In-situ generated active substances
a view from industry

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On behalf of A.I.S.E.

ECHA Stakeholder day, 1 September 2015

Diversey Europe, part of Sealed Air

SEALED AIR CREATES A BETTER WAY FOR LIFE.

At Sealed Air, our goal is to protect a growing world with sustainable solutions that improve food safety and security. Helping create a cleaner, healthier environment and safeguarding your business against damage and loss.

- Food safety and security, facility hygiene and product protection
- 25,000 employees serving 175 countries

- Including many disinfection and other biocidal products that require BPR registrations.

Introducing A.I.S.E.
International Association for Soaps, Detergents and Maintenance Products

- Members:
  - 31 National Associations (Europe & beyond)
  - 9 direct member companies
- About 900 companies - 60% SMEs
- Consumer + Professional Cleaning & Hygiene (PC&H)
- Biocidal Product formulators
  - Disinfectants PT1 to PT5
  - In-can preservatives: PT6
  - Insecticides and repellents: PT18 and PT19





Presentation lay-out

- **What are in-situ products?**
- **What guidance is there?**
- **A.I.S.E. Support to its members**
  - One case example in more details
- **Challenges for formulators**
- **Next steps for A.I.S.E.**

BPR: In-situ defined

‘**biocidal product’** means

- any substance or mixture, in the form in which it is supplied to the user, consisting of, containing **or generating one or more active substances, with the intention** of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action,
- any substance or mixture, **generated from substances or mixtures which do not themselves fall under the first indent, to be used with the intention** of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action.

…

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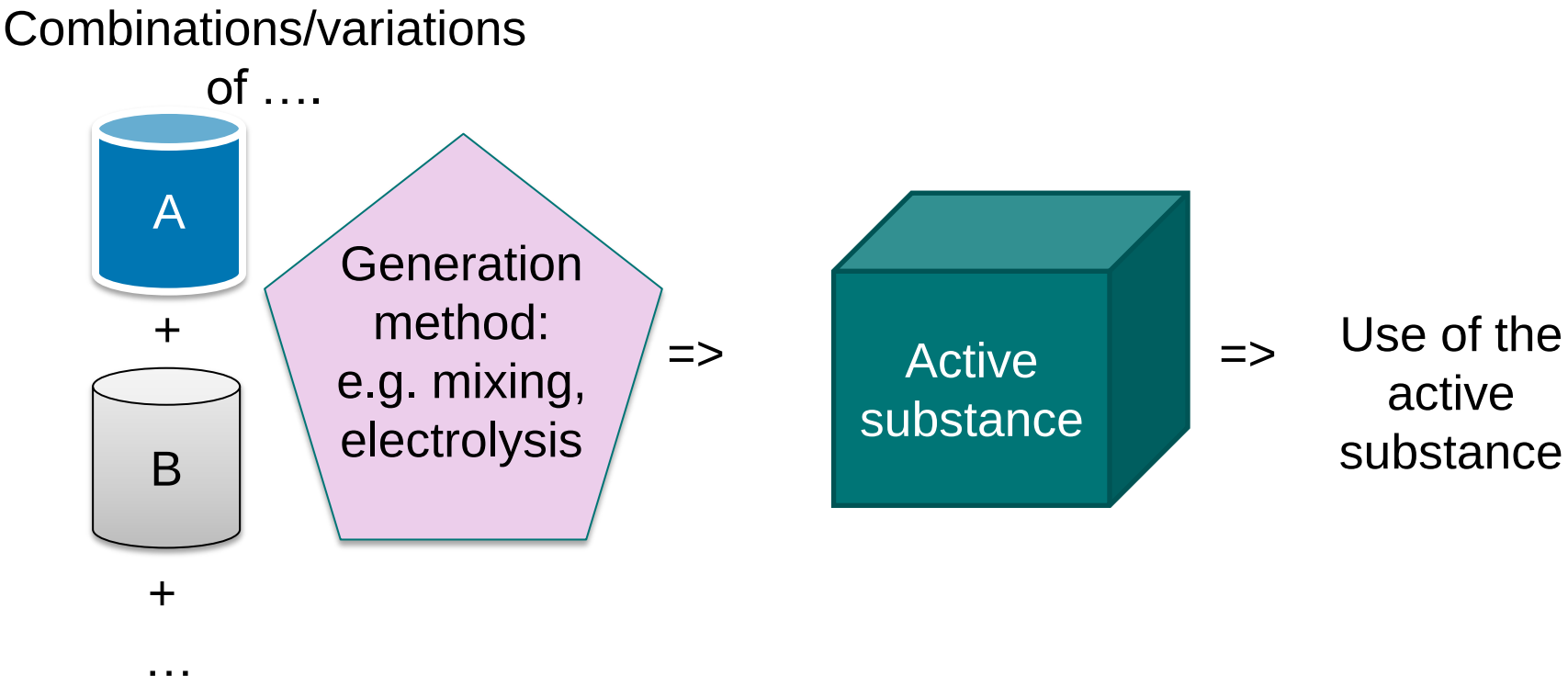
In-situ: some examples

Active generated at the place of use from one or more precursors.



Some history

- Extension of the definition from BPD to BPR.
- Applicants of already submitted active dossier have taken various approaches.
- Commission initiated a wide consultation to stakeholders and a workshop in 2014.

Commission's note

Management of *in situ* generated active substances in the context of the BPR"

CA-March15-Doc.5.1-Final Revised on 23 June 2015

EUROPEAN COMMISSION
HEALTH AND FOOD SAFETY DIRECTORATE GENERAL
Safety of the food chain
Pesticides and Biocides

CA-March15-Doc.5.1-Final
Revised on 23 June 2015

59th meeting of representatives of Members States Competent Authorities for the implementation of Regulation 528/2012 concerning the making available on the market and use of biocidal products

Management of in situ generated active substances in the context of the BPR

1. PURPOSE OF THE DOCUMENT

This document provides details of the management of in situ generated active substances

Commission's note (1)

- In situ systems are now defined by both the precursor(s) **and** the active substance generated

- In situ systems currently supported in the review programme have been redefined and have been added to Article 95 list.

Example of redefined entry

Work programme and Article 95 listing

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Article 95 List 129 (152)

Entity Name	Country	Supplier Type	Inclusion Reason	Inclusion Date
Active chlorine generated from sodium chloride by electrolysis (Redefined from Active Chlorine: manufactured by the reaction of hypochlorous acid and sodium hypochlorite produced in situ)		**EC: Mixture**	**CAS: Not applicable**	
Product Type: 1				
Aqualution Systems Ltd	United Kingdom	Substance Supplier	RP Participant	24-Sep-14
PuriCore Europe	United Kingdom	Substance Supplier	RP Participant	24-Sep-14
Product Type: 2				
Aqualution Systems Ltd	United Kingdom	Substance Supplier	RP Participant	24-Sep-14
PuriCore Europe	United Kingdom	Substance Supplier	RP Participant	24-Sep-14
Product Type: 3				
Aqualution Systems Ltd	United Kingdom	Substance Supplier	RP Participant	24-Sep-14
PuriCore Europe	United Kingdom	Substance Supplier	RP Participant	24-Sep-14
Product Type: 4				
Aqualution Systems Ltd	United Kingdom	Substance Supplier	RP Participant	24-Sep-14
PuriCore Europe	United Kingdom	Substance Supplier	RP Participant	24-Sep-14
Product Type: 5				
Aqualution Systems Ltd	United Kingdom	Substance Supplier	RP Participant	24-Sep-14
PuriCore Europe	United Kingdom	Substance Supplier	RP Participant	24-Sep-14

Commission's note (2)

- Currently non supported precursors-active systems can still be placed on the market providing they are supported via:
  - Art. 13 of the Review Programme Regulation, or
  - Art. 93 of BPR.

- Technical Equivalence will be replaced by Technical Specification, which still needs to be further defined

A.I.S.E. Support to its members

AISE experts members together analyzed the Commission's notes.

AISE experts prepared cases illustrate article 95

Prepared webinars to support members to help understanding these notes

AISE analysis of Commission note

Case study:

- **Peracetic Acid (PAA)**

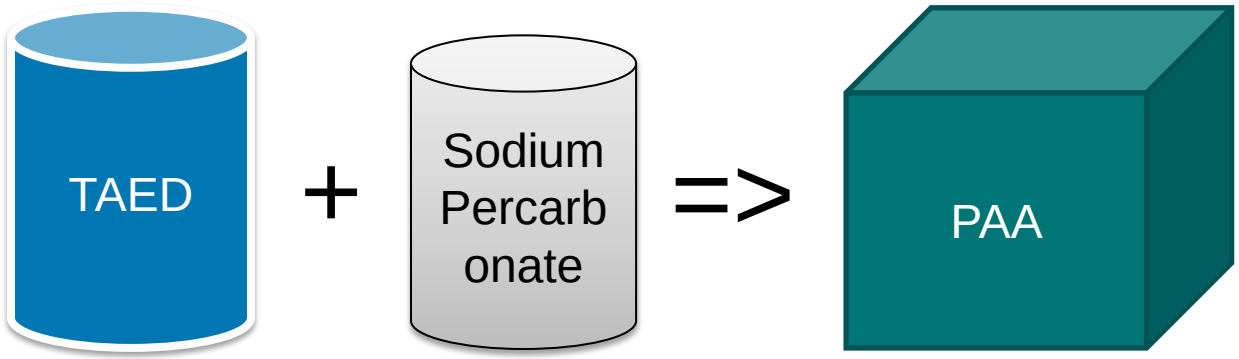
- **Chlorine dioxide**
  1) Chlorine dioxide generated from sodium chlorite (by electrolysis, acidification or oxidation)
  2) Chlorine dioxide generated from sodium chlorate
  3) Chlorine dioxide generated from TCDO

Case study: Peracetic Acid (PAA)

Example: biocidal laundry product

In situ - Peracetic Acid (example: biocidal laundry product)

System : Peracetic acid (PAA) generated from tetra-acetylethylenediamine (TAED) and sodium percarbonate (SPC)

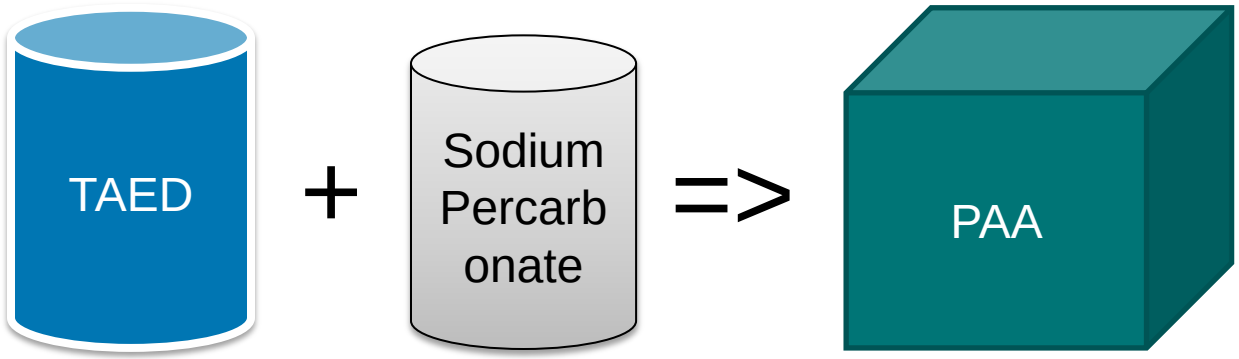


SUPPORTED IN THE REVIEW PROGRAMME

In situ - Peracetic Acid (example: biocidal laundry product)

In situ - Peracetic Acid (example: biocidal laundry product)

System : Peracetic acid (PAA) generated from tetra-acetylethylenediamine (TAED) and sodium percarbonate (SPC)



SUPPORTED IN THE REVIEW PROGRAMME

Annex I from CA note CA-March15-Doc.5.1-Final Revised on 23 June 2015

Annex I

In situ generated active substances

New name

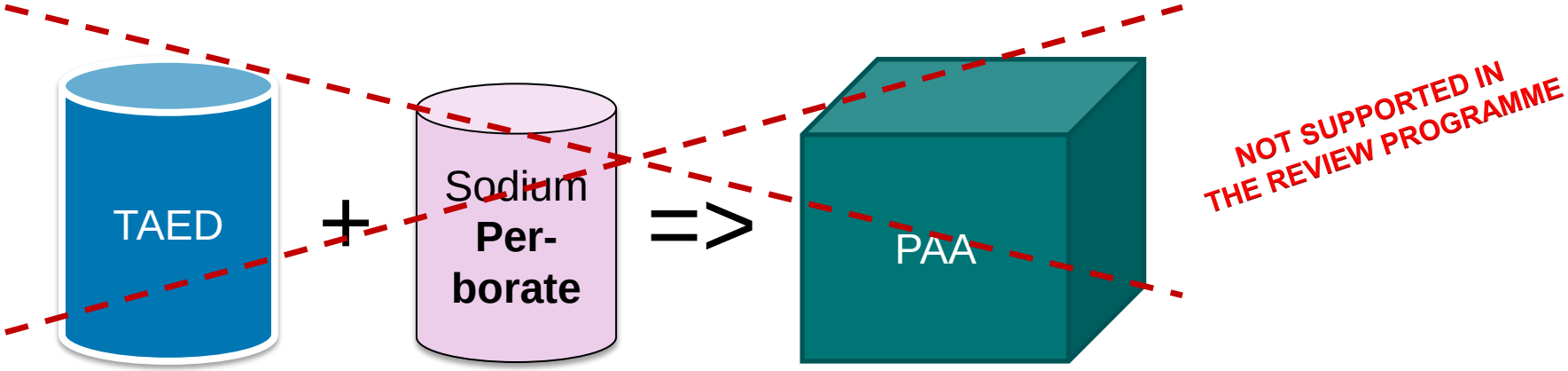
	Current name	Current precursor(s)/active substance combinations[7]	Additional precursor(s)/active substance combinations[8]	RMS	Legal basis for taking over[9]
6. Peracetic acid					
70	Peracetic acid[25]	n/a		FI 1, 2, 3, 4, 5, 6, 11, 12	n/a
70	Peracetic acid	Peracetic acid generated from tetra-acetylethylenediamine (TAED) and sodium percarbonate[26]		FI 2, 3, 4	n/a
			Peracetic acid generated of Tetra-acetylethylenediamine (TAED) and sodium perborate/ sodium perborate monohydrate		Art. 13 (70)

Old name

Not supported in the Review Program

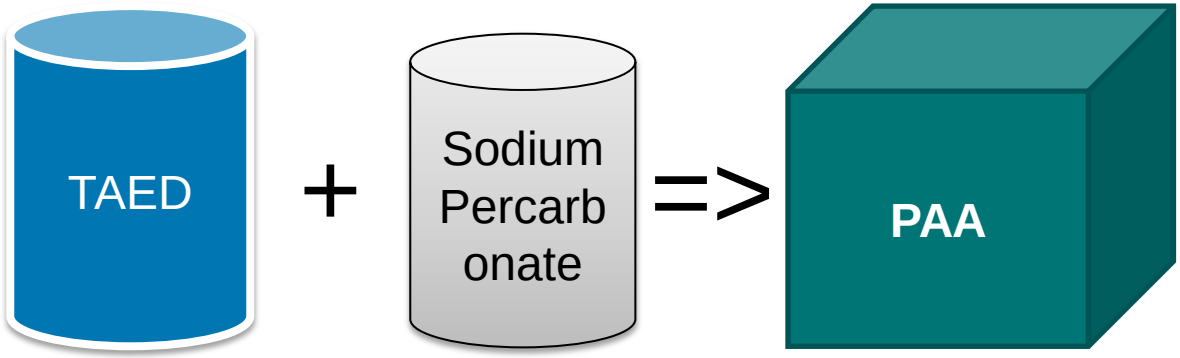
In situ - Peracetic Acid (example: biocidal laundry product)

System : Peracetic acid (PAA) generated from an acetate donor (including acetic acid) and a peroxide (including hydrogen peroxide)



- Unless system is supported via Art. 13 of the Review Programme Regulation

In situ PAA - Conformity Art. 95



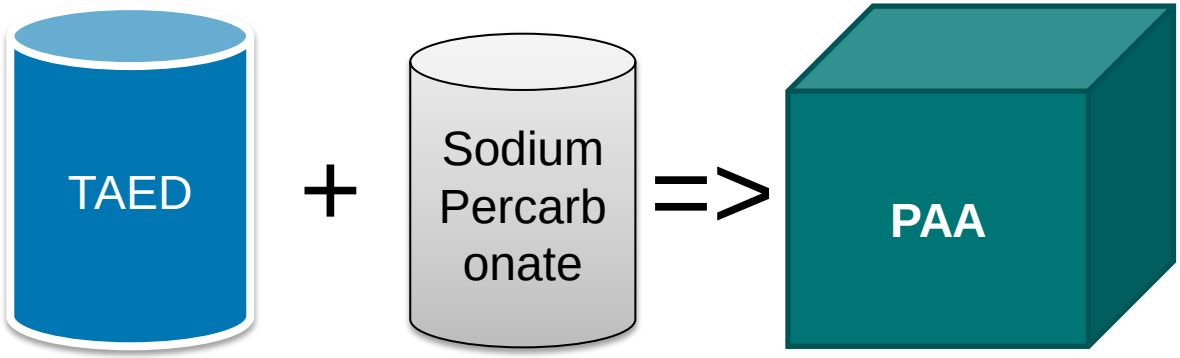
Art 95. list

"Peracetic acid generated from tetra-acetylethylenediamine (TAED) and sodium percarbonate"

List of suppliers

TAED Manufacturer/ Importer	SPC Manufacturer/ Importer	Formulator	Art 95 compliant?

In situ PAA - Conformity Art. 95



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"Peracetic acid generated from tetra-acetylethylenediamine (TAED) and sodium percarbonate"

List of suppliers

TAED Manufacturer/ Importer	SPC Manufacturer/ Importer	Formulator	Art 95 compliant?
		Listed	Yes
		Listed	Yes
		Listed	Yes

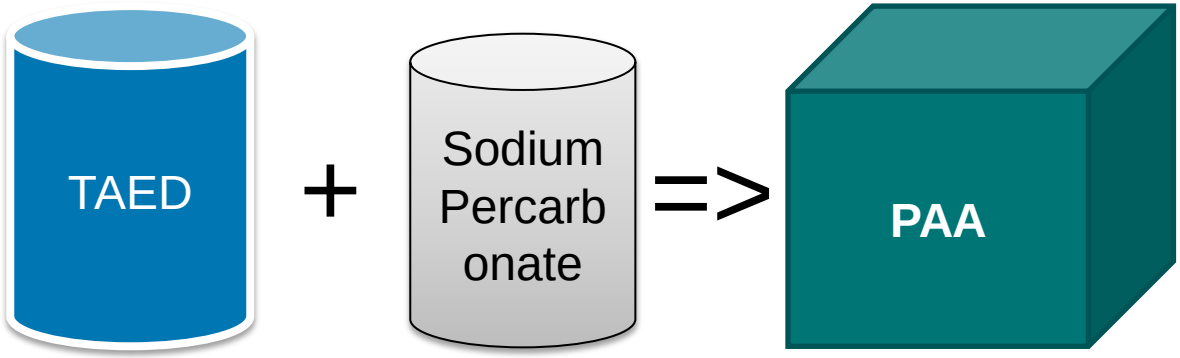
How do we make the product

Formulators reality

Supplier A: tetra-acetylethylenediamine (TAED)
Supplier B: sodium percarbonate (SPC)

Supplier A and B are the same.
Supplier A and B are not the same.

In situ PAA - Conformity Art. 95



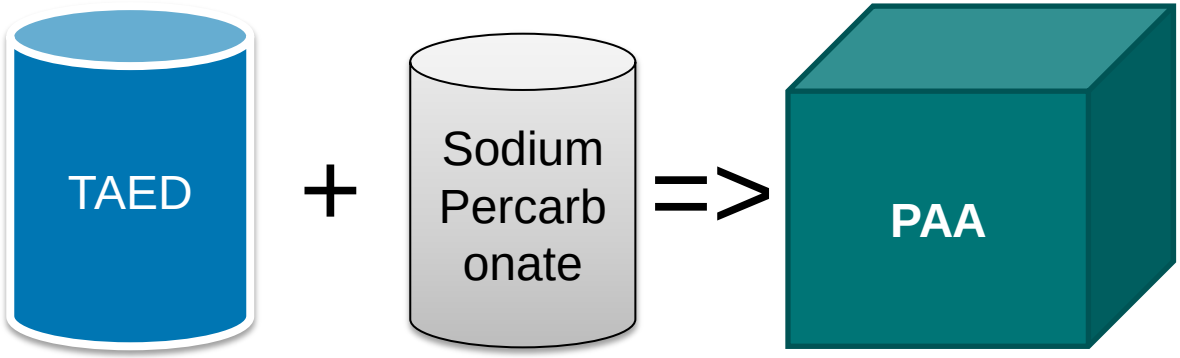
Art 95. list

"Peracetic acid generated from tetra-acetylethylenediamine (TAED) and sodium percarbonate"

List of suppliers

TAED Manufacturer/ Importer	SPC Manufacturer/ Importer	Formulator	Art 95 compliant?
Not listed	Not listed	Listed	Yes
Listed	Not listed	Listed	Yes
Not listed	Listed	Listed	Yes

In situ PAA - Conformity Art. 95



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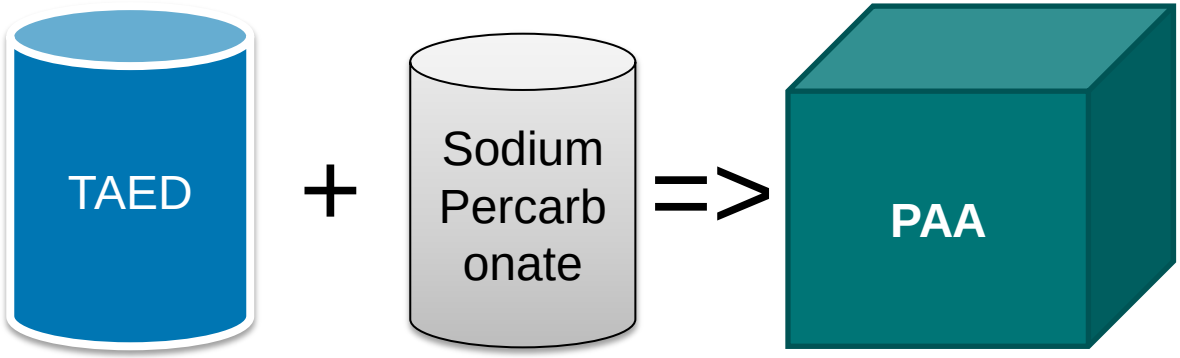
List of suppliers

TAED Manufacturer/ Importer	SPC Manufacturer/ Importer	Formulator	Art 95 compliant?
Listed	Listed	Not listed	Yes
Not listed	Not listed	Listed	Yes
		Not listed	
Listed	Not listed	Listed	Yes
		Not listed	
Not listed	Listed	Listed	Yes

In situ PAA - Conformity Art. 95



Art 95. list

"Peracetic acid generated from tetra-acetylethylenediamine (TAED) and sodium percarbonate"

List of suppliers

TAED Manufacturer/ Importer	SPC Manufacturer/ Importer	Formulator	Art 95 compliant?
Listed	Listed	Not listed	Yes
Not listed	Not listed	Listed	Yes
Listed	Not listed	Not listed	No
Listed	Not listed	Listed	Yes
Not listed	Listed	Not listed	No
Not listed	Listed	Listed	Yes

How do we make the product

Formulators reality

Supplier A: tetra-acetylethylenediamine (TAED)
Supplier B: sodium percarbonate (SPC)

Supplier A and B are the same.
Supplier A and B are not the same.

Supplier A1, A2 and A3
Supplier B1, B2 and B3

Check the article 95 list

Do the check for all your suppliers!

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Article 95 List

Prepared as of 17 August 2015

Entity Name	Country	Supplier Type	Inclusion Reason	Inclusion Date
Peracetic acid generated from tetra-acetylethylenediamine (TAED) and sodium percarbonate (Redefined from Peracetic acid)		EC: 201-186-8	CAS: 79-21-0	
Product Type: 2				

Challenges…

- **Art 95 compliance by 1 September 2015 with guidance still changing till March 2015.**
  - Trusting your suppliers to get listed
  - Own negotiations with AS supporting consortia/ companies:
    - Long and costly process
    - Negotiations Letter of Access – need legal expertise (many companies do not have a legal department)
- **Registration under local legislation (transition law)**
- **Dossier requirements for in-situ systems**
  - How to use standard forms and systems?
  - Labels of precursors?
- **Technical equivalence/Technical specifications for in-situ systems unclear**

Next steps for A.I.S.E.

- Keep close eye on all BPR future developments and contribute as appropriate

- Support members and local associations

Thank you for your attention

For more information

For European organizations: Please contact the A.I.S.E.

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