



Bayer

2. REACH-Symposium

Informationen zum

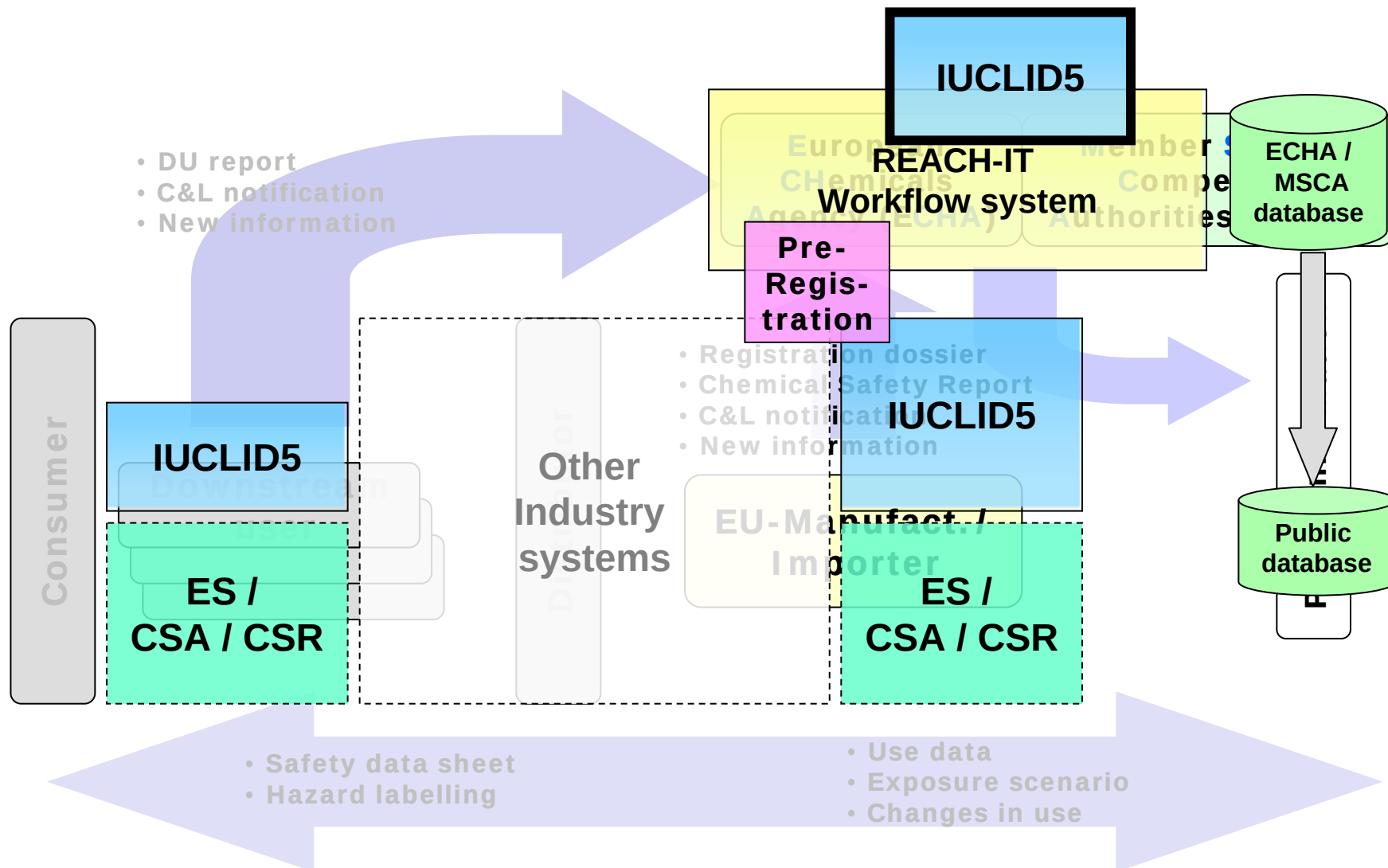
Datenaustausch/ IUCLID 5

22. November 2007

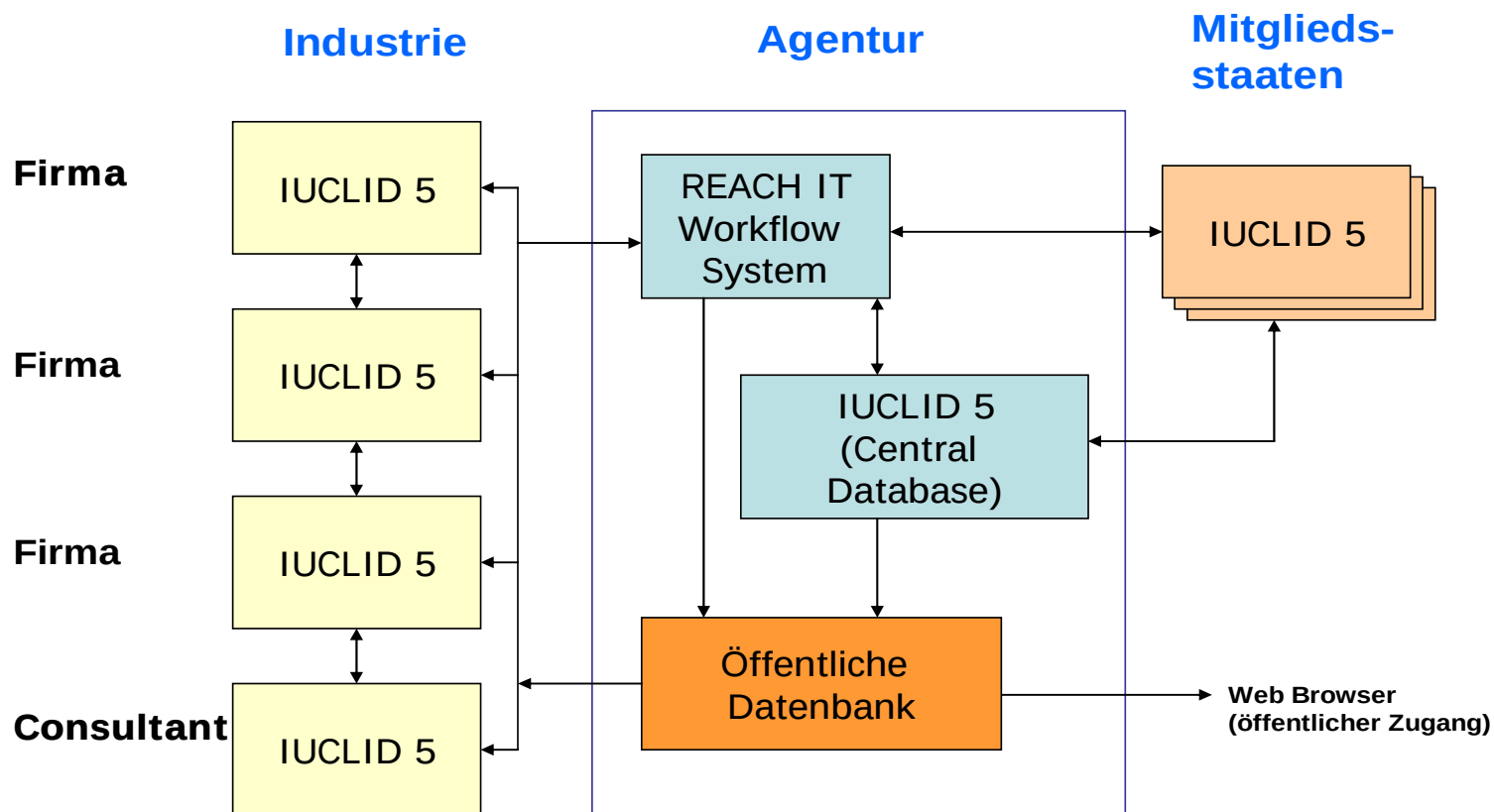
Berlin

Dr. Andrea Paetz
Bayer AG
Corporate Center
Environment & Sustainability

IT Systeme – Entwicklung durch die EU-Kommission



IUCLID5



Harmonisierte Datensätze

- ❖ Grundlage für IUCLID 5 sind die OECD Harmonized Templates.
- ❖ Die OECD hat in Zusammenarbeit mit den Behörden und der Industrie harmonisierte Datensätze entwickelt.
- ❖ Diese finden Verwendung für das Existing Chemicals Programme der OECD, ICCA HPV Initiative, das EPA HPV Program, die Biozidrichtlinie, die Pflanzenschutzrichtlinie und für REACH.
- ❖ Für jeden Endpunkt (intrinsische Eigenschaften) sind die Felder genau spezifiziert (z. B. Testtyp, Methode, Spezies, Stamm, Anzahl der Tiere, Verabreichungsweg, Kontrollgruppe, Ergebnis, unterer Wert, oberer Wert, Freitexte ...)
- ❖ Zusätzlich sind Templates („Formblätter“) hinterlegt, um auch die Angaben im Freitext zu füllen.
- ❖ Diese Datensätze bilden die Grundlage von IUCLID - 1:1 umgesetzt.
- ❖ Es gibt verschiedene Sichten auf die Datenbank, so dass man nur bestimmte Endpunkte sehen kann (z.B. nur Annex VII für Stoffe zwischen 1 und 10 t)
- ❖ Man sieht aber immer den kompletten Endpunkt (alle Felder).

IUCLID5

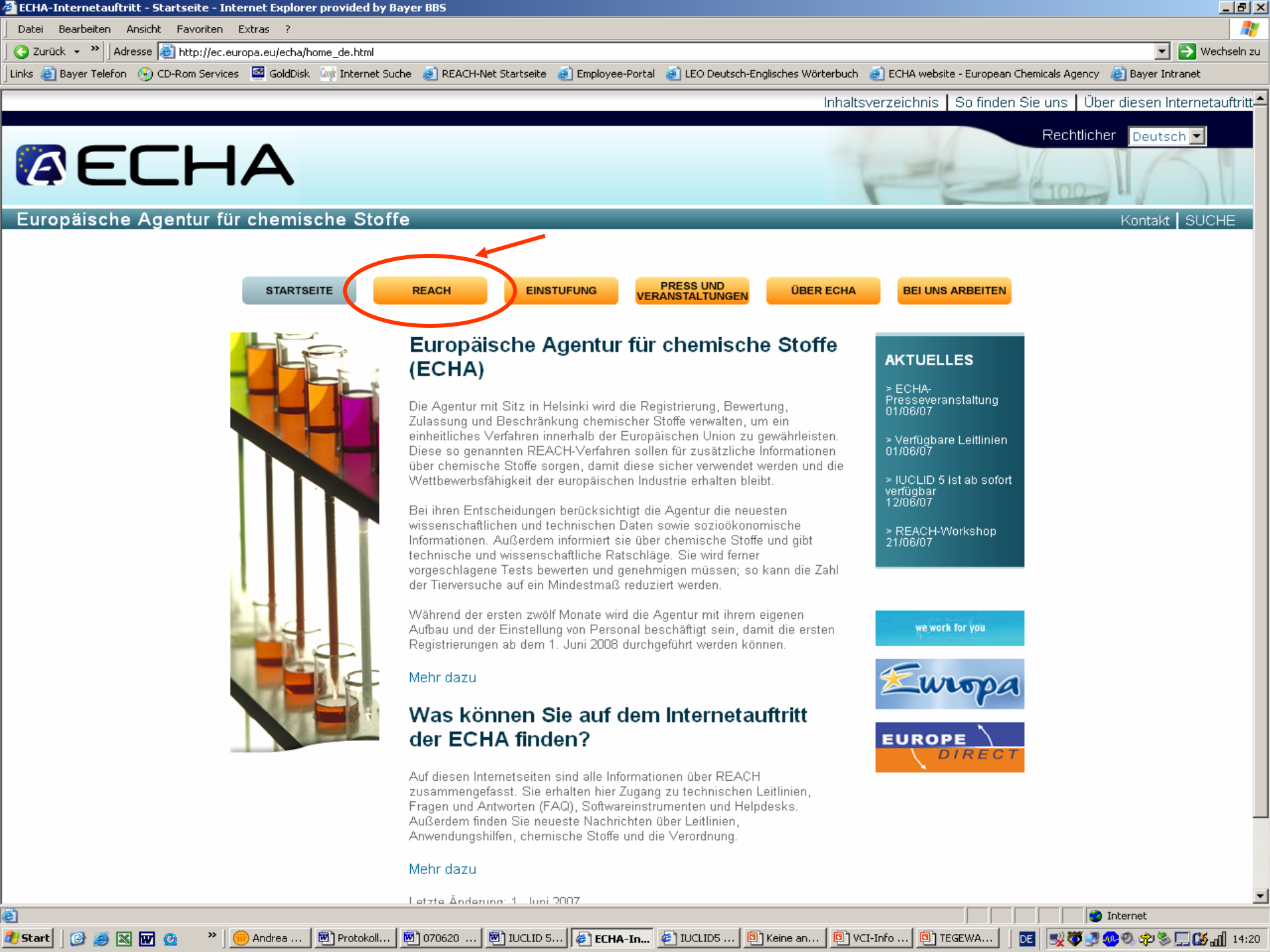
- ❖ Download von der ECHA-Seite <http://iuclid.eu>
- ❖ IUCLID wird der Industrie kostenlos zur Verfügung gestellt.
- ❖ Haupttool für die Registrierung (Industrie) - muss verwendet werden!
- ❖ Datenbank für Firmen
- ❖ Tool für Dossiererstellung
- ❖ Zentrale Datenbank für alle Dossiers in der Agentur
- ❖ Es kann als **stand-alone** oder als Netzwerkversion installiert werden:
 - **Open source software** (PostgreSQL, Tomcat)
oder
 - **Commercial software** (Oracle, Bea Weblogic)
- ❖ Die Firmen müssen sich vor der Installation überlegen, welche Konfiguration benötigt wird (welche Software, wie viele Installationen, welche Anwender, wie viele Anwender...)

Entwicklung IUCLID

- ❖ Die IUCLID-Entwicklung wurde bisher gemeinsam von DG ENTR, DG ENV und DG JRC durchgeführt (Finanzierung DG ENTR)
- ❖ In Zukunft wird die ECHA eine IUCLID Management Group (IMG) einrichten.
- ❖ Diese ist für die Lizenz, die Verträge, die Weiterentwicklung, neue Versionen und die Finanzierung von IUCLID zuständig.
- ❖ Sie leitet auch das OECD IUCLID User Expert Panel
- ❖ Das OECD IUCLID User Expert Panel wird aus drei Kanälen gespeist:
 - ECHA Service Desk (Help desk) für REACH bezogenen Themen (Vorschläge werden vor der Weitergabe von IMG zusammengeführt)
 - BIAC/CEFIC für Industrievorschläge
 - Nationale OECD Delegationen - Vorschläge der Mitgliedsstaaten.
- ❖ Das OECD IUCLID User Expert Panel diskutiert die neue Anforderungen an IUCLID und bringt sie in die IMG.
- ❖ Anforderungen, die von der IMG nicht finanziert werden, können auch durch Dritte umgesetzt werden, wenn die Anforderungen den Quellcode nicht berühren.

Entwicklung IUCLID

- ❖ Folgende Tools werden derzeit entwickelt:
 - Query Tool
 - Tool für die Vorregistrierung
 - SNIF Migration (Neustoffe)
 - Ein verbessertes Migrationstool (IUCLID 4 -> IUCLID 5) wird auf der IUCLID-Website (ECHA) zur Verfügung gestellt.
- ❖ Um den Austausch mit anderer Software zu erleichtern (Schnittstellen) ist das Format XML-Format für IUCLID auf der IUCLID Website veröffentlicht worden.
- ❖ IUCLID 5 berücksichtigt dieses Format. Wer IUCLID benutzt, ist daher auf der sicheren Seite.





ECHA > REACH

[Kontakt](#) | [SUCHE](#)

STARTSEITE

REACH

EINSTUFUNG

PRESS UND
VERANSTALTUNGEN

ÜBER ECHA

BEI UNS ARBEITEN

> REACH

[Leitlinien](#)[Softwareinstrumente](#)[Fragen und Antworten](#)[Helpdesks](#)[Rechtsvorschriften](#)

Über REACH

Dieser Abschnitt gibt einen Überblick über die REACH-Verordnung. Hier wird erklärt, was REACH-Verfahren sind, welche chemischen Stoffe unter die Verordnung fallen, welche Methoden und Hilfsmittel verwendet werden und wer zu den Beteiligten zählt.

[Mehr dazu](#)

Navigator

Navigator ist ein interaktives Werkzeug für Unternehmen, die Fragen zu bestimmten Stoffen haben und schnell wissen wollen, was sie gemäß den REACH-Vorschriften tun müssen.

[Mehr dazu](#)

Leitlinien

Die REACH-Leitlinien liefern ergänzende Informationen zur Verordnung. Dabei geht es um alle technischen Aspekte von REACH. Diese Unterlagen wurden mit Hilfe und Unterstützung der Behörden der Mitgliedstaaten, der Europäischen Kommission und der Industrie erstellt. Deshalb sollten Unternehmen erst in diese Leitlinien schauen, wenn sie nicht genau wissen, wie sie ihre REACH-Verpflichtungen erfüllen müssen.

[Mehr dazu](#)

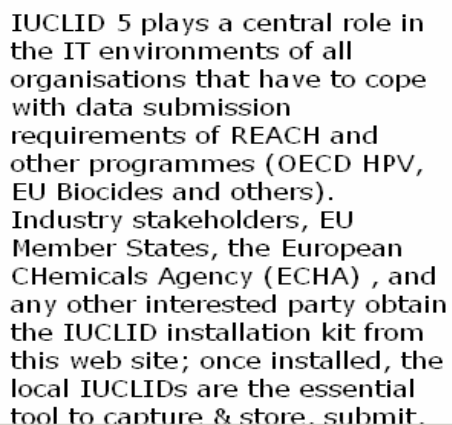
Softwareinstrumente für REACH

Zur Verwaltung der Daten über chemische Stoffe und Registrierungsanträge im Rahmen von REACH dienen zwei Programme: REACH-IT und IUCLID5.

[Mehr dazu](#)

Whatever you do





IUCLID 5, the main tool for the Chemical Industry to fulfill their REACH legal obligations, will be released in the coming days.



IUCLID 5

INTERNATIONAL UNIFORM CHEMICAL INFORMATION DATABASE



Tasks



Legal entity

Create and update company /organisation related information

[New](#) [Update](#)



Substance

Create and update substance related information

[New](#) [Update](#)



Template

Create and update template related information

[New](#) [Update](#)



Dossier

View dossier data

[View](#) [Compare](#)



Legal entity site

Create and update legal entity sites

[New](#) [Update](#)



Mixture

Create and update mixture related information

[New](#) [Update](#)



Category

Create and update category related information

[New](#) [Update](#)

Inventories



Inventory

View EC inventory related information

[View](#) [Import](#)



Literature reference

View literature reference inventory related information

[View](#)



Reference substance

Create and update reference substance related information

[New](#) [Update](#)

Tools and administration



Manage users, roles, preferences, etc.

[User preferences](#), [Set password](#), [User management](#), [Role management](#)



Import

Import data from other IUCLID 5 systems

[Import](#), [Bulk import](#)

Plugins



Navigation

Query results Section tree

Complete

- 0 Related Information
- 1 General Information
- 2 Classification and Labelling
- 3 Manufacture, use and exposure
- 4 Physical and chemical properties
- 5 Environmental fate and pathways
- 6 Ecotoxicological Information
- 7 Toxicological information
- 8 Analytical methods
- 9 Residues in food and feedingstuffs
- 10 Effectiveness against target organisms
- 11 Guidance on safe use
- 12 Literature search
- 13 Assessment Reports

IUCLID-Kapitel

Substance: 1,2,3-Trichlor-IUCLIDOGEN-5 / Bayer Industry Services GmbH & Co. OHG / Leverkusen / Germany

Substance identification

Chemical name: 1,2,3-Trichlor-IUCLIDOGEN-5

Legal entity flags: [CBI, core business of manufacturer] EU: REACH

Legal entity: Bayer Industry Services GmbH & Co. OHG / Leverkusen / Germany

Third party flags: [CBI] EU: REACH

Third party:

Role in the supply chain

Role flags:

Role: ☒ Manufacturer ☐ Importer ☐ Only representative ☐ Downstream user

Reference substance

Type of substance

Composition:

Origin:

Trade names

Trade names flag:

Name

Information

Access Consultation Attachments Annotations Validation

Information Modification history

Bayer Industry Services GmbH & Co. OHG , wwbm



Navigation

Query results Section tree

Complete

- 1.2 Composition
- 1.3 Identifiers
- 1.4 Analytical information
- 1.5 Joint submission
- 1.6 Sponsors
- 1.7 Suppliers
- 1.8 Recipients
- 1.9 Product and process oriented re
- 2 Classification and Labelling
 - 2.1 GHS
 - 2.2 DSD - DPD
- 3 Manufacture, use and exposure
 - 3.1 Technological process
 - 3.2 Estimated quantities
 - 3.3 Sites
 - 3.4 Form in the supply chain
 - 3.5 Identified uses and exposure sc
 - 3.6 Uses advised against
 - 3.7 Waste from production and use
 - 3.8 Exposure estimates
 - 3.9 Biocidal information
 - 3.10 Application for authorisation o
- 4 Physical and chemical properties
- 5 Environmental fate and pathways
- 6 Ecotoxicological Information
- 7 Toxicological information
- 8 Analytical methods
- 9 Residues in food and feedingstuffs
- 10 Effectiveness against target organis
- 11 Guidance on safe use
- 12 Literature search

Substance: 1,2,3-Trichlor-IUCLIDOGEN-5 / Bayer Industry Services GmbH & Co. OHG / Leverkusen / Germany

Classification and Labelling according 67/548/EEC (DSD)**General information**Name ☐ Not classifiedStatus Index number ATP inserted ATP last update Remarks **Classification**

	Classification	Reason for no classification
Explosiveness		
Oxidising properties		
Flammability		
Thermal stability		
Acute toxicity		

Information

Access

Consultation

Attachments

Annotations

Validation

Information

Modification history



Navigation

Query results Section tree

Complete

- 1.2 Composition
- 1.3 Identifiers
- 1.4 Analytical information
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Substance: 1,2,3-Trichlor-IUCLIDOGEN-5 / Bayer Industry Services GmbH & Co. OHG / Leverkusen / Germany

Uses and exposure**Overall use and exposure****Main use category**

- ☐ Industrial use
- ☐ Professional use
- ☐ Consumer use

Specification for industrial and professional use

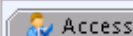
- ☐ Used in closed system
- ☐ Use resulting in inclusion into or onto matrix
- ☐ Non-dispersive use
- ☐ Dispersive use

Significant routes of exposure**Human exposure**

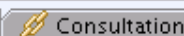
- ☐ Oral
- ☐ Dermal
- ☐ By inhalation

Environmental exposure

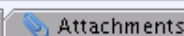
- ☐ Water
- ☐ Air

Information

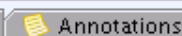
Access



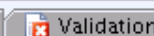
Consultation



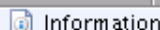
Attachments



Annotations



Validation



Information



Modification history



Schmelzpunkt

Navigation

Query result

Complete

0 Related

1 General

2 Classification

3 Manufacturing

4 Physical

4.1 Appearance

4.2 Melting point

4.3 Boiling point

4.4 Density

4.5 Partition coefficient

4.6 Vapor pressure

4.7 Solubility

4.8 Water solubility

4.9 Solubility in organic solvents

4.10 Stability

4.11 Physical stability

4.12 Chemical stability

4.13 Photostability

4.14 Biodegradability

4.15 Ecotoxicity

4.16 Acute toxicity

4.17 Subacute toxicity

4.18 Chronic toxicity

4.19 Reproductive toxicity

4.20 Developmental toxicity

4.21 Immunotoxicity

4.22 Genotoxicity

4.23 Carcinogenicity

5 Environmental

6 Ecotoxicity

Endpoint study record: Melting point/freezing point.001

Detail level

Administrative Data

Data source

Materials and methods

all fields

Results and discussions

Overall remarks, attachments

Applicant's summary and conclusion

data submitter is data owner

Data protection claimed

yes, but not willing to share

Cross-reference to same study

Materials and methods

Test guideline

Qualifier	Guideline	Deviations
according to	OECD Guideline 102 (Melting point / Melting Range)	no data
Add...	Edit...	Delete
Move up	Move down	

Type of method

capillary method

Principles of method if other than guideline

GLP compliance

Test materials

Test material equivalent to submission substance identity

Information



Schmelzpunkt

Navigation

Query result

Complete

- 0 Related
- 1 General
- 2 Classification
- 3 Manufacturing
- 4 Physical and chemical properties
 - 4.1 Appearance
 - 4.2 Melting point
 - 4.3 Boiling point
 - 4.4 Density
 - 4.5 Vapour pressure
 - 4.6 Viscosity
 - 4.7 Partition coefficient
 - 4.8 Water solubility
 - 4.9 Solubility
 - 4.10 Stability
 - 4.11 Flammability
 - 4.12 Explosive limits
 - 4.13 Flash point
 - 4.14 Boiling point
 - 4.15 Critical point
 - 4.16 Critical pressure
 - 4.17 Critical temperature
 - 4.18 Critical volume
 - 4.19 Critical density
 - 4.20 Critical mass
 - 4.21 Critical volume
 - 4.22 Critical density
 - 4.23 Critical mass
- 5 Environmental fate
- 6 Ecotoxicology

Endpoint study record: Melting point/freezing point.001

Detail level

Administrative Data

Data source

Materials and methods

all fields

Results and discussions

Overall remarks, attachments

Applicant's summary and conclusion

Test materials

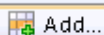
Test material equivalent to submission substance identity



Test material identity

Identifier

Identity



Add...



Edit...



Delete



Move up



Move down

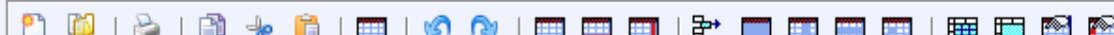
Details on test material



Confidential details on test material



Any other information on materials and methods incl. tables



Normal

Agency FB

8

A

B

I

U

List

List

List

List

List

List

List

List

List

List

List

List

Information



Schmelzpunkt

Navigation

Query result

Complete

0 Related

1 General

2 Classifi

3 Manufac

4 Physical

4.1 Ap

4.2 Me

4.3 Bo

4.4 De

4.5 Pa

4.6 Va

4.7 Pa

4.8 W

4.9 Sc

4.10 S

4.11 P

4.12 A

4.13 P

4.14 E

4.15 C

4.16 C

4.17 S

4.18 S

4.19 S

4.20 p

4.21 D

4.22 V

4.23 A

5 Environ

6 Ecotoxi

Endpoint study record: Melting point/freezing point.001

Detail level

Administrative Data

Data source

Materials and methods

all fields

Results and discussions

Overall remarks, attachments

Applicant's summary and conclusion

Results and discussions

Melting / freezing point

Melt./Freez. pt.	Atm. pressure	Decomposition	Decomp. temp.	Sublimation	Subl. temp.	Remark
Add...	Edit...	Delete	Move up	Move down		

Remarks on results including tables and figures

Rich text editor toolbar with icons for document, print, copy, paste, undo, redo, bold, italic, underline, bulleted list, numbered list, link, unlink, and a dropdown menu.

Overall remarks, attachments

Overall remarks

Rich text editor toolbar with icons for document, print, copy, paste, undo, redo, bold, italic, underline, bulleted list, numbered list, link, unlink, and a dropdown menu.

Information



Schmelzpunkt

Navigation

Query result

Complete

0 Related

1 General

2 Classifi

3 Manufac

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4.1 Ap

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4.4 De

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4.6 Va

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4.8 W

4.9 Sc

4.10 S

4.11 P

4.12 A

4.13 P

4.14 E

4.15 C

4.16 C

4.17 S

4.18 S

4.19 S

4.20 p

4.21 D

4.22 V

4.23 A

5 Environ

6 Ecotoxi

Endpoint study record: Melting point/freezing point.001

Detail level

Administrative Data

Data source

Materials and methods

all fields

Results and discussions

Overall remarks, attachments

Applicant's summary and conclusion

Overall remarks, attachments

Overall remarks

Rich text editor toolbar with icons for text formatting, alignment, and document management. Includes dropdowns for font style (Normal), font face (Agency FB), and font size (8). Bold (B), Italic (I), and Underline (U) buttons are present.

Attached background material

Attached document	Remarks
Add... Edit... Delete Move up Move down	

Attached full study report

Attached full study report
Add... Edit... Delete Move up Move down

Applicant's summary and conclusion

Conclusions

Large text area for conclusions with vertical scrollbars.

Executive summary

Horizontal scroll bar for the executive summary section.

Information



Fischtoxizität

Navigation

Query results

Complete

- 0 Related Information
- 1 General Information
- 2 Classification and Lab
- 3 Manufacture, use and
- 4 Physical and chemical
- 5 Environmental fate and
- 6 Ecotoxicological Infor
- 6.1 Aquatic toxicity
 - 6.1.1 Short-term
 - 6.1.2 Long-term
 - 6.1.3 Short-term
 - 6.1.4 Long-term
 - 6.1.5 Toxicity to
 - 6.1.6 Toxicity to
 - 6.1.7 Toxicity to
 - 6.1.8 Toxicity to
- 6.2 Sediment toxicity
- 6.3 Terrestrial toxic
- 6.4 Biological effects
- 6.5 Biotransformatio
- 6.6 Additional ecoto
- 7 Toxicological informa
- 8 Analytical methods
- 9 Residues in food and f
- 10 Effectiveness against
- 11 Guidance on safe use
- 12 Literature search
- 13 Assessment Reports

Endpoint study record: Short-term toxicity to fish.001

Detail level

all fields

[Administrative Data](#)[Data source](#)[Materials and methods](#)[Results and discussions](#)[Overall remarks, attachments](#)[Applicant's summary and conclusion](#)

Test materials

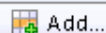
Test material equivalent to submission substance identity



Test material identity

Identifier

Identity



Add...



Edit...



Delete



Move up



Move down

Details on test material



Confidential details on test material



Details on properties of test surrogate or analogue material



Analytical monitoring



Details on sampling



Information



Fischtoxizität

Navigation

Query results

Complete

- 0 Related Information
- 1 General Information
- 2 Classification and Lab
- 3 Manufacture, use and
- 4 Physical and chemical
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Endpoint study record: Short-term toxicity to fish.001

Detail level

all fields

[Administrative Data](#)[Data source](#)[Materials and methods](#)[Results and discussions](#)[Overall remarks, attachments](#)[Applicant's summary and conclusion](#)

Analytical monitoring

[Details on sampling](#)[Details on analytical methods](#)

Vehicle

[Details on test solutions](#)

Test organisms

Test organisms (species)

Information



Navigation

Query results

Complete

- 0 Related Information
- 1 General Information
- 2 Classification and Lab
- 3 Manufacture, use and
- 4 Physical and chemical
- 5 Environmental fate and
- 6 Ecotoxicological Infor
- 6.1 Aquatic toxicity
 - 6.1.1 Short-term t
 - Short-term t
 - 6.1.2 Long-term
 - 6.1.3 Short-term
 - 6.1.4 Long-term
 - 6.1.5 Toxicity to
 - 6.1.6 Toxicity to
 - 6.1.7 Toxicity to
 - 6.1.8 Toxicity to
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- 6.6 Additional ecoto

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- 8 Analytical methods
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- 10 Effectiveness against
- 11 Guidance on safe use
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Endpoint study record: Short-term toxicity to fish.001

Detail level

all fields

[Administrative Data](#)[Data source](#)[Materials and methods](#)[Results and discussions](#)[Overall remarks, attachments](#)[Applicant's summary and conclusion](#)

Test organisms

Test organisms (species)

[Details on test organisms](#)

Study design

Test type

Water media type

Limit test

Total exposure duration

Remarks

[Post exposure observation period](#)

Test conditions

Information

Fischtoxizität



Navigation

Query results

Complete

- 0 Related Information
- 1 General Information
- 2 Classification and Lab
- 3 Manufacture, use and
- 4 Physical and chemical
- 5 Environmental fate and
- 6 Ecotoxicological Infor
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Endpoint study record: Short-term toxicity to fish.001

Detail level

all fields

[Administrative Data](#)[Data source](#)[Materials and methods](#)[Results and discussions](#)[Overall remarks, attachments](#)[Applicant's summary and conclusion](#)

Test conditions

Hardness

Test temperature

pH

Dissolved oxygen

Salinity

Nominal and measured concentrations

Details on test conditions



Information

Fischtoxizität



Navigation

Query results

Complete

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Endpoint study record: Short-term toxicity to fish.001

Fischtoxizität

Detail level

Administrative Data

Data source

Materials and methods

all fields

Results and discussions

Overall remarks, attachments

Applicant's summary and conclusion

Details on test conditions

Reference substance (positive control)

Any other information on materials and methods incl. tables

Rich text editor toolbar with icons for text formatting, alignment, and document management.

Results and discussions

Effect concentrations

Duration	Endpoint	Effect conc.	Nominal/Measured	Conc. based on	Basis for effect	Re
Add...	Edit...	Delete	Move up	Move down		

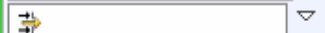
Information



Navigation

Query results

Complete



0 Related Information

1 General Information

2 Classification and Lab

3 Manufacture, use and

4 Physical and chemical

5 Environmental fate and

6 Ecotoxicological Infor

6.1 Aquatic toxicity

6.1.1 Short-term t

6.1.2 Long-term

6.1.3 Short-term

6.1.4 Long-term

6.1.5 Toxicity to

6.1.6 Toxicity to

6.1.7 Toxicity to

6.1.8 Toxicity to

6.2 Sediment toxicity

6.3 Terrestrial toxic

6.4 Biological effects

6.5 Biotransformatio

6.6 Additional ecoto

7 Toxicological informa

8 Analytical methods

9 Residues in food and f

10 Effectiveness against

11 Guidance on safe use

12 Literature search

13 Assessment Reports

Endpoint study record: Short-term toxicity to fish.001

Detail level

all fields

Administrative Data

Data source

Materials and methods

Results and discussions

Overall remarks, attachments

Applicant's summary and conclusion

Fischtoxizität

Results and discussions

Effect concentrations

Duration	Endpoint	Effect conc.	Nominal/Measured	Conc. based on	Basis for effect	Re
Add...	Edit...	Delete	Move up	Move down		

Details on results

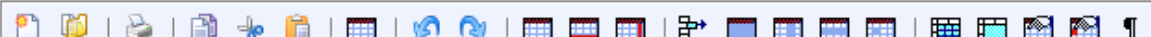


Results with reference substance (positive control)



Reported statistics and error estimates

Any other information on results incl. tables



Normal Agency FB 8 A B I U

Information

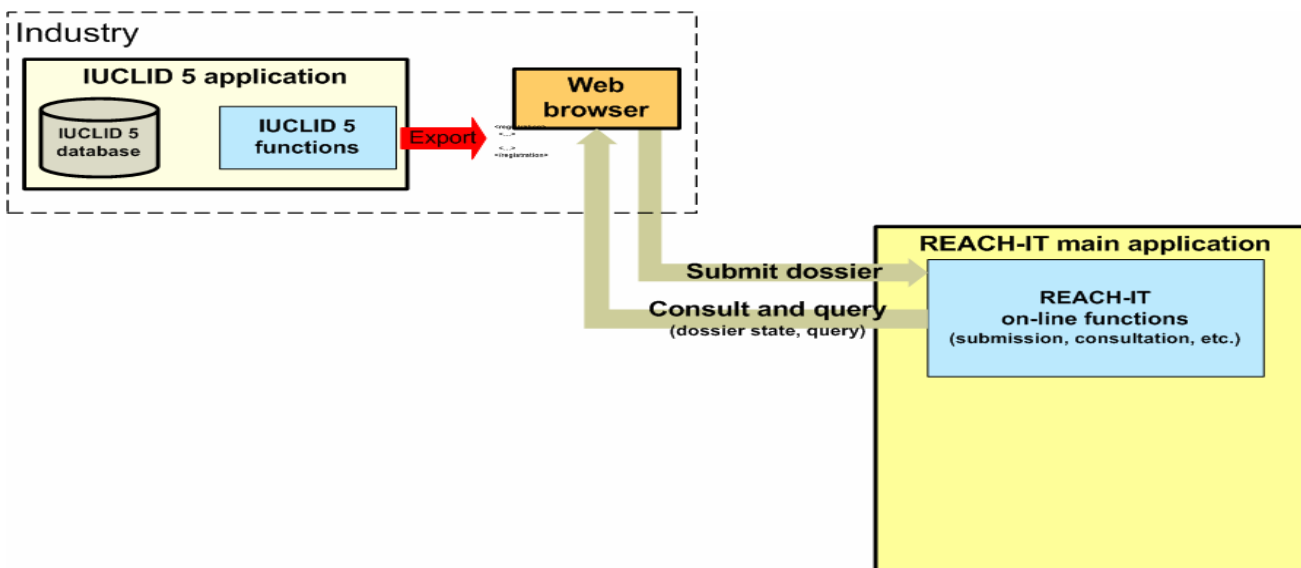
Was muss abgegeben werden?

Technisches Dossier + Chemical Safety Report

- ❖ Technisches Dossier (IUCLID-Datensatz)
 - Identität (Firma/Stoff)
 - Herstellung und Verwendung
 - Sicherheitshinweise
 - Einstufung/Kennzeichnung
 - Informationen zur Exposition
 - Study Summaries - Robust Study Summaries
 - Testvorschläge
 - Verschiedene Statements (z.B. Vertraulichkeit)
- ❖ Chemical Safety Report (> 10 t)
 - Dokument wird außerhalb von IUCLID erstellt und dann als Anhang zugefügt (pdf)

Von IUCLID 5 zur Agentur

Das Registrierdossier wird in IUCLID 5 erstellt, exportiert und dann an die Website der Europäischen Chemikalienagentur (REACH IT) geschickt



Was passiert danach?

- ❖ Eine Submission Number wird zugeteilt.
- ❖ Das Registrierdossier wird in der IUCLID 5 Datenbank der Agentur gespeichert.
- ❖ Das Dossier wird einem **Completeness Check** unterzogen
- ❖ Eine **Rechnung** wird ausgestellt und der registrierende Firma zugänglich gemacht.
- ❖ Wenn das **Dossier komplett** ist und die **Gebühr bezahlt** wurde, bekommt man die **Registriernummer** zugeteilt.
- ❖ Alle Dossiers werden in der IUCLID 5 Datenbank der ECHA gespeichert.
- ❖ Die nicht vertraulichen Daten werden in die öffentliche Datenbank eingestellt.
- ❖ Auf die öffentliche Datenbank hat jeder Zugriff.



Bayer

2. REACH-Symposium
Informationen zum
Datenaustausch / IUCLID 5

22. November 2007

Berlin