.pdf
Proposed Import HS code	293911
EDQM long term storage conditions	+5°C+/-3°C
Dispatching conditions	Ambient temp.
UN Code	Not classified
Shipping group	A2A
Price*	79 EUR
Availability	Available
Sales restriction	No

Batches

batch 2 is valid at this date

Print BVS

RS webshop

Direct link to Webstore

Need 2-3 weeks to be processed by French authorities.
Composition to declare is provided.

SDS

Origin of goods **NEW** – Country of origin

Proposed HS code

EDQM dispatch and storage conditions

Availability
Sales restriction are provided

Necessary documents in some cases

For **precursors**, **psychotropic** and **narcotic** substances	For ***ODS substances**	For **biological material**	Some specific documents available from the website
• An original import permit to be sent to the EDQM	• A valid LabODS number (EU) or license (outside EU) is required (refer to specific FAQ for further guidance)	• Please check that you have the import permit (e.g. USA and Australian permits)	• Letter replacing CoA • Legal Framework and Diplomatic Status of Reference Standards for Customs Purposes

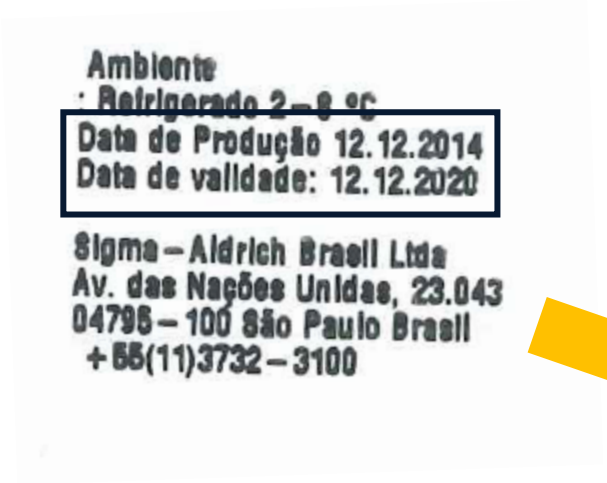
Ordering

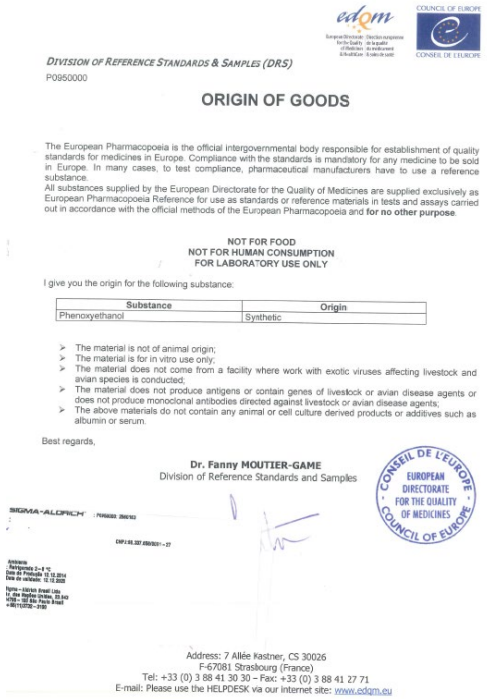
Where to order

- Ph.Eur. RS can be ordered directly from EDQM:

  https://www.edqm.eu/en/ph-eur-reference-standards-orders-catalogue

- Care should be taken when ordering from other sources:





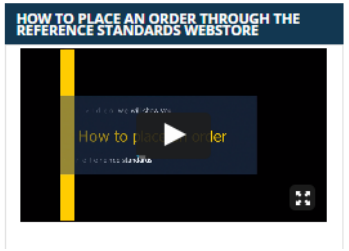
Where to order

- EDQM does not have authorised distributors

….but EDQM provides a list of organisations or companies known to re-sell EDQM products.

This list is available through the website.

- A video explaining how to use the webstore is available from the website.



- Reference spectra are mailed as a pdf file since 2021.

Certificates of origin

NEW: revised certificates of origin are now online

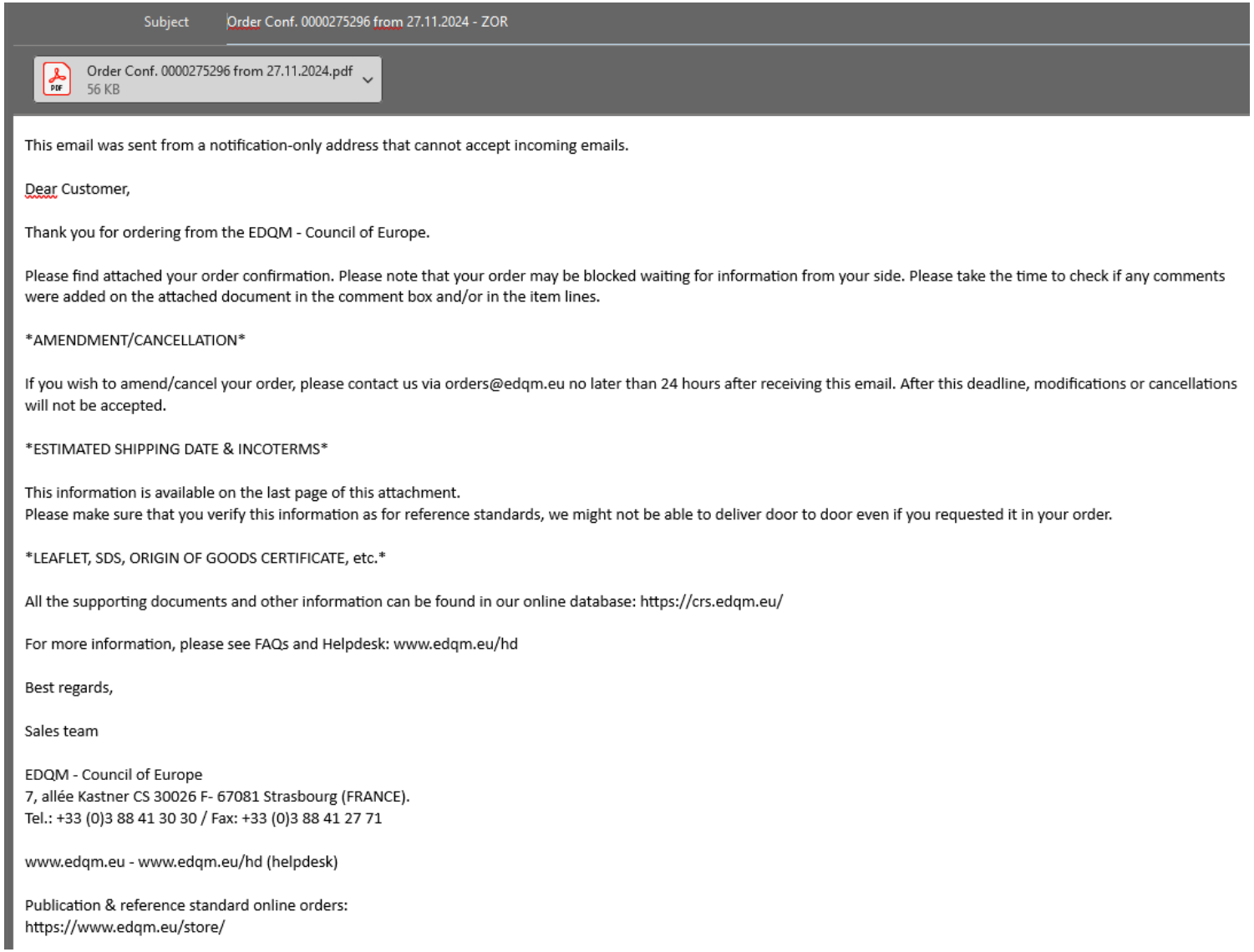
(from the online catalogue)

YET

Be aware that the EDQM is not in a position to release **EUR.1 movement certificate**

(also known as **EUR.1 certificate**, or **EUR.1**).

Ordering



Subject Order Conf. 0000275296 from 27.11.2024 - ZOR

Order Conf. 0000275296 from 27.11.2024.pdf
56 KB

This email was sent from a notification-only address that cannot accept incoming emails.

Dear Customer,

Thank you for ordering from the EDQM - Council of Europe.

Please find attached your order confirmation. Please note that your order may be blocked waiting for information from your side. Please take the time to check if any comments were added on the attached document in the comment box and/or in the item lines.

AMENDMENT/CANCELLATION

If you wish to amend/cancel your order, please contact us via orders@edqm.eu no later than 24 hours after receiving this email. After this deadline, modifications or cancellations will not be accepted.

ESTIMATED SHIPPING DATE & INCOTERMS

This information is available on the last page of this attachment.
Please make sure that you verify this information as for reference standards, we might not be able to deliver door to door even if you requested it in your order.

LEAFLET, SDS, ORIGIN OF GOODS CERTIFICATE, etc.

All the supporting documents and other information can be found in our online database: https://crs.edqm.eu/

For more information, please see FAQs and Helpdesk: www.edqm.eu/hd

Best regards,

Sales team

EDQM - Council of Europe
7, allée Kastner CS 30026 F- 67081 Strasbourg (FRANCE).
Tel.: +33 (0)3 88 41 30 30 / Fax: +33 (0)3 88 41 27 71

www.edqm.eu - www.edqm.eu/hd (helpdesk)

Publication & reference standard online orders:
https://www.edqm.eu/store/

- When an order is sent, you have **24 hours** to correct or cancel the order.

- Then, the order is blocked **24 hours** for preparation (no possible change).
- We privilege door-to-door shipment.

Ordering

Line	Item code	Description	Qty	Unit price	Handling charges	Net value	Estimated shipping date
10	Y0001745	**Glucose monohydrate CRS** 1 vial(s) per sales unit ; 750 mg per vial	18	79,00	45,00	1.467,00	23/05/2022
20	F0400000	**Fosfomycin trometamol CRS** 1 vial(s) per sales unit ; 1500 mg per vial	17	79,00	42,50	1.385,50	23/05/2022
30	Y0000400	**Naltrexone hydrochloride CRS** 1 vial(s) per sales unit ; 50 mg per vial	6	79,00	15,00	489,00	23/05/2022
40	Y0001629	**Follitropin CRS** 1 vial(s) per sales unit ; 0,2 mg per vial	16	79,00	40,00	1.304,00	23/05/2022

Ambient, not controlled nor dangerous (shipping group A1A)
DELIVERY TERMS: DAP [redacted] - Door to door

Item	Item code	Description	Qty	Proposed HS code	Estimated ship. date
10	Y0001745	Glucose monohydrate CRS	18	170230	23/05/2022
20	F0400000	Fosfomycin trometamol CRS	17	294190	23/05/2022
30	Y0000400	Naltrexone hydrochloride CRS	6	293919	23/05/2022
50	Y0001816	Sodium aminosalicylate dihydrate for equipment qualification	4	292250	23/05/2022

Dry-ice, not controlled nor dangerous (shipping group D1A)
DELIVERY TERMS: DAP [redacted] - Door to door

Item	Item code	Description	Qty	Proposed HS code	Estimated ship. date
40	Y0001629	Follitropin CRS	16	293719	23/05/2022

Always have a close look to the Acknowledgement of Receipt

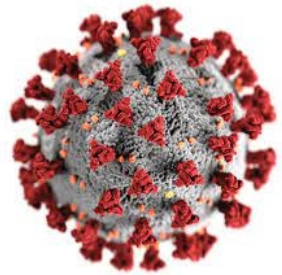
NEW: split per shipping group

- Shipping dates are known at the time of parcel preparation, not before
- Impossible to make door-to-door for some destinations because of shipping companies restrictions (even if requested at order stage!!)
- Ice: delivered at the closest "customs" airport!

Chase your broker, if any (especially for ice / dry ice) & ANTICIPATE CUSTOMS ISSUES

Shipping issues are the new reality

- Flights are subject to last minute change without notice.
- Due to safety issues, some destinations are suspended at last minute leading to difficulties to ship to some areas.
- Some countries may still block parcels for claimed sanitary reason.



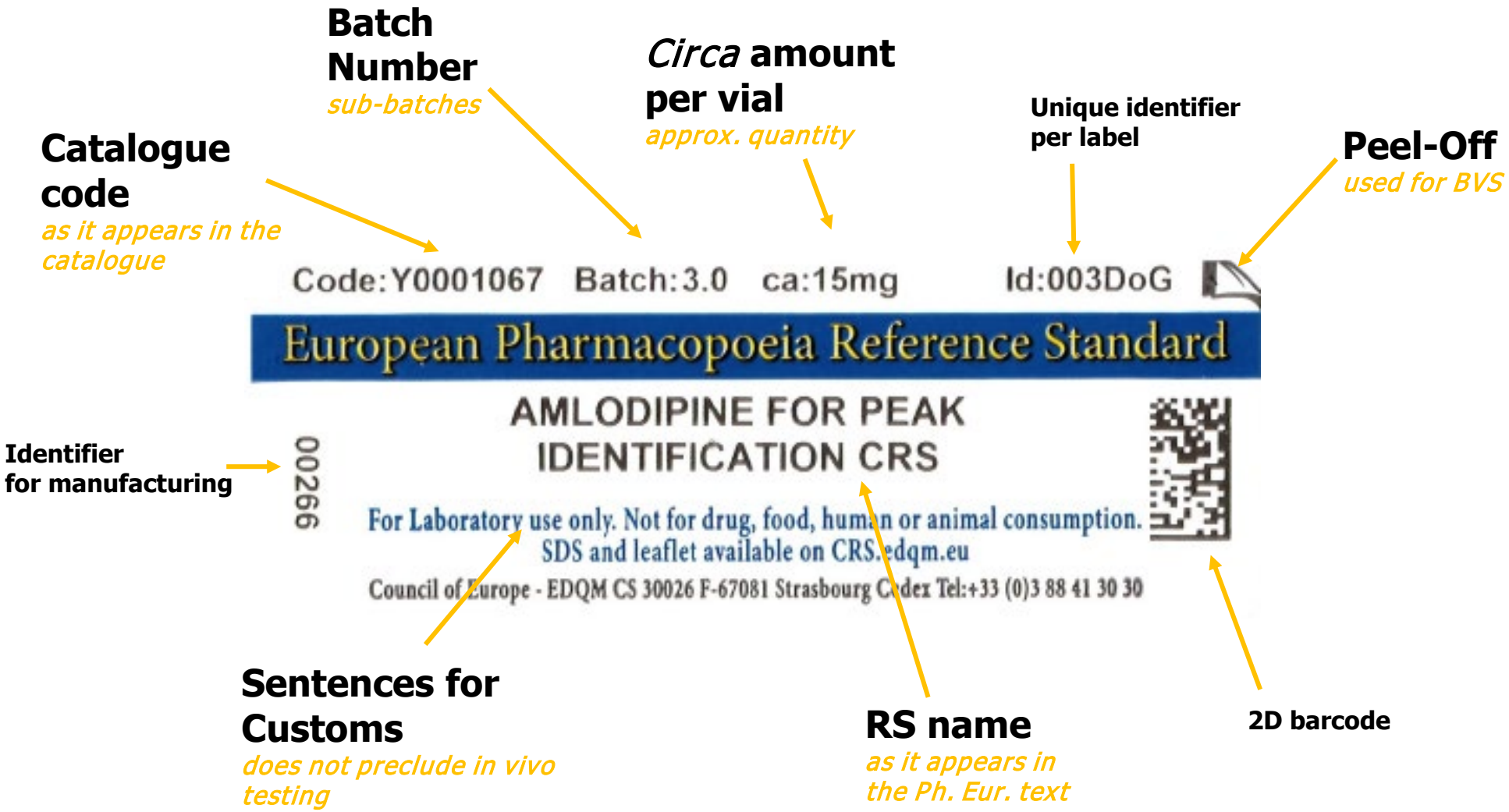
- We try to do our best to continue privileging door-to-door shipment or asking for the closest airport but we cannot guarantee that we are successful.

Labelling

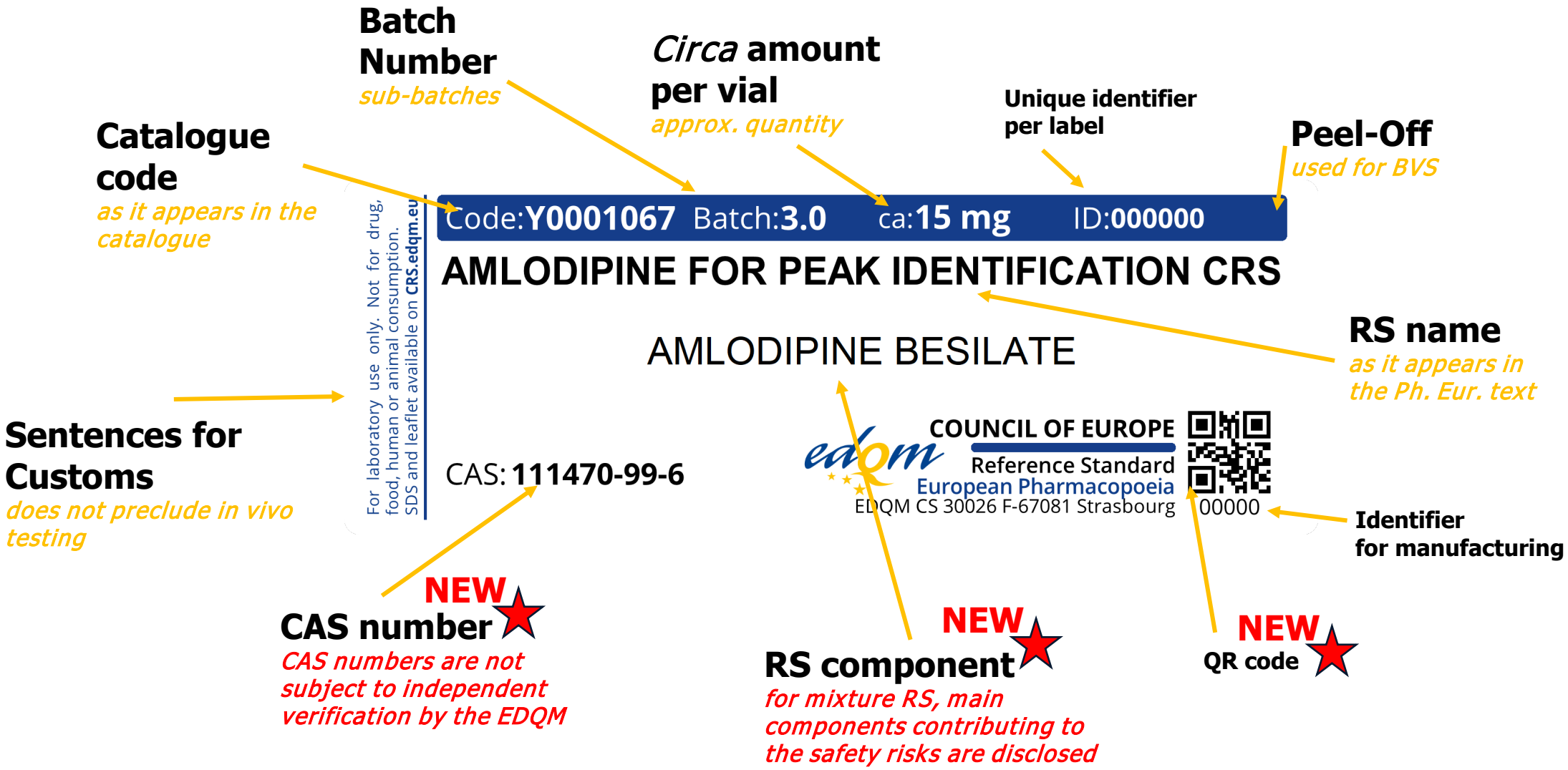
What the label includes

- Primary label AND the pictogram;
- Secondary label (displaying the pictograms on the outer package);
- Leaflet

Informations on the label



A new label is on the way



Safety information

Safety information

Warning tag (if any)

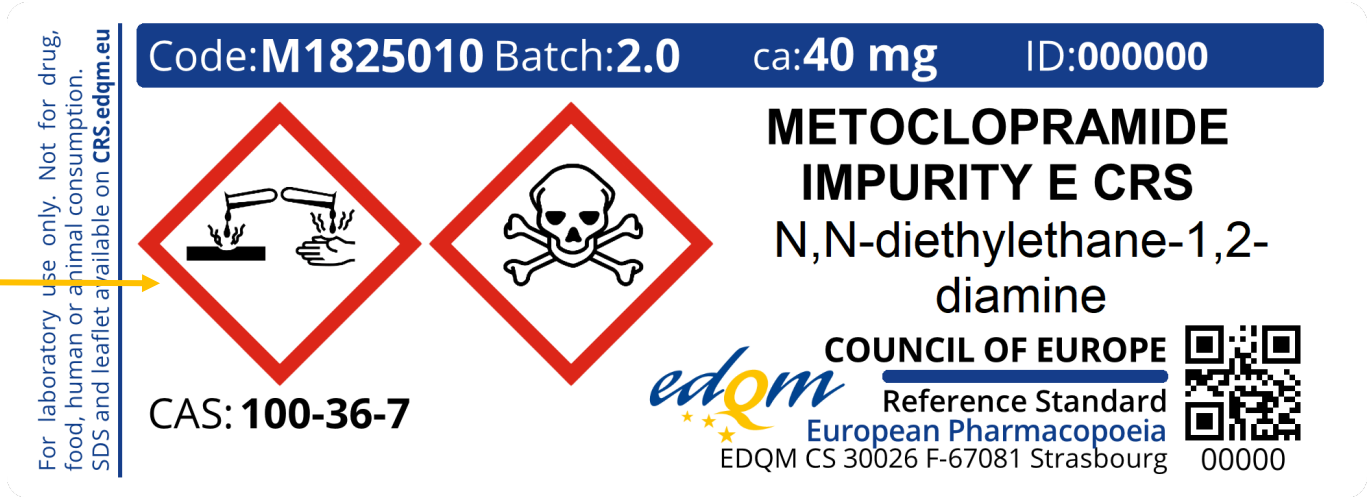
Safety information

… on the new label to come

NEW

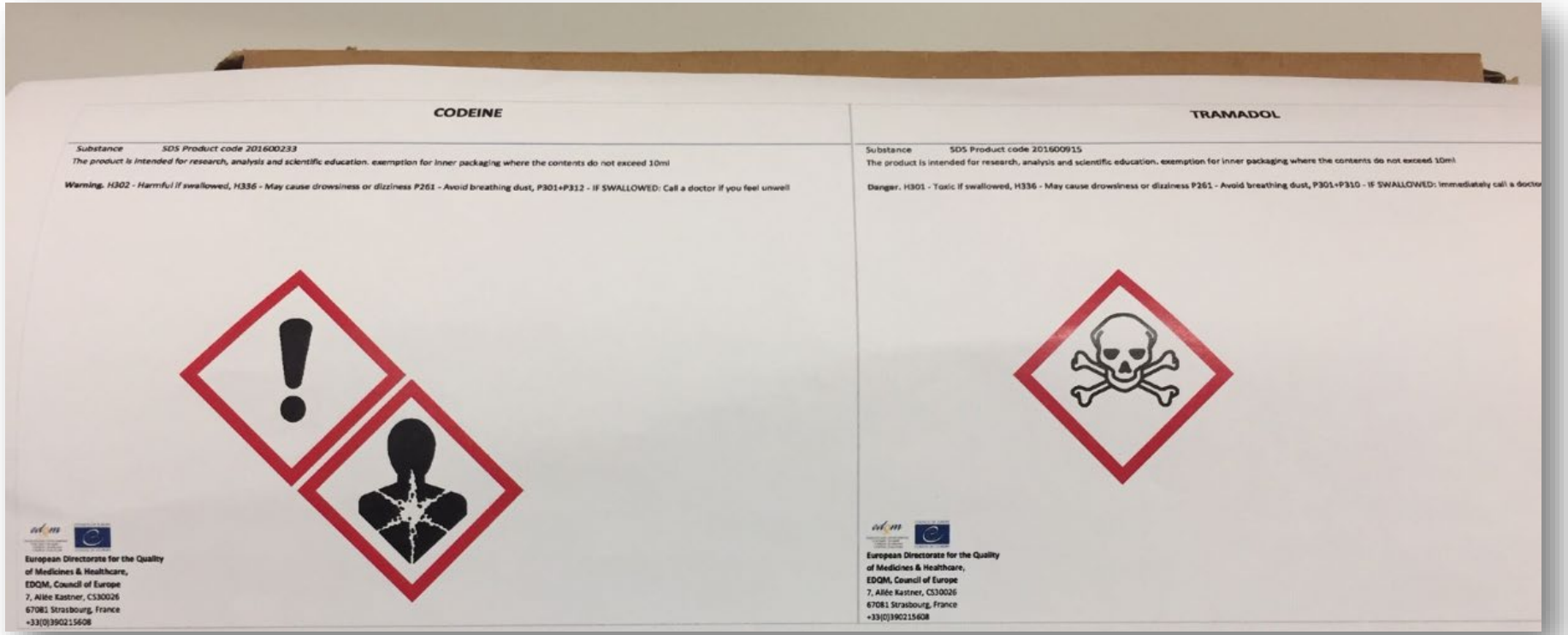
Pictograms

incorporated directly into the content of the primary label



Safety information

Safety Information is also provided on the external secondary package: pictograms and warnings (in the language of the country).



Leaflet

Additional information is provided in the information leaflet:

* if used as an assay standard the following information is also given:

  - the assigned percentage content;
  - or, the content in mg or mL of the chemical entity in the container;
  - or, the assigned potency (for biological assays or microbiological assays) in units either per mg or per vial.

This is not mentioned on the primary label or in the catalogue!

* type-chromatograms, stoichiometric conversion factor, etc. are also available in the leaflet.

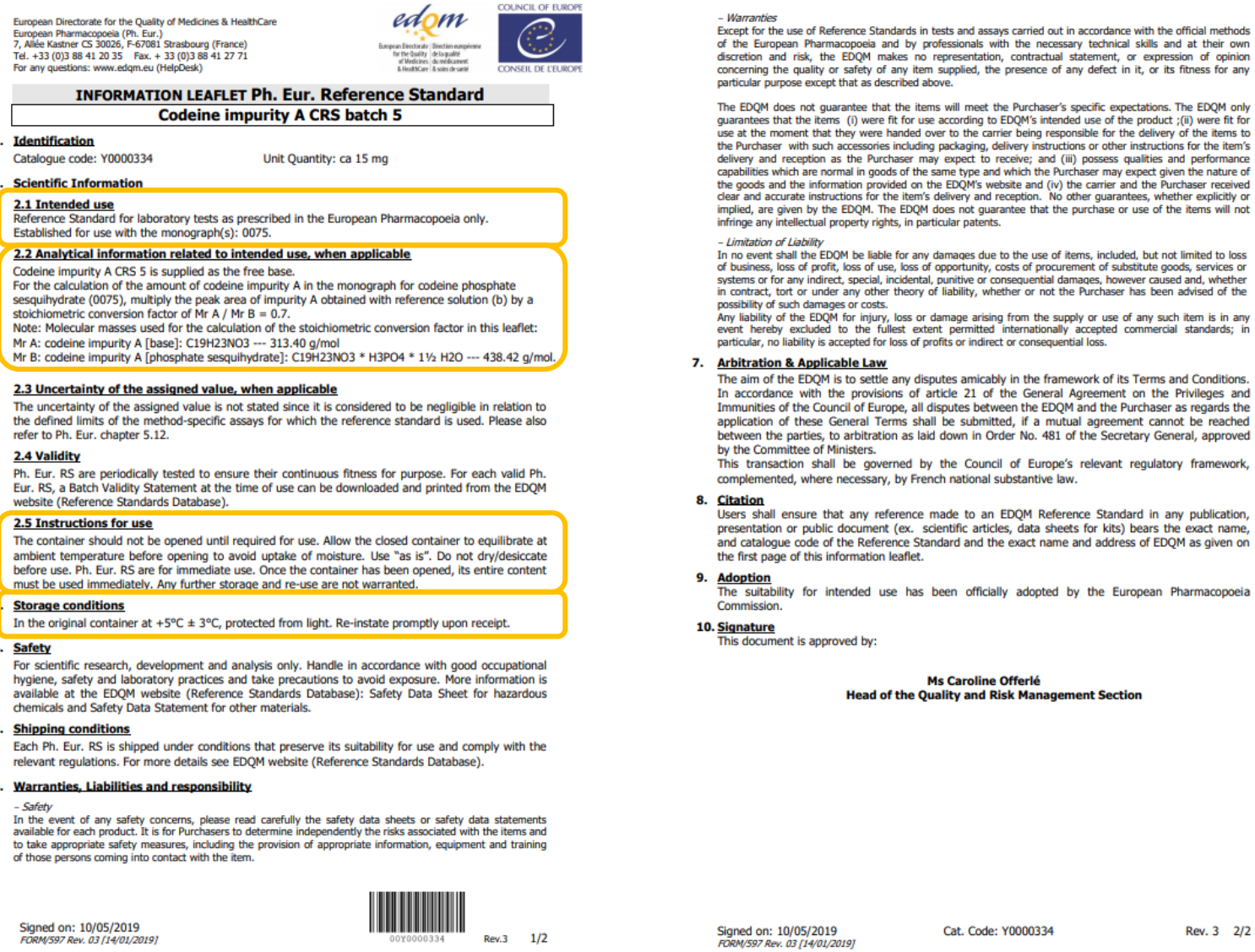
Leaflet

Provides mono number

Analytical information

Specific instruction

EDQM storage conditions



European Directorate for the Quality of Medicines & HealthCare
European Pharmacopoeia (Ph. Eur.)
7, Allée Kastner CS 30026, F-67081 Strasbourg (France)
Tel. +33 (0)3 88 41 20 35 Fax. + 33 (0)3 88 41 27 71
For any questions: www.edqm.eu (HelpDesk)

INFORMATION LEAFLET Ph. Eur. Reference Standard

Codeine impurity A CRS batch 5

1. **Identification**

Catalogue code: Y0000334 Unit Quantity: ca 15 mg

2. **Scientific Information**

2.1 Intended use

Reference Standard for laboratory tests as prescribed in the European Pharmacopoeia only.
Established for use with the monograph(s): 0075.

2.2 Analytical information related to intended use, when applicable

Codeine impurity A CRS 5 is supplied as the free base.
For the calculation of the amount of codeine impurity A in the monograph for codeine phosphate sesquihydrate (0075), multiply the peak area of impurity A obtained with reference solution (b) by a stoichiometric conversion factor of Mr A / Mr B = 0.7.
Note: Molecular masses used for the calculation of the stoichiometric conversion factor in this leaflet:
Mr A: codeine impurity A [base]: C19H23NO3 --- 313.40 g/mol
Mr B: codeine impurity A [phosphate sesquihydrate]: C19H23NO3 * H3PO4 * 1½ H2O --- 438.42 g/mol.

2.3 Uncertainty of the assigned value, when applicable

The uncertainty of the assigned value is not stated since it is considered to be negligible in relation to the defined limits of the method-specific assays for which the reference standard is used. Please also refer to Ph. Eur. chapter 5.12.

2.4 Validity

Ph. Eur. RS are periodically tested to ensure their continuous fitness for purpose. For each valid Ph. Eur. RS, a Batch Validity Statement at the time of use can be downloaded and printed from the EDQM website (Reference Standards Database).

2.5 Instructions for use

The container should not be opened until required for use. Allow the closed container to equilibrate at ambient temperature before opening to avoid uptake of moisture. Use "as is". Do not dry/desiccate before use. Ph. Eur. RS are for immediate use. Once the container has been opened, its entire content must be used immediately. Any further storage and re-use are not warranted.

3. **Storage conditions**

In the original container at +5°C ± 3°C, protected from light. Re-instate promptly upon receipt.

4. **Safety**

For scientific research, development and analysis only. Handle in accordance with good occupational hygiene, safety and laboratory practices and take precautions to avoid exposure. More information is available at the EDQM website (Reference Standards Database): Safety Data Sheet for hazardous chemicals and Safety Data Statement for other materials.

5. **Shipping conditions**

Each Ph. Eur. RS is shipped under conditions that preserve its suitability for use and comply with the relevant regulations. For more details see EDQM website (Reference Standards Database).

6. **Warranties, Liabilities and responsibility**

– Safety

In the event of any safety concerns, please read carefully the safety data sheets or safety data statements available for each product. It is for Purchasers to determine independently the risks associated with the items and to take appropriate safety measures, including the provision of appropriate information, equipment and training of those persons coming into contact with the item.

Signed on: 10/05/2019
FORM/597 Rev. 03 [14/01/2019]

00Y0000334

Rev.3 1/2

– Warranties

Except for the use of Reference Standards in tests and assays carried out in accordance with the official methods of the European Pharmacopoeia and by professionals with the necessary technical skills and at their own discretion and risk, the EDQM makes no representation, contractual statement, or expression of opinion concerning the quality or safety of any item supplied, the presence of any defect in it, or its fitness for any particular purpose except that as described above.

The EDQM does not guarantee that the items will meet the Purchaser's specific expectations. The EDQM only guarantees that the items (i) were fit for use according to EDQM's intended use of the product ;(ii) were fit for use at the moment that they were handed over to the carrier being responsible for the delivery of the items to the Purchaser with such accessories including packaging, delivery instructions or other instructions for the item's delivery and reception as the Purchaser may expect to receive; and (iii) possess qualities and performance capabilities which are normal in goods of the same type and which the Purchaser may expect given the nature of the goods and the information provided on the EDQM's website and (iv) the carrier and the Purchaser received clear and accurate instructions for the item's delivery and reception. No other guarantees, whether explicitly or implied, are given by the EDQM. The EDQM does not guarantee that the purchase or use of the items will not infringe any intellectual property rights, in particular patents.

– Limitation of Liability

In no event shall the EDQM be liable for any damages due to the use of items, included, but not limited to loss of business, loss of profit, loss of use, loss of opportunity, costs of procurement of substitute goods, services or systems or for any indirect, special, incidental, punitive or consequential damages, however caused and, whether in contract, tort or under any other theory of liability, whether or not the Purchaser has been advised of the possibility of such damages or costs.
Any liability of the EDQM for injury, loss or damage arising from the supply or use of any such item is in any event hereby excluded to the fullest extent permitted internationally accepted commercial standards; in particular, no liability is accepted for loss of profits or indirect or consequential loss.

7. **Arbitration & Applicable Law**

The aim of the EDQM is to settle any disputes amicably in the framework of its Terms and Conditions. In accordance with the provisions of article 21 of the General Agreement on the Privileges and Immunities of the Council of Europe, all disputes between the EDQM and the Purchaser as regards the application of these General Terms shall be submitted, if a mutual agreement cannot be reached between the parties, to arbitration as laid down in Order No. 481 of the Secretary General, approved by the Committee of Ministers.
This transaction shall be governed by the Council of Europe's relevant regulatory framework, complemented, where necessary, by French national substantive law.

8. **Citation**

Users shall ensure that any reference made to an EDQM Reference Standard in any publication, presentation or public document (ex. scientific articles, data sheets for kits) bears the exact name, and catalogue code of the Reference Standard and the exact name and address of EDQM as given on the first page of this information leaflet.

9. **Adoption**

The suitability for intended use has been officially adopted by the European Pharmacopoeia Commission.

10. **Signature**

This document is approved by:

Ms Caroline Offerlé
Head of the Quality and Risk Management Section

Signed on: 10/05/2019
FORM/597 Rev. 03 [14/01/2019]

Cat. Code: Y0000334

Rev. 3 2/2

What is expected from the user

Before using a Ph. Eur. Reference Standard

Immediately before using a Ph. Eur. Reference Standard, the following shall be checked:

- that the reference standard batch number is current at the time of use. Print the real-time batch validity statement (BVS) available online;
- that the container/closure system integrity is maintained, i.e. absence of visible defects originating from shipping;
- that the reference standard after receipt has been stored at the conditions prescribed in the Ph. Eur. RS catalogue (or according to your specifications, if any).

Before using a Ph. Eur. Reference Standard

- Moreover, allow the RS to equilibrate to lab temperature before opening.
- Use “as is” unless indicated in the leaflet.
- Depending on the quantity in the vial, two main glass vials may be used:

For filling weights > 15 mg

Brown glass vials (type 7 mL)

N.B.: also used for evaporation and freeze-dried references

For filling weights < 15 mg

V-vials facilitating the recovery of the powder

Proving validity

Validity

No expiry date nor retest date is stated on the label or leaflet

Use BVS!

Batch Validity Statement (BVS)

To get the BVS, go the detailed view of the catalogue

Catalogue Code	B1220000
Name	Ibuprofen impurity B CRS
Current batch number	11
Unit quantity per vial	1.15 ML
Number of vials per sales unit	1
Used in monograph(s)	0721
Assigned content	See Leaflet
Additional information	
Leaflet	click to download the leaflet
Chemical hazard	Click to download Safety Data Sheet
Biological hazard	none identified
SDS Product Code	201601020
CAS Registry Number	N/A
Origin	n/a
Proposed Import HS code	291639
EDQM long term storage conditions	+5°C+/-3°C
Dispatching conditions	Ambient temp.
UN Code	1648
Shipping group	A1A
Price	79 EUR
Availability	Available
Sales restriction	No

Batches

batch 11 is valid at this date

Print BVS

RS webshop

New Search

Batch Validity Statement (BVS)

Ibuprofen impurity B CRS batch number = **11** => Check online BVS

BATCH VALIDITY STATEMENT
EUROPEAN PHARMACOPOEIA REFERENCE STANDARDS (CRS) & (BRP)
This Batch Validity Statement has to be used in conjunction with Ph. Eur. general chapter 51200 Reference Standards.

European Directorate for the Quality of Medicines & HealthCare (EDQM) – Council of Europe
Postal address: 7 Allée Kastner CS 30026 F - 67081 STRASBOURG (France)
Phone: +33 (0)3 88 41 30 30
Fax: +33 (0)3 88 41 27 71
Internet: http://www.edqm.eu

Name	Ibuprofen impurity B CRS
Catalogue code	B1220000
Batch number*	11
Assigned value	
Validity	Batch 11 is valid at this date
Additional information	
Storage conditions	Recommended EDQM storage conditions for unopened containers : +5°C+/-3°C
Safety data	Safety Data Sheet is available from the detailed view or upon request.
Leaflet	Click on the hyperlink to download the leaflet containing the instructions for use, click to download the leaflet
Origin	Click on the hyperlink to download the origin to check if import permit is required in your country, n/a

Batch 11 is official at the time of printing

* This BVS also includes sub-batches.
This statement is valid at the date of printing : 2024-7-23

Also valid at the date of printing for sub-batches (e.g. 11.1; 11.2, etc.)

Batch Validity Statement (BVS)

BUT: batch 10 is still valid until 31/05/2025 ➔ Check online BVS

Catalogue Code	B1220000
Name	Ibuprofen impurity B CRS
Current batch number	11
Unit quantity per vial	1.15 ML
Number of vials per sales unit	1
Used in monograph(s)	0721
Assigned content	See Leaflet
Additional information	
Leaflet	click to download the leaflet
Chemical hazard	Click to download Safety Data Sheet
Biological hazard	none identified
SDS Product Code	201601020
CAS Registry Number	N/A
Origin	n/a
Proposed Import HS code	291639
EDQM long term storage conditions	+5°C+/-3°C
Dispatching conditions	Ambient temp.
UN Code	1648
Shipping group	A1A
Price	79 EUR
Availability	Available
Sales restriction	No

Batches

batch 11 is valid at this date

batch 10 : validity until 31 January 2025

batch 11 is valid at this date

RS webshop

New Search

Batch Validity Statement (BVS)

BUT : batch 10 is still valid until 31/05/2025 ➔ Check online BVS

BATCH VALIDITY STATEMENT
EUROPEAN PHARMACOPOEIA REFERENCE STANDARDS (CRS) & (BRP)
This Batch Validity Statement has to be used in conjunction with Ph. Eur. general chapter 51200 Reference Standards.

European Directorate for the Quality of Medicines & HealthCare (EDQM) – Council of Europe
Postal address: 7 Allée Kastner CS 30026 F - 67081 STRASBOURG (France)
Phone: +33 (0)3 88 41 30 30
Fax: +33 (0)3 88 41 27 71
Internet: http://www.edqm.eu

Name	Ibuprofen impurity B CRS
Catalogue code	B1220000
Batch number*	10
Assigned value	See leaflet
Validity	Batch 10 : validity until 31 January 2025
Additional information	
Storage conditions	Recommended EDQM storage conditions for unopened containers : +5°C+/-3°C
Safety data	Safety Data Sheet is available from the detailed view or upon request.
Leaflet	Click on the hyperlink to download the leaflet containing the instructions for use, click to download the leaflet
Origin	Click on the hyperlink to download the origin to check if import permit is required in your country, click to download Origin Of Goods.pdf

Batch 10 is still official at the time of printing (23/07/2024)

* This BVS also includes sub-batches.

This statement is valid at the date of printing : 2024-7-23

Proving validity

BATCH VALIDITY STATEMENT
EUROPEAN PHARMACOPOEIA REFERENCE STANDARDS (CRS) & (BRP)
This Batch Validity Statement has to be used in conjunction with Ph. Eur. general chapter 51200 Reference Standards.

European Directorate for the Quality of Medicines & HealthCare (EDQM) – Council of Europe
Postal address: 7 Allée Kastner CS 30026 F - 67081 STRASBOURG (France)
Phone: +33 (0)3 88 41 30 30
Fax: +33 (0)3 88 41 27 71
Internet: http://www.edqm.eu

Name	Ibuprofen impurity B CRS
Catalogue code	B1220000
Batch number*	11
Assigned value	See leaflet
Validity	Batch 11 is valid at this date
Additional information	
Storage conditions	Recommended EDQM storage conditions for unopened containers : +5°C+/-3°C
Safety data	Safety Data Sheet is available from the detailed view or upon request.
Leaflet	Click on the hyperlink to download the leaflet containing the instructions for use, click to download the leaflet
Origin	Click on the hyperlink to download the origin to check if import permit is required in your country, n/a

* This BVS also includes sub-batches.

This statement is valid at the date of printing : 2024-7-23

At the time of analysis:

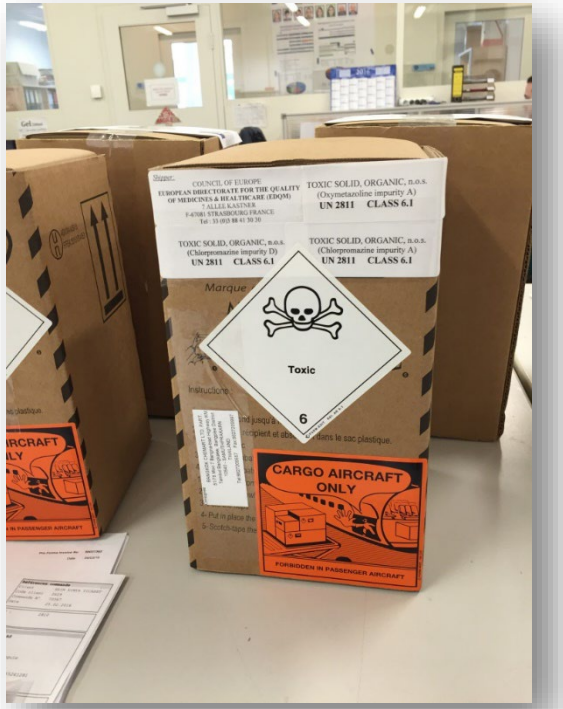
- Print out the BVS **and**
- Stick the peel-off label.

This ensure that you have used the official CRS at the time of use

Shipping and Storing

Packing materials

Packing materials (carton, boxes) are selected to minimise the risk of damage during transport and are compliant to the transport regulation prescription when applicable (IATA, ADR, IMDG).



Packing materials

Packing materials should ensure respect of T° for three days.

Specifications

+5°C ➔ +1°C / +8°C

-20°C ➔ -15°C / -25°C

Dry ice ➔ -70°C / -50°C

Dispatch and Storage Conditions

Dispatching conditions:

- Ambient temperature
- Under ice
- Under dry ice

Recommended storage conditions:

- +5°C or -20°C
- +5°C or -20°c
- -20°C or -80°C or Liq. N_2

Dispatch at ambient temperature – short excursions from the long-term storage temperature during shipping do not impact the quality of the reference standard.

Storage conditions

EDQM storage conditions are established for **long-term** storage.

They are based on :

- Stability data,
- Data received from supplier of the bulk material,
- Monitoring,
- Literature,
- Ph. Eur. information.

User is free to adopt other storage conditions, under its own responsibility.

Storage conditions

For optimal stability, storage temperature one level below monograph prescription, if any.

- Room temperature -> +5°C
- +2 to 8°C -> -20°C (if possible, liquids…)
- Under -15°C -> -20°C
- -20°C -> -80°C (if possible)
- -50°C -> -80°C
- -80°C -> liquid nitrogen

Shipping and Storing – In case of new data

In case new data is generated and has an impact, an information is published in the RS News published on the EDQM website usually the month before the change is implemented.

Information on change of EDQM storage/shipping conditions

Based on new stability information, storage and shipping conditions has been changed on **15 June 2024** for the following reference standard:

- Captopril impurity J CRS (Y0001450) **batch 3** is stored at -20°C (previously +5°C) and remain shipped at ambient temperature.

We also try to inform users in advance in other cases (e.g. change in sales unit / prices / amount per unit).

Change of sales units

- None

Information on change of amount per unit

- Testosterone enantate impurity H CRS (Y0001313) **batch 2** contains 15 mg per unit (10 mg previously)
- Asparagine impurity C CRS (Y0002076) **batch 2** contains 15 mg per unit (10 mg previously)
- Zidovudine for system suitability A CRS (Y0002266) **batch 2** contains 15 mg per unit (10 mg previously)

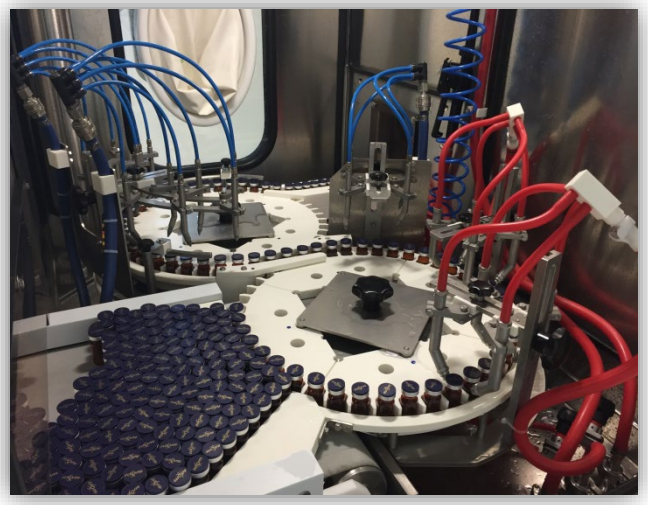
Information on change of price

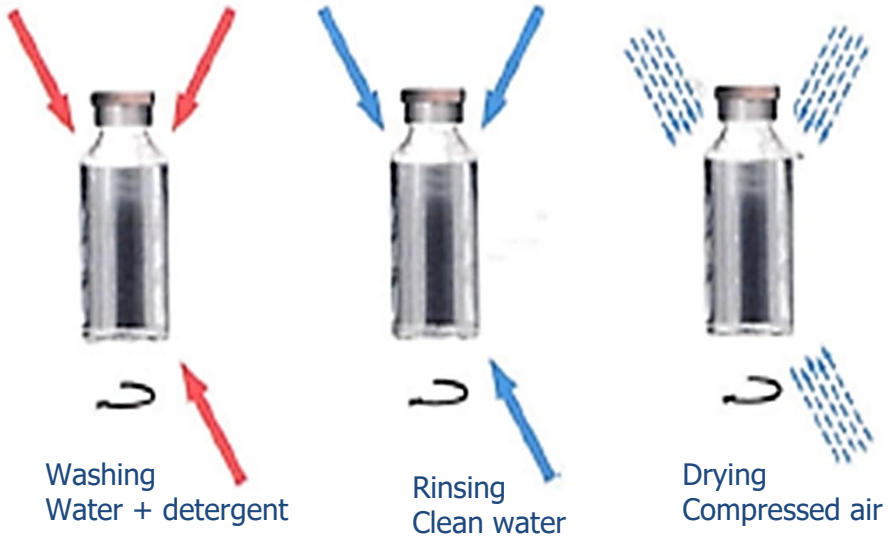
- None

Safety

Vials washing

The external part of the vials containing Substances of Very High Concern is washed after manufacturing to protect staff using CRS.





Safety Data

How to access the SDS

SDS can be accessed via the European Pharmacopoeia RS database:

Search Ph. Eur. RS

And the WHO RS databases:

Search ISA RS

Search ICRS RS

Safety Data Sheet (chemicals) and Safety Data Statement (bio) are available from website.

NOTES:

- **Hazardous Chemicals**: the EDQM complies with UNECE globally harmonised system for classification and labelling of chemicals; as enacted in the EU.

SDSs are not provided for materials for which no hazard has been identified. In such cases, the hazard status of the material is available in the database and is also published on the shipping documents (with the text: ”Hazard: none identified”).

- **Biologicals**: Directive 2000/54/EC applies. EDQM issues Safety Data Statements if a hazard has been identified.
- Safety documentation is provided for occupational health only and is not part of quality standards.
- You may also find which SDS have been updated in a compiled document published on the website.

Other sources of information & FAQ

RS Newsletter

The RS Newsletter contains:

- New and Replacement batches
- Removed (and future removal) items

  Removed RS are kept for an additional 12 months in the catalogue for RA requirements in some countries (6 months for sale -if stock available- and 6 additional months to print documents)

- Change of sales unit, price, quantity
- Information on changes of storage / shipping conditions

  Unless QA issue, changes are announced in advance (change will occur on the 15th of the next month, if possible)

NEW

Subscribe to the EDQM's RS Newsletter:
https://www.edqm.eu/en/rs-newsletter1

FAQ

Directly available from the website.

TOP 10 Questions

FAQ – TOP 10 Questions

- How can I obtain the CoA?

The EDQM does not provide certificate of analysis.

Needed data is available in the information leaflet.

If you want to use the RS for another use, it is done under your responsibility.

FAQ – TOP 10 Questions

- I do not find the expiry date

No expiry date is provided. It is down to the user to demonstrate that the CRS/BRP used in an official Ph. Eur. test or assay was current at the time of use. The BVS is used for this purpose. In case of replacement batch, a validity is provided in the online catalogue.

Therefore, it is recommended to purchase only a sufficient amount for analysis and to use the products as soon as possible.

Once the container has been opened, weighing should be carried out immediately. Any further storage and re-use are not warranted.

FAQ – TOP 10 Questions

- I do not find the purity

RS are established for a precise intended use. In case the purity / assigned value / activity is not mentioned in the information leaflet, it means that this value is not needed to carry out the test/assay described in the related monograph(s) and therefore it is not provided.

!! it cannot be assumed to be 100%. The only exception is the purity of an impurity CRS, which can be estimated to be 100% for the tests of the monographs, if the EDQM has not stated the purity.

FAQ – TOP 10 Questions

- If there are two weights declared: on the label and on the leaflet, which one should I use?

INFORMATION LEAFLET Ph. Eur. Reference Standard

VERBENALIN CRS batch 2

1. **Identification**

   Catalogue code: Y0000661

2. **Scientific Information**

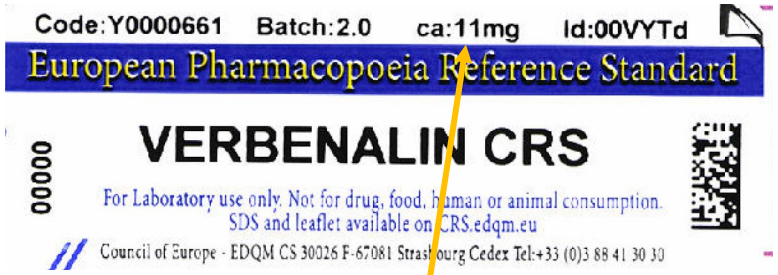
   2.1 Intended use

   Reference Standard for laboratory tests as prescribed in the European Pharmacopoeia only.
   Established for use with the monograph(s): 1854.

   2.2 Analytical information related to intended use, when applicable

   The "as is" content is : **1.00 mg of C17H24O10**

Declared content to be used for analytical purpose



« gravimetric » weight declared for customs (may also be on the leaflet)

!! ca quantity

In this case: freeze drying qty = (API+excipients)

FAQ – TOP 10 Questions

- I cannot recover the quantity from the vial

Each vial or ampoule is individually weighed during manufacturing and therefore contains a quantity sufficient for the prescribed use.

Nevertheless, since there is usually a very low quantity, the product may be distributed between the inner surface and the rubber stopper.
To avoid this problem and recover the full quantity, we usually recommend gently tapping the bottom of the vial several time in order to bring down the product. You can also use an anti-magnetic device to easily collect the powder.

If the test / product allows, you can also work by differential weighing.

FAQ – TOP 10 Questions

- The parcel arrived with cool packs thawed, is it suitable for use, may I obtain stability data?

Excursion outside recommended temperature usually does not jeopardise the quality of the RS.

In case of question, the EDQM will analyse the case with available data and will make a recommendation, if possible.

Stability data cannot be shared.

FAQ – TOP 10 Questions

- Is there a QMS applied to RS? May I have a copy of the certificate?

The EDQM follows the principle of ISO 9001 and ISO 17034 for the conduct of laboratory studies and RS production.

The EDQM laboratory is also ISO 17025 accredited for several analytical techniques used in the RS establishment.

The certificate is available from the website (EDQM / About us)

FAQ – TOP 10 Questions

- May I store the RS at different conditions than those stated in the catalogue?

The storage conditions mentioned in the catalogue are intended to preserve the integrity of the CRS during **long-term** storage.

We base our conditions on supplier's information, stability data (when available), monitoring data and bibliography.
Our storage conditions are in most cases more stringent than those given in the monograph.

Provided that you can demonstrate that the RS is fit for use at your chosen T°, nothing prevent you to do so.

FAQ – TOP 10 Questions

- I want an old BVS / leaflet

For the leaflet, it can be provided on request.

For the BVS, it is not possible.

FAQ – TOP 10 Questions

- I disagree with the CAS number provided in the catalogue

The CAS numbers provided are not independently verified by the EDQM.

They are provided only to help the user and most of the time refer to the CAS number of the parent substance mentioned in the Pharmacopoeia, so it can differ.

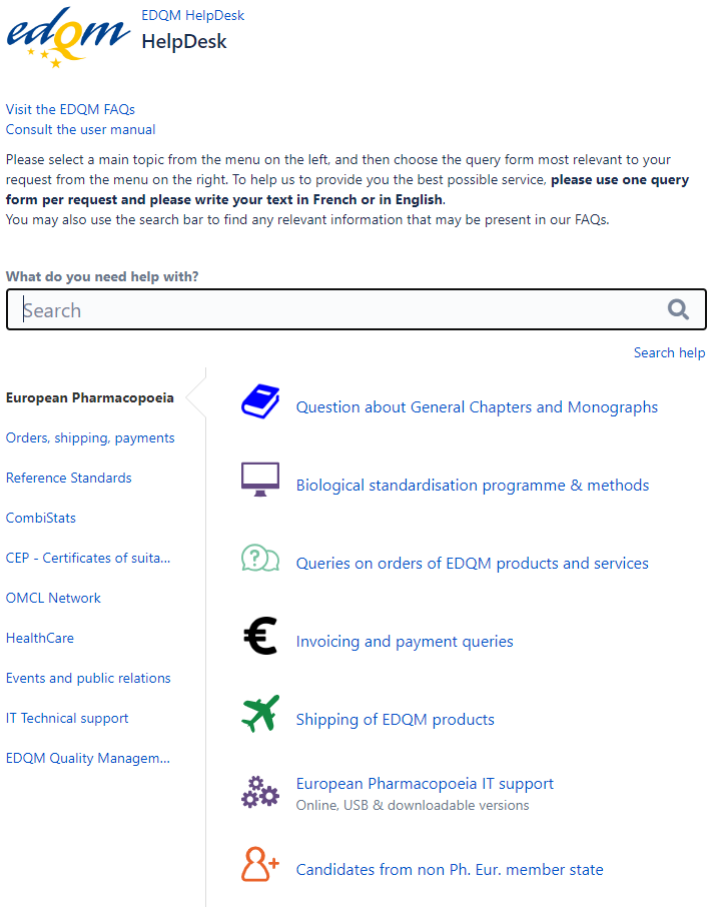
If you identify a discrepancy, please contact the EDQM via the Helpdesk.

FAQ – TOP 10 Questions

Still a question?

Helpdesk

Directly available from the website with a direct link to FAQs



Thank you for your attention

Stay connected with the EDQM

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