

Practical considerations using IUCLID for Microbials

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IUCLID is a free platform;

IUCLID 6 is available in three different versions:

- Cloud services
 - IUCLID 6 Desktop
 - IUCLID 6 Server
- No need to install IUCLID locally
 - Direct access to latest version
 - Multiple users can use IUCLID at the same time
 - 1 GB storage
 - Automatic back-up
 - Helpdesk support

IUCLID is a free platform;

IUCLID 6 is available in three different versions:


- Cloud services
 - IUCLID 6 Desktop —
 - IUCLID 6 Server
- Runs on a single machine
 - No network connection necessary
 - Database stored locally

IUCLID is a free platform;


IUCLID 6 is available in three different versions:

- Cloud services
- IUCLID 6 Desktop
- IUCLID 6 Server


- Runs on an application server
- Users can log in via any computer with network access
- Multiple users can use IUCLID at the same time
- No need to install database software separately

 Guided dossier preparation
4




 Substances
2301



 Mixtures
42

 Articles
0

Import IUCLID file(s) ? Overwrite settings: If newer than existing ▼

 Drop file to import or

New submission type

Select submission type



- (obsolete) AU Industrial Chemicals Certificate App
- AICIS Assessment and Evaluation
- AICIS Certificate application - Comparable hazard
- AICIS Certificate application - Environment focus
- AICIS Certificate application - Health and environ
- AICIS Certificate application - Health focus
- AICIS Certificate application - Very low to low risk
- AICIS Commercial Evaluation Authorisation
- BPR Active substance information
- BPR Basic information (substance)
- BPR Microorganisms
- BPR Substance of concern
- Category document selector table of contents
- Chesar input information
- CLP Alternative name request
- CLP Notification
- CLP Poison centres notification (substance inform
- CLP Regulation - CLH dossier
- Complete table of contents
- Endpoints information
- EU PPP Active substance information
- EU PPP Basic information (substance)
- EU PPP Microorganisms
- EU PPP Other substance for assessment
- Exchange or experimental data
- NZ HSNO Full assessment
- OECD harmonised templates
- OECD SIDS
- REACH Annex XV - Restriction
- REACH Annex XV - SVHC
- REACH Application for authorisation

Dashboard > Substances > WWI_microbial

WWI_microbial
6ab4724f-b2da-4cfa-b49c-306816176606

Submission Type: EU PPP Microorganisms

EU PPP Microorganisms

1. Identity of the microorganism
2. Biological properties of the microorganism
3. Further information on the microorganism
4. Analytical methods
5. Effects on human health
6. Residues in or on treated articles, food and feed
7. Fate and behaviour in the environment
8. Effects on non-target organisms
10. Summary and evaluation

Substance information

Substance name: WWI_microbial
IUPAC name
Legal entity: Charles River Laboratories Den Bosch B.V.
CAS number

Templates

1 Identity of the microorganism

1.1 (Cf. 1.3) Applicant

1.2 Microorganism manufacturer

1.2.1 Location of manufacturing plant(s)

1.3 Name and species description, strain characterisation

WWI_microbial
Last Modified: 15/10/2020 21:34

5 Effects on human health

+ New

3

5.1 Basic information

+ New

5.2 Basic studies

3

5.3 (Cf. 5.2.2.2) Specific toxicity, pathogenicity and infectiveness studies

5.4 In vivo studies in somatic cells

+ New

- Study summaries follow OECD Harmonized templates
- Import from CADDY is expected to be possible
- For microbials: where possible relevant units are included (cfu/mL. ...),
Alternatively “other: FREETEXT” can be used
- Importing study summary from other dossier very easy
- Waivers can be used, but general waivers in drop-down menu
do not apply for microbials-
instead “other:FREETEXT” can be used

IUCLID input for open literature

2 Biological properties of the microorganism

2.1 History of the microorganism and its uses. Natural occurrence and geographical distribution

2.2 Information on target organism(s)

2.3 Host specificity range and effects on species other than the target harmful organism

i 2.4 (Cf. 2.1) Development stages/life cycle of the microorganism

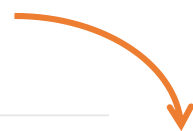
i 2.5 (Cf. 2.1) Infectiveness, dispersal and colonisation ability

i 2.6 (Cf. 2.1) Relationships to known plant or animal or human pathogens

i 2.7 (Cf. 2.1) Genetic stability and factors affecting it

i 2.8 (Cf. 2.1) Information on the production of metabolites (especially toxins)

i 2.9 (Cf. 2.1) Antibiotics and other anti-microbial agents



Biological properties of the microorganism

General information on the microorganism

None

Historical background

None

Historical uses

None

Origin, natural occurrence and geographical distribution

None

Development stages / life cycle of the microorganism

None

Relationships to known plant or animal or human pathogens

None

Genetic stability and factors affecting it

None

Challenges:

- Strict Validation Check
 - will it work for microbial dossiers with lower data density?
 - Will it work for studies that are not performed following OECD guidelines
- Reporting format: under development, challenging for microbials with a-typical data-sets and dossiers
- Handling confidential data not yet clear

Overall remark:

The new platform will require additional time and know-how for dossier building

Following steps:

For early submitters renewal dossiers support for MS and applicants: Hypercare

For others no further information yet

Many thanks!

