environmental affairs
Department:
Environmental Affairs
REPUBLIC OF SOUTH AFRICA

THE ABS CAPACITY DEVELOPMENT INITIATIVE
L'INITIATIVE DE RENFORCEMENT DES CAPACITES POUR L'APA

Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

Swiss Confederation

Federal Department of Economic Affairs,
Education and Research EAER
State Secretariat for Economic Affairs SECO

EU regulatory requirements

The work presented here has been commissioned by the ABS Compliant Bio-Trade in South(ern) Africa (ABioSA) programme that is funded by Swiss State Secretariat for Economic Affairs (SECO) and implemented by the Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ)

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Federal Ministry
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ORGANISATION INTERNATIONALE DE la francophonie

INSTITUT DE LA FRANCOPHONIE POUR LE DÉVELOPPEMENT DURABLE IFDD

Schweizerische Eidgenossenschaft
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implemented by

giz Deutsche Gesellschaft
für Internationale
Zusammenarbeit (GIZ) GmbH

LISAM SYSTEMS
Enabling full compliance.

Indigenous Natural Ingredients targeted for the Cosmetic and Personal Product sector: International Legal Requirements to enhance export to countries within the European Union

By: GIZ in collaboration with Lisam South Africa (Pty) Ltd

www.lisam.com

LISAM

Contents

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LISAM

Our History and Values

Founded in 1999, Lisam Systems is a global provider of Environmental, Health and Safety (EH&S) compliance management software solutions and services, operating from 18 offices worldwide.

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Our Values:

Think Ahead **Be Passionate** **Strive for Excellence** **Foster Knowledge** **Value Customers**

20 years of experience in the chemical compliance market.

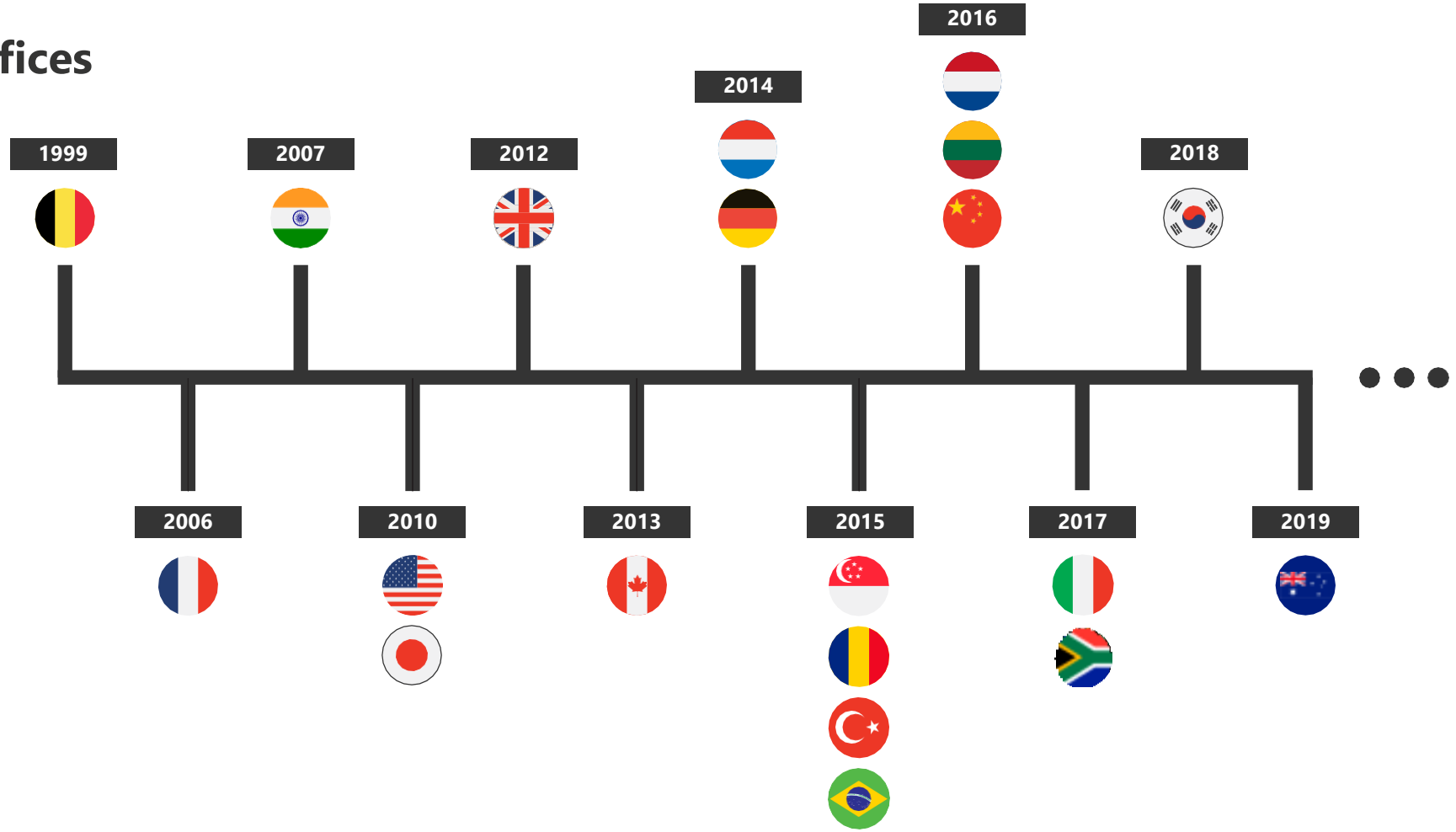
LISAM Regulatory services

We have a **local support team**: with GHS expertise (globally), technical expertise and product expertise (waste, cosmetics (including Safety Assessments for the EU), industrial chemicals, gas, retail products, biocides) and **18 offices globally** enabling us to provide you with **up-to-date regulatory advice and software support;**

- **REACH Registration**
- **REACH Only Representative (OR) services**
- **REACH Volume Tracking - EU Volume Tracking**
- **EU Poison center Notification**
- **Legal entity**
- **EU regulatory assessments**

About Us

Global Offices



More than 200 employees In 21 different countries

INTRODUCTION

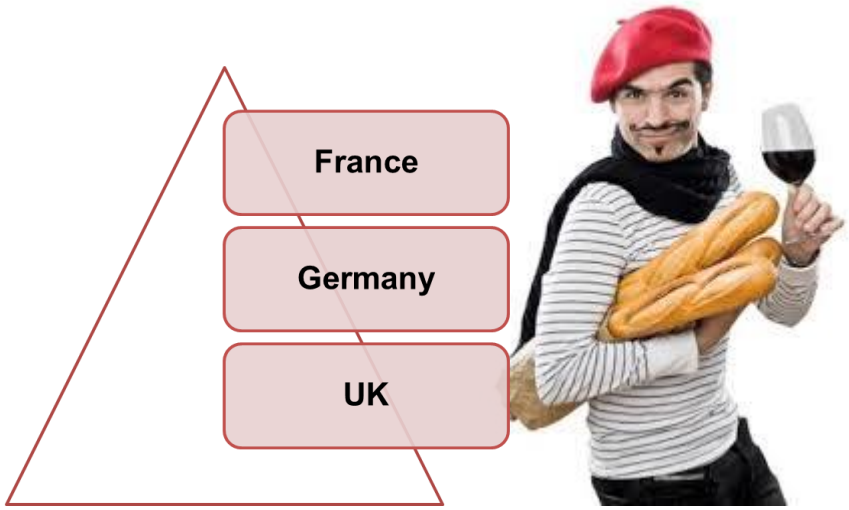
Why should you comply with REACH, CLP and the EU Cosmetics Regulation?

- A compliant and professional market approach will ensure the growth of the BioTrade industry in Southern Africa
- Compliance would mean ease of access to large markets with huge buying power, sophisticated and highly regulated markets
- Compliance would achieve the sustainable goals and aim of the ABS programme by:

  - ***Creating jobs***
  - ***Creating sustainable value chains***
  - ***Creating high value sustainable markets through confidence and reliability of the products***
  - ***Productive and sustainable use of Southern African biodiversity***

INTRODUCTION

Why the EU?



- The EU is the biggest importer of essential oils
- Essential oil imports grew considerably between 2012-2016
  - imports 60,000 tonnes valued at €1.2 B
- The French market :
  - speciality oils used in the cosmetics sector are **sort-after** and France acts as a chemical and cosmetic hub for industry across Europe
  - Countries that import a relatively large portion of high-value vegetable oils include Germany and the UK.

INTRODUCTION

Why South Africa?

- Rich biodiversity, a variety of climates, strong human resources and technological base

- Demand for seed oils has increased
  - seed oils as ingredients for food, cosmetics and biofuel

- Globally seed oils are obtained from:
  - 15 plant species out of nearly half a million known to man

- South Africa has great potential in Europe by providing vegetable and essential oils:
  - of high quality, regulatory compliant
  - are indigenous to the region and may have specific stories around ethnicity, indigenous knowledge or organic production

INTRODUCTION

South African essential oil exports

❖ One of the major challenges is **market access**

❖ The market for cosmetic raw materials is predominantly driven by:

- consistency of supply,
- quality guarantees,
- regulatory compliance,
- and the assurance that the contents of the oil is safe for human use.

MARKET ACCESS

EU regulations

- REGULATION EC 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 December 2006 for the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH); and Product readiness;

- REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures (CLP); and

- REGULATION (EC) NO 1223/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 30 November 2009 on cosmetic products

REACH LEGISLATION

WHAT IS REACH?

- EC 1907/2006
- **R**egistration, **E**valuation, **A**uthorisation and Restriction of **Ch**emicals (REACH)
- Adopted adopted on 18 December 2006. Published on 30 December 2006
- Enhancing the competitiveness of the EU Chemical industry

REACH LEGISLATION

- **Protection of human health**

REACH LEGISLATION

- **Protection of the Environment**

REACH LEGISLATION

- **Reduce the number of tests conducted on animals**

REACH requires:
read-across

REACH requires:
alternate methods to animal testing

https://youtu.be/n9z-h2XafW4?list=PLOPGDACSd6qyHFvw-Y2shr0CVcDkXTTjX

REACH

What is REACH?

NO DATA NO MARKET

Before REACH: Authorities had to demonstrate that a chemical is safe

After REACH: Industry is responsible for the safe use of their chemicals

- **The onus for assessing the impact of substances on human health and the environment is placed on the manufacturers and importers of substances**

Geographical

- REACH applies to the European economic area (EEA), that is, all EU member states, including Iceland, Liechtenstein and Norway

- REACH is a **Regulation,** not a **Directive**
  - Applies directly in the EEA

ROADMAP: REACH Registration - A Step by Step Approach

STEP 1: Know your portfolio

STEP 2: Appoint an only representative (OR)...

STEP 3: Find co-registrants...

STEP 4: Share data....

STEP 5: Assess the hazards...

STEP 6: Prepare your dossier in IUCLID..

STEP 7: Keep your registration up-to-date..

STEP 1: KNOW YOUR PORTFOLIO

What kind of products does your company produce for export to the EU? Is it a substance?

Substance

Does my substance need to be registered?

Do I reach the one tonne a year threshold for at least one importer?

No

The importer does NOT need to register the substance

What is your tonnage band?

Your volume determines your tonnage band, and your tonnage band determines the amount of your registration fee and which information you will need to provide for your registration. If you want to cover several importers with your registration, you must sum up the quantities sold to those importers.

There are four tonnage bands for standard registrations:

1-10 tonnes a year;

10-100 tonnes a year;

100-1000 tonnes a year;

and more than 1000 tonnes a year

Principles of REACH

- REACH registration applies to substances:
- It applies to all individual chemical substances on their own, in mixtures or in articles
- Each substance needs its own registration

Botanical name: *Helichrysum odoratissimum*
essential oil REACH: substance

Essential oil blend
REACH: Mixture

REACH LEGISLATION

❖ Substances

Well defined substances:
"sufficient to enable each substance to be identified"

- The name or other identifier of the substance
- Name(s) in the IUPAC nomenclature or other international chemical name(s)
- Other names (usual name, trade name, abbreviations)
- EINECS or ELINCS number (if available and appropriate)
- CAS name and CAS number (if available)
- Other identity code (if available)

UVCB substances
Unknown or **V**ariable composition, **C**omplex reaction products or **B**iological materials
Example:

Helichrysum odoratissimum essential oil

STEP 1: KNOW YOUR PORTFOLIO

What kind of products does your company produce for export to the EU? Is it a substance?

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There are four tonnage bands for standard registrations:

1-10 tonnes a year;

10-100 tonnes a year;

100-1000 tonnes a year;

and more than 1000 tonnes a year

Exemption of Vegetable oils from REACH

- "obtained from natural sources"-original source must be natural material (plants)
- "Not chemically modified"
- "fatty acids from **C6 to C24**" and their potassium, sodium, calcium and magnesium salts'
- However, If the oil - is classified as hazardous according to CLP or meets criteria for PBTs (persistent, bioaccumulative and toxic) and vPvBs then it **MUST be registered**
- Does not apply to synthetic materials/ Hydrogenated fats and hydrogenated oils

WORKSHOP: ACTIVITY 1

- **If an antioxidant or stabiliser is added to a vegetable oil is it still exempt from REACH or is it regarded as chemically modified and will have to be registered under REACH?**

Vegetable oil +antioxidant/stabiliser = Exemption from REACH or
= REACH registration

ANSWER : ACTIVITY 1

The first question: Does the addition of an antioxidant or stabiliser to the substance "vegetable oil" make it a mixture?

Answer: NO

According to the definition of a substance:

"1. substance: means a chemical element and its compounds in the natural state or obtained by any manufacturing process**, including any additive necessary to preserve its stability** and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition;"

ANSWER : ACTIVITY 1

The second question: Is the oil chemically modified?

Answer: NO

It is precisely the **purpose of such an additive that this substance remains chemically unchanged**. The substance that is going to be registered is the substance "vegetable oil + its antioxidant or stabiliser".

ANSWER : ACTIVITY 1

There's ALWAYS A BUT!

Answer:

The substance: "vegetable oil + its antioxidant or stabiliser" must still meet the "(non) classification" criteria for exemption of entry 9:

"The following substances obtained from natural sources, if they are not chemically modified, *unless they meet the criteria for classification as dangerous* according to Directive 67/548/EEC13 *with the exception of those only classified as* flammable [R10], as a skin irritant [R38] or as an eye irritant [R36] *or unless they are persistent, bioaccumulative and toxic or very persistent and very bioaccumulative* in accordance with the criteria set out in Annex XIII *or unless they were identified* in accordance with Article 59(1) at least two years previously as substances giving rise to an equivalent level of concern as set out in Article 57(f):"

REACH LEGISTLATION

- ***Exemption from REACH registration ≠ Exemption from REACH regulation***

  Manufacturers/ formulators of vegetable oils must still keep a dossier proving exemption from REACH registration

STEP 2: APPOINT AN OR

As a non-EEA manufacturer you should start by appointing an only representative (OR) to fulfil obligations of importers under REACH.

Why?

Requirements for REACH and CLP, such as registration or labelling, lies with the importers established in the European Union, or for REACH obligations, with the only representative of a non-EU manufacturer established in the European Union.

More importantly

Non-EEA manufacturers should opt for an OR as communication of information needed by the importers would require the disclosure of confidential business information

Responsibility of the Non-EU manufacturer

To send a letter confirming this appointment to their OR who must have it available in case of inspection by the relevant Member State's enforcement authority.

Responsibility of the OR

- To comply with the registration obligations of the importers
- To submit an inquiry, followed by a registration dossier for the substance imported into the EEA above 1 tonne per year to the European Chemicals Agency (ECHA)
- To keep the information available and updated

STEP 3: FIND CO-REGISTRANTS

The OR/importer will make an Inquiry with ECHA whether a registration has already been submitted for that substance.

Prepare an electronic inquiry dossier. When preparing the dossier, specific attention should be paid to the substance identity information.

The inquiry dossier will then be used by ECHA to direct inquirers to the relevant Co-Registrants page in REACH-IT where they can find contact details of the Lead registrant, other registrants and potential registrants of the same substance.

For substances where no registrants or potential registrants exist or with ambiguous identifiers, ECHA verifies the substance identity information.

If ECHA is able to conclude on the substance identity of the inquired substance, the Agency directs inquirers to the relevant Co-Registrants page in REACH-IT.

ECHA puts potential registrants and previous registrants in contact with each other to share data and to submit a joint registration.

JOINT REGISTRATION

❖ If a substance is not registered SMEs:

- work together with their co-registrants in a SIEF (Substance Information Exchange Forum) with their co-registrants

- Appoint a **Lead registrant** who will submit the lead registration dossier, to enable the **co-registrants** to submit their member registration dossiers

JOINT REGISTRATION

The Lead registrant's dossier includes the information submitted on behalf of all the co-registrants, such as the composition of the substance, classification and labelling of the substance, uses etc. The lead registrant will also add their own company-specific and substance-specific registration information in the same dossier.

The member dossier includes information specific to their company and substance. This covers, for example, information about the identity of their substance (composition, analytical data), the identified uses that are relevant for their company, and the estimated volumes of manufacture or import.

STEP 4: SHARE DATA

Why should I share data

- The requirement to share information about the substances manufactured, imported, placed on the market and used in the EU is a fundamental aspect of REACH;

- By doing this, registrants of the same substance can **reduce registration costs**

- Avoid unnecessary testing, especially on vertebrate animals

- Studies that don't involve vertebrate animal testing should also be shared to reduce the costs of registration.

STEP 5: ASSESS THE HAZARDS

Information required depends on tonnage and uses:

- 1-10 tonnes: Possible reduced data requirements for less hazardous substances;
- If you exceed 10 tonnes then a chemical safety report is needed
- Pay attention to data quality: relevance, adequacy and reliability
- Animal testing is the last resort- consider alternatives first
- Some long-term studies require a testing proposal

STEP 6: PREPARE DOSSIER: IUCLID

After you discuss and exchange data within the SIEF, the lead registrant and each member registrant should have all the relevant information available to create their registration dossiers using the IUCLID format.

To do this you may use the IUCLID Cloud for SMEs which helps you to avoid any installation and gives you easy access, automated, regular back-ups and updates by ECHA. The cloud version enables the OR to transparently collaborate with all SME clients and to easily and securely share IUCLID information with them.

Check and update the information that is relevant for registration in REACH-IT.

Carefully assess your SME status (Reduced fees may be applicable to smaller SME's).

Set up or join the joint submission in REACH-IT.

Submit your registration dossier: first the lead registrant, then all co-registrants and then follow up on REACH-IT.

STEP 7: DOSSIER UPDATED

A registration dossier has to reflect the most up-to-date knowledge on how a substance can be used safely.

This is a legal obligation for all registrants, so it is recommended to maintain the cooperation platform with your co-registrants..

The selection for compliance check is either random or concern-based.

The task of the only representative is to keep the information available and updated on the quantities imported, importers covered by the appointment, as well as supply the latest update of the SDS.

LISAM SYSTEMS
Enabling full compliance.

GAP Analysis study:

PROJECT METHODOLOGY

Gap analysis project

- **6 seed/vegetable oils** and **5 essential oils** were selected for the gap analysis study
- **Selection criteria:**
  - traditional knowledge,
  - ecological sustainability,
  - market demand,
  - potential for value-adding and job creation,
  - participation of Indigenous People and Local Communities (IPLCs) and Small Medium Enterprises (SMEs).

OIL	BOTANICAL NAME	USE
SEED OIL		
Marula oil	*Sclerocarya birrea*	cosmetics
Baobab oil	*Adansonia digitata*	cosmetics, food industry
Mongongo oil	*Schinziophyton rautanenii*	cosmetics and hair products
Kalahari melon oil	*Citrillus lanatus*	cosmetics, food and pharmaceuticals
Sour Plum oil	*Ximenia Americana* *Ximenia var.* *Ximenia caffra/* *Ximenia natalensis*	cosmetics
Mafura oil	*Trichilia emetica*	cosmetics
Mafura butter	*Trichilia emetica*	cosmetics and hair products
ESSENTIAL OIL		
Lippia oil	*Lippia javanica* *Lippia rehmani* *Lippia scaberrima*	insect repellent, tea, pharmaceutical, research for insecticides and fungicides
Rose geranium oil	Cultivated from two or three of the following: *Pelargonium graveolens* *Pelargonium radens* *Pelargonium capitatum* resulting in the hybrid Pelargonium var rose	Perfumery, flavouring, aromatherapy and pharmaceutical industries
Helichrysum oil	*Helichrysum splendidum/* *Helichrysum odoratissimum etc*	Mood enhancemant plant and perfumery
Buchu oil	*Agathosma betulina* *Agathosma crenulata*	Flavouring, fragrance and pharmaceutical
Cape camomile oil	*Eriocephalus species* *Eriocephalus punctulatus* *Eriocephalus africanus* *Eriocephalus comosum* *Eriocephalus racemosus*	Perfumery, flavoruing, aromatherapy and pharmaceutical industries

GAP ANALYSIS STUDY

Industry associations

Industry associations	Approximate No. Of members
Cosmetic Export Council of South Africa (CECOSA)	105*
Society of Cosmetic Chemists South Africa (Coschem)	420*
South African Essential Oils Producers' Association (SAEOPA)	54*

GAP ANALYSIS STUDY

Industry associations

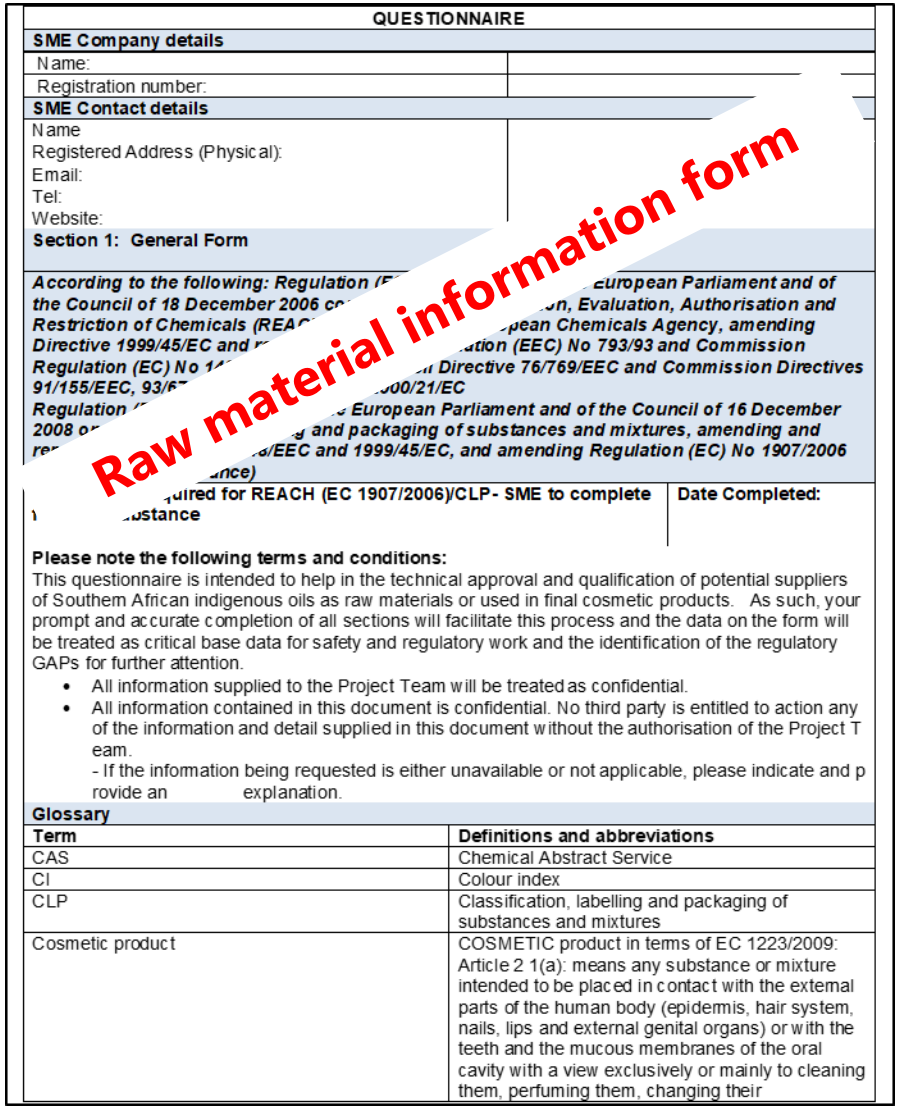
Industry associations	Approximate No. Of members
Cosmetic Export Council of South Africa (CECOSA)	
Society of Cosmetic Chemists South Africa (Coschem)	
South African Essential Oil Producers' Association (SAEOPA)	

58 SME's

PRE-SELECTION

FINAL PHASE

- REGULATION EC 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 December 2006 for the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH); and Product readiness;
- REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures (CLP); and
- REGULATION (EC) NO 1223/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 30 November 2009 on cosmetic products



QUESTIONNAIRE

SME Company details

Name:	
Registration number:	

SME Contact details

Name	
Registered Address (Physical):	
Email:	
Tel:	
Website:	

Section 1: General Form

According to the following: Regulation (E… …European Parliament and of the Council of 18 December 2006 co… …n, Evaluation, Authorisation and Restriction of Chemicals (REA… …pean Chemicals Agency, amending Directive 1999/45/EC and r… …ation (EEC) No 793/93 and Commission Regulation (EC) No 1… …Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/6… …000/21/EC Regulation … European Parliament and of the Council of 16 December 2008 o… …g and packaging of substances and mixtures, amending and re… …/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 re… …ance)

…quired for REACH (EC 1907/2006)/CLP- SME to complete …bstance | **Date Completed:**

Please note the following terms and conditions:

This questionnaire is intended to help in the technical approval and qualification of potential suppliers of Southern African indigenous oils as raw materials or used in final cosmetic products. As such, your prompt and accurate completion of all sections will facilitate this process and the data on the form will be treated as critical base data for safety and regulatory work and the identification of the regulatory GAPs for further attention.

- All information supplied to the Project Team will be treated as confidential.
- All information contained in this document is confidential. No third party is entitled to action any of the information and detail supplied in this document without the authorisation of the Project T eam.

- If the information being requested is either unavailable or not applicable, please indicate and p rovide an explanation.

Glossary

Term	Definitions and abbreviations
CAS	Chemical Abstract Service
CI	Colour index
CLP	Classification, labelling and packaging of substances and mixtures
Cosmetic product	COSMETIC product in terms of EC 1223/2009: Article 2 1(a): means any substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their

Raw material information form

Final Questionnaires

Regulations	Total no. of questionnaires submitted	Total No. of questionnaires submitted for vegetable/essential oils	
		vegetable oils	essential oils
REACH and CLP	14	10	7
Cosmetics	7	7	4

REACH GAPS

Vegetable seed oils

- Based on the information provided, the tentative results indicated that all **6 seed/vegetable oils** are exempt from REACH
- However, more information is required to further support this result
- **Important:** Manufacturers/ formulators of vegetable oils **must still keep a dossier <u>proving exemption from REACH registration</u>**

RESULTS GAP ANALYSIS

Vegetable seed oils

- All oils were obtained from natural sources and were not chemically modified
- Generally the manufacturing process for extracting the oil from the seeds involved a physical process such as cold-pressing and filtering
- **Gap 1: Some SMEs did not submit a full manufacturing method**

Vegetable seed oils

- Annex V guidelines refer to: "fatty acids from **C6 to C24**", and their potassium, sodium, calcium and magnesium salts'

- Means that the chemical structure of the 'fatty acids from C6 to C24, and their potassium, sodium, calcium and magnesium salts' **"substance cannot be changed"**

- **Gap 2: Missing data for the fatty acid composition/profile (C6: C24)**

- SME's submitted partial fatty acid profile
- No SME provided a complete fatty acid profile from C6:C24

RESULTS GAP ANALYSIS

Vegetable seed oils

- The majority of oils were found to be non-hazardous
- **Gap 3: some oils could not be classified due to insufficient information provided**
- SME's did not provide enough regulatory documents/test data to confirm that their oils were exempt from REACH registration.

ESSENTIAL OILS

❖ **Gap 1: Several SME's failed to identify the family, genus and species that they work with**

- Botanical source refers to the family, genus and species of the organism from which the substance has been derived
- EFEO/IFRA guidelines on substance identification and sameness of Natural complex substances (NCS)

❖ **Gap 2: full manufacturing methods were not submitted**

- is imperative in determining if the essential oils are obtained from the same generic process

CASE STUDY

Essential oils and lavender farms affected by REACH

- In 2013
- French lavender oil producers ran a successful campaign against REACH and CLP
- IFRA to facilitate a dialogue between the 'supply' chain (mainly farmers and essential oil producers) and EU institutions in order to facilitate a resolution
- French farmers wanted to comply
- 2 years
- Dialogue
- Workshops were held to identify the producers needs,
- Roadmaps of actions and deliverance on sector-specific guidelines
- Guidelines on the identification of essential oils, as **natural complex substances (NCS)** was developed.

Natural complex substances

❖ NCSs of botanical origin are a very diverse family of substances
- used as ingredients in fragrance formulations and [directly or indirectly]
- added to cosmetic
- other consumer products

❖ Identification and characterization of NCSs
- Guidance for the Identification and Naming of Substances under REACH

❖ The most common NCS's are **essential oils**

Natural complex substances (NCS)

❖ NCSs have distinguishing characteristics that make them a unique class of UVCBs with regards to REACH:

Example: botanical products vary in the chemical composition

- region of growth
- annual variations in climate within a region
- variations that exist naturally between species of the same family
- part of the plant
- use of different methodologies for processing: drying, cutting, expression, extraction, distillation, fractionation, concentration, precipitation, etc

Natural complex substances (NCS)

❖ In principle, the main parameters to characterise NCSs are:

1. the botanical source
2. the manufacturing process
3. **the chemical composition**

RESULTS GAP ANALYSIS

ESSENTIAL OILS

❖ **Gap 3:** SME's did not do a full GC analysis of their oils

- Some SMEs supplied laboratory reports that were not carried out on their own oils

❖ **Importance of GC analysis:**

- In order to assess the hazards
- In order to determine if essential oils produced by different SME's have the same or "similar composition"
- Identifying essential oils of "similar composition" is important for identifying SME's that can form part of a **"joint registration"**

JOINT REGISTRATION

Example

- a single UVCB registration can be made for two or more NCSs with a similar composition but obtained from different botanical sources
- EFEO/IFRA guidelines on substance identification and sameness of Natural complex substances (NCS) under REACH and CLP

Example: Spearmint essential oil

Spearmint essential oil is produced by distillation treatment of two mentha species: *Mentha spicata/gracilis* (EC # 283-656-2) and *Mentha cardiaca/gracilis* (EC # 294-809-8). The source concerns the same areal parts of the plants, which are processed in the same way (cutting and field drying followed by steam distillation) to obtain Spearmint oil. All qualities of the oils share the same classification and are very similar in composition as shown in the below table:

COMPOSITION OF SPEARMINT OILS	CAS no	Spearmint oil (Mentha spicata/ gracialis)		Spearmint oil (Mentha cardiaca/gracilis)	
CONSTITUENT % v/v		Typical % w/w	Range % w/w	Typical % w/w	Range % w/w
L-Carvone	6485-40-1	68	62-80	68	49-85
Limonene (1L)	5989-54-8	11	5-16	17	2-20
Other 8 identified constituents ≤ 2,5 and ≥ 1.0% present in both NCS*		11		6	
Other 23 identified constituents < 1.0%		7		7	
Not identified		3		2	
Total		100		100	
*myrcene-beta, terpinen-4-ol, Cineol 1, 8, beta-bourbonene, trans-dihydrocarvone germacrene D, sabinene hydrate, 3-octanol					

Spearmint oils from *Mentha spicata/gracilis* and *Mentha cardiaca/gracilis* as obtained by the above described process consist of the same constituents in typically the same concentrations with minor variations in the concentration ranges.

A single UVCB registration for spearmint oil would thus be possible in this case. The substance would be identified in the registration dossier according to the rules for UVCBs sub-type 3, i.e.: "Essential oil of Spearmint obtained from the aerial part of *Mentha spicata/gracilis* and *Mentha cardiaca/gracilis* by distillation".

The multi-constituent approach may also be considered in this case because of the typical concentration and ranges of the main constituents (see chapter 3.2.).

JOINT REGISTRATION

Example

- a single UVCB registration can be made for two or more NCSs with a similar composition but obtained from different botanical sources
- EFEO/IFRA guidelines on substance identification and sameness of Natural complex substances (NCS) under REACH and CLP

Example: Spearmint essential oil

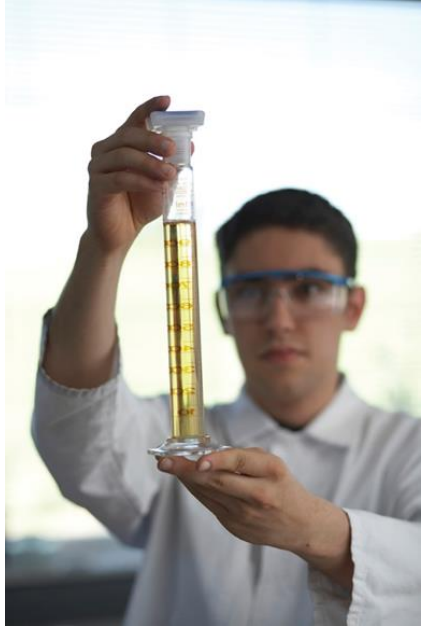
Spearmint essential oil is produced by distillation treatment of two mentha species: *Mentha spicata/gracilis* (EC # 283-656-2) and *Mentha cardiaca/gracilis* (EC # 294-809-8). The source concerns the same areal parts of the plants, which are processed in the same way (cutting and field drying followed by steam distillation) to obtain Spearmint oil. All qualities of the oils share the same classification and are very similar in composition as shown in the below table:

COMPOSITION OF SPEARMINT OILS	CAS no	Spearmint oil (Mentha spicata/ gracialis)		Spearmint oil (Mentha cardiaca/gracilis)	
CONSTITUENT % v/v		Typical % w/w	Range % w/w	Typical % w/w	Range % w/w
L-Carvone	6485-40-1	68	62-80	68	49-85
Limonene (1L)	5989-54-8	11	5-16	17	2-20
Other 8 identified constituents ≤ 2,5 and ≥ 1.0% present in both NCS*		11		6	
Other 23 identified constituents < 1.0%		7		7	
Not identified		3		2	
Total		100		100	
*myrcene-beta, terpinen-4-ol, Cineol 1, 8, beta-bourbonene, trans-dihydrocarvone germacrene D, sabinene hydrate, 3-octanol					

Spearmint oils from *Mentha spicata/gracilis* and *Mentha cardiaca/gracilis* as obtained by the above described process consist of the same constituents in typically the same concentrations with minor variations in the concentration ranges.

A single UVCB registration for spearmint oil would thus be possible in this case. The substance would be identified in the registration dossier according to the rules for UVCBs sub-type 3, i.e.: "Essential oil of Spearmint obtained from the aerial part of *Mentha spicata/gracilis* and *Mentha cardiaca/gracilis* by distillation".

The multi-constituent approach may also be considered in this case because of the typical concentration and ranges of the main constituents (see chapter 3.2.).



Natural complex substances (NCS)

❖ A REACH registration for NCS requires the following:

- Data from tests conducted with a representative quality of the NCS
- Data directly obtained on the identified constituents
- Data indirectly obtained by read-across from data on substances related to the constituents and other non-test methods

❖ Industry Guidance: "Protocol for REACH Registration of Natural Complex Substances" (revision 2, January 7, 2009)

RECOMMENDATIONS

REACH

Minimum testing requirements to be performed by South African laboratories:

1. Fatty acid analysis (C6-C24) to be carried out on all vegetable oils
2. A full GC analysis is required for all vegetable and essential oils at an accredited laboratory OR that follows Good laboratory practice (GLP)
3. Tests must be carried out on every batch
4. Testing required to obtain physical chemical data on the various oils should be done on a range to reduce costs and at an accredited laboratory that follows GLP
5. Analytical profiles of the oils are crucial if a REACH dossier is identified and the SME wants to join that particular registration

RECOMMENDATIONS

REACH - Recommendation to industry to reduce costs:

1. A joint registration should be completed for each of the essential oils
2. SME's should appoint the same OR
3. SME's need to clearly identify the size of their company (smaller SME's have reduced fees)
4. Essential oils exported should not exceed 10 tonnes (contain the costs involved) which includes Joint registration (keep under 10 tonnes)
5. A platform should be created to allow collaboration between co-registrants
6. Development of Guidelines for South African indigenous oils

What is CLP?

- **C**lassification, **L**abelling and **P**ackaging of substances and mixtures (EC 1272/2008)

- based on the United Nations' Globally Harmonised System (GHS)

- Its purpose is to ensure:
  - a high level of protection of human health
  - protection of the environment
  - Free movement of substances, mixtures and articles

Geographical

- CLP is **legally binding across the Member States** and directly applicable to all industrial sectors
- It requires manufacturers, importers or downstream users of substances or mixtures to classify, label and package their hazardous chemical products appropriately before placing them on the market.

What are your Obligations under the CLP Regulation as a non-EU manufacturers?

- The obligation to ensure that a product is classified, labelled and packaged in accordance with the CLP Regulation lies with the EU-importer
- However, the non-EU manufacturer of a substance or a mixture should cooperate with their importer to check the relevant requirements regarding the packaging and labelling of their product
- The non-EU manufacturer should also cooperate to ensure **proper hazard classification of the product**
- One of the main aims of CLP is to determine whether a substance or mixture displays properties that lead to a hazardous classification

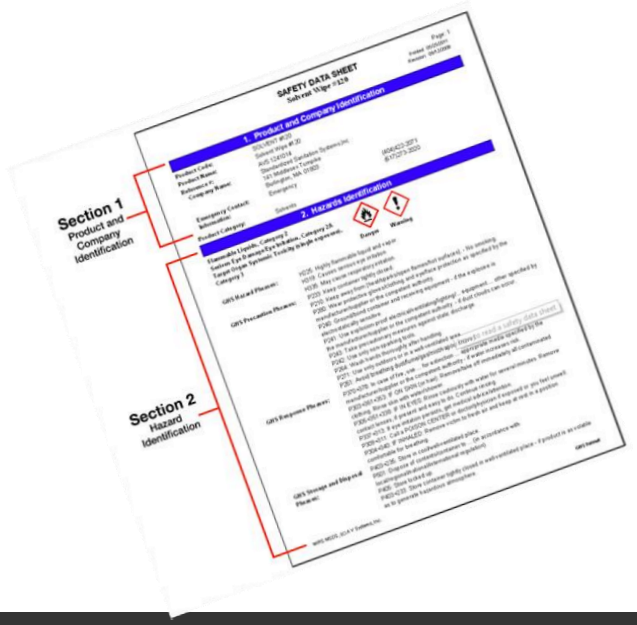
What are hazard classes or categories?

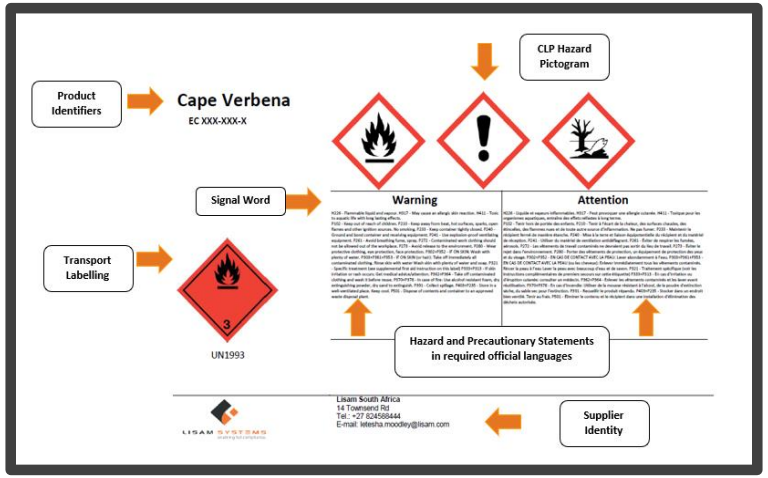
- When a substance /chemical classifies as hazardous under CLP, the hazards are identified by assigning a hazard class or category
- The hazard classes in CLP cover:

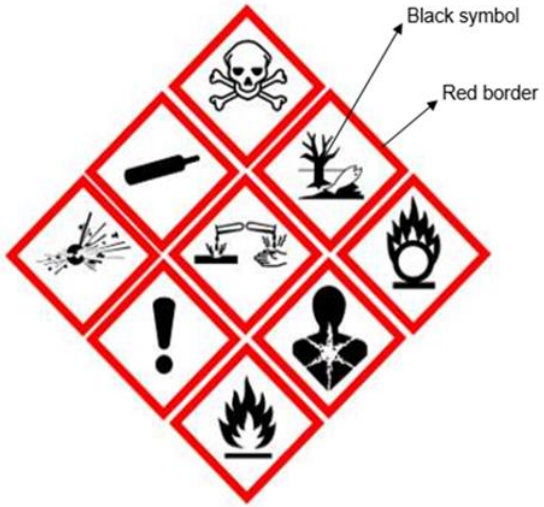
1. Physical
2. Health
3. Environmental

Why do we need harmonised classification and labelling?

- Once a substance or mixture is classified, the identified hazards must be communicated to other actors in the supply chain, including consumers.
- Hazard labelling allows the hazard classification, with labels and safety data sheets, to be communicated to the user of a substance or mixture, to alert them about the presence of a hazard and the need to manage the associated risks.







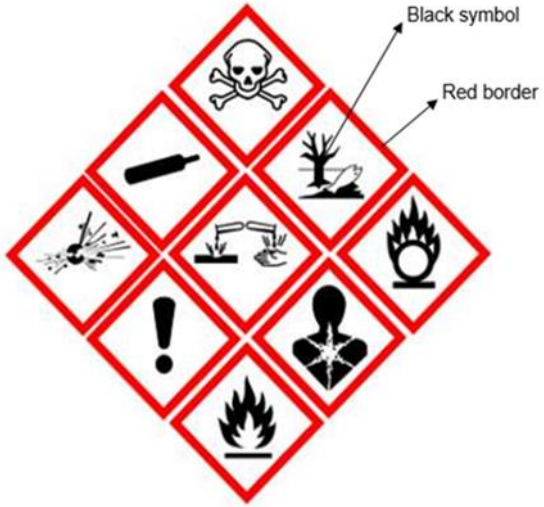
Why do we need harmonised classification and labelling? (continued)

- CLP sets detailed criteria for the labelling elements:
- pictograms, signal words and standard statements for hazard, prevention, response, storage and disposal, for every hazard class and category

Hazard statement(s)	
H301 + H311 + H331	Toxic if swallowed, in contact with skin or if inhaled
H317	May cause an allergic skin reaction.
H351	Suspected of causing cancer.
H372	Causes damage to organs (Liver, Kidney) through prolonged or repeated exposure if inhaled.

- It also sets general packaging standards to ensure the safe supply of hazardous substances and mixtures.
- The classification and labelling of certain hazardous chemicals is harmonised to ensure adequate risk management throughout the EU.

Why do we have Road Traffic signs?



REACH GAP ANALYSIS

Some major CLP Gaps

- No SME was found to be compliant with CLP
- Labels provided minimal information
- Many labels provided did not have GHS pictograms

REACH GAP ANALYSIS

Some major CLP Gaps

- Classification of oils as hazardous in terms of CLP and exemptions to REACH was not possible for all SMEs' as many did not provide SDS and full GC

- Many Regulatory GAPS in terms of SDSs (CLP) were identified

- SME's are muddling South African and EU regulations

RECOMMENDATIONS

CLP

1. Safety data sheets that are GHS compliant for Europe and South Africa
2. GHS compliant Labels
3. Webinars/seminars to educate SME's on REACH, CLP, GMP and GLP
4. Webinars/seminars to educate SME's on REACH, CLP, GMP and GLP

WORKSHOP ACTIVITY 2

- **Can I use an EU SDS in South Africa and vice versa?**

Introduction of ZA GHS

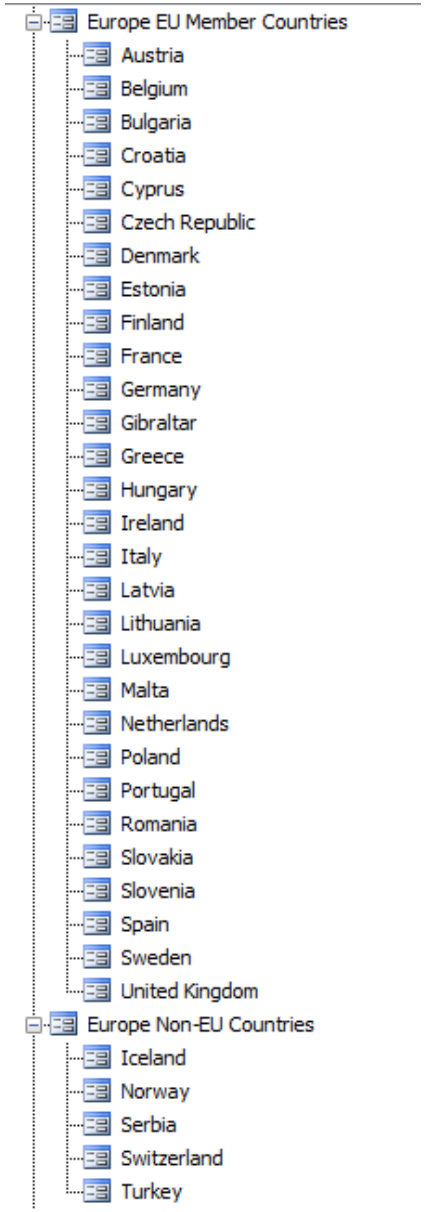
Regulations in ZA with links to GHS

- GHS regulation is translated to " SANS 10234"
- For the Transport :
  - SANS 10228:2012 – The identification and classification of dangerous goods for transport by road and rail modes
  - SANS 10231:2018 – Transport of dangerous goods by road
  - SANS 10232-1:2018 – Transport of dangerous goods – Emergency information systems
  - SANS 10232-4:2018 – Transport Emergency card

What is typical in GHS for the EU

EEA has regulations in most of its member states. ECHA covers the EU member states

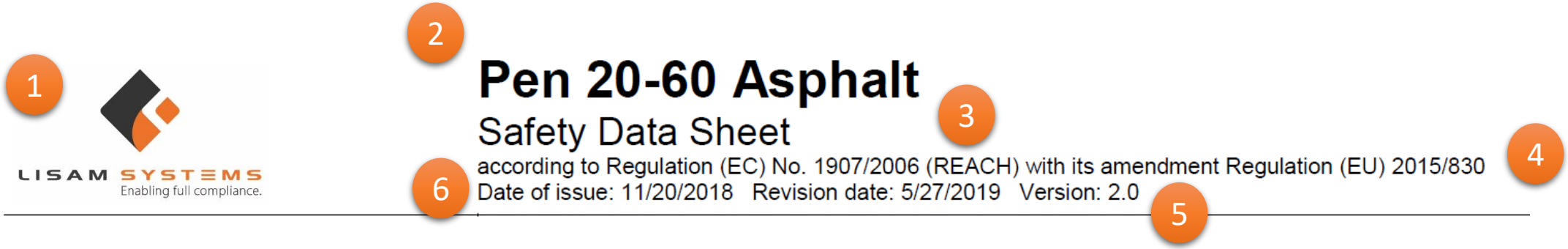
- The SDS needs to be created in the **language of the country**
- Some countries have **multiple languages**
  - BELGIUM : NL + FR + D
  - Switzerland : FR + D + IT
- Each country has specific data for
  - Section 8 : OEL and BLV data
  - Section 13 : For Waste management
  - Section 15 : Regulatory Information
- Some countries have local Preference translations for :
  - H and P statements
  - SDS Titles and Subtitles



SDS HEADER

SDS header information

1. Company Logo
2. Name of the Product
3. SDS name
4. Reference to the applicable regulation
5. Version information
6. Date information



WORKSHOP ACTIVITY 3

- **Using the SDS provided : What information can you find in Section 1 and why is it important ?**

SECTION 1: Identification of the substance/mixture and of the company/undertaking

- Product Identifiers in :
  - CAS number
  - EC number
  - EC index number
- USES need to be defined using the EU use descriptor system. There are " identified uses " and " Uses advised against " to report
- Company information should include a general contact possibility (e-mail address/ website)
- Reference to an official emergency centre/person

SDS Section 2

SECTION 2: Hazards identification

- GHS ZA takes the complete set of **building blocks into account**
- SDS Section 2.1. (classification) can have additional information different from Section 2.2. (label information)
- SDS ZA section 2.2. should include the same information as the distributed labels in the market for that product

acrylonitrile
Safety Data Sheet
according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

*** DRAFT ***

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Flammable liquids, Category 2	H225
Acute toxicity (oral), Category 3	H301
Acute toxicity (dermal), Category 3	H311
Acute toxicity (inhal.), Category 3	H331
Skin corrosion/irritation, Category 2	H315
Serious eye damage/eye irritation, Category 1	H318
Skin sensitisation, Category 1	H317
Carcinogenicity, Category 1B	H350
Specific target organ toxicity — Single exposure, Category 3, Respiratory tract irritation	H335
Hazardous to the aquatic environment — Chronic Hazard, Category 2	H411

Full text of H statements : see section 16

Adverse physicochemical, human health and environmental effects

No additional information available

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP) :

GHS02 GHS05 GHS06 GHS08 GHS09

Signal word (CLP) : Danger

Hazard statements (CLP) : H225 - Highly flammable liquid and vapour.
H301+H311+H331 - Toxic if swallowed, in contact with skin or if inhaled.
H315 - Causes skin irritation.
H317 - May cause an allergic skin reaction.
H318 - Causes serious eye damage.
H335 - May cause respiratory irritation.
H350 - May cause cancer (in contact with skin).
H411 - Toxic to aquatic life with long lasting effects.

Precautionary statements (CLP) : P201 - Obtain special instructions before use.
P202 - Do not handle until all safety precautions have been read and understood.
P210 - Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P233 - Keep container tightly closed.
P240 - Ground and bond container and receiving equipment.
P241 - Use explosion-proof equipment.

2.3. Other hazards

This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII

This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

SDS section 2

Hazard Classification

Hazard classification is broken into 3 main classes:

1. Health Hazard
2. Physical Hazard
3. Environmental Hazard

What is a hazard category?

- It is the division of criteria within each hazard class
- For example: Hazard class flammable liquids can be divided into 4 categories, among which category 1 represents the most severe hazard

Category	Criteria
1	Flash point < 23 °C and initial boiling point ≤ 35 °C
2	Flash point < 23 °C and initial boiling point > 35 °C
3	Flash point ≥ 23 °C and ≤ 60 °C
4	Flash point > 60 °C and ≤ 93 °C

Comparison between regions

Comparison between the Physical hazard classes between ZA and EU

GHS Building blocks (*)	EU	ZA
Unstable explosives		
Explosives, Div1.1		
Explosives, Div1.2		
Explosives, Div1.3		
Explosives, Div1.4		
Explosives, Div1.5		
Explosives, Div1.6		
Flammable gases, Cat. 1A		
Flammable gases, Cat. 1B		
Flammable gases, Cat. 2		
Flammable gases, Cat. 1A (Pyrophoric Gas)		
Flammable gases, Cat. 1A (Chemical Unstable gases, Cat. A)		
Flammable gases, Cat. 1A (Chemical Unstable gases, Cat. B)		
Aerosol, Cat. 1		
Aerosol, Cat. 2		
Aerosol, Cat. 3		
Oxidizing gas		
Gases under pressure, Compressed gas		
Gases under pressure, Liquidfied gas		
Gases under pressure, Refrigerated liquidfied gas		
Gases under pressure, Dissolved gas		
Flammable liquids, Cat. 1		
Flammable liquids, Cat. 2		
Flammable liquids, Cat. 3		
Flammable liquids, Cat. 4		

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Comparison between regions

Comparison between the Health hazard classes between ZA and EU

GHS Building blocks (*)	EU	ZA
Acute toxicity, Cat. 1		
Acute toxicity, Cat. 2		
Acute toxicity, Cat. 3		
Acute toxicity, Cat. 4		
Acute toxicity, Cat. 5		
Skin corrosion/irritation, Cat. 1		
Skin corrosion/irritation, Cat. 1A		
Skin corrosion/irritation, Cat. 1B		
Skin corrosion/irritation, Cat. 1C		
Skin corrosion/irritation, Cat. 2		
Skin corrosion/irritation, Cat. 3		
Serious Eye damage/Eye Irritation, Cat. 1		
Serious Eye damage/Eye Irritation, Cat. 2		
Serious Eye damage/Eye Irritation, Cat. 2A		
Serious Eye damage/Eye Irritation, Cat. 2B		
Respiratory or Skin Sensitisation, Cat. 1		
Respiratory or Skin Sensitisation, Cat. 1A		
Respiratory or Skin Sensitisation, Cat. 1B		
Germ Cell Mutagenicity, Cat. 1A		
Germ Cell Mutagenicity, Cat. 1B		
Germ Cell Mutagenicity, Cat. 2		
Carcinogenicity, Cat. 1A		
Carcinogenicity, Cat. 1B		
Carcinogenicity, Cat. 2		
Reproductive toxicity, Cat. 1A		
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GHS Building blocks (*)	EU	ZA
Reproductive toxicity, Cat. 1B		
Reproductive toxicity, Cat. 2		
Reproductive toxicity Lactation		
STOT Single exposure, Cat. 1		
STOT Single exposure, Cat. 2		
STOT Single exposure, Cat. 3		
STOT Repeated exposure, Cat. 1		
STOT Repeated exposure, Cat. 2		
Aspiration hazard, Cat. 1		
Aspiration hazard, Cat. 2		
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Comparison between regions

Comparison between the Environmental hazard classes between ZA and EU

GHS Building blocks (*)	EU	ZA
Acute hazards to aquatic environment, Cat. 1		
Acute hazards to aquatic environment, Cat. 2		
Acute hazards to aquatic environment, Cat. 3		
Long-term hazards to the aquatic environment, Cat. 1		
Long-term hazards to the aquatic environment, Cat. 2		
Long-term hazards to the aquatic environment, Cat. 3		
Long-term hazards to the aquatic environment, Cat. 4		
Hazard to the ozone layer		

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- [ ] USA (US)
- [ ] Uruguay (UY)
- [ ] Vietnam (VN)
- [x] South Africa (ZA)

Difference between SA and EU SDS

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to the United Nations GHS

Flammable liquids, Category 3	H226
Skin corrosion/irritation, Category 3	H316
Skin sensitisation, Category 1	H317
Hazardous to the aquatic environment — Acute Hazard, Category 2	H401
Hazardous to the aquatic environment — Chronic Hazard, Category 2	H411

Full text of H statements : see section 16

SA SDS

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Flammable liquids, Category 3	H226
Skin sensitisation, Category 1	H317
Hazardous to the aquatic environment — Chronic Hazard, Category 2	H411

Full text of H statements : see section 16

10/21/2019 (Version: 1.0) GB - en

EU SDS

SDS Section 3

SECTION 3: Composition/information on ingredients

- On a ZA SDS: ZA classifications must be given for the components/ingredients
- Specific Concentration limits need to be reported on the SDS
- There are specific rules to respect for component/ingredient disclosure . The rules take into account the OEL information and multiple parameters clearly defined in the GHS and SDS regulation, including well defined concentration limits for dedicated classification end points

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Comments : All these chemical compounds are not added deliberately as such

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
aceton (demo)	(CAS-No.) 67-64-1 (EC-No.) 200-662-2 (EC Index-No.) 606-001-00-8 (REACH-no) 12-1234567890-12-4444	10 - 20	Not determined
di-2-ethylhexylphthalate (stabilizer, Monomer) substance listed as REACH Candidate (Bis (2-ethyl(hexyl)phthalate) (DEHP)) substance listed in REACH Annex XIV (Bis(2-ethylhexyl) phthalate (DEHP))	(CAS-No.) 117-81-7 (EC-No.) 204-211-0 (EC Index-No.) 607-317-00-9	10 - 20	Repr. 1B, H360FD
LOCTITE adhesives,based on alkyl-alpha-cyanoacrylate (Constituent)	(REACH-no) 9874-58	6.72	Flam. Liq. Not classified Skin Irrit. 2, H315 Eye Irrit. 2, H319 STOT SE 3, H335
coumafuryl (residueel monomeer)	(CAS-No.) 117-52-2 (EC-No.) 204-195-5 (EC Index-No.) 607-058-00-1	5 - 10	Acute Tox. 2 (Oral), H300 STOT RE 1, H372 Aquatic Chronic 3, H412
cadmium chloride (Impurity) substance listed as REACH Candidate	(CAS-No.) 10108-64-2 (EC-No.) 233-296-7 (EC Index-No.) 048-008-00-3	2 - 5	Acute Tox. 3 (Oral), H301 Acute Tox. 2 (Inhalation:dust,mist), H330 Muta. 1B, H340 Carc. 1B, H350 Repr. 1B, H360FD STOT RE 1, H372 Aquatic Acute 1, H400 Aquatic Chronic 1, H410
benzyl alcohol (Additive)	(CAS-No.) 100-51-6 (EC-No.) 202-859-9 (EC Index-No.) 603-057-00-5	< 5	Not determined
BBP; benzyl butyl phthalate (Impurity) substance listed as REACH Candidate (Benzyl butyl phthalate (BBP)) substance listed in REACH Annex XIV (Benzyl butyl phthalate (BBP))	(CAS-No.) 85-68-7 (EC-No.) 201-622-7 (EC Index-No.) 607-430-00-3	< 5	Repr. 1B, H360D Aquatic Acute 1, H400 Aquatic Chronic 1, H410

Specific concentration limits:

Name	Product identifier	Specific concentration limits
cadmium chloride (Impurity)	(CAS-No.) 10108-64-2 (EC-No.) 233-296-7 (EC Index-No.) 048-008-00-3	(0.01 =<C < 100) Carc. 1B, H350 (0.1 =<C < 7) STOT RE 2, H373 (7 =<C < 100) STOT RE 1, H372

Comments : NOTE 1 : This comment is to confirm that all info is given in % w/w

Full text of H-statements: see section 16

Health and additional hazards

Example

- Each component and its concentration within a mixture must be listed
- Even components at a very low concentration can affect the overall classification of a mixture

Peppermint oil

Product				Non-additive	Additive				
Ingredient	GHS ZA classification	CAS-No.	%	Skin Sens. 1;H317	Asp. Tox. 1;H304	Skin Irrit. 2;H315	Skin Irrit. 3;H316	Eye Irrit. 2A;H319	Eye Irrit. 2B;H320
Oxiteno - Alkest TW 20	Flam. Liq. Not classified Acute Tox. Not classified (Oral) Acute Tox. 3 (Inhalation:vapour);H331 Aquatic Acute Not classified	9005-64-5	70						
Menthol	Flam. Liq. 4;H227 Acute Tox. 5 (Oral);H303 Skin Irrit. 2;H315 Eye Irrit. 2B;H320 Aquatic Acute 3;H402	89-78-1	<= 30.000			>= 10 | 3	Skin Irrit. 2 => >= 1 | 30		>= 10 | 3
d,l-Limonene (isomer unspecified)	Flam. Liq. 3;H226 Skin Irrit. 2;H315 Skin Sens. 1B;H317 Asp. Tox. 1;H304 Aquatic Acute 1;H400 Aquatic Chronic 1;H410	7705-14-8	<= 0.750	(Skin Sens. 1B => >= 1 | 0.75)	(>= 10 | 0.075)	(>= 10 | 0.075)	(Skin Irrit. 2 => >= 1 | 0.75)		
4,5,6,7-Tetrahydro-3,6-dimethylbenzofuran	Flam. Liq. 4;H227 Acute Tox. 4 (Oral);H302 Skin Irrit. 2;H315 Eye Irrit. 2A;H319 Aquatic Acute 2;H401 Aquatic Chronic 2;H411	494-90-6	<= 0.750			(>= 10 | 0.075)	(Skin Irrit. 2 => >= 1 | 0.75)	(>= 10 | 0.075)	
Menthyl acetate (1alpha,2beta,5alpha)	Flam. Liq. 4;H227 Aquatic Acute 2;H401 Aquatic Chronic 2;H411	89-48-5	<= 0.750						
alpha-Pinene	Flam. Liq. 3;H226 Acute Tox. 5 (Oral);H303 Skin Irrit. 2;H315 Skin Sens. 1B;H317 Asp. Tox. 1;H304 Aquatic Acute 1;H400 Aquatic Chronic 1;H410	80-56-8	<= 0.750	(Skin Sens. 1B => >= 1 | 0.75)	(>= 10 | 0.075)	(>= 10 | 0.075)	(Skin Irrit. 2 => >= 1 | 0.75)		
beta-Pinene	Flam. Liq. 3;H226 Skin Irrit. 2;H315 Skin Sens. 1B;H317 Asp. Tox. 1;H304 Aquatic Acute 1;H400 Aquatic Chronic 1;H410	127-91-3	<= 0.750	(Skin Sens. 1B => >= 1 | 0.75)	(>= 10 | 0.075)	(>= 10 | 0.075)	(Skin Irrit. 2 => >= 1 | 0.75)		
Isopulegol	Flam. Liq. 4;H227 Acute Tox. 4 (Oral);H302 Skin Irrit. 2;H315 Eye Irrit. 2A;H319 Aquatic Acute 3;H402	89-79-2	<= 0.750			(>= 10 | 0.075)	(Skin Irrit. 2 => >= 1 | 0.75)	(>= 10 | 0.075)	
Menthone	Flam. Liq. 4;H227 Acute Tox. 5 (Oral);H303 Skin Irrit. 2;H315 Skin Sens. 1B;H317 Aquatic Acute 3;H402	10458-14-7	<= 0.750	(Skin Sens. 1B => >= 1 | 0.75)		(>= 10 | 0.075)	(Skin Irrit. 2 => >= 1 | 0.75)		
Mixture						3	30		3
Result						**Skin Irrit. 2;H315**			**Eye Irrit. 2B;H320**
(*) Specific concentration limit									

Environmental hazards acute

Example

Peppermint oil

		Additivity formula						
Ingredient	**CAS-No.**	**ConcentrationSign**	**%**	**Fish**	**Crustacea**	**Algae**	**Minimum**	
		Summation method						
Ingredient	**CAS-No.**	**GHS ZA classification**	**Classification forced**	**M-Factor acute (GHS-ZA)**	**%**	**Aquatic Acute 1;H400**	**Aquatic Acute 2;H401**	**Aquatic Acute 3;H402**
Menthol	89-78-1	Aquatic Acute 3;H402	No	1	<= 30.000			>= 25 | 1.2
d,l-Limonene (isomer unspecified)	7705-14-8	Aquatic Acute 1;H400	No	1	<= 0.750	>= 25 | 0.03	Aquatic Acute 1 => >= 25 | 0.3	Aquatic Acute 1 => >= 25 | 3
4,5,6,7-Tetrahydro-3,6-dimethylbenzofuran	494-90-6	Aquatic Acute 2;H401	No	1	<= 0.750		(>= 25 | 0.03)	(Aquatic Acute 2 => >= 25 | 0.3)
Menthyl acetate (1alpha,2beta,5alpha)	89-48-5	Aquatic Acute 2;H401	No	1	<= 0.750		(>= 25 | 0.03)	(Aquatic Acute 2 => >= 25 | 0.3)
alpha-Pinene	80-56-8	Aquatic Acute 1;H400	No	1	<= 0.750	>= 25 | 0.03	Aquatic Acute 1 => >= 25 | 0.3	Aquatic Acute 1 => >= 25 | 3
beta-Pinene	127-91-3	Aquatic Acute 1;H400	No	1	<= 0.750	>= 25 | 0.03	Aquatic Acute 1 => >= 25 | 0.3	Aquatic Acute 1 => >= 25 | 3
Isopulegol	89-79-2	Aquatic Acute 3;H402	No	1	<= 0.750			(>= 25 | 0.03)
Menthone	10458-14-7	Aquatic Acute 3;H402	No	1	<= 0.750			(>= 25 | 0.03)
Mixture						**0.09**	**0.9**	**10.2**
Result								**Aquatic Acute 3;H402**

SDS Section 4

SECTION 4: First aid measures

The reported information should include the :

1. First Aid measures
2. symptoms/effects when accidental contact happens
3. medical advice for treatment

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general	: Check the vital functions. Unconscious: maintain adequate airway and respiration. Respiratory arrest: artificial respiration or oxygen. Cardiac arrest: perform resuscitation. Victim conscious with laboured breathing: half-seated. Victim in shock: on his back with legs slightly raised. Vomiting: prevent asphyxia/aspiration pneumonia. Prevent cooling by covering the victim (no warming up). Keep watching the victim. Give psychological aid. Keep the victim calm, avoid physical strain. Depending on the victim's condition: doctor/hospital.
First-aid measures after inhalation	: Remove the victim into fresh air. Immediately consult a doctor/medical service.
First-aid measures after skin contact	: Wash immediately with lots of water. Soap may be used. Do not apply (chemical) neutralizing agents. Remove clothing before washing. Consult a doctor/medical service.
First-aid measures after eye contact	: Rinse immediately with plenty of water for 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Take victim to an ophthalmologist.
First-aid measures after ingestion	: Rinse mouth with water. Immediately consult a doctor/medical service. Call Poison Information Centre (www.big.be/antigif.htm). Take the container/vomit to the doctor/hospital. Ingestion of large quantities: immediately to hospital. Doctor: administration of chemical antidote.

4.2. Most important symptoms and effects, both acute and delayed

Symptoms/effects after inhalation	: Inhibition of enzyme production. Irritation of the respiratory tract. Irritation of the nasal mucous membranes. Headache. Nausea. Vomiting. Dizziness. EXPOSURE TO HIGH CONCENTRATIONS: Feeling of weakness. Respiratory difficulties. Blue/grey discolouration of the skin. Tremor. Cramps/uncontrolled muscular contractions. Disturbances of consciousness. Emotional instability. FOLLOWING SYMPTOMS MAY APPEAR LATER: Enlargement/affection of the liver. Yellow skin.
Symptoms/effects after skin contact	: Tingling/irritation of the skin. Red skin. Swelling of the skin. FOLLOWING SYMPTOMS MAY APPEAR LATER: Blisters. Symptoms similar to those listed under inhalation.
Symptoms/effects after eye contact	: Corrosion of the eye tissue. Redness of the eye tissue. ON CONTINUOUS EXPOSURE/CONTACT: Inflammation/damage of the eye tissue.
Symptoms/effects after ingestion	: Risk of aspiration pneumonia. Symptoms similar to those listed under inhalation.
Chronic symptoms	: ON CONTINUOUS/REPEATED EXPOSURE/CONTACT: Feeling of weakness. Skin rash/inflammation. Gastrointestinal complaints. Respiratory difficulties. Lung tissue affection/degeneration. Change in the haemogramme/blood composition. Enlargement/affection of the liver.

4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SDS Section 5 and 6

- **SECTION 5: Firefighting measures**
- **SECTION 6: Accidental release measures**

Follows closely the GHS UN purple book

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media	: Quick-acting ABC powder extinguisher. Quick-acting BC powder extinguisher. Quick-acting class B foam extinguisher. Quick-acting CO2 extinguisher. Class B foam (not alcohol-resistant).
Unsuitable extinguishing media	: Water (quick-acting extinguisher, reel); risk of puddle expansion. Water; risk of puddle expansion.

5.2. Special hazards arising from the substance or mixture

Fire hazard	: DIRECT FIRE HAZARD: Highly flammable liquid and vapour. Gas/vapour flammable with air within explosion limits. INDIRECT FIRE HAZARD: Substance contains stabilizer against polymerization. Heat destroys stabilizer against polymerization. May be ignited by sparks. Gas/vapour spreads at floor level: ignition hazard. Reactions involving a fire hazard: see "Reactivity Hazard".
Explosion hazard	: DIRECT EXPLOSION HAZARD: Gas/vapour explosive with air within explosion limits. INDIRECT EXPLOSION HAZARD: Heat may cause pressure rise in tanks/drums: explosion risk. may be ignited by sparks. Reactions with explosion hazards: see "Reactivity Hazard".
Hazardous decomposition products in case of fire	: On burning: release of toxic and corrosive gases/vapours (nitrous vapours, carbon monoxide - carbon dioxide).

5.3. Advice for firefighters

Firefighting instructions	: Cool tanks/drums with water spray/remove them into safety. Physical explosion risk: extinguish/cool from behind cover. Do not move the load if exposed to heat. After cooling: persistant risk of physical explosion. Dilute toxic gases with water spray. Take account of toxic/corrosive precipitation water. Take account of toxic fire-fighting water. Use water moderately and if possible collect or contain it.
Protection during firefighting	: Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Protective equipment	: Gas-tight suit.
Emergency procedures	: Keep upwind. Mark the danger area. Consider evacuation. Seal off low-lying areas. Close doors and windows of adjacent premises. Stop engines and no smoking. No naked flames or sparks. Spark- and explosionproof appliances and lighting equipment. Keep containers closed. Wash contaminated clothes.

6.1.2. For emergency responders

Protective equipment	: Compressed air/oxygen apparatus.

6.2. Environmental precautions

Prevent soil and water pollution. Prevent spreading in sewers.

6.3. Methods and material for containment and cleaning up

For containment	: Contain released product, pump into suitable containers. Plug the leak, cut off the supply. Dam up the liquid spill. Try to reduce evaporation. Measure the concentration of the explosive gas-air mixture. Dilute combustible/toxic gases/vapours with water spray. Take account of toxic/corrosive precipitation water. Provide equipment/receptacles with earthing. Do not use compressed air for pumping over spills.
Methods for cleaning up	: Liquid spill: cover with foam or sand/earth. Scoop absorbed substance into closing containers. Carefully collect the spill/leftovers. Containers must not be sealed hermetically. Damaged/cooled tanks must be emptied. Do not use compressed air for pumping over spills. Clean contaminated surfaces with an excess of water. Take collected spill to manufacturer/competent authority. Wash clothing and equipment after handling.
Other information	: Dispose of materials or solid residues at an authorized site.

6.4. Reference to other sections

For further information refer to section 13.

SDS Section 8

SECTION 8: Exposure controls/personal protection

- Community OEL information is mandatory . Each country requires the regional OEL information for the relevant country to be part of the SDS
- In South Africa there are
  - Recommended Limits
  - Control limits
  - Airborne pollutants
- It is recommended to show Personal Protection Equipment pictograms and to specify the details of the PPE to be used.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

acrylonitrile (107-13-1)

United Kingdom - Occupational Exposure Limits

WEL TWA (mg/m³)	4.4 mg/m³
WEL TWA (ppm)	2 ppm

acrylonitrile (107-13-1)

DNEL/DMEL (Workers)

Acute - local effects, inhalation	10 mg/m³
Long-term - systemic effects, dermal	1.4 mg/kg bw/day
Long-term - local effects, inhalation	1.8 mg/m³

DNEL/DMEL (General population)

Acute - local effects, inhalation	1 mg/m³
Long-term - systemic effects,oral	0.009 mg/kg bw/day
Long-term - systemic effects, inhalation	0.1 mg/m³
Long-term - systemic effects, dermal	0.009 mg/kg bw/day
Long-term - local effects, inhalation	0.06 mg/m³

8.2. Exposure controls

Appropriate engineering controls:

Ensure good ventilation of the work station.

Materials for protective clothing:

GIVE EXCELLENT RESISTANCE: butyl rubber. GIVE LESS RESISTANCE: tetrafluoroethylene. GIVE POOR RESISTANCE: natural rubber. neoprene. nitrile rubber. polyethylene. PVA. PVC. styrene-butadiene rubber. viton. neoprene/SBR. leather

Condition	Material	Standard
Poor resistance:		

Hand protection:

Protective gloves against chemicals (EN374)

Type	Material	Permeation	Thickness (mm)	Penetration	Standard
Reusable gloves					

Eye protection:

Safety glasses

Skin and body protection:

Head/neck protection. Protective clothing

Respiratory protection:

Full face mask with filter type A at conc. in air > exposure limit. Self-contained breathing apparatus if conc. in air > 1 vol %

Device	Filter type	Condition	Standard
		Protection for Solid particles	

Personal protective equipment symbol(s):

Environmental exposure controls:

Avoid release to the environment.

SDS Section 9

SECTION 9: Physical and chemical properties

- In this section, all physical and chemical data associated with the product must be stated
- Extra information is encouraged:
    - Dust (particles)
    - Flammability and Explosion data

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Appearance	: Liquid.
Molecular mass	: 53.06 g/mol
Colour	: Pure substance: colourless. Commercial substance: light yellow.
Odour	: Almost odourless. Irritating/pungent odour. Sweet odour.
Odour threshold	: No data available
pH	: 5.5 - 7.5 (5 %)
Relative evaporation rate (butylacetate=1)	: 4.5
Melting point	: -84 °C (1013 hPa)
Freezing point	: No data available
Boiling point	: 77 °C (1013 hPa)
Flash point	: 0 °C (Open cup, 1013 hPa)
Critical temperature	: 246 °C
Auto-ignition temperature	: 481 °C (1013 hPa)
Decomposition temperature	: No data available
Flammability (solid, gas)	: Not applicable
Vapour pressure	: 115 hPa (20 °C)
Vapour pressure at 50 °C	: 395 hPa
Critical pressure	: 35400 hPa
Relative vapour density at 20 °C	: 1.8
Relative density	: 0.81 (20 °C)
Relative density of saturated gas/air mixture	: 1.1
Density	: 806 kg/m³
Solubility	: Moderately soluble in water. Substance floats in water. Soluble in ethanol. Soluble in ether. Soluble in acetone. Soluble in methanol. Soluble in ethylacetate. Soluble in isopropanol. Soluble in petroleum spirit. Soluble in tetrachloromethane. Soluble in toluene. Soluble in xylene. Water: 7.3 g/100ml (20 °C) Ethanol: complete Ether: complete Acetone: complete
Log Pow	: 1.02 - 1.05 (Experimental value, EU Method A.8: Partition Coefficient, 21 °C)
Viscosity, kinematic	: 0.422 mm²/s
Viscosity, dynamic	: 0.34 mPa·s (25 °C)
Explosive properties	: No data available
Oxidising properties	: No data available
Explosive limits	: 2 - 28 vol %
Lower explosive limit (LEL)	: 2 vol %
Upper explosive limit (UEL)	: 28 vol %

9.2. Other information

Minimum ignition energy	: 0.16 mJ
Saturation concentration	: 253 g/m³
VOC content	: 100 %
Other properties	: Gas/vapour heavier than air at 20°C. Clear. Volatile.

SDS Section 10

SECTION 10: Stability and reactivity

Follows closely the GHS UN purple book

SECTION 10: Stability and reactivity

10.1. Reactivity

Violent polymerisation on exposure to light: heat release resulting in increased fire or explosion risk. Reacts violently with (strong) oxidizers: (increased) risk of fire/explosion. Polymerizes with many compounds e.g.: with (some) acids/bases: heat release resulting in increased fire or explosion risk.

10.2. Chemical stability

Unstable on exposure to heat. Unstable on exposure to light.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

Avoid contact with hot surfaces. Heat. No flames, no sparks. Eliminate all sources of ignition.

10.5. Incompatible materials

No additional information available

10.6. Hazardous decomposition products

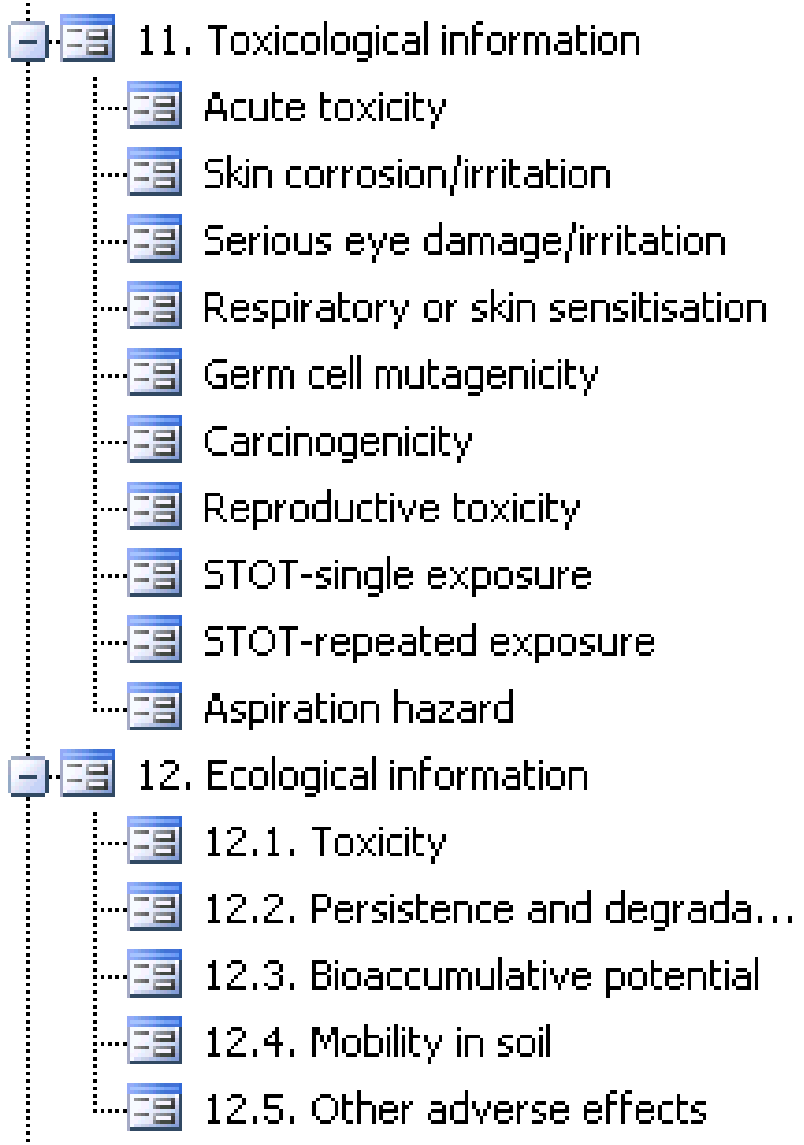
On heating: release of toxic/corrosive/combustible gases/vapours (hydrogen cyanide).

SDS Section 11 and 12

SECTION 11: Toxicological information

SECTION 12: Ecological information

- All health and environmental end points are mandatory to report on the SDS
- All relevant information from components/ingredients related or causing the final classification should be added on the SDS
- Additional information related to end point classification should be given as extra information
- The Ozone depletion hazard is defined separately from the environmental hazards and is part of 12.5.



SDS Section 11 and 12

SECTION 11: Toxicological information

SECTION 12: Ecological information

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity (oral)	: Toxic if swallowed.
Acute toxicity (dermal)	: Toxic in contact with skin.
Acute toxicity (inhalation)	: Toxic if inhaled.

acrylonitrile (107-13-1)	
LD50 oral rat	95 mg/kg bodyweight (Rat, Female, Experimental value, Oral)
LD50 dermal rat	> 200 mg/kg bodyweight (4 h, Rat, Male / female, Experimental value, Dermal)
LC50 inhalation rat (mg/l)	2.05 mg/l (OECD 403: Acute Inhalation Toxicity, 4 h, Rat, Male / female, Experimental value, Inhalation (vapours), 14 day(s))

Skin corrosion/irritation	: Causes skin irritation. pH: 5.5 - 7.5 (5 %)
Serious eye damage/irritation	: Causes serious eye damage. pH: 5.5 - 7.5 (5 %)
Respiratory or skin sensitisation	: May cause an allergic skin reaction.
Germ cell mutagenicity	: Not classified
Carcinogenicity	: May cause cancer (in contact with skin).
Reproductive toxicity	: Not classified
STOT-single exposure	: May cause respiratory irritation.
STOT-repeated exposure	: Not classified
Aspiration hazard	: Not classified

acrylonitrile (107-13-1)	
Viscosity, kinematic	0.422 mm²/s

Potential adverse human health effects and symptoms	: Obstructs oxygen absorption. Produces effects on the nervous system. Toxic if swallowed. Toxic in contact with skin. Causes skin irritation. Toxic if inhaled. May cause respiratory irritation. Causes serious eye damage. Caution! Substance is absorbed through the skin.

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general	: Dangerous for the environment.
Ecology - air	: Not included in the list of fluorinated greenhouse gases (Regulation (EU) No 517/2014). Photodegradation in the air. Not classified as dangerous for the ozone layer (Regulation (EC) No 1005/2009).
Ecology - water	: Toxic to crustacea. Toxic to crustacea with long lasting effects. Toxic to fishes. Toxic to fish, with long lasting effects. Groundwater pollutant. Fouling to shoreline. Inhibition of activated sludge. Harmful to algae. No significant hydrolysis.
Acute aquatic toxicity	: Not classified
Chronic aquatic toxicity	: Toxic to aquatic life with long lasting effects.

acrylonitrile (107-13-1)	
LC50 fish 1	8.6 mg/l (OECD 203: Fish, Acute Toxicity Test, 96 h, Cyprinodon variegatus, Semi-static system, Salt water, Experimental value, GLP)
EC50 Daphnia 1	7.6 - 22 mg/l (48 h, Daphnia magna, No reliable data available)
ErC50 (algae)	14.1 ppm (Other, 72 h, Skeletonema costatum, Static system, Salt water, Experimental value, GLP)

12.2. Persistence and degradability

acrylonitrile (107-13-1)	
Persistence and degradability	Biodegradable in the soil. Inherently biodegradable. Not readily biodegradable in water.
Biochemical oxygen demand (BOD)	0.72 g O_2/g substance
Chemical oxygen demand (COD)	1.39 g O_2/g substance
ThOD	3.17 g O_2/g substance

12.3. Bioaccumulative potential

acrylonitrile (107-13-1)	
BCF fish 1	48 (672 h, Lepomis macrochirus, Fresh water, Literature study)
Log Pow	1.02 - 1.05 (Experimental value, EU Method A.8: Partition Coefficient, 21 °C)
Bioaccumulative potential	Low potential for bioaccumulation (BCF < 500).

12.4. Mobility in soil

acrylonitrile (107-13-1)	
Surface tension	26.6 mN/m (25 °C)
Ecology - soil	No (test)data on mobility of the substance available.

12.5. Results of PBT and vPvB assessment

acrylonitrile (107-13-1)
This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII
This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

12.6. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

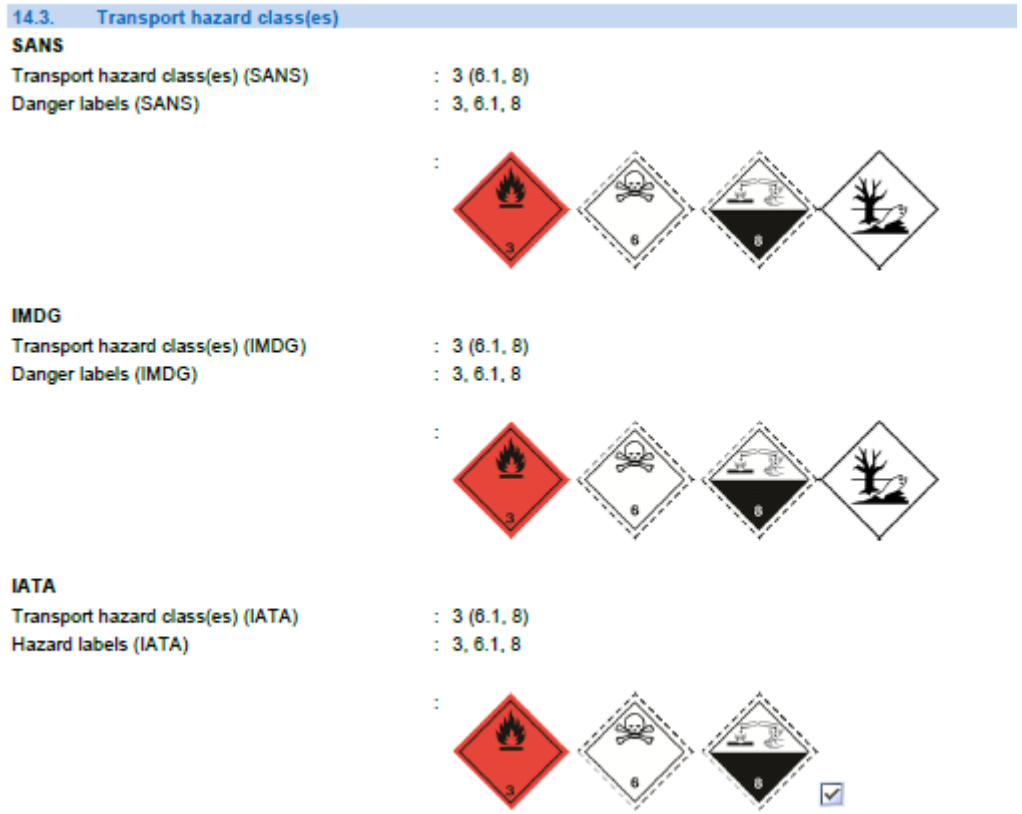
- ZA has dedicated Waste regulations
- Specific waste disposal methods must be stated in Section 13.

SECTION 13: Disposal considerations	
13.1. Waste treatment methods	
Waste treatment methods	: Dispose of contents/container in accordance with licensed collector's sorting instructions.
Product/Packaging disposal recommendations	: Do not discharge into drains or the environment. Remove waste in accordance with local and/or national regulations. Hazardous waste shall not be mixed together with other waste. Different types of hazardous waste shall not be mixed together if this may entail a risk of pollution or create problems for the further management of the waste. Hazardous waste shall be managed responsibly. All entities that store, transport or handle hazardous waste shall take the necessary measures to prevent risks of pollution or damage to people or animals. Incinerate under surveillance with energy recovery.
Additional information	: Hazardous waste according to Directive 2008/98/EC, as amended by Regulation (EU) No 1357/2014 and Regulation (EU) No 2017/997.

SDS Section 14

SECTION 14: Transport information

- In ZA , 3 transport modes can be part of the SDS :
  - SANS for Road transport
  - IMDG for Sea transport
  - IATA for Air transport
- The Section 14 of the SDS does not replace the TEC (Transport emergency card)
- For hazardous products, DGD (Dangerous Goods Declaration) must also accompany the vehicle and load
- Transport Pictograms have precedence on equivalent GHS pictograms on labels
- It is allowed to combine Transport and GHS labels for transport purposes


14.3. Transport hazard class(es)

SANS

Transport hazard class(es) (SANS) : 3 (6.1, 8)

Danger labels (SANS) : 3, 6.1, 8

IMDG

Transport hazard class(es) (IMDG) : 3 (6.1, 8)

Danger labels (IMDG) : 3, 6.1, 8

IATA

Transport hazard class(es) (IATA) : 3 (6.1, 8)

Hazard labels (IATA) : 3, 6.1, 8

SDS Section 15

SECTION 15: Regulatory information

- The regulation is not precise on the full Section 15 mandatory content . Most rules are based on the minimum Regulatory defined International agreements
- The SDS ZA includes at minimum
  - Specific regulatory information .
  - Additional regulatory information on detergent and cosmetic regulations

SECTION 15: Regulatory information		
15.1. Safety, health, and environmental national regulations specific for the product		
Regulatory reference	:	SANS 10234:2008; SANS 11014:2010; SANS 10228:2012;SANS 10229:2010; SANS 10232(1,2,4), SANS 10231:2018; Occupational Health and Safety Act 85 of 1993; National Road Traffic Act 93 of 1996.
Other information, restriction and prohibition regulations	:	SAWIS Hazardous Waste Code: HW11:01.

SDS Section 16

SECTION 16: Other information

- Indicate used abbreviations and acronyms
- Refer to source information
- Should include a clear overview of the changes compared with a previous SDS version
- Must have a legal disclaimer

SECTION 16: Other information			
Indication of changes:			
Section	**Changed item**	**Change**	**Comments**
5.1	Suitable extinguishing media		Review with Fireworkers team 21.04.2019
9.1	pH	Modified	New test results Ref 29.01.OECD
14	ADR Regulatory status	Modified	Updated after uncomplete information reported

Abbreviations and acronyms:	
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
ATE	Acute Toxicity Estimate
ATE	Acute Toxicity Estimate
LC50	Median lethal concentration
LD50	Median lethal dose
LOAEL	Lowest Observed Adverse Effect Level
NOAEC	No-Observed Adverse Effect Concentration
vPvB	Very Persistent and Very Bioaccumulative
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
PNEC	Predicted No-Effect Concentration
PBT	Persistent Bioaccumulative Toxic
Data sources	: REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.
Training advice	: Normal use of this product shall imply use in accordance with the instructions on the packaging.
Other information	: None.

Full text of H- and EUH-statements:	
Acute Tox. 3 (Dermal)	Acute toxicity (dermal), Category 3
Acute Tox. 3 (Inhalation)	Acute toxicity (inhal.), Category 3
Acute Tox. 3 (Oral)	Acute toxicity (oral), Category 3
Aquatic Chronic 2	Hazardous to the aquatic environment — Chronic Hazard, Category 2
Carc. 1B	Carcinogenicity, Category 1B
Eye Dam. 1	Serious eye damage/eye irritation, Category 1
Flam. Liq. 2	Flammable liquids, Category 2
Skin Irrit. 2	Skin corrosion/irritation, Category 2
Skin Sens. 1	Skin sensitisation, Category 1
STOT SE 3	Specific target organ toxicity — Single exposure, Category 3, Respiratory tract irritation
H225	Highly flammable liquid and vapour.
H301	Toxic if swallowed.
H311	Toxic in contact with skin.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H331	Toxic if inhaled.
H335	May cause respiratory irritation.
H350	May cause cancer.
H411	Toxic to aquatic life with long lasting effects.
Full text of use descriptors	
ERC6a	Use of intermediate
PROC3	Manufacture or formulation in the chemical industry in closed batch processes with occasional controlled exposure or processes with equivalent containment condition
SU8	Manufacture of bulk, large scale chemicals (including petroleum products)

SDS EU (REACH Annex II)

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

DEFINITION OF A COSMETIC

- **Regulatory Reference for Cosmetics in the EU: EC 1223/2009**

- **Article 2 1(a): means**

"any substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly for:

- Cleaning them
- perfuming them,
- changing their appearance,
- protecting them,
- keeping them in good condition
- correcting body odours

DEFINITION OF A COSMETIC

WHAT is NOT a cosmetic?

- a substance or mixture intended to be ingested, inhaled, injected or implanted into the human body shall not be considered to be a cosmetic product
- Nutro cosmetics are NOT cosmetics - the primary function of the cosmetic must be as per the allowable definition for cosmetics
- Biocidal Products are not cosmetics
- Cosmetics cannot take the form or shape of a toy

Cosmetic EU Legislation

Why the requirement for Cosmetic Regulations in the EU

- EEC – 28 Nations
- 512 Million Citizens
- 22% of the global GDP
- Ensure free movement of goods
- Provide for a self regulated system
- Accessibility of product Information (PIF)
- Market surveillance and reporting (RP and Authorities)
- Protecting Human Health at a high level by:
    - assessment of exposure risk based
    - Applying current scientific principles and knowledge
    - applying the most relevant toxicological principles

Cosmetic EU Legislation

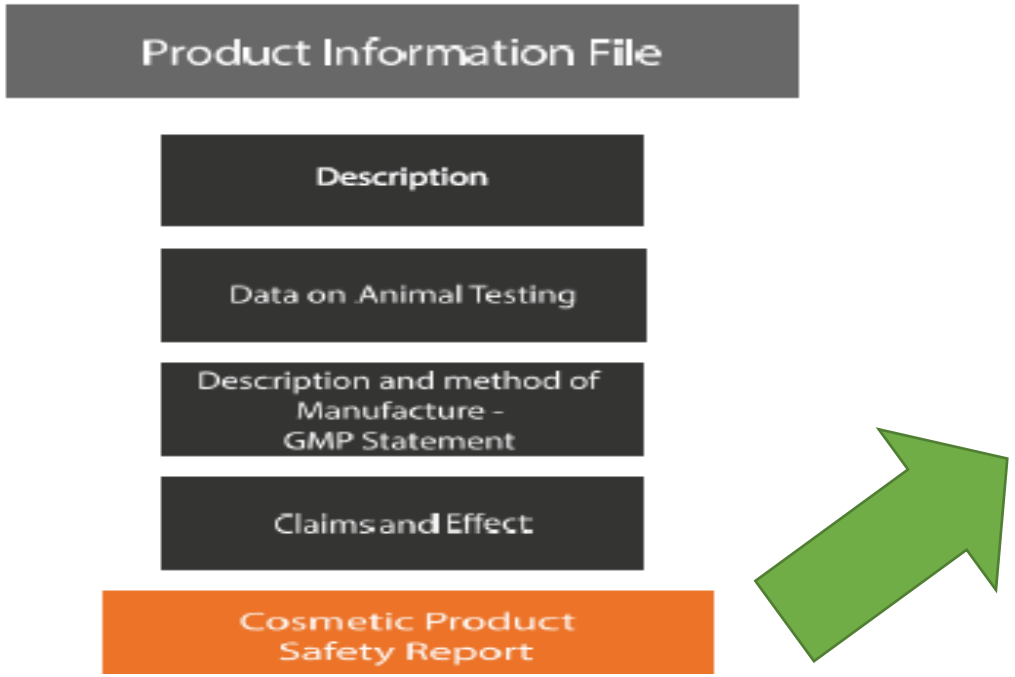
WHAT IS REQUIRED?

1. **Product Information File**
2. **Cosmetic Product Safety Report**
3. **Signed Safety Assessment**
4. **Legal appointment of a Responsible person (RP)**
   a. RP is LEGALLY responsible for the SAFETY and COMPLIANCE of the **cosmetic product**
   b. Default RP:
      I. EU Manufacturer
      II. EU Importer
      III. Distributor if product is changed in any way
   c. RP Legally appointed

WHAT IS REQUIRED?

5. **Registration on the CPNP:** https://ec.europa.eu/growth/sectors/cosmetics/cpnp_en
    a. The CPNP is accessible to:
        I. Poison Centres
        II. Competent Authorities
        III. Responsible Person (RP)
        IV. Distributors (where legal RP)

Cosmetic EU Legislation



PART A
Cosmetic Product Safety Information

- Composition of Cosmetic Product at substance level and function of each component in formulation;
- Physical and chemical characteristics of cosmetic product and components;
- Stability;
- Microbiological quality – product and raw materials (including Challenge test);
- Impurities;
- Clinical and Market trials;
- Packaging material information;
- Foreseeable use, storage conditions and misuse;
- Market surveillance;
- Exposure to the Cosmetic Product -Margin of Safety (MoS) -calculated for each component including contaminants based on the human toxicological profile of each component;
- Undesirable effects;
- Additional Information;

PART B
Cosmetic Product Safety Assessment

- Assessment conclusion and reasoning;
- Labelled warnings and instructions of use;
- Assessor's credentials
- Assessor's approval (signing) of part B.

CHECKLIST for INFORMATION required for a PIF

- Details of Brand owner
- Details of EU Importer
- Details of EU distributor or re-packer
- Details of Original Manufacturer
- Details of Responsible Person in the EU
- Countries that product will be sold in the EU
- Details of Safety Assessor for the EU
- Formulation
  - Exact % of each chemical in the cosmetic product
- Frame Formulation
  - Formulation and function of each ingredient

CHECKLIST for INFORMATION required for a PIF

- Physical and Chemical of individual ingredients
  - Solubility
  - Particle size
  - pH
  - Nano?
  - Contaminants
  - Heavy metals
- Supplier SDS's
- Technical Data sheets or Certificates of Analyses:
- GLP analyses
- GMP statement

CHECKLIST for INFORMATION required for a PIF

- Source of Raw Material/Ingredient
  - Botanical
  - Animal
  - Mineral
  - Biotechnology
- Supplier SDS's
- Technical Data sheets or Certificates of Analyses:
- GLP analyses
- GMP statement

CHECKLIST for INFORMATION required for a PIF

- Cosmetic Product Information
  - Brand;
  - Product Name;
  - Product Code;
  - Formula code and Name;
  - Use instructions;
  - User group/s: Adult, Baby, Children (Age range), elderly
  - Foreseeable uses;
  - Recommended warnings;
  - User group – consumer, professional, industrial;

CHECKLIST for INFORMATION required for a PIF

- Cosmetic Product Information
  - Physical form (Solid, emulsion, aerosol, liquid, liquid with different phases, gas);
  - Homogeneity and stability;
  - pH of final formulation;
  - Viscosity;
  - UVA, UVB tests results if sun protection formula;
  - If solid powder, particle size distribution, inhalable fraction;
  - If a sprayed formulation, a description of the droplet size, density;
  - Any further physical and chemical properties if relevant for safety evaluation;
  - Complete Challenge tests for formula;
  - Complete stability testing or in process with interim report suggesting self-life period based on testing regime;
  - Microbiology testing protocol for final product must be provided

CHECKLIST for INFORMATION required for a PIF

- Cosmetic Product Packaging
  - Food grade certificate for each component of the packaging – if not available, leach test for each component as per a recognised food packaging standard method;
  - Complete stability tests for using exact formula in the exact packaging to be placed on the EU market; Any changes to formula require a new stability test;
  - Exact excerpt/description/photos of all labels and wording (PDF);
  - Photos of all packaging parts;
  - Net Weight/volume as defined by EU regulation and E-mark if applicable complying with EC:76/21,
  - Volume of packaging (empty)

CHECKLIST for INFORMATION required for a PIF

- Non-animal testing declaration
- Market Surveillance Report
- Claims/advertising
  - Any reference to healing must be accompanied by a medico-clinical trial;
  - Any claims must be accompanied by the necessary test reports to substantiate the claim
  - Legal claims e.g. this product complies with EU regulations is not allowed.
  - Claim must be truthful;
  - Relevant evidential support required for claims;
  - Claims should be honest – example if a claimed is based on a combined use with another product in the range this should be specified;
  - No claim can be made that a sunscreen 100 % protection from UV radiation (such as ‘sunblock’, ‘sunblocker’ or ‘total protection’;

CHECKLIST for INFORMATION required for a PIF

- Claims/advertising
  - Sun protection level must be determined using standardised, reproducible test methods;
  - Claims should be fair – should be objective and should not unfairly criticize ingredients e.g. does not contain parabens;
  - Claims should be clear and understandable;
  - Market data may be a legitimate source in order to substantiate a claim (e.g. “best seller in France” – must be substantiated by sales data for the are specified).
  - Validity of consumer questionnaires must be demonstrated in terms of being clear and well understood by participants must be. A report should be made available that clearly identifies the product that was surveyed.
  - The term **hypoallergenic** must be substantiated with robust statistically, reliable, scientific user information and the product may not contain any allergens that have been identified in legislation, classified under GHS/CLP, reported as allergens/sensitizers by the SCCS or any other official risk assessment committee, generally recognised;

FRAME FORMULA

Raw material trade name	% in formula	Density	Refractive index	Max % contaminants	Appearance	Cosmetic function
Water						
INCI n						%
Aqua						100.0000 - 100.0000
Sulfochem ES-7						osting
INCI n						%
Sodiu						67.0000 - 71.0000
Aqua						29.0000 - 33.0000
Sodiu						0.0000 - 2.5000
Sodiu						0.0000 - 0.6000
1,4-Di						0.0000 - 0.0010
Plantacare 818						)
INCI n						%
Aqua						47.0000 - 49.0000
Laury						30.0000 - 50.0000
Capry						10.0000 - 20.0000
Magn						0.0000 - 0.0500
Dehyton KE						osting
INCI n						%
Aqua					7732-18-5 231-791-2 Ingredient	63.0000 - 64.0000
Cocamidopropyl Betaine					61789-40-0 263-058-8 Ingredient	30.0000 - 30.0000
Sodium Chloride					7647-14-5 231-598-3 Contaminant	5.5000 - 6.0000
Sodium Benzoate					532-32-1 208-534-8 Additive	0.5000 - 0.5000
Sodium Chloride (Orica)	1.000000		Unknown			oral care
INCI name					CAS number EC number Composition function	%
Sodium Chloride					7647-14-5 231-598-3 Ingredient	99.6000 - 100.0000

INCI name	Dermal absorption(%)	Log P(o/w)	Mol weight	SED (dermal) chronic (mg/kg.bw/day)
Aqua	1			0.029018
Sodium C10-16 Pareth-2 Sulfate / Sodium Laureth Sulfate	100		385	0.280000
Lauryl Glucoside	0.01	NA	348,47	0.000007
Sodium Chloride	100	-3,0	58,5	0.036450
Caprylyl/Capryl Glucoside	0.01	0,89	292	0.000002
Cocamidopropyl Betaine	6	NA	350	0.000600
Dipropylene Glycol	100	-0,462	134	0.008333
Sodium Sulfate	100	-3	142,04	0.005000
Sodium Hydroxymethylglycinate	100	-6,19	127,1	0.003333
Methyldihydrojasmonate	45.9	2,93	226,3	0.001148
Tetramethyl Acetyloctahydronaphthalenes	15	5,65	234,4	0.000250
Ethylene Dodecanedioate	100			0.000833
Tetrahydro-Methyl-Methylpropyl)-Pyran-4-Ol	40	1,65	172,27	0.000333
Isobornyl Acetate	100	3,86		0.000833
2-Methyl 5-Phenylpentanol	40			0.000247
Limonene	0.16	4,38	136,23	0.000001
2-T-Butylcyclohexyl Acetate	40	3,96	198,3	0.000133
Sodium Benzoate	100	-2,27	144,11	0.000167
Dimethyltetrahydro Benzaldehyde	100	2,67	138,21	0.000100
Hexyl Acetate	100			0.000100
Gamma-Undecalactone	40	3,6	184	0.000040
Magnesium Oxide	100		40,3	0.000042

CALCULATING MARGIN OF SAFETY

Skin Surface Area exposed: SCCS Notes of Guidance (2018)

Data source: RIVM (Bremmer, 2006)

Data source: Colipa studies (Hall, 2007; Hall, 2011)

Product type	*Surface area involved (cm^2)*	*Parameters (if specified)*	*Frequency of application*
Bathing, showering			
Shower gel	17500	total body area	1.43/day
Hand wash soap	860	area hands	10/day[3]
Bath oil, salts, etc.	16340	area body- area hands	1/day
Hair care			
Shampoo	1440	area hands+ ½ area head	1/day
Hair conditioner	1440	area hands+ ½ area head	0.28/day
Hair styling products	1010	½ area hands+ ½ area head	1.14/day
Semi-permanent hair dyes (and lotions)	580	½ area head	1/week (20min.)
Oxidative/ permanent hair dyes	580	½ area head	1/month (30min.)
Skin care			
Body lotion	15670	area body-area head (female)	2.28/day
Face cream	565	½ area head (female)	2.14/day
(+applied on neck)	320[1]		
(+ applied on back of neck)	80[1]		
Hand cream	860	area hands	2/day
Make-up			
Liquid foundation	565	½ area head (female)	1/day
Make-up remover	565	½ area head (female)	1/day
Eye shadow	24		2/day
Mascara	1.6		2/day
Eyeliner	3.2		2/day
Lipstick, lip salve	4.8[3]		2/day

CALCULATING EXPOSURE TO A SUBSTANCE

INCI name	Dermal absorption(%)	Log P(o/w)	Mol weight	SED (dermal) chronic (mg/kg.bw/day)
Aqua	1			0.029018
Sodium C10-16 Pareth-2 Sulfate / Sodium Laureth Sulfate	100		385	0.280000
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Gamma-Undecalactone	40	3,6	184	0.000040
Magnesium Oxide	100		40,3	0.000042

CALCULATING MARGIN OF SAFETY

$$MoS = \frac{POD\ (NOAEL/BMD)}{SED}$$

SAFETY ASSESSMENT

INCI name	End point	Property	Value	MoS / Evaluation	Source
	Chronic toxicity	Chronic toxicity - Oral NOAEL	1000	> 1000	ECHA, IUCLID 5
	Skin irritation	Irritation - Skin	Irritant	No evidence	Reach Registration File 11-2-2019 Löffler H1, Happle R. Contact Dermatitis. 2003 Jan;48(1):26-32
	Skin sensitization	Sensitisation - Skin	Not sensitizing	No evidence	ECHA, IUCLID 5
	Reprotoxicity	Reprotoxicity (fertility) - Oral NOAEL	> 1000	> 1000	CIR Final Safety Assessment Decyl Glucoside and Other Alkyl Glucosides as Used in Cosmetics, December 19, 2011
	Reprotoxicity (development)	Reprotoxicity (development) - Oral NOAEL	> 1000	> 1000	CIR Final Safety Assessment Decyl Glucoside and Other Alkyl Glucosides as Used in Cosmetics, December 19, 2011
Sodium Chloride					
	Chronic toxicity	Chronic toxicity - Estimate oral	1330	> 1000	ECHA, IUCLID 5 (ref. Exp Supporting Repeated dose toxicity: oral.003)
	Skin irritation	Irritation - Skin	Slightly irritant	No evidence	ECHA, Reach Registration Toxicological File 26-Feb-2019
	Skin sensitization	Sensitisation - Estimate skin	Not sensitizing	No evidence	ECHA, IUCLID 5, Herouet et al., 1999, Contact sensitizers decrease 33D1 expression on mature Langerhans cells, European Journal of Dermatology. Volume 9, Number 3, 185-90, April- May 1999, Revues
	Carcinogenic potential	Carcinogenicity - Oral NOEL	Not carcinogenic	No evidence	ECHA, IUCLID 5
	Reprotoxicity	Reprotoxicity (fertility) - Estimate fertility	Not reprotoxic	No evidence	Reach Registration File 08-10-2019
	Reprotoxicity (development)	Reprotoxicity (development) - Estimate development	Not teratogenic	No evidence	Reach Registration File 08-10-2019
Caprylyl/Capryl Glucoside					
	Chronic toxicity	Chronic toxicity - Dermal NOAEL	540	> 1000	Report Alkyl Polyglycoside Surfactants, GRAS approval
	Skin irritation	Irritation - Skin	Moderately irritant	No evidence	MSDS Cognis; Löffler H1, Happle R. Contact Dermatitis. 2003 Jan;48(1):26-32
	Skin sensitization	Sensitisation - Human skin	Not sensitizing	No evidence	Report Alkyl Polyglycoside Surfactants, GRAS approval
	Carcinogenic potential	Carcinogenicity - Estimate	Not carcinogenic	No evidence	Based on the results for mutagenicity and genotoxicity.
	Reprotoxicity	Reprotoxicity (development) - Oral NOAEL	1000	> 1000	Report Alkyl Polyglycoside Surfactants, GRAS approval
	Reprotoxicity (development)	Reprotoxicity (development) - Oral NOAEL	1000	> 1000	Report Alkyl Polyglycoside Surfactants, GRAS approval

PIF CONTENT

CONTENT ACCORDING TO ARTICLE 11 REGULATION (EC) NO 1223/2009

1. Product description
2. Cosmetic Product Safety Report

   Part A Cosmetic product safety information
   1. Quantitative and qualitative composition
   2. Physical/chemical characteristics and stability
   3. Microbiological quality
   4. Impurities, traces, information about the packaging material
   5. Normal and reasonably foreseeable use
   6. Exposure to the cosmetic product
   7. Exposure to the substances
   8. Toxicological profile - Margins of safety
   9. Undesirable effects and serious undesirable effects
   10. Information on the cosmetic product

   Part B Cosmetic product safety assessment
   1. Assessment conclusion
   2. Labelled warnings and instructions of use
   3. Reasoning
   4. Assessor's credentials and approval of part B

3. Method of manufacture and statement of GMP compliance
4. Proof of effect for the product
5. Data on animal testing

Cosmetic EU Legislation

Regulatory Process

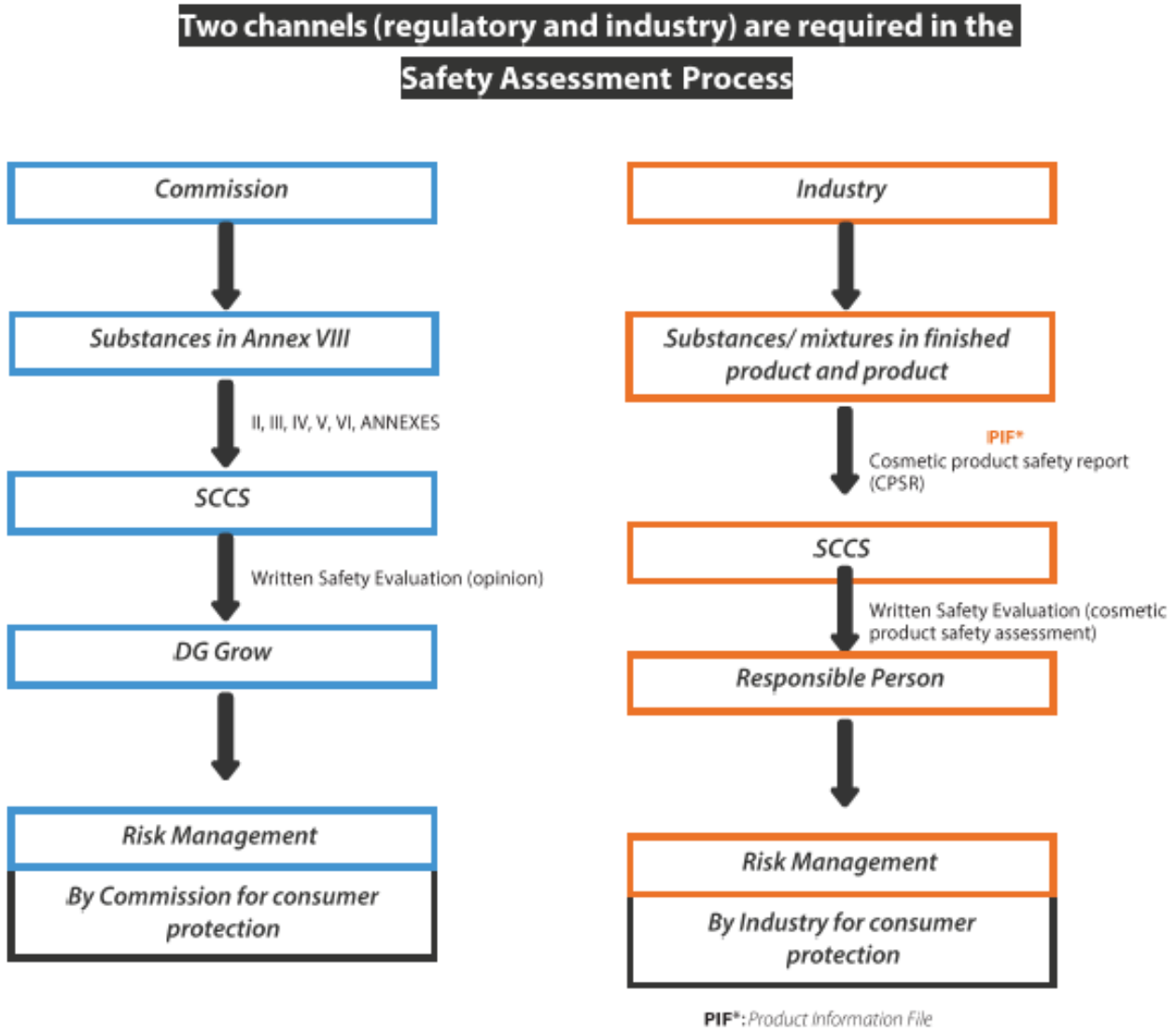


Figure1: Human health safety evaluation of cosmetic ingredients in the EU

Reference: SCCS NoG rev 10 2018

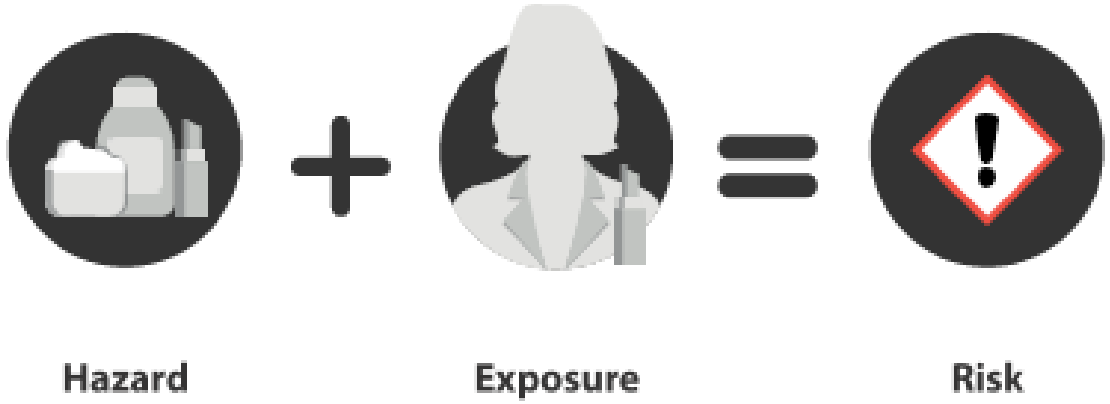
WHAT IS REQUIRED? Guidelines to be followed:

1. Independent non-food scientific Committees:
   a. Scientific Committee on Consumer Safety (SCCS)
   b. Scientific Committee on Health, Environmental and Emerging Risks (SCHEER)
2. SCCS Notes of Guidance (NoG – latest: Rev 10)
3. SCCS opinions
4. Proven Scientific approaches
5. The European Food Safety Authority (EFSA)
6. The European Medicine Agency (EMA)
7. The European Centre for disease Prevention and Control (ECDC)
8. The European Chemical Agency (ECHA)

WHAT IS SAFE?

Section 9 of the regulation states:

"Cosmetic products should be safe under normal or reasonably foreseeable conditions of use. In particular, a risk-benefit reasoning should not justify a risk to human health." The safety risk is assessed by looking at:



FAQs and GUIDANCE

- **Testing ban on animals for FINISHED COSMETICS?**
  - 11 Sep 2004
- **Testing ban on ingredients**
  - 11 March 2009
- **What is a Borderline Product?**
  - Is an item of clothing that releases a substance onto the skin a cosmetic?
  - Is a patch a cosmetic product?
  - Is a washable tattoo a cosmetic?
  - Is a toothpaste a cosmetic?
  - Is a seed oil which is placed directly on the skin a cosmetic?
  - Is a wipe a cosmetic?

FAQs and GUIDANCE

- **What is a Borderline Product?**
  - Is a wet razor that releases a substance a cosmetic?
  - What is the definition of food in the EU?
    - any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans.
  - Bath products for children with a play value?
    - What is the main purpose? Toy or cosmetic?
  - Is an essential oil that is intended to be inhaled a cosmetic?
    - definition of cosmetic products covers "any substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity so inhalation is NOT covered

FAQs and GUIDANCE

- **What is a Borderline Product?**
  - Is a leave on product which according to its presentation an antiseptic/antibacterial a cosmetic product?
    - A product which presents itself as “antiseptic” or “antibacterial” may be a biocidal product, a cosmetic product, a medicinal product or a medical device
    - Treating or preventing disease
    - Case-by-case basis

REFER TO THE MANUAL OF THE WORKING GROUP ON COSMETIC PRODUCTS (SUB-GROUP ON BORDERLINE PRODUCTS) ON THE SCOPE OF APPLICATION OF THE COSMETICS

FAQs and GUIDANCE

- Who needs to register the product on the CPNP?
- The RP which by default is:
  - EU Manufacturer
  - EU Importer
  - Distributor if product is changed in any way e.g. re-packed
  - Alternatively, a company selling cosmetics in the EU may legally appoint an INDEPENDENT RP;

RESULTS GAP ANALYSIS

COSMETICS

- **Gap 1: No evidence that the EU cosmetic regulatory requirements were taken into account prior to the formulation and during the planning**

- **Gap 2: Full manufacturing methods were not submitted and evidence of GMP**

- **Gap 3: Detailed use instructions on labels were not available**

- **Gap 4: Detailed description of the application**
  - Where the product is to be applied
  - How it is to be applied
  - What sector of the population is it intended for (babies, children, adults, aged-adults)
  - Foreseeable uses

RESULTS GAP ANALYSIS

COSMETICS

- **Gap 5: Non-animal testing data not supplied for raw materials or products**
- **Gap 6: Description and Method of manufacturing according to GMP not supplied**
- **Gap 7: Detailed precautions were not supplied on labels;**
- **Gap 8: Details of allergens in ingredient list not provided on the labels that were provided**

RESULTS GAP ANALYSIS

COSMETICS

- **Gap 9: Correct INCI names in correct order for the labels**

- **Gap 10: Net weight/volume and correct spacing not correct on the labels that were provided**

- **Gap 11: Ongoing market surveillance reports**
  - complaints
  - Compliments
  - adverse effects
  - medical report for adverse effects

- **Gap 12: use of REACH registered raw materials**

COSMETICS

- **Gap 13: Claims on labels are made as part of the description of the product/s with no supporting clinical/market trials**
  - Medical clinical trials required for any references to healing
  - Claims must be substantiated by test reports
  - Legal claims e.g. this product complies with EU regulations is not allowed
  - Claim must be truthful
  - Claims should be honest – e.g. claim based on a combined use with another product in the range this should be specified
  - No claim can be made that a sunscreen 100 % protection from UV radiation (such as ‘sunblock’, ‘sunblocker’ or ‘total protection’;
  - Sun protection level must be determined using standardised, reproducible test methods
  - Claims should be fair –should not unfairly criticize ingredients e.g. does not contain parabens;

COSMETICS

- **Gap 13 cont: Claims on labels are made as part of the description of the product/s with no supporting clinical/market trials**
  - Claims should be clear and understandable;
  - Market data required to substantiate a claim e.g. “best seller in France” – must be substantiated by sales data for the are specified
  - Validity of consumer questionnaires must be demonstrated in terms of being clear and well understood by participants must be. A report should be made available that clearly identifies the product that was surveyed.
  - The term hypoallergenic cannot be used unless substantiated by scientific user information and the product may not contain any allergens that have been identified in legislation, classified under GHS/CLP, reported as allergens/sensitizers by the SCCS or any other official risk assessment committee, generally recognised

- **Gap 14: Claims made by using product names that border on medicinal claims**

RESULTS GAP ANALYSIS

COSMETICS

- **Gap 15: Raw Material Analyses were copied and summarised on supplier COA's**
  - no reference to the performing laboratory
  - no refence to a qualified signatory
  - no reference to accreditation or GLP

- **Gap 16: Raw Material Detailed information**
  - Require detailed component information
  - Frame formulations
  - Exact formula content down to substance level
  - Non-compliant SDS for raw materials
  - Limited storage condition information

RESULTS GAP ANALYSIS

COSMETICS

Gap 17: PIFs and Safety Assessments

- Except for 3 submissions
- no refence to a qualified signatory
- no reference to accreditation or GLP

Gap 18: Packaging Information

- No food grade packaging used
- If not food grade, no leach testing provided
- Details of all components of packaging not available

RECOMMENDATIONS

COSMETICS

1. Develop an action plan to provide Industry with a set of guideline documents for the regulatory requirements for the EU.
2. Provide a “knowledge database” to industry of available expertise in South Africa
3. Provide industry with guideline documents for the safe use levels of indigenous oils in cosmetic products as per the product types listed by the SCCS notes of guidance (NoG)
4. The use of REACH registered raw materials.
5. Ensure that suppliers of raw materials are able to provide the level of information that will be required for the Safety assessment
6. Availability of an non-animal testing declaration for all raw materials and final product
7. All analyses are declared to have been conducted according to EU regulatory requirements and were conducted according to GLP;

RECOMMENDATIONS

COSMETICS

8. All necessary physical and chemical test have been conducted or are available for the final product;
9. Microbiological testing including challenge tests available for the final product formulation;
10. Stability tests available under variable conditions to determine shelf life as per EU requirements has been conducted for the exact formulation (no substitution of raw materials, if so, then test must be repeated. This applies to all testing conducted on the final product);
11. Sourcing of food grade packaging (all components);
12. Manufacture of product according to the principles of GMP;
13. Be sure to identify all components/substances for all the raw materials
14. Identify all preservatives, additives and impurities

RECOMMENDATIONS

COSMETICS

15. Microbiological testing of raw materials and final product including challenge tests;
16. Additional information required for natural ingredients
17. Frame formulation (% of each raw material and the intended use in the)
18. Exact % of each chemical in the cosmetic product (Formulation)
19. All claims are supported by either clinical or market data.
20. Keep an ongoing market surveillance report

TEA BREAK

Brazil

- In Brazil the Health Regulatory Agency (**ANVISA**) is an autarchy linked to the Ministry of Health, part of the Brazilian National Health system (SUS)
- ANVISA acts as the coordinator of the Brazilian Health Regulatory System (SNVS)
- ANVISA's role is to promote the protection of the population's health by implementing sanitary control of the production, marketing and use of products and services subject to:

- Health regulation
- Processes
- Ingredients and technologies
- Control in ports
- Control in airports
- Control at borders

Brazil

- "Pre-market approval" : is the legal act that recognizes the suitability of a product to the Brazilian sanitary regulation, and it is issued by ANIVISA
- Pre-market approval is a control measure only for the categories of products that are considered to be of greatest health risk
- Pre-market approvals are published in the Official Gazette
- Once pre-market approval is published in the official gazette for a product, this publication can be used as proof from ANVISA, as an exemption from having to submit further documentation such as certificates and declarations and the product can be freely marketed in the Brazilian territory

Brazil- Foreign companies

- Like the REACH regulation in the EU, in Brazil foreign companies cannot make administrative arrangements for issuing of pre-market approvals directly from ANIVISA

- Foreign companies must have partner companies legally constituted in Brazil that will be legally responsible for the products imported to and distributed in the Brazilian territory, very similar to the role of the Only representative in the EU.

DEVELOPING COUNTRIES

Brazil

Recognised as a National Regulatory Authority of Regional Reference by the Pan American Health Organization

2010 → **2012** → **2015** → **2016**

DEVELOPING COUNTRIES

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Co-founds the International Medical Device Regulators Forum (IMDRF)

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Controls performed by ANVISA for pharmaceutical ingredients are recognised as equivalent to those of the European community

Member of the International Cooperation on Cosmetics Regulation (ICCR)

2016

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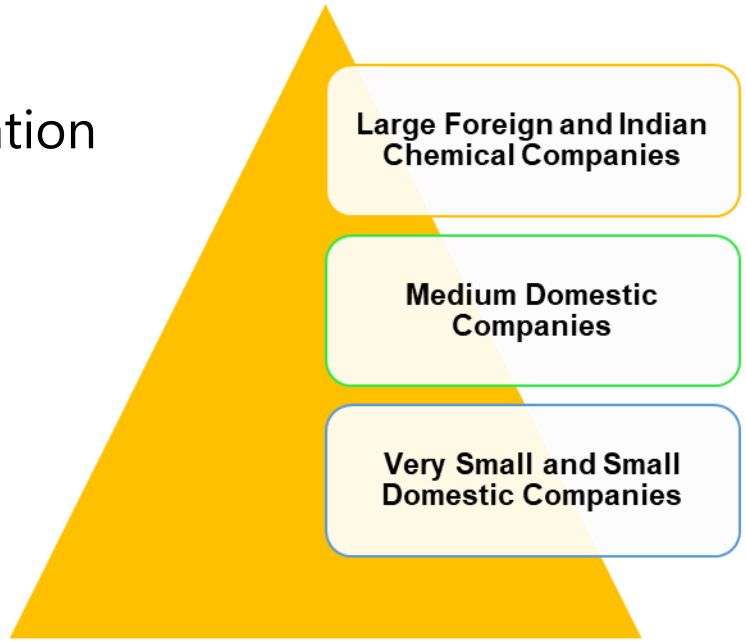
Member of the International Cooperation on Cosmetics Regulation (ICCR)

2016

member of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH)

India

- The regulations and legislations for chemicals management in India are not at the level of European regulations such as REACH
- Formal and informal Chemical industry is very strong in India
- India's fragmented Chemical industry is what drives legislation



India

- India is reluctant to participant in most international treaties
- Locally India's chemical industry operates outside of global standards
- There is no centralised REACH body to monitor REACH preparedness, instead have many ministries such as:
  - Ministries of Chemicals and Fertilizers,
  - Ministry of Commerce and
  - Ministry of Environment & Forests issues guidelines related to environment, etc

CHEMEXCIL
Basic Chemicals, Cosmetics & Dyes Export Promotion Council
(Set up by the Ministry of Commerce & Industry Government of India)

India

- Ministry of Commerce supports the REACH-compliance needs of Indian Chemical companies through CHEMEXCIL REACH-Help desk

- Confederation of Indian Industry (CII) along with Sustainability Support Services (SSS) Europe also provides REACH Support through their Help desk, for Indian companies

CHEMEXCIL
Basic Chemicals, Cosmetics & Dyes Export Promotion Council
(Set up by the Ministry of Commerce & Industry Government of India)

CHEMEXCIL

- Basic Chemicals, Cosmetics & Dyes Export Promotion Council popularly known as **CHEMEXCIL**
- Founded by the Ministry of Commerce & Industry Government of India in 1963
- >4000 members
- Website: Make trade enquiries and view trade enquiries

CHEMEXCIL
Basic Chemicals, Cosmetics & Dyes Export Promotion Council
(Set up by the Ministry of Commerce & Industry Government of India)

CHEMEXCIL

❖ Objective promote exports from India to various countries abroad.

- Panel I: Dyes and dye intermediates
- Panel II: Basic inorganic and organic chemicals, including Agrochemicals
- Panel III: Cosmetics, Soaps, Toiletries & Essential Oils
- Panel IV : Specialty Chemicals, Lubricants and Castor oil

WORKSHOP QUESTION?

- **What do you think are the Benefits of REACH and CLP in developing countries?**

TAKE HOME

Benefits of REACH and CLP in developing countries

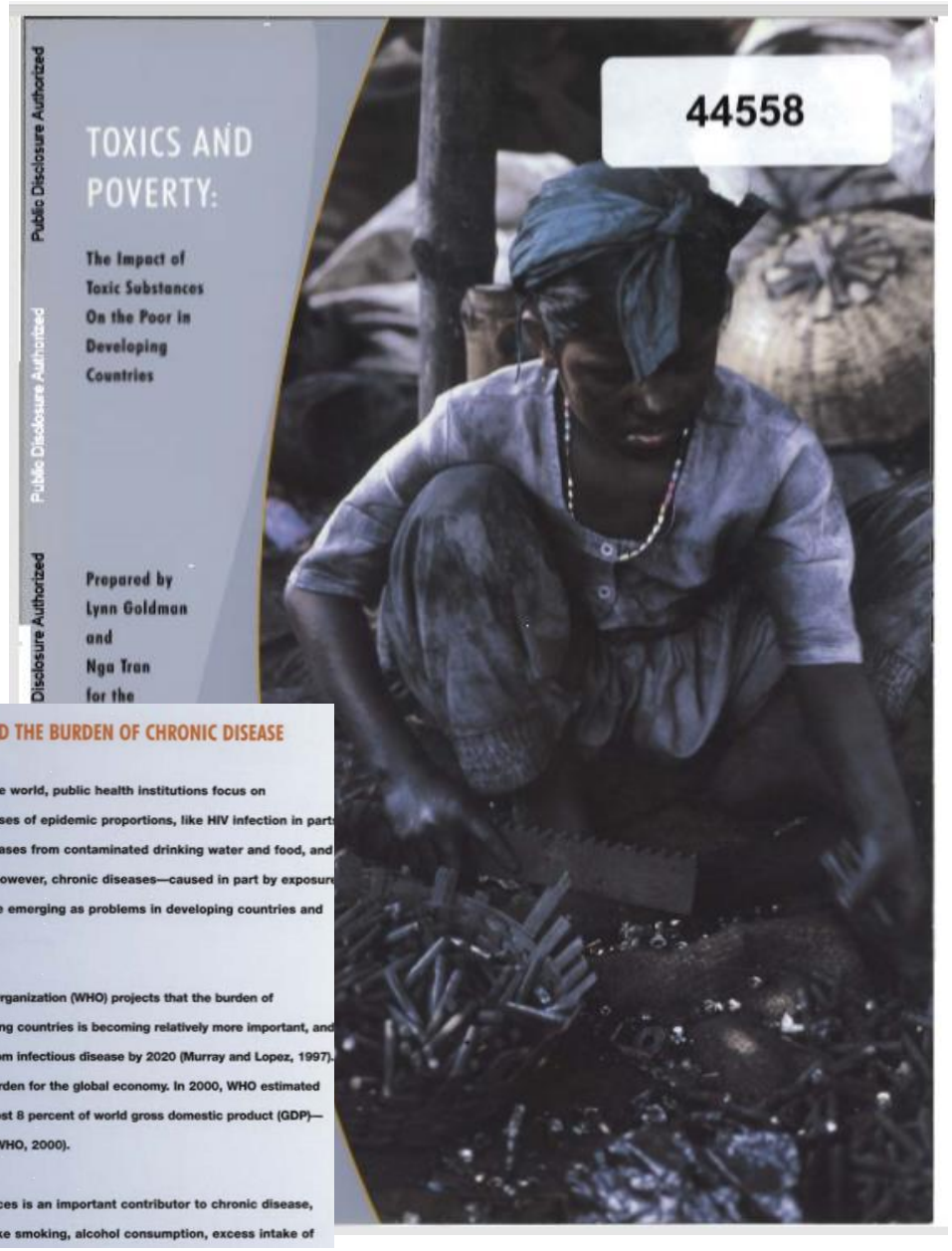
- Regulation of hazardous chemicals should not be viewed as a rich country's luxury imposed on low income exporters.

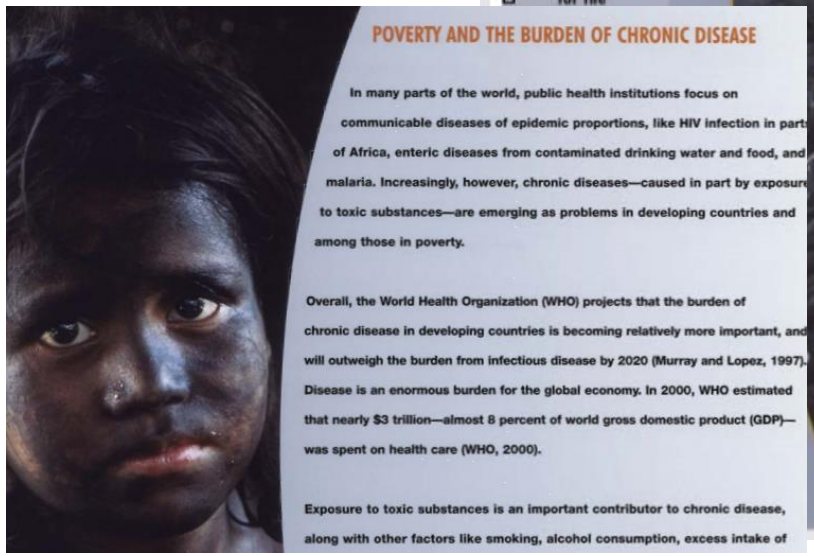
- Businesses will gain access to crucial information about the effects of their products and the materials and substances they use:
  - this will help them to identify and adopt safer alternatives,
  - avoid future liability for damages

- Public health will be improved by better information and appropriate limits on chemical exposures.

CONCLUSION

- Goldman and Tran, 2002 prepared a report to the World Bank: toxic chemicals are a significant and growing threat to health among the poor in developing countries
- Toxic exposures,
- Chronic diseases are increasing in developing countries and are expected to exceed the burden from infectious disease by 2020





CONCLUSION

Benefits of REACH and CLP in developing countries

- Workers will benefit
- Compliance with REACH will also facilitate developing countries' efforts to create domestic systems for sound chemicals management (Gärtner *et al.*, 2003)

GHS regulatory support

- **Don’t Worry , Be happy : there are consultants and supporting software in the market**

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Thank you!

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