## **ESSILOR**

#### SEEING THE WORLD BETTER



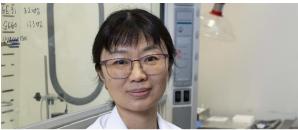












## Chemical Regulatory Challenges in Asia Pacific Markets

November 13, 2019





### **Global Link to Chemical Tools**

### New chemicals: Stages & Gates Requirements

GATE	OBJECTIVES	HOW	WHO	
Gate 2	Ensure new chemical products do not contain any priority chemical listed in Essilor PCL lists.	Screen new chemicals with CHEM Hazard and ensure they do not contain any PCL1 or PCL2 priority chemicals.	R&D / Global Engineering	Chem Hazard
Concept Approval	Complete Process Hazard Analysis (PHA)		EHS Local / R&D/GE	<u>Process Hazard Analysis</u> <u>Form-V0</u>
Gate 3				
FEASIBILITY PROJECT	Ensure compliance with Global Chemical Regulations, get from suppliers all information and documents required to proceed with import registration or notifications.	Carry out verifications according to GEHS 02.013 - Global EHS requirements for Chemicals Ordering.	Purchasing GS&P/ Local	GEHS 02.013 - Global EHS Requirements for Chemicals Ordering
Proof of Technical feasability	Carry out product safety evaluation and prepare product safety summary when required.	According to GEHS 02.014 procedure for Lens Safety Evaluation.	Global EHS	GEHS 02.014 - Lens Safety Evaluation
	Create a safety data sheet for all chemicals intended to be manufactured/mixed at Essilor entities.	All necessary Safety Data Sheets for chemicals manufactured by Essilor must be requested to Global EHS.	Global EHS	SDS Request form
industrialization industry industry Market authorization	Prepare registration or import notification dossiers. Verify additional local regulatory requirements that may apply and ensure all obligations are fullfilled.	Compliance check and registration/notification dossiers will be completed and submitted to authorities by local EHS and local purchasing.	Local Purchasing/ EHS	

## SDS Process – The request for new chemical

ESSILOR INTERNATIONAL - Global EHS Department

SAFETY DATA SHEET ISOST REQUEST FORW

ESSILOR ESSILOR INTERNATIONAL - Global EHS Department SAFETY DATA SHEET ISOST REQUEST FORM Requestor Name/Organization: Request Date: Year Intended userson leater SDS Number Packaging size(s) or Weight: Product Identifier (Product Code, etc.) "Manufacturer ESSILOR International Company Name elaphane Number +33 (0) 1.49.77.42.24 N°, ORFILA - Tel : +33 (0) 1.45.42.59.59 Email (displayed on the MSDS) responsible for SDS/Dessilor.com Company Name Contact Person (displayed on the SDS mergency Telephone Number United Nationa CHS UN Purple Book SDS and **D**English LISA Other Canada DEsolish DEFrench Other **D**English Brazil **DPortuguese** Other: Moxico **D**Scenish **D**Enolish Other: Middle bast and Africa DHindi **D**English DHobrow **D**English Other: Saudi Arabia DAtabio

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Partugui ElPortuguese ElEnglish	h	Other:
Romania DRomanian DEnglish	h	Other:
Russia DRussian DEnglish	h	Other:
Slovekia DSlovek DEnglish	h	Other:
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Sweden DSwedish DEnglish	h	Other:
Switzerland DiCerran DiFrench	Ditelien	Other:
Ukraine DUkrainian DEnglish		

Chemical Chemical		CAS Number	% (white	Confidential	Purpase in
CHINE	· ·	CROHATON	/a (man)	CYING?	Material
DXICOLOGICAL TEST D	AIA				
I oncological data avails		whole?	DYes	C1No	
	Describe test results, t	ost species and m	ethods		
Oral LD50	Species:	Method:			
Domal LD50	Species:	Method:			
Inhalation LC50	Species:	Method:			
ITTERESTATE DOZUM					
	Species:	Method:			
Sensitipation*	Species:	Method:			
Sensitipation*	Species:	Method:			
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ESSILOR INTERNATIONAL - Global EHS Department SAFETY DATA SHEET ISOSI REQUEST FORM PHYSICALICHEMICAL DATA! Color "F Test method: Flash Point 107 Tat Specific Gravity (Relative Density 107 Vapor Pressure (Lee 1C) Molting Point °C / Test Method - Completely Soluble (100% ) 9 Solubility in Water - Soluble ( 10-99% ) - Moderate Soluble (1-10%) - Slightly Soluble ( 0.1-1% ) - Insoluble ( <0.1% ) Salubility (Salvant: Partition coefficient: n-octava/water (Log Evaporation Rate (n-But/sex Viscosity (25 °C/77 °F) Viscosity (40 °C/104 °F) (Unit: Upper Flammability Limit (UFL) Auto-ignition Temperature (E.g. Particle Size, Volatiles, Freezing Point, Plammability (Solid))

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For polymers, provide the average MW and content of all residual reactar talmonomers.

Indicate Suc. No. or port. The total composition must be 100%. Ranges are accepted and in these cases. 3E will perform the heared and risk evaluation from a work-over, standpoint.

If Yay, Indicate whether the name and/or opposituation are proprietary. Provide the generic name or HMRSC number Canada) and/or concentration range to be upod. Please note that for EU member states the use of generic names is subject

5 Date from sensitization and other tests <u>will counted</u> with the installation of the MSCS but will be used for the hazard evaluation of the account, which will be examined via obtained.

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Flease note: Physicalichemical data should reflect the results of tests performed on the product itself Flammable and explicative are synonymous. ESSILOR

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No local translation is permitted as SDSs must be kept up-to-date with regulations as well as product composition changes.

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New formats or translations required by Essilor entities should be requested to Global EHS Department who will coordinate the work with 3E Company. In case there is a modification in the composition of an existing product (for example new raw material validation): this information has to be provided to Global EHS Department who will make sure that all safety data sheets available for this product are updated accordingly.

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## Essilor Priority Chemical Lists

Essilor has set Priority Chemicals Lists (PCL) to ensure better control over hazardous substances in its products and processes and the replacement of those with unacceptable risk.

Any new or existing chemical must be <u>screened against Priority Chemicals Lists</u> by using Chem Hazard tool.

Refer to <u>GEHS 02.013</u> procedure for more information about Global EHS requirements for chemicals ordering. The procedure describes the general steps that must be followed by Corporate Sourcing and Procurement, Global Engineering, R&D departments and Manufacturing Sites, to identify major requirements prior ordering chemicals.

## Chem Tool Rules



Substitute it Now!

The use of chemicals listed in PCL 1 list is prohibited in any Essilor workplaces.



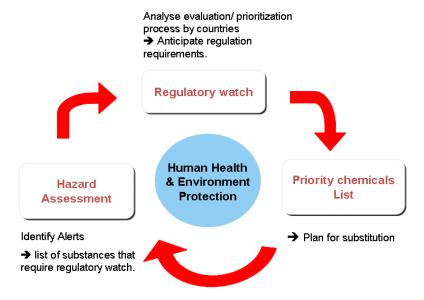
Plan for replacement

PCL 2 chemicals are banned for new product or process development purpose, and must be replaced where a safer alternative exists. For existing uses where there is no known alternative solution, strong efforts must be made to identify & validate replacement solutions.



Consider safer chemical (if technically possible) PCL3 chemicals should be replaced by safer alternative when it is technically/economically possible. This list should be used as a guide for R&D selection of new chemicals.

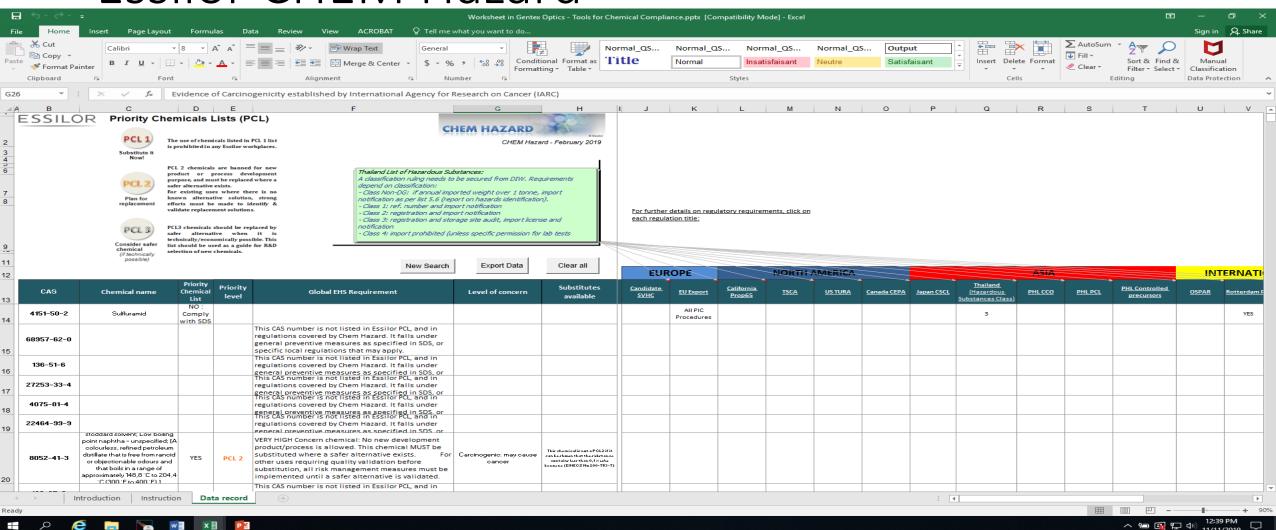
### **Priority Chemicals Lists (PCL)**



- Priority chemicals listed in PCL 1 and PCL 2 cannot be used in R&D for new product development purpose if it is intended after study to be deployed in other Essilor workplaces.
- The requirements set up in Essilor Priority Chemicals lists (PCL) are a worldwide internal Essilor Policy even if local regulatory requirement may be less restrictive. The lists are continuously updated as new information/regulation on hazardous chemicals become available.



## Essilor CHEM Hazard

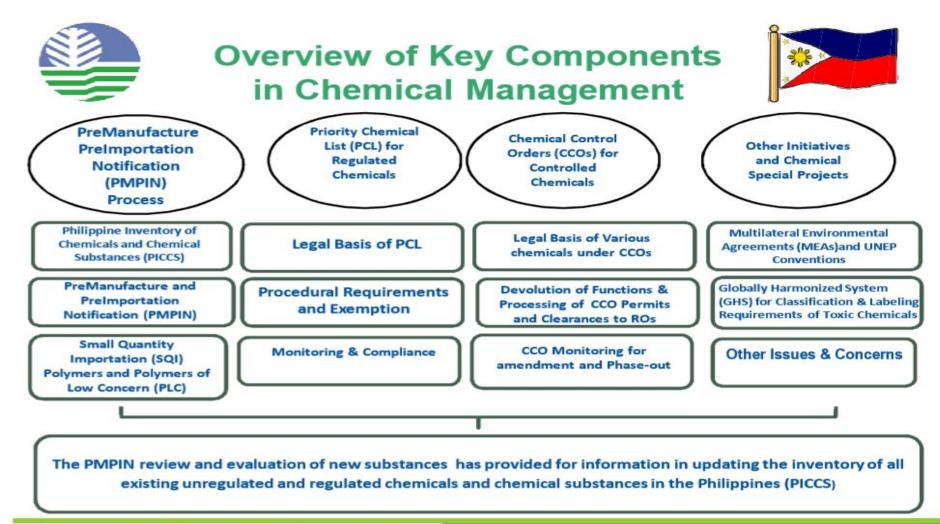




## Government Agencies That Control Chemicals in the Philippines

AGENCY REGULATING	CHEMICALS BASED ON USAGE	LAW	Chemical Examples
DENR - EMB	Industrial Chemicals	Republic Act (RA) 6969	Mercury, Formaldehyde, Lead, Benzene etc.
DDB-PDEA	Dangerous Drugs	RA 9165	Ketamine Amineptine
DA - FPA	Fertilizers and Pesticides (Agricultural Use)	PD 1144	Endosulfan Chlorothalonil
DOST – PNRI	Radioactive Chemicals	RA 5207	Cesium Cobalt Iridium
DOH - FDA	Chemicals for human consumption	RA 10620 / PD 881	Cosmetic Products Vitamins
DILG-PNP	Explosives	RA 9516	Aluminum Nitrate Ammonium Acetate Iron Nitrate

## Introduction to Philippine Chemical Management



Department of Environment & Natural Resources
Environmental Management Bureau

# Philippine Priority Chemicals List (PCL) and PCL Compliance Certificate

- ➤ Philippine Priority Chemicals List (PCL) is a short list of hazardous chemicals that have been determined to potentially pose unreasonable risks to public health, workplace and environment in the Philippines (i.e., bio-accumulative, highly toxic, persistent).
- > There are currently 92 chemicals on Philippine Priority Chemicals List (PCL).
- ➤ PLC compliance certificate was once required before you can manufacture or import them. This is no longer a requirement.

PCL List - 92

**CasREgistry** 

## Philippine Chemical Control Order (CCOs)

- Chemicals that are subject to Chemical Control Order (CCO) are restricted or banned (limit or regulate the use, manufacture, import, transport, processing, storage, possession and wholesale) due to their serious risks to human health or the environment.
- You need to obtain permission from DENR-EMB (Department of Environment and Natural Resources, Environmental Management Bureau) first before importing them into the Philippines. They are also subject to mandatory GHS SDSs and labelling.
- Chemicals subject to CCOs include:
  - Ozone-depleting substances,
  - > Lead and Lead Compounds, (Example: 6 year phase out of lead in paint 2013 -2019)
  - Polychlorinated Biphenyls (PCBs),
  - Mercury, (Phase out date 2022 for manufacture and importation, exemptions allowed.)
  - Asbestos and
  - Cyanide and Cyanide Compounds.
- General Exemptions under the CCO Rules
  - > Chemical substances and mixtures regulated by laws other than RA 6969
  - Special circumstances as determined by DENR-EMB

## How to Comply with Chemical Control Orders (CCO)

For chemical substances subject to Chemical Control Orders, you need to register them with DENR-EMB & obtain import clearance.

In addition to that, you need to meet the following requirements:

- Limitation in Industrial Use:
  - Gradual phase out of import and manufacturing or
  - Gradual substitution of the chemical uses and premises
- Annual Report to DENR-EMB.
  - All manufacturers, importers, and industrial users of chemicals must submit an annual report to DENR-EMB that includes information on production, exposure data, waste, storage, and treatment.
- Labeling Requirements
- Storage Requirements
- Treatment and Disposal Requirements
- Self-Inspection
- Reporting and Recordkeeping Requirements

## Chemical Control Order

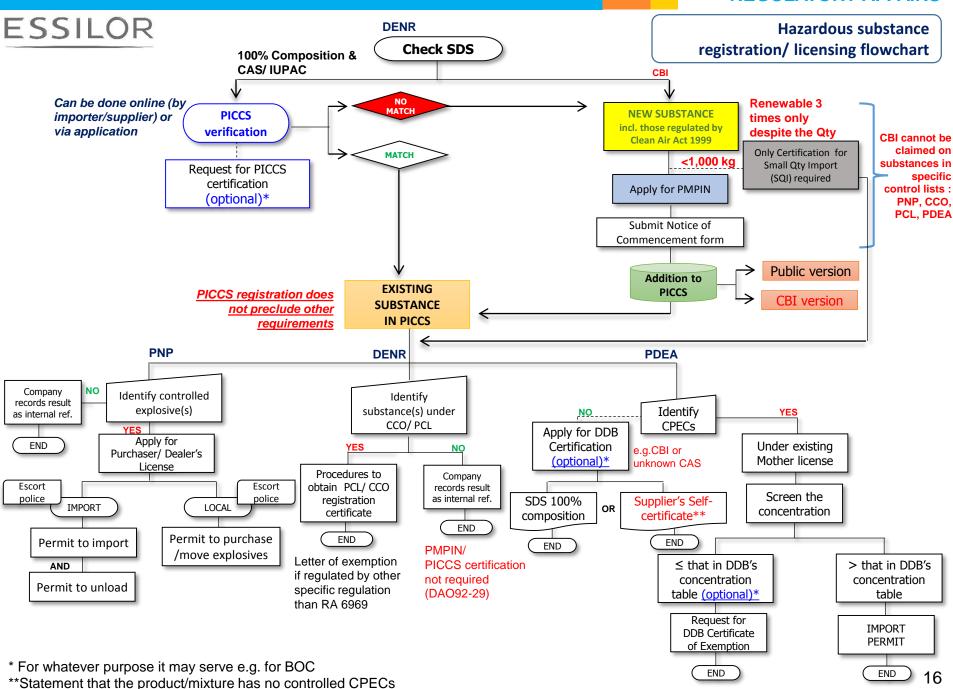
- All CCO importation clearance should be secured and approved prior to the actual arrival at the Port of Entry.
- No Importation Clearance shall be issued when the chemical is already at the port of entry as endorsed by the Bureau of Custom (BOC)
- Any special instructions or procedures that are being introduced or done by respective Offices (other than those stated in harmonization policy under DAO 2015) must inform EMB-CO to ensure uniform implementation of the CCO Procedures.

## PICCS Online Search System

- ➤ The Philippine Inventory of Chemicals and Chemical Substances (**PICCS**) is a list of all existing chemical substances used, sold, distributed, imported, manufactured, stored, exported, treated or transported in the Philippines. It was first published in 1995 with 15,000 listed chemicals. By 2015 there were over 47,000
- Manufacturers and importers don't have to conduct new chemical notification (PMPIN) if their chemicals are already listed in the PICCS, unless the chemicals are listed in the Priority Chemicals List (PCL) or subject to Chemical Control Orders (CCO).
- Although new chemicals are added in PICCS annually, the online database of the authority is not usually up-to-date. Tip: Enterprises should do the new chemicals search on their own first, and then contact the authorities if necessary (for example, the CBI issues).

http://119.92.161.2/internal/CasREgistry.aspx

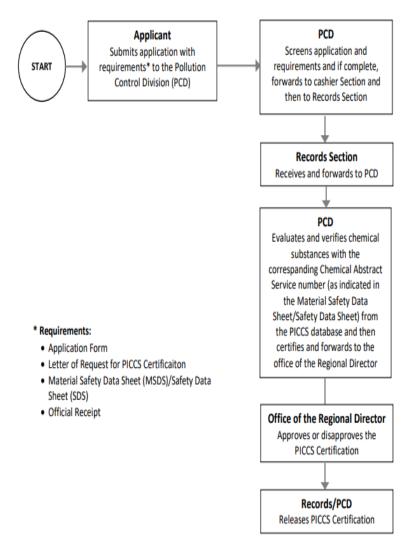
#### **REGULATORY AFFAIRS**



## PICCS Certification

- The purpose of <u>PICCS certification</u> is to show the Bureau of Customs or other authorities that a substance is indeed listed on <u>PICCS</u> and thus is exempt from <u>PMPIN</u>.
- Even though PICCS certificate is not a mandatory requirement, the Bureau of Customs or other authorities may request importers to present PICCS certificate <u>before releasing the goods.</u>
- Companies may apply for PICCS certification for their substances by submitting the following info
- Completed PICCS application form and notarized copy
- (M)SDS in ISO11014 or GHS format
- Letter of request for PICCS certification
- Official receipt of processing fee (~10 USD per substance)

#### PICCS Certificate Process Flow Chart



## PICCS Questions

### What if my substance is not on PICCS?

- A substance that cannot be found on PICCS will be regarded as a new substance in the Philippines.
- Manufacturers or importers need to submit a <u>Pre-Manufacture and</u> <u>Pre-Importation Notification</u> (<u>PMPIN</u>) of new substance to the (DENR-EMB) and secure clearance.

### What if my substance is on PICCS?

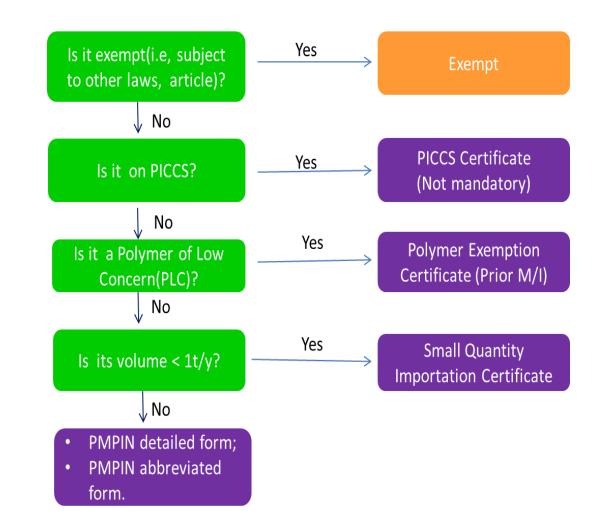
- You do not need to prepare an notification for your substance to secure clearance from DENR-EMB prior to production or importation provided that these chemicals are not on <u>Priority</u> <u>Chemical Lists (PCL)</u> and not are subject to <u>Chemical Control Orders (CCO)</u>.
- Tip: Know that the Bureau of Customs sometimes request companies to prove that their substances are listed on PICCS. In that case, the recommendation to companies has been to apply for <u>PICCS</u> <u>certification</u> in advance. This will save time.

## PMPIN Exemptions

#### The following substances are exempt from PMPIN.

- Chemicals and chemical substances included in PICCS;
- Small scale premises;
- Small quantity chemicals;
- Certain polymers and other substances exempt from PICCS requirements;
- Non-isolated intermediates;
- Articles;
- New chemicals manufactured exclusively for export;

Note: For small quantity of new substances(<1t/y) which are exempt from PMPIN, you must apply for Small Quantity Importation Certification (SQI). Even for substances listed on PICCS, you may apply for PICCS certification(not a compulsory requirement).



## PMPIN Abbreviated & Detailed Form

Section A: Premise Information

(Importer/Manufacturer)

Premise Name:

Premise Address (Facility/Warehouse):

Mailing/Office Address:

Responsible Person:

Contact Number:

Section B: Chemical Identification Information

Chemical (CAS) Name:

CAS RN:

IUPAC:

Common Name:

Molecular Formula/Structure:

Synonyms for the New Chemical:

Trade Name of the New Chemical

Section D: Occupational Exposure

Type of Activity:

Number of Workers:

Exposure of Activity:

Section E: Estimate Environmental

Release and Disposal

Release Quantity:

Release Media:

Control Measure:

Section F: Regulatory Status in other Country

Country Name:

Regulatory Status in the Country:

Is MSDS available in the Country:

Section G: Statement on Physicochemical Characteristics

Form:

Color:

Boiling Point:

Melting/Freezing Point:

Flash Point:

Density:

Solubility:

Vapor Pressure:

Partition Coefficient:

Others:

Section I: Statement on Environmental Effects

Acute Aguatic Toxicity (Fish/Daphnia/Algae):

Degradability/Persistency:

Bioaccumulation:

Chronic Aquatic Toxicity:

Section C: Production Import and Intended Use

Intended use:

Total Quantity Produced/Imported in 12 months (Kg):

Estimate the new quantity in the following categories

(Kg):

Site Limited Commercial

Industrial Consumer

Section H: Statement on Toxicological Effects

Acute Toxicity (Oral/Dermal/Inhalation):

Skin Irritation/Corrosion:

Eye Irritation/Corrosion:

Sensitization:

Carcinogenicity:

Genotoxicity:

Mutagenicity:

Chronic Toxicity:

Specific Target Organ Toxicity (STOT):

Others:

Section J: List of Other Companies (Joint Submission)

Company Name:

Company Address:

Contact Person:

Contact Number:

#### PMPIN APPLICATION

- Detailed PMPIN Form
  - ➤ Chemicals not yet listed in any countries
  - $\geq$  120 180 working days (Processing Time)
- ➤ Abbreviated PMPIN Form
  - Chemicals already listed USA, Japan, Canada, Australia, EU and Koriea
  - ➤ 90 Working days (Processing Time)

## Pre-Manufacture and Pre-Importation Notification (PMPIN) of New

Substance in Philippines

#### **PMPIN Documentary Requirements**

SUBJECT: New Requirements for Applicants of Pre-Manufacture Pre-Importation Notification (PMPIN).

As per provisions of DENR A.O. 29 the Implementing Rules and Regulations (IRR) of Republic Act 6969 entitled "Tittle II: The Management of Chemicals and Toxic Substances" the following are the new requirements in compliance with the PMPIN Rules.

#### A. PROCEDURAL Requirements

- Notifier: Name of Philippine Company and/or Firm Only importers or industries that are registered to manufacture in or licensed to import into the Philippines will be allowed to apply or notify.
- Substance must be defined as new chemical or fuel additive. New chemical is defined as chemical not listed in the Philippine Inventory of Chemicals & Chemical Substances (PICCS).
- Notarized and completed PMPIN-3 Abbreviated or PMPIN-4 Detailed Form PMPIN-3: for chemicals manufactured or includes in the Inventory of USA, EU, Australia, Canada. Japan or Korea
  - PMPIN-4: for chemicals manufactured or imported from other countries not listed in PMPIN-3
  - PMPIN Forms are available at: www.emb.gov.ph/portal/chemical/downloadables.aspx
- 4. Material Safety Data Sheet (MSDS) / Safety Data Sheet (SDS) in ISO-11014 format
- 5. Specific Use of the Chemical
- 6. Annual volume of import
- 7. Notification must be filed at least 100 days before date of manufacture or importation.
- 8. Two hard copies of PMPIN duly notarized 1 receiving copy & 1 CD format.
- 9. Payment of processing fee: for PMPIN3- P 2,150

#### for PMPIN4- P 3,750

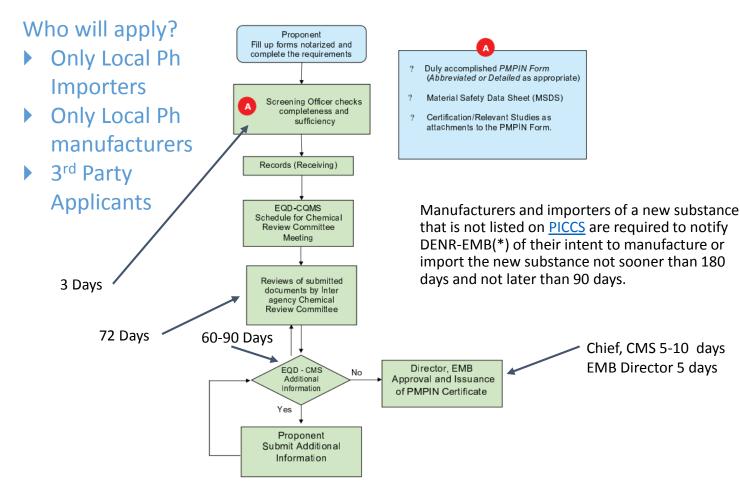
 Request for Confidential Business Information (CBI) – for PMPIN application containing confidential business information.

#### B. SUBSTANTIVE Requirements

- 1. Complete information of MSDS/SDS following 16 sections
- 2. For sufficiency of submitted MSDS/SDS giving more focus on:
  - a. Toxicological Information
  - b. Ecological Information
- 3. For PMPIN-4, laboratory reports for the following information are required:
  - a. Physical and Chemical Properties
- b. Toxicological Information
- c. Ecological Information

#### PROCEDURAL FLOW:

Pre-Manufacturing and Pre-Importation Notification (PMPIN) Certification



\*DENR-EMB: The Department of Environment and Natural Resources Environmental Management Bureau (DENR-EMB).

## What is Confidential Business Information (CBI)?

- The local counterpart will apply reflecting the information in the PMPIN Form by following the SDS of the products and not the individual chemical.
- Supplier will directly disclose the new chemicals with CBI to the EMB Central Office through chemicals.emb.gov.ph or www.emb.gov.ph
- Or the supplier may send the information through the EMB-NCR, EMB- Region 4A and EMB-Region 3.

#### **Current Issues**

- Disclosure of confidential information is hard to acquire
  - The supplier is different from the manufacturer of the chemical/substance. The supplier doesn't have the chemical information.
  - The supplier and manufacturer of the chemical/substance do not want to disclose information even to Regulatory Office.
- Confidential information sent by email sometimes does not indicate anything about the importer.

Ref: EMB Memorandum Circular No. 2014-01

#### **Hazardous substance Supplier's concerns on Confidential Business Information (CBI)** registration/licensing flowchart Check 100% http://emb.gov.ph/internal/CasREgistry.aspx composition against **CBI** PICCS database Customs regulated-O No match with Regulated **Exposure level** imported list AND imported list NO MATCH WITH BOTH REGULATED PICCS database Microsoft Office Adobe Acrobat **PDF File** IMPORTED LIST + PICCS = Match with PICCS **Regulated import Excel Worksheet** Document PCL Draft 032618 Customs regulated-**PICCS PICCS** imported list Supplier database 2012 database Please refer to the Undergo CBI Secure a PMPIM\* Memorandum Circular procedure using from EMB no.010 Series of 2014 CBI form Adobe Acrobat Document Control **Authorities** Controlled NO Controlled substance(s) substance under PNP, under PNP, CCO, PCL, PDEA CCO, PCL, PDEA No CBI No CBI disclosure disclosure √ Obtain a Self-Registration of **CBI** shall be indicated certificate as new substance **Importer** on a specific confirmation (Only product/ certificate applied by substance name from supplier importer for a purpose will appear in SQI/ it may serve PMPIN certificate) END

**REGULATORY AFFAIRS** 



\*Pre-manufacture and Pre-importation Notification

## PMPIN Compliance Certificate



A copy of the Certificate shall be retrieved and print directly by the company at their own computer.

Copy of the Bureau of Custom (BOC)at the Port of Entry.

## Small Quantity Importation Certification

- > This is an exemption to the PMPIN Process
- ➤ Small Quantity Importation Certification(SQI) is required prior to the importation of less than 1,000 kg./yr of pure chemical substances or component chemical in percentage by weight of product, mixtures not listed in PICCS into the Philippines.
- > The following info is required for application of SQI.
- > Letter of request for SQI clearance
- > SDS in ISO11014 or GHS format
- > Completed application form and notarized copies
- ➤ Official receipt of processing fee (~11 USD per substance)

13.11.2019

Regional Director Environmental Management Bureau DENR Region 1V-A, Roxas Boulevard, Manila Attention: Miss Marissa DC Malabana Chief, Chemicals & Hazardous Waste management section

Subject: Request for Disclosure of business information according to the MC no.010 Series of 2014

Dear Ms. Malabana

This letter is in relation to Name of local business entity application for the Small Quantity Importation Clearance of the following products

Name of Product

Confirming herewith, the components of the products above are:

Components of Product x	CAS no#	Concentration
Fill in chemical names and CAS #		25 - 30
With % in product. Ranges are		5 - 10
Acceptable.		1-5
		<1
		< 0.5
Ingredients withheld on SDS for CBI	CAS no#	Concentration
Chemical family name on PICCS		20 - 40%
CAS# and % in product		20 - 40%
		10 - 30%
TOTAL		100%

Because this products are composed of substances we bought from different suppliers which themselves also have confidentiality concerns, limiting our ability to provide full chemical disclosure, we have provided chemical family names which highly represent the materials.

We do hope that you will find the information on this letter to be suitable and sufficient in granting approval for the Small Quantity Importation Clearance application.

Please feel free to contact (name of local expert), by phone at 333-333-3333 or by email at (include email address) should there be further clarifications needed.

Sincerely yours, Corporate Seal

Name and signature of managing official

Example: EHS Director

#### Insert Supplier's Letterhead

Supplier's address

#### dd.mm.2016

Regional Director
Environmental Management Bureau
DENR Region 1V-A, Roxas Boulevard, Manila
Attention: Miss Marissa DC Malabana
Chief, Chemicals & Hazardous Waste management section

Subject: Request for Disclosure of business information according to the MC no.010 Series of 2014

Dear Ms. Malabana

This letter is in relation to \_\_\_\_\_\_, Inc application for the Pre-manufacture Pre-import notification of the following products:

- Product name
- Product name

Confirming herewith, the components of the products above are

#### Available product components

Because these 2 products are composed of substances we bought from different suppliers which themselves also have confidentiality concerns to provide us detailed composition, we have invited them to send the composition of the following substances to you to complete this letter:

- 1. Chemical Product Name 1
- 2. Chemical Product Name 2
- 3. Chemical Product Name 3
- 4. Chemical Product Name 4

We do hope that you will find the information on this letter as well as the ones that will be sent by our suppliers suitable and sufficient in granting approval for the Pre-manufacture Pre-import notification application.

Please feel free to contact me via phone or email (.....) should there be further clarifications needed.

Sincerely yours,

Signature of legal representative & Company's seal [Position]





FOR INTERNAL USE

Process for the validation of new Hazardous Substances under DIW's Control in Thailand

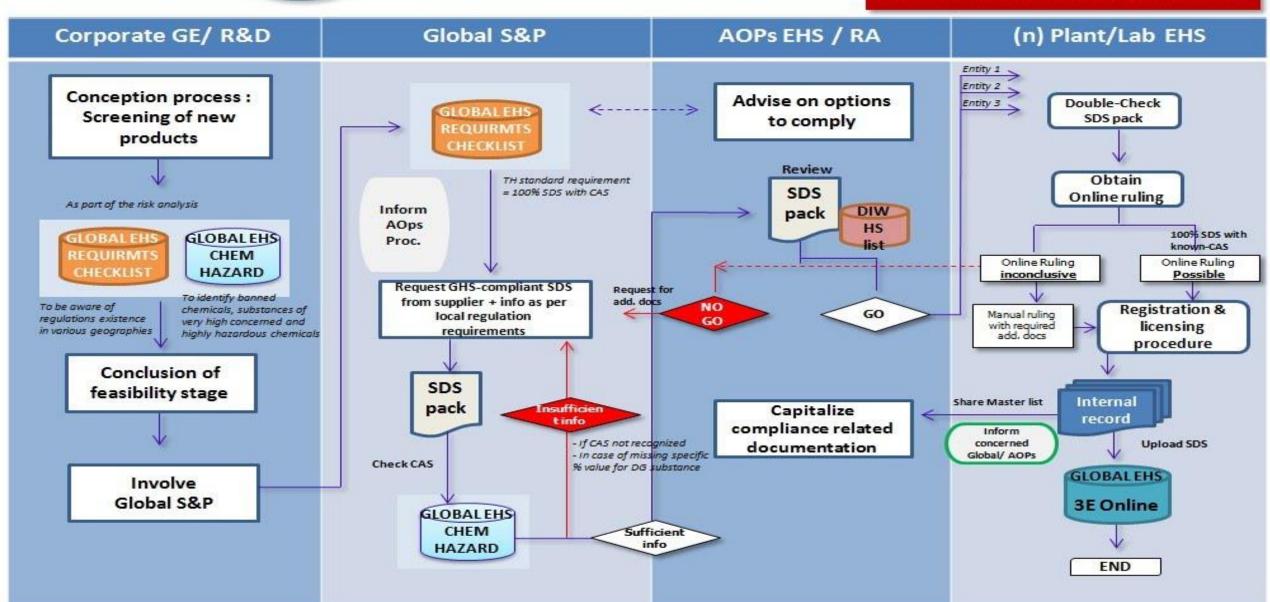
New Global product

**Buyer**: Global S&P Category buyer

User: Thai Plants / Labs (multi-sites)

10 December 2015

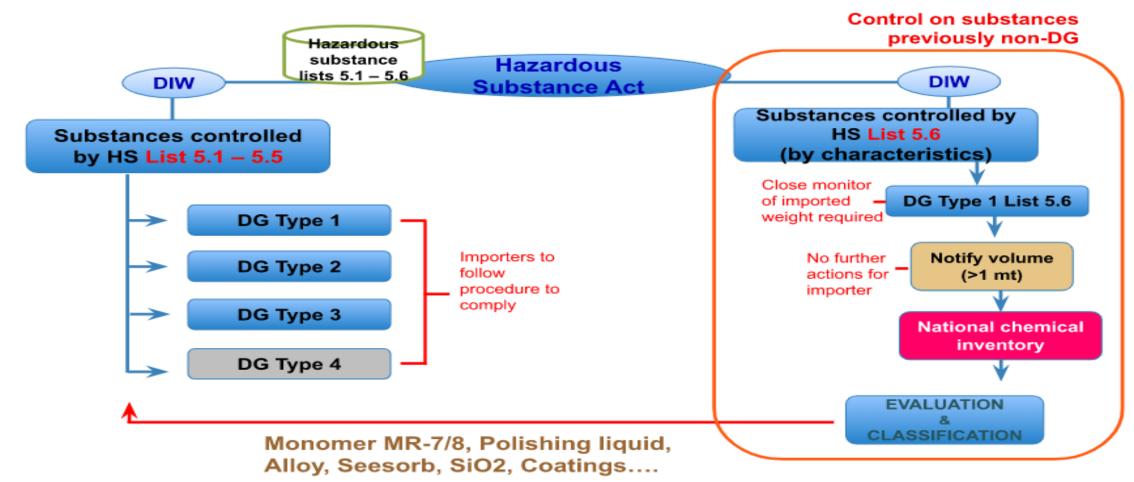
#### New DG validation flowchart



#### **Hazardous Substance Act**

#### Most important chemicals control law in TH

- Non-DG chemicals from other countries can be DG in Thailand (vice versa)
- Same classification is applicable to both import/export chemicals



How to know if my DG needs to comply?





How to get to know the classification & procedure to comply?

#### Example : Product A

#### 100% composition with CAS

Chemical Name	CAS Number	Content (%)
1-METHOXY-2-PROPANOL	107-98-2	19.5
BUTANOL-norm	71-36-3	20.5
METHANOL	67-56-1	12
SILANE TREATED SILICA	63148-61-8	29
WATER	7732-18-5	19





How to get to know?

A Self-assessment

Chemical Name	CAS Number	Content (%)
1-METHOXY-2-PROPANOL	107-98-2	19.5
BUTANOL-norm	71-36-3	20.5
METHANOL	67-56-1	12
SILANE TREATED SILICA	63148-61-8	29
WATER	7732-18-5	19

Look-up from DIW HS list – See demonstration

B) DIW Online ruling

Responsible: Procurement or EHS

ชื่อทางเคมี Chemical name	CAS NUMBER	%ส่วนผสม Concentration	DG type ชนิดที่ เ
1-METHOXY-2-PROPANOL	107-98-2	19.5	-7.
SILANE TREATED SILICA	63148-61-8	29	
เมทานอล (methanol) หรือ เมทิลแอลกอฮอล์ (methyl alcohol)	67-56-1	12	
BUTANOL-norm	71-36-3	20.5	-
Water	7732-18-5	19	-

= DG type 1

How to get to know?

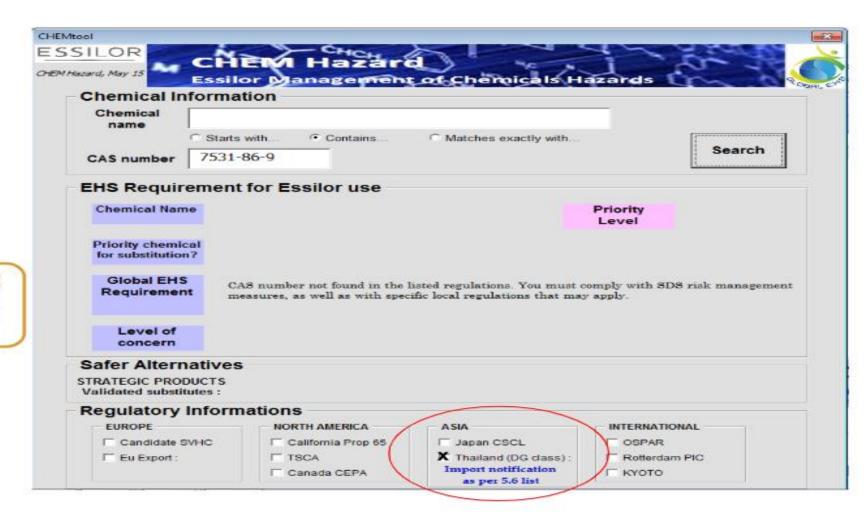


**CHEM Hazard** 

## Assessment tool for the sourcing of new chemicals

CHEM Hazard provide a possibility to identify Essilor banned chemicals and to track global regulatory change

This tool takes into account the DIW HS list 5.1 – 5.5 & List 5.6





**Supplier Confidentiality concerns** 

### 1) Supplier not knowledgeable of Thai DG regulation

### 2) Suppliers do not want to disclose their full compositions

#### **Examples**

Sigma Aldrich – "We sell to France (EI), not to Thailand. We are compliant with EU regulation. You need to find solutions with your HQ"

BWT (distributor) – "Sorry, we cannot do more, you are allowed to deal directly with our supplier"

NIKON – "As a distributor of Essilor, we will do our best, but it will take time since NDA must be signed between us and our suppliers".

#### Some other

"Why now??? I used to ship to Thailand in the past without having to provide 100% composition"

"Sorry, this is the maximum we can do."



#### **Supplier Confidentiality concerns**

#### What are alternatives to SDS with 100% composition?

- Side letter to accompany standard SDS
- 2. SDS with **interval range** (possible when the product is not DG type 1-4)
- 3. Manufacturer's self-certification (MSC) based on DIW's HS list
- Offer suppliers to sign NDA
- Supplier to send directly their composition as CBI to the Director of DIW



#### Supplier Confidentiality concerns

## Alternative #1 Side letter

#### When?

Supplier is in difficulties to provide the chemical composition on the SDS

#### How?

Supplier details the product composition on a side letter, outside the standard SDS



Ecological Cleaning Solutions

#### DECLARATION REGARDING OUR PRODUCT CEROWEG EXTRA ULTRASONIC CLEANING PRODUCT FOR POLISHING COMPOUNDS REMOVING

We certify that our product CEROWEG EXTRA is composed of the following ingredients:

%	CAS Number
3%	1310-73-2
12%	1310-58-3
7%	7320-34-5
8%	61791-56-8
15%	527-07-1
55%	7732-18-5
	3% 12% 7% 8% 15%

Nyon, the 23.10.2014

NGL CLEANING TECHNOLOGY SA Mrc BORRUTO Aurélia Technical Manager



**Supplier Confidentiality concerns** 

## Alternative #2 SDS with interval range

This alternative works out when the Product is non-hazardous only

#### 3.2 Mixture

This product is a mixture.

CAS-No. / EC-No. / Index	REACH No.	Amount	Component	Classification: REGULATION (EC) No 1272/2008
CAS-No. 69011-20-7 EC-No. Polymer	_	>= 20.0 - <= 30.0 %	Sulfonated polymer of styrene, ethylstyrene and divinylbenzene in the hydrogen form	Eye cor/irr, 1, H318
CAS-No. 69011-18-3 EC-No. Polymer	_	>= 20.0 - <= 30.0 %	Trimethylamine functionalised copolymer of styrene and divinylbenzene in the hydroxide form	Eye cor/irr, 1, H318
CAS-No. 7732-18-5 EC-No.	_	>= 40.0 - <= 60.0 %	Water##	Not classified
231-791-2	Make sure a	II the com	oosition adds up	to 100%

Classification DG1 List 5.6 (= NON-DG)

### **Supplier Confidentiality concerns**

### Alternative #2 SDS with interval range

Crest Ultrasonics Corporation			ERIAL SAFETY DA	- Victoria de la companione de la compan	
CHEM-CREST 515		Uses: Ultrasonic liquid detergent concentrate used for the removal of oils, greases, carbon residues, various oxides, particulate matter, and various other contaminants from steels, ceramics, glasses, and other compatible materials. Contact a Crest Ultrasonics chemical specialist for process specific recommendations			
Section I – Product and Company Identif	ication				
Supplier: CREST ULTRASONICS CORPORATION SCOTCH ROAD, TRENTON MERCER AIRPORT TRENTON, NJ 08628 UNITED STATES OF AMERICA		Emergency Telephone Number (800) 424-9300 (USA Chemtrec) or (703) 527-3887 (Int'l Chemtrec) Telephone Number for Information (609) 883-4000 Last update: 24 June 2014			
					Section III - Composition / Information or COMPONENTS:
PROPRIETARY NON-IONIC SURFACTANTS	25-35%	N/E	-	68648-87-3 68081-81-2 127087-87-0	
			5-5-5	1300-72-7 9014-93-1	
			uz dorașilană	68584-24-7	
2-METHYL-2,4-PENTANEDIOL	5-20%	125 mg/m3 (inhalation)	203-489-0	107-41-5	
PROPRIETARY INGREDIENTS, INERT	45-70%			144-33-2 25322-68-3 7732-18-5	
			and the second s	7757-82-6	

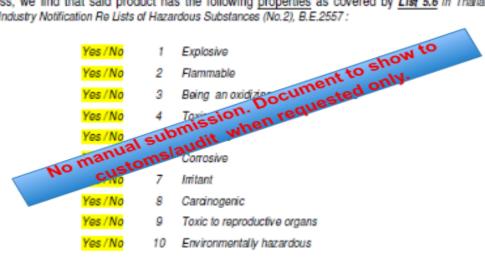
### Supplier Confidentiality concerns

#### MSC - DG1 List 5.6 What for? Suppliers certify "no DG component(s) in their product".

Having reviewed the chemical composition details of our product ..... batch no#... we find that none of the components of said product are specifically covered by :-

 Thailand's Ministry of Industry Notification Re Lists of Hazardous Substances, B.E. 2556 (dated 27 Sep 2013), and Thailand's Ministry of Industry Notification Re Lists of Hazardous Substances (No.2), B.E. 2557 (dated 5 Jan 2015)

Nonetheless, we find that said product has the following properties as covered by List 5.6 in Thailand's Ministry of Industry Notification Re Lists of Hazardous Substances (No.2), B.E.2557:



This document is to be used in conjunction with the product's GHS-compliant Safety Data Sheet.

### Alternative #3 MSC – Manufacturer's Self-Certification

#### MSC – DG specific

What for? Suppliers certify "there is DG component(s) in their product and confirm the % of the said component(s).

Dear Director,

Having reviewed the chemical composition details and properties of our product ..... batch no#..., we find that the component(s) of said product which is/are covered by Lists 5.1 - 5.5 as per :-

- 1) Thailand's Ministry of Industry Notification Re Lists of Hazardous Substances, B.E.2556 (dated 27th September 2013), and
- 2) Thailand's Ministry of Industry Notification Re Lists of Hazardous Substances (No.2), B.E.2558 (dated 19th February 2015)

include(s) the following:-

Name of substance	CAS no.	HS Type	Concentration	
				%
				%

The remainder of the composition adding up to the full composition at 100%, which are not Type 1, Type 2, Type 3 or Type 4 hazardous substances, are as follows:

- Xxxx (product name is sufficient)
- Xxxx (product name is sufficient)
- Xxxx (product name is sufficient)

This document is to be used in conjunction with the product's GHS-compliant Safety Data Sheet.

### **Supplier Confidentiality concerns**

## Alternative #3 MSC – Manufacturer's Self-Certification

#### Guideline for Manufacturer's Self-Certification (MSC)

Before requesting for MSC, an internal check should be performed.

- Check components against Thailand's Hazardous Substances Lists
  - Check <u>both</u> CAS # and molecular structure of the substance; consider also its synonyms
  - A substance is considered hazardous when its concentration is ≥ 1%.
  - A substance having <u>same/similar molecular structure</u> as any on the List is also considered DANGEROUS in Thailand, even though its CAS # or name does not explicitly covered in the List.

#### Thailand Hazardous Substance List Table Header

List 5.1 Controlled Substances

No.	Name of Hazardous Substance	CAS Number	Type of	Condition	
			Hazardous		
			Substance		
325	Methyl vinyl ketone	78-94-4	3		
326	Methyl acrylate	96-33-3	2		
327	Methyl acetate	79-20-9	1		
328	Methyl ethyl ketone	78-93-3	3	Having concentration > 50% w/w	

- ☐ For DG items, the Certification Letter must specify exact %; intervals are not acceptable
- ☐ The Certification Letter should be signed by the Manufacturer's authorized person.
- Required attachment to Certification Letter: business registration certificate (e.g. Article of Incorporation) or other document showing the legally-authorized person's name.
- □ DG Classes 1-3 may be imported into Thailand subject to certain procedures; DG Class 4 is prohibited from importation into Thailand

**Supplier Confidentiality concerns** 

Alternative #4
Offer supplier's to sign
a Non-Disclosure Agreement (NDA)

Please contact Asia Regulatory Affairs or local responsible person to handle this

Before the signature of NDA, there can be back & forth exchanges of NDA for revision which can take weeks/months

Therefore, LEAD-TIME (obtaining of 100% composition + procedure with DIW) to consider.

#### **Supplier Confidentiality concerns**

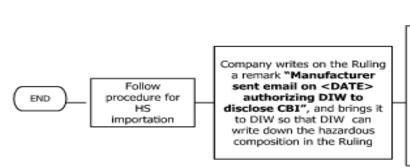
## Alternative #5 Supplier to directly send CBI to DIW

#### When?

Supplier does not at all want to disclose the product composition to the 3<sup>rd</sup> party

#### Inconvenience of this option?

Supplier must be aware that once their composition is DG, they are obliged to disclose the DG components to the 3<sup>rd</sup> party



\*\*\* Manufacturer emails
(1) Letter Authorizing CBI
Release (only hazardous
component) for registration
purposes, (2)
Manufacturer's Corp
Registration Doc. and (3)
scanned Ruling file to
director.cbi@diw.mail.
go.th and then notifies the
Company about the email
date

NDA

Company scans the Ruling and emails to Manufacturer, and asks Manufacturer to email (1) Letter Authorizing CBI Release (only hazardous component) for registration purposes, (2) Manufacturer's Corp Registration Doc. and (3) scanned Ruling file to director.cbi@diw.mail.

go.th

Manufacturer's

Self-Certification (MSC)

Print Online Result, and write down a remark
"Manufacturer will email CBI directly to the
Director", bring it together with SDS and other
documents (if any) to DIW

CBI Case

Company writes tracking # on the Online Result Print-out, scans it as PDF and sends to Manufacturer, asking Manufacturer to email CBI and the PDF Online Result to director.cbi@diw.mail.go.th

DIW issues Tracking #

Manufacturer emails **CBI and PDF Online Result** to <u>director.cbi@diw.mail.go.th</u> and then notifies the Company about the email date

DIW reviews CBI

DG1,2,3,4

List 5.6

DG1

Monitor
annual
volume

Company

records result

as internal ref.

END

DIW

Essilor

**Essilor** 

Supplier

Essilor

Submit

WOOK.20

### Introduction to PH & CN regulations

#### Comparative summary

	THAILAND	PHILIPPINES	CHINA *
Chemical database	DIW Hazardous substance list no.1 & no.2 Preliminary list of existing chemical both DG & Non-DG (Q1-2016)	PICCS     Others: Controlled chemicals under lists of DENR-EMB, PNP, PDEA	1. Inventory of Existing Chemical Substances Produced or Imported in China (IECSC) 2. Others: Catalog of hazardous chemicals 2015, Prohibited chemicals, Precursors and chemicals used in the production of Narcotic drug, etc.
Registration & Licensing	DG 3 as per the above lists	Controlled chemicals as per above lists	Controlled chemicals as per above lists
REACH-LIKE system	Notification of new chemical not listed National chemical inventory (Implementation date to be confirmed)	Priority Chemicals list (PCL) & Chemical Control Orders (CCO)	Notification of new chemical not listed in the IECSC since Oct 2010
GHS implementation	Substance March 2013 Mixture March 2017	Starting from Q2-2016 (for instance, only applicable for substances & compounds under CCO/ PCL)	Since Dec 2012 under Decree 591. Company must provide GHS-compliant SDS in order to obtain a registration certificate





## Thank you!