

IUCLID



IUCLID – different options

IUCLID is used to prepare technical dossiers for submission under various EU regulations;

- REACH (Article 111)
- BPR (Article 79)
- CLP notifications / notification updates
- (Poison centre notifications *coming 2019*)

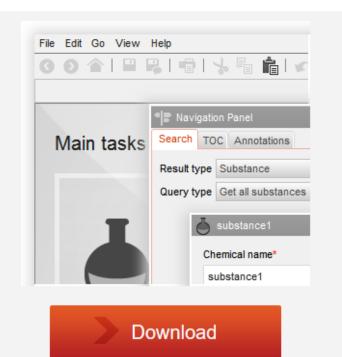
IUCLID can be downloaded as a Desktop / Server version

IUCLID can be used through the REACH-IT online dossiers

IUCLID can be accessed via the ECHA Cloud Services

- <u>https://iuclid6.echa.europa.eu/</u>
- <u>https://echa.europa.eu/support/dossier-submission-tools/echa-cloud-services</u>





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29 April 2016

IUCLID 6 is available

A new major version of IUCLID, used for managing scientific information in a regulatory context, is now online. Updated manuals and plugins are also available.

12 April 2016

A new IUCLID 6 test version is available

This test version includes bugs fixes and improvements.

5 February 2016

Test a new version of IUCLID 6

You can now download the latest IUCLID 6 test versions directly from this website.

24 November 2015

Register to be part of the IUCLID 6 testing

IUCLID 6 development continues and new test versions are made available to registered testers.

IUCLID: creating a complete dossier

• Create the dataset

• Fill-in the information

- Run the Validation Assistant on the dataset
- Correct the failures
- Create the dossier
- Run the Validation Assistant on the dossier
- In case of failures, correct the dataset or re-create the dossier

3

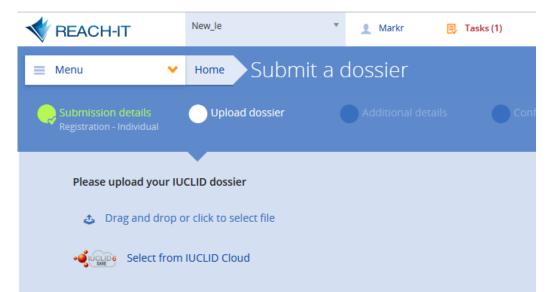
IUCLID: Submitting a dossier

 Export the dossier, save the file, and submit to REACH-IT



OR

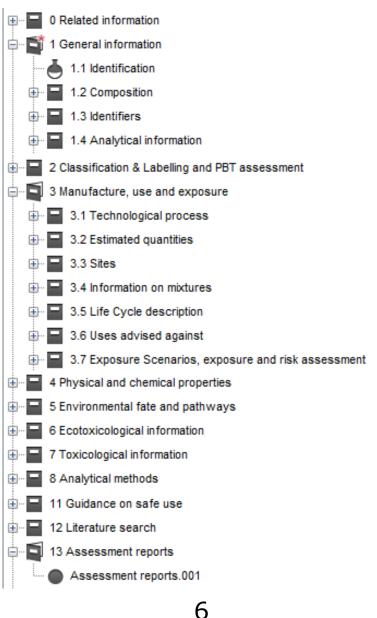
 If you are using IUCLID in the Cloud, then you can simply fetch it directly using REACH-IT





IUCLID: dataset content and format

- Section 1:
 - Substance identification
 - Composition(s)
- Section 3: manufacture, use and exposure
 - Section 3.2 Estimated quantities
 - Section 3.5 Life cycle description: brief description of uses based on the REACH use descriptor system
 - Section 3.7 Exposure scenarios, exposure and risk assessment
- Sections 4 7 (OECD Harmonised templates)
- Section 13: assessment reports
 - The CSR document is attached to this section as a Word or PDF file

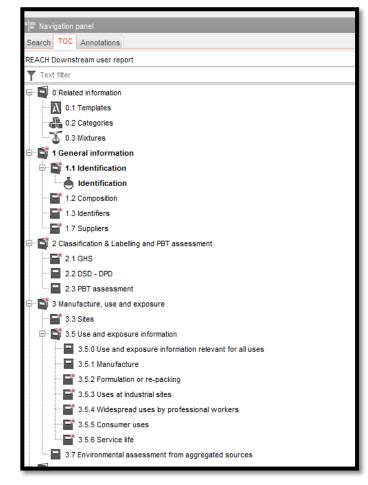




IUCLID: dataset content and format

Example: downstream user report (*REACH Article 38(1)*)

Search TOC Annotations						
REACH Downstream user report SUBMISSION TYPE						
Text filter	<u>SELECTED</u>					
O Related information						
General information						
⊕						
🗄 📲 3 Manufacture, use and exposure						
4 Physical and chemical properties	4 Physical and chemical properties					
5 Environmental fate and pathways						
G Ecotoxicological information						
Toxicological information						
8 Analytical methods						
12 Literature search						
13 Assessment reports						
14 Downstream user report						



echa.europa.eu



IUCLID version 6.3 and the IUCLID release plan





- **Every year** one major release of IUCLID 6 which includes
 - Format changes
 - Bug fixes
 - New features / improvements

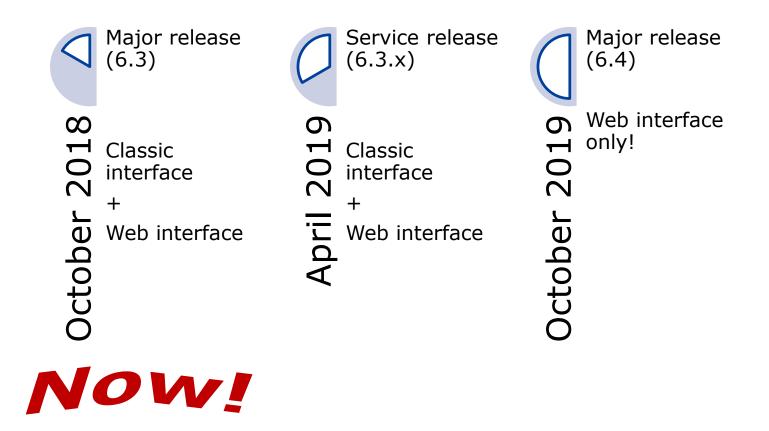
This year is quite special – release of IUCLID 6 with an optional web interface (first developed for IUCLID in the Cloud last year)

The web interface has been developed to:

Ensure the Cloud distribution of IUCLID can be extended To take advantage of web technology

To allow IUCLID to be used without JAVA

IUCLID Interface Development



FORMAT CHANGES

- Evolution of the regulations
 - CLP, update for the submission of information to Poison Centres <u>https://echa.europa.eu/regulations/clp/legislation</u>
- Updated or new test guidelines which have been translated into OECD Harmonised Templates
- Issues or improvements reported by the user community: ECHA, MSCAs, Industry, OECD Secretariat and Member Countries, for example:
 - Polymers information
 - Endpoint summaries minor updates
 - PBT assessment in Australia
 - BPR improvements (particularly for microorganisms)

FORMAT CHANGES - List of modified documents (OECD harmonised templates)

- All: confidential information on test materials
- Uses documents (article categories and product codes)
- Hydrolysis
- Biodegradation in water and sediment: simulation tests
- Biodegradation in soil
- Toxicity to terrestrial arthropods
- Short-term toxicity to aquatic invertebrates
- Long-term toxicity to aquatic

invertebrates

- Toxicity to aquatic plants other than algae
- Repeated dose toxicity: oral
- Repeated dose toxicity:
 inhalation
- Repeated dose toxicity: dermal
- Genetic toxicity in vitro
- Toxicity to reproduction
- Pesticides templates, small corrections

FORMAT CHANGES - COMPATIBILITY

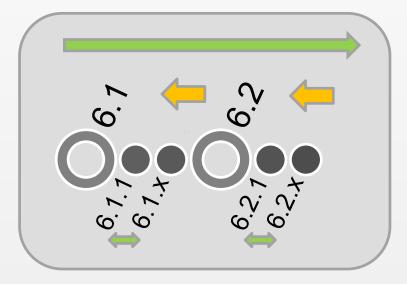
Forward compatibility provided: all IUCLID 6 files (even IUCLID 5.6) can be imported to the latest version

Backward compatibility offered for the previous major version: export 6.2 files from 6.3

It is recommended for IUCLID 6.1 users to upgrade to 6.3

Submission to ECHA can be made with any IUCLID 6 version

The latest version of the Validation Assistant is improved in each version however not impacting the validation outcome



ECHA Cloud Services



- A new platform for delivery of Business Information systems in ECHA - Released today!
- Triggers
 - 1. The need to maintain an operational IUCLID version has been raised as a burden for Small and Medium size Enterprises (SMEs)
 - 2. The usage of IUCLID for non-frequent users is seen as complex
- Solution
 - Provide IUCLID 6 as a Cloud service and simplify the usage for nonfrequent users



Always work on the latest version of the application

Data is more secure because of reduced number of local copies Reduced risks of data loss (backups managed by ECHA)

ECHA Cloud Services

No cost for users managing installations and hardware Facilitate working anywhere (easier remote access) and delegation to consultants

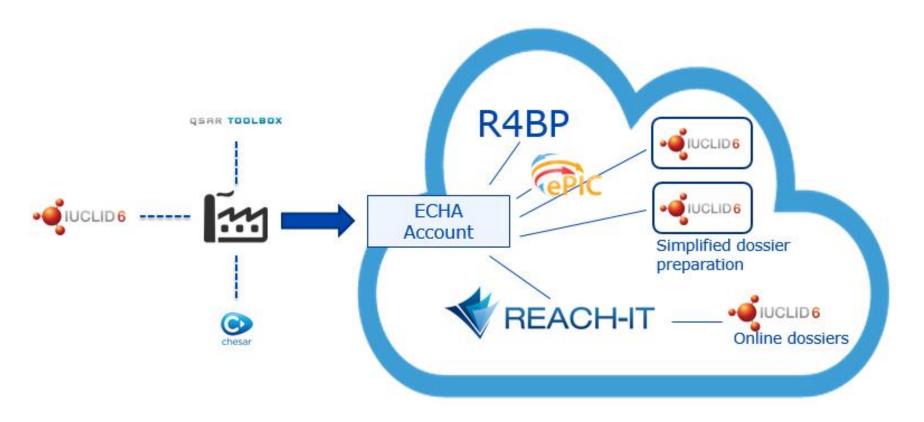
Possibilities for better online support

echa.europa.eu





ECHA Cloud Services







What service are provided?





echa.europa.eu

An agency of the European	1 Union	News and Events	Press Contact	English (en)	
EUROPEAN CHEMICALS AGENCY			Search the ECHA W	/ebsite	
About Us F	Addressing Chemicals of Concern	Information on Chemicals	Chemicals in our	Life Support	
ECHA > Support > Dossier Submis	sion Tools > ECHA Cloud Services			f 🔰 🗟 🔄 🕂 🛛 0	
+ About Us	ECHA Cloud Services				
+ Regulations	ECHA Cloud Services is a secure online pla	tform used to distribute EC	HA's IT		
+ Addressing Chemicals of Concern	applications in a cloud environment. The first services focus on IUCLID as it is c		Access ECHA Cloud Services		
+ Information on Chemicals	Their functionalities are prioritised for the r enterprises (SMEs). The IUCLID Cloud app complements the IUCLID application in hel	nd, therefore,	See also		
+ Chemicals in our Life	the upcoming registration deadline.				
 Support Guidance 	have an ECHA Account, you can create one on the ECHA Cloud Services web p				
• Getting started	Once you are logged in, you can select bet 1. IUCLID Cloud Trial	s:	Terms and conditions for using the Cloud Services		
 Q&As Support Testing methods and alternatives 	2. IUCLID Cloud for SMEs		 [PDF] REACH 2018: Prepare your registration as a IUCLID dossier 		
+ Webinars				 Simpler IUCLID for smaller companies, Newsletter 	
 Dossier Submission Tools Manuals 	Try out the service by working fully on a wo locally. This service gives you 100 MB of da updated whenever there is a new release are no backups taken of the data or dedice	4/2016			
+ REACH-IT	You can either use the IUCLID Cloud applic mixture and dossier datasets or launch the	e IUCLID Cloud client (tradi	tional IUCLID		
> IUCLID	that stores data in the cloud) to edit datas use all IUCLID functionalities. These will be Cloud for SMEs is launched.				

IUCLID – new web user interface



THE DASHBOARD

• e iua	CLID 6		l	?	SuperUser Test Legal Entity
⇒	Dashboard		Search dossier by UUID		0
	Guided dossier preparation @	>	Import IUCLID file(s) 🕢		
	Substances 23	>	Drop file to upload or Bro	owse	
	Mixtures 1	>			

This is the Dashboard

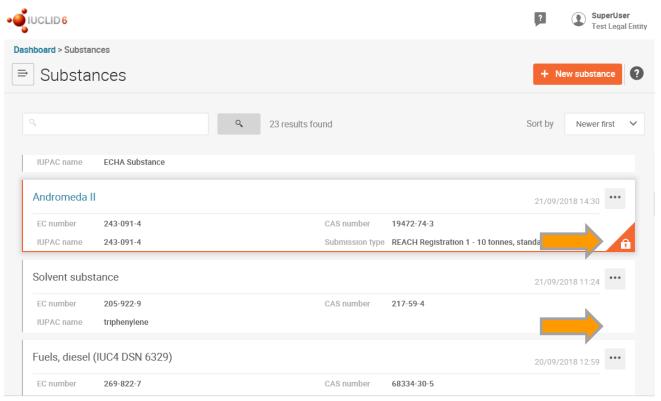
- Top bar resources + Help
- Logout
- Search Dossier by UUID is the best way to get your dossier

Widgets

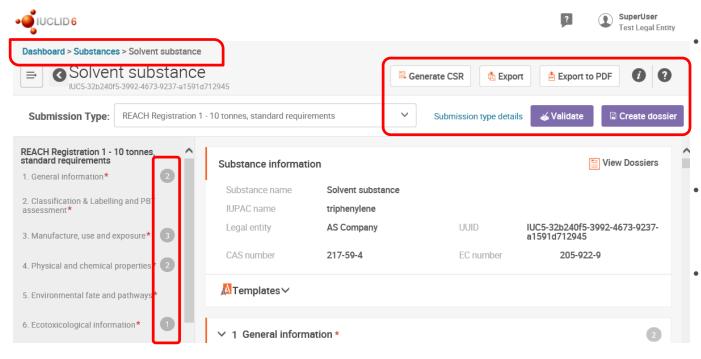
- Combined list of substances and dossiers
- Combined list of Mixtures
- Guided dossier
 preparation
- Import (also in bulk)

VIEW SUBSTANCE DATASETS AND DOSSIERS IN A COMBINED LIST

- The new Substances list in the web interface combines, in a single list, substances with their dossiers
- They are grouped by substance as provided by the registrants
- The latest dossier or modified substance is displayed
- The Mixtures/products list follows the same concept

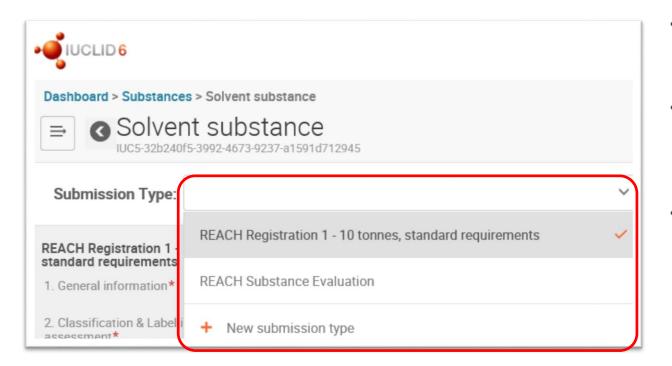


THE SUBSTANCE DATASET VIEW



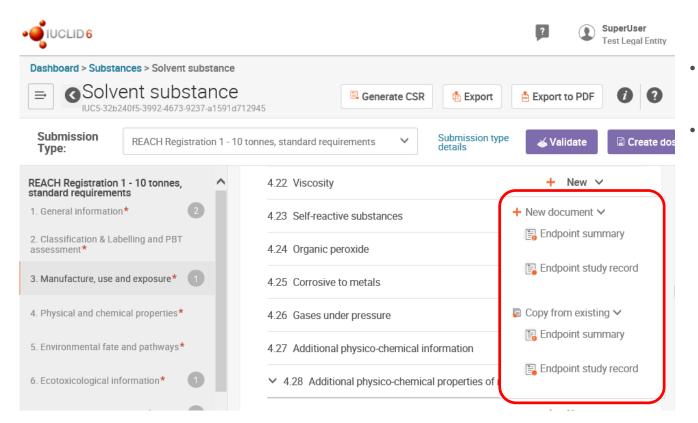
- Table of contents indicates the number of records available per section and the red star which sections are mandatory
- Quick access to the main relevant features for substance datasets
- Breadcrumb indicates the path (location) and eases the navigation

SUBSTANCE DATASET INFORMATION – EDIT DOSSIER HEADER



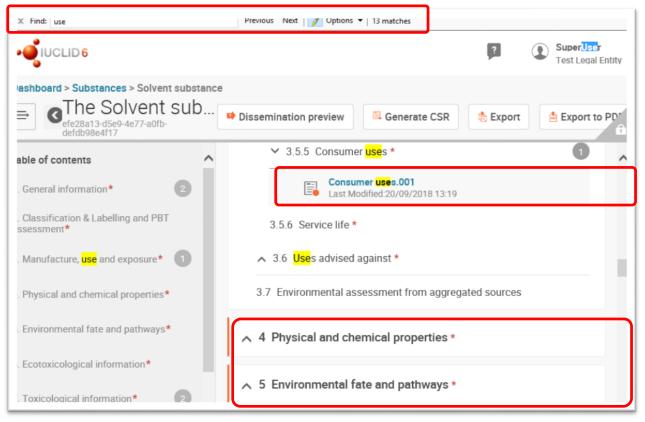
- Users can select one or more submission types for the same substance
- A link to the submission type details allows users to edit the dossier header easily
- The Table of Contents dynamically shows, according to the submission type selected, the sections that need to be filled in

COPYING DATA



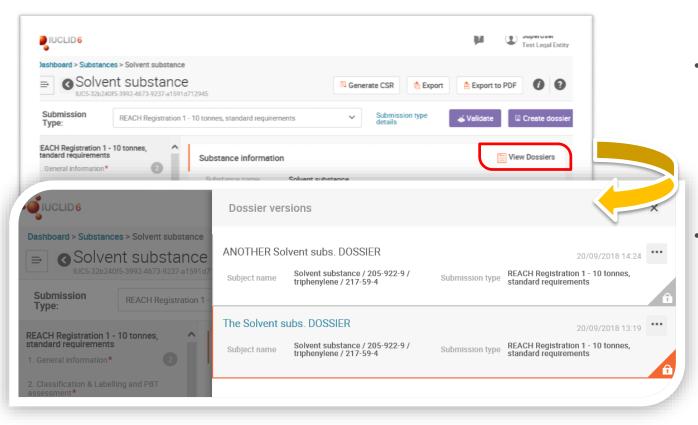
- Users can copy from existing records
- Relevant records are displayed depending on the section you work with

SEARCH THROUGH SECTIONS



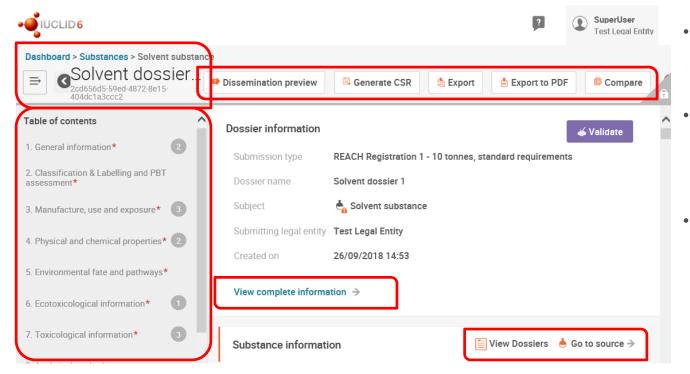
- Use your browser search feature 'Ctrl + F' to find content in the page
- Last modification time visible for each record
- By default all sections are expanded (section 3 in the image) but they can be collapsed as well to limit the search or simplify the view (sections 4 and 5 in the image)
- Possibility to copy any information displayed in the screen (no more greyed-out texts)

ACCESS ALL RELATED DOSSIERS FROM THE SUBSTANCE DATASET



- Users can now view and access all related dossiers of a particular substance dataset from the substance information section
 - All related dossiers, regardless the submission type selected, are listed sorted by date. This way, access to the latest dossier available is easy

THE DOSSIER VIEW



- Quick access to the main functionalities for dossiers
- View complete dossier header information in one click (including all attachments)
 - From a dossier, users can easily access the substance dataset (if available) and other dossiers that may exist for that particular substance

BOOKMARKING IUCLID PAGES AND SHARING WITH COLLEAGUES

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IUCLID6	×							
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Save	Open		and exposure*	Submission	REACH S		Subject name	triphenylene / 217-5
	Open in new tal							
	Open in new wi	ndow						
	Save target as							

Every page in IUCLID has a URL

- which can be bookmarked to manage your work in IUCLID via your Favourites to
- easily share with your colleagues specific parts of the dossier and
- access them directly, without having to navigate through IUCLID to it.
- You can open multiple tabs or windows and work simultaneously with them

IUCLID – Future enhancements



2019 IUCLID updates

CURRENT PLANS FOR THE WEB UI (TARGET FOR THE APRIL RELEASE)

- For implementation
 - Improve the generated comparison report
 - Advanced dossier creation

 (without document selection, but
 with re-using user's stored options)
 - Repeatable block headers in Edit mode (ITEM-based configuration)
 - Fee calculator
 - Generation of all available reports for a dataset or dossier
 - Display Legal Entity in combined lists



2019 IUCLID updates

CURRENT PLANS FOR THE WEB UI (ADDITIONAL WORK TO BE COMMITTED)

- Inventories including
 - Categories
 - Templates
 - Entities
- Implementation of elements incepted
 - Dynamic content rules
 - Rich-text fields
 - Advanced options for export, import, (finalisation of) dossier creation, including document selection
 - Bulk operation / basket concept
- Edition and dataset-content navigation improvement
- User profile (display of role and LE management, display groups), password, user preferences
- Basic search
- Error and exception handling and background jobs



2019 IUCLID updates

REMAINING SCOPE TO COMPLETE THE SWITCH TO THE WEB USER INTERFACE

- DNEL/PNEC calculators
- Document summary for endpoint summary, category matrix
- Copy as reference
- Advanced report generator
- Advanced filtering
- Inventory manager
- User and role management and group management (but only for system admin) including upload of csv file
- Aggregation user interface



IUCLID – Support / News





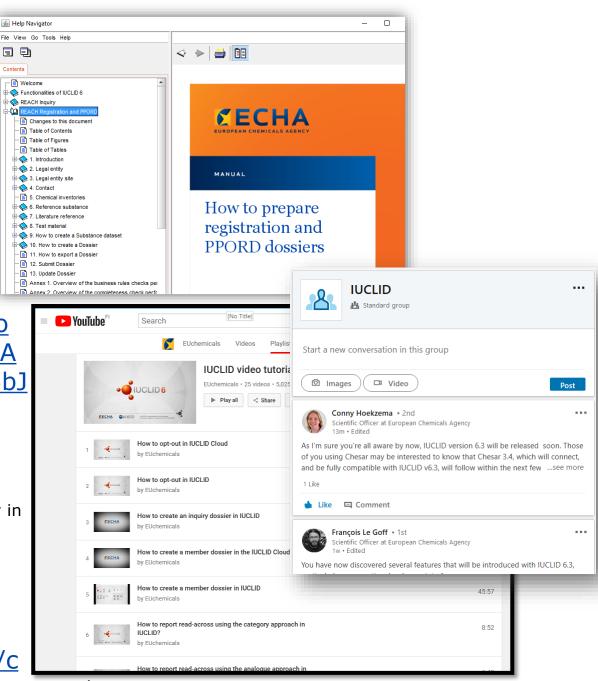
Support

- IUCLID 6 website
- IUCLID video tutorials

https://www.youtube.co m/playlist?list=PLOPGDA CSd6qyDkdXwPua1Fjb5bJ ksY75k

- Inside IUCLID
 - functionalities manual
 - submission manuals (only in classic interface)
- LinkedIn Group
- ECHA Helpdesk

https://echa.europa.eu/c ontact



echa.europa.eu



Thank you!

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