Cosmetics: Regulation, Ingredient and MSDS







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Outline:

- EU Cosmetic Regulation (EC1223/2009)
 - Definition
 - Annex
 - Product information file (PIF)
 - Cosmetic Product Safety Report (CPSR)
- Ingredient: COSING
 - INCI
 - Registration
 - REACH
- MSDS
 - Content
 - How to make MSDS

EU Regulation (EC 1223/2009)

28 Member States + 3 EEA countries + Monaco

Austria Italy Belgium Latvia Bulgaria Lithuania Croatia Luxembourg Cyprus Malta Czech Republic Netherlands Denmark Poland Estonia Portugal Finland Romania France Slovakia Germany Slovenia Greece Spain Sweden Hungary Ireland United Kingdom Iceland Norway Principality of Liechtenstein

Principality of Monaco (EU agreement signed)



All these countries follow Regulation (EC) No 1223/2009 on cosmetic products

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Product information file: PIF

- 1. Description of the cosmetic product
- 2. The Cosmetic Product Safety Report
 - Part A: Safety information on ingredient and product
 - Part B: Safety assessment
- 3. Manufacturing method + GMP Compliance statement
- 4. Proof of the effects claimed
- 5. Data on animal testing

Content of Safety assessment

PART A: safety information on ingredients and product

- 1. Qualitative and quantitative composition of the product
- 2. Physical/chemical characteristics and stability of the product
- 3. Microbiological quality
- 4. Impurities, traces, information on packaging material
- 5. Normal and reasonably foreseeable use
- Exposure to the cosmetic product
- Exposure to the substances
- 8. Toxicological profile of the substances
- 9. Undesirable effects and serious undesirable effects
- 10. Information on the cosmetic product

PART B: safety assessment

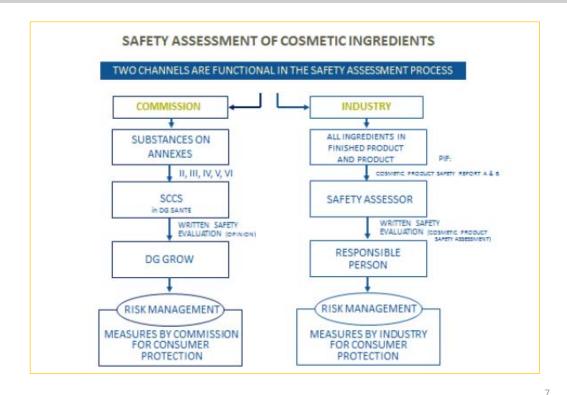
- 1. Assessment conclusion
- 2. Labelled warnings and instructions of use
- 3. Reasoning
- Assessor's credentials and approval

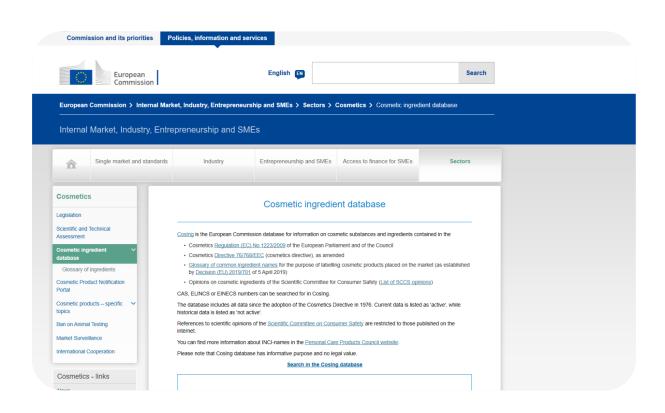
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Product information file: PIF

- Products which is placed on the market
- Responsible person: kept for a period of 10 years after the last batch of cosmetic product
- Electronic or other format
- Available in a language which can be easily understood by the competent authorities of the Member State

Actual EU Cosmetics Legislation















SulforaWhite Phyto agent for visible whitening

SulforaWhite Phyto agent for visible whitening

Whitening with a New Mechanism

SulforaWhite is a liposomal preparation of Swiss garden cress sprouts rich in sulforaphane, a powerful antioxidant phytonutrient.

Market trends reflect a general demand for whitening products to lighten the skin complexion, to lessen differences in pigmentation but also to give a more radiant look. SulforaWhite effectively inhibits pigmentation by targeting two key upstream reaction steps in the melanin cascade:

- · Neutralization of reactive oxygen species
- Inhibition of α-MSH, a natural hormone which stimulates skin pigmentation.

To facilitate absorption into the skin and to target melanocytes, garden cress extract was incorporated into liposomes.

The whitening effect of SulforaWhite was proven both in vitro and in vivo. Its mechanism was clearly demonstrated and its lightening efficacy was proven both on Asian and Caucasian skin types.

Claim Ideas for SulforaWhite

- · Effectively inhibits melanin formation
- · Provides exceptional brightening benefits
- Fades the appearance of dark spots and discolorations
- Reduces the effects of daytime stressors
- Evens skin tone

Applications

- Brightening for face and body
- Anti-aging with correction of age spot and pigmentation disorders
- · Protective formulations

Formulating with SulforaWhite

- Recommended concentration: 2-5%
- Incorporation: For cold processes, dissolve SulforaWhite into the aqueous phase. In cold/hot processes, add during the cooling phase below 40°C.
- Thermostability: temperatures of up to 60°C for a short time do not affect the stability of SulforaWhite.

INCI (EU/PCPC) Declaration

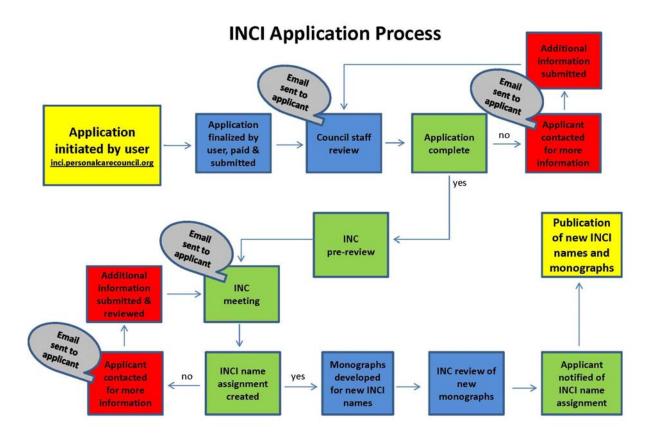
Lepidium Sativum Sprout Extract (and) Glycerin (and) Lecithin (and) Phenoxyethanol (and) Aqua/Water

Additional Information

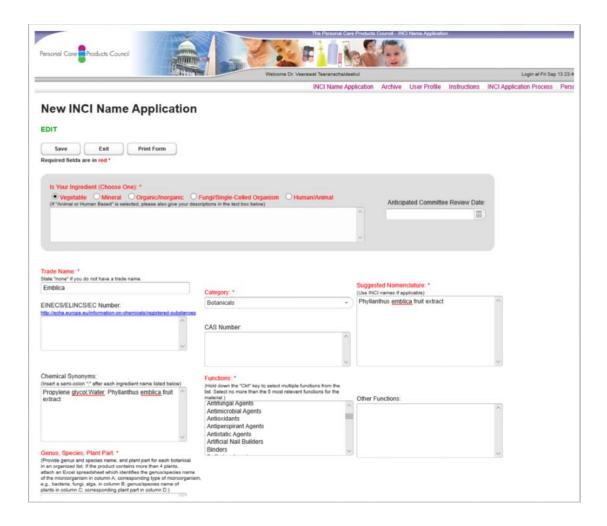
Available in a preservative-free version

INCI application

- One trade name per application
- Additional information: word, excel, pdf (Max: 8 MB)
- 400 US per application (credit card)







Category of ingredient

- Biotechnology
- Botanicals
- Ferments
- General chemistry
- Mineral/Inorganics
- Polymer/Silicones

Each category corresponds to a specific application which contains required fields about the ingredient's identity and composition. Details about these fields are described as follows

Trade Name – A trade name or commercial name for the ingredient should be provided. Applicants that do not want their trade name or company name published should check "no" at the end of the application where it states: "Do you want this trade name published in the International Cosmetic Ingredient Dictionary and supplier company name published in the Council's International Buyers' Guide?"

INCI application form

- Suggested Nomenclature Applicants may recommend an INCI name. Suggested names should be based on INCI Conventions. If you are submitting an ingredient that is similar to an existing INCI name, or relates to a trade name previously submitted by your company, be sure to provide this information.
- Chemical Structure Where applicable, structures may be submitted as attachments to the application. Descriptions for R groupings, (e.g., alkyl groups), or repeating units (e.g., moles ethylene oxide or propylene oxide) must be provided

- Empirical Formula Provide where applicable.
- CAS Number Provide if available. CAS Numbers are provided by the Chemical Abstracts Service and are unique numerical identifiers of chemical substances.
- Chemical Synonyms Provide related chemical, technical or common names
- Composition Statement If the final product is a blended mixture, identify the components in an organized list in descending order of predominance. Indicate approximate percentages of each component when possible. If the product is not a mixture, this field may be used to provide additional compositional information.

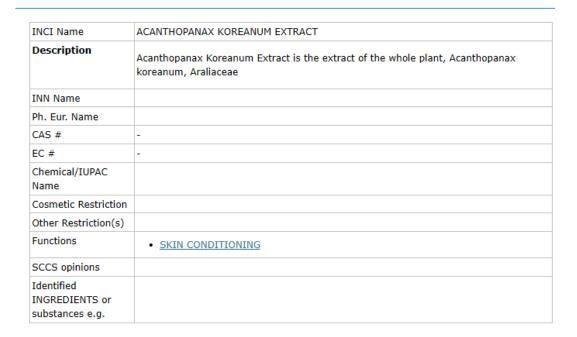
INCI application form

- Manufacturing Method A detailed, step-by-step manufacturing method must be provided, including complete identification of all starting materials.
 - Reaction schemes, flow charts or process diagrams are very helpful and may be added as an attachment.
 Preservatives used to protect the raw material are not typically included in the INCI name unless requested by the applicant
- **Solvents or Diluents** List the name and relative percentage of any solvents or diluents present in the raw material as it is sold for use in finished products.

- Botanicals: provide the genus, species and plant part for each botanical material in the product, and manufacturing information
 - If specific component(s) is isolated, the manufacturing information should clearly describe the isolation technique, the relative % purity of the isolated fraction based on <u>dry weight</u>, the chemical identity of the fraction and method used to characterize its identity and purity

Genus	Species	Plant Part
Daucus	sativa	Root
Pyrus	malus	seed, peel
Camellia	sinensis	Leaf
Glycine	soja	Whole

Ingredient: ACANTHOPANAX KOREANUM EXTRACT



Ingredient: ETLINGERA ELATIOR EXTRACT 🏂

INCI Name	ETLINGERA ELATIOR EXTRACT		
Description	Etlingera Elatior Extract is the extract of the whole plant, Etlingera elatior. See "Regulatory and Ingredient Use Information," regarding use of EU Trivial names in Volume 1, Introduction, Part A.		
INN Name			

Ingredient: ETLINGERA ELATIOR FLOWER EXTRACT

INCI Name	ETLINGERA ELATIOR FLOWER EXTRACT
Description	Etlingera Elatior Flower Extract is the extract of the flowers of Etlingera elatior, Zingiberaceae.

INCI application form

Animal-Derived Ingredients —For this category, applicants
must include the identity of the animal and its
genus/species, part of animal material is derived from, and
step-by-step details for manufacturing method. If a specific
component is isolated, the % purity of the isolated fraction
based on dry weight must be provided, its chemical identity
and method used to characterize the identity and purity.

NCI Name	SNAIL EXTRACT
Description	Snail Extract is the extract of the body of the snail, Pomacea canaliculata.
NN Name	

INCI Name	SNAIL SECRETION FILTRATE
Description	Snail Secretion Filtrate is the product obtained from the filtered secretion of one or more species of snails

INCI Name	SACCHAROMYCES/SNAIL SECRETION FILTRATE FERMENT FILTRATE
Description	Saccharomyces/Snail Secretion Filtrate Ferment Filtrate is a filtrate of the product obtained by the fermentation of Snail Secretion Filtrate (q.v.) by the microorganism, Saccharomyces.







• **Polymers** - The manufacturing details must list all starting monomers, all cross-linking agents, and a reaction scheme that describes step-wise process. For monomers that are alkoxylated, the degree of alkoxylation must be indicated (moles EO, PO, etc.) The degree of polymerization of any polyether must be provided. All R groups, (e.g., alkyl groups) must be disclosed.

Ingredient: CERAMIDE 3 % **INCI Name** CERAMIDE 3 Description Ceramide 3 (Retired) is the N-acylated phytosphingosine having the erythro structure that conforms generally to the formula, where m has a value ranging from 12 to 28 in which the acyl moiety may be saturated, mono-unsaturated, or di-unsaturated and n has a value ranging from 10 to 20. The INCI Name, Ceramide 3, originally developed in 1997, was designated with a retired status in 2014. For an interim period of time, trade name assignments formerly published with the INCI Name Ceramide 3 will be retained in the retired monograph, and also published with the new name assignment, Ceramide NP. CH3(CH2)nCH2CHCHCHCH2OH C(CH₂)_mCH₃ OH HN-

Ingredient :	CROSSPOLYMER

INCI Name	ACRYLATES/C10-30 ALKYL ACRYLATE CROSSPOLYMER
Description	C10-30 alkyl propenoate, polymer with propenoic acid, butenoic acidand/or alkyl propenoates, product with propenyl sucrose ether or propenyl 2,2-dihydroxymethyl-1,3-propanediol
INN Name	
Ph. Eur. Name	

SilSense® Copolyol-1 silicone has humectant properties and can be used to aid moisturization properties. It is pro-foaming and may be used in cleansers and personal wash products to enhance

In hair care applications, SilSense® Copolyol-1 silicone can be used in gels and fixatives to plasticize the polymers, thereby improving tactile properties without reducing hold.

In gel systems containing Carbopol® polymers, SilSense® Copolyol-1 silicone will add slip and improve feel. It will also serve to protect the polymer from salts, and is especially useful in aloe

SilSense® Copolyol-1 silicone is 100% active and is normally used at a level of 0.25 wt % to 5.0 wt % of a formulation.

White, waxy

solid

80

0.4

100

40 (104)

and stabilize foam.

vera gel formulations.

Typical Properties:

Appearance at 25°C (77°F)

Viscosity at 70°C (158°F), cps

Melt Point, COC, °C (°F)

pH, 1% in water

Active Content, %

Acid Value, mg KOH/gram





TDS-269 Edition: June 27, 2005 Previous Edition: March 3, 2002 / June 17, 2003

SilSense®* Copolyol-1 Silicone **Dimethicone Copolyol Blend**

Product Description:

SilSense® copolyol blends are proprietary blends of personal care grade polyethylene glycols and dimethicone copolyol (a copolymer of a pdydmethylsiloxane and polyovgalikylene ethylsilosse® Copolyol-1 silicone is 100% active, and its silicone portion has the chemical structure depicted below;

Features:

- Surfactant properties due to PEO pendant
- Surfactant properties due to PEO pendant group Soluble in a range of solvents, including water Compatible with resins Low-odor, oxidatively stable Compatible with a wide range of cosmetic

- · Suppresses static

Benefits:

- Useful as an emulsifier, co-emulsifier, wetting and spreading agent
 Plasticizes resins in hair spray and gel products without diminishing hold
- Imparts improved skin feel, wet and dry combability and conditioning of hair
 Reduces agglomeration of powders
 Applicable for use in fragrance-free formulations.

- formulations

 May reduce irritancy in anionic surfactant systems

CTFA / INCI Designation:

PEG-33 and PEG-8 Dimethicone and PEG-14

Suggestions for Use:

Dimethicone copolyol blends such as SilSense® Copolyol-1 silicone have different solubility characteristics and surface activity than dimethicones, resulting in a range of useful performance features and benefits.

SilSense® Copolyol-1 silicone is recommended for use in skin care emulsions and gels, such as moisturizing lotions and creams. SilSense® Copolyol-1 will help to improve skin care products by reducing tack, improving spreading, and providing the silicy skin feel associated with silicones, but without greasiness.

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Technical data file

Microbiology and Genetically Modified Organisms (GMO)

SilSense® Copolyol-1 silicone has passed Mixed Innoculum Preservative Efficacy Testing (Challenge Testing).

SilSense® Copolyol-1 silicone is manufactured solely from synthetic raw materials. It does not contain and is not derived from any material of plant or animal origin.

Regulatory Information

SilSense® Copolyol-1 silicone is exempt from TSCA according to the polymer exemption for personal care products. SiSense® Copolyol-1 silicone complies with the current European Union Cosmetic Directive.

Handling and Storage

SilSense® Copolyol-1 silicone should be used within one year of date of delivery.

Storage Conditions

SilSense[®] Copolyol-1 silicone should be stored in closed, factory sealed containers at temperatures not exceeding 90°F (32°C).

55 gallon non-returnable drum, 440 pounds net.

5 gallon pail, 40 pounds net.

General Information

Toxicological Data

Toxicological Data relating to SilSense® Copolyol-1 silicone is available upon request. Please contact your Lubrizol Advanced Materials, Inc. sales representative, or visit our website at www.personalcare.noveon.com.

SilSense® Copolyol-1 silicone is soluble in ethanol, propylene glycol and water. It is insoluble in isopropyl myristate and mineral oil.

The information provided above is indicative of typical values and properties for this product. These properties are not intended to be used as product specifications. Product specifications are available upon request.

 Ferments – Complete step-by-step details of the fermentation method should be provided in addition to a description of any downstream processing. Products that are derived by spontaneous fermentation, or co-fermentation, should be specified. The identity of the genus of all microorganisms must be provided; genus and species must be provided for pathogenic organisms.

Microorganism	Genus	Species	Plant Part	Other
Lactobacillus	Or y za	sativa	Whole	honey
Saccharomyces	Rosmarinus	officinalis	Leaf	royal jelly
	Phyllostachis	bambusoides	Rhizome	
	P y rus	malus	fruit, peel, seed	

INCI application form

- Minerals and Inorganics Mineral composition information must be provided, along with manufacturing details. For mined materials, describe mining process and particle size of final product. Attach X-ray diffraction pattern of product, synthesized and natural, in addition to a Bureau Standard.
- Biotech Ingredients Complete step-by-step manufacturing details must be provided.
 - For ingredients derived by plant tissue culture, process details are very important; clearly indicate when a callus is isolated, and if the culture media is removed from the final preparation.
 - For peptides, identify if the protein originates from a gene directly isolated from a human cell; or if it is a chemically synthesized copy of a human gene or gene fragment produced in a gene synthesizer. If the peptide is derived from other organisms, provide the common name and genus/species for the organism.
 - Provide the protein name and reference number; identify the total number of amino acids in the peptide; and attach a word document with complete amino acid sequence by single letter designation. If the peptide is a fusion peptide, provide the sequence for each fragment along with each corresponding protein name and protein reference numbers.
 - Provide % purity of the final protein and purification method. If the final product is a blended mixture, identify the components in an organized list in descending order of predominance. Indicate approximate percentages of each component when possible.

Mica

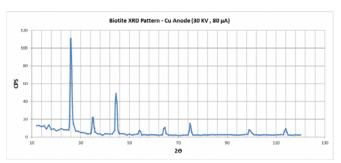


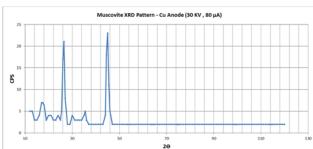
Chemically, micas can be given the general formula

 $X_2Y_{4-6}Z_8O_{20}(OH,F)_4$ Where

X is K, Na, Ca or less commonly Ba, Rb or Cs **Y** is Al, Mg, Fe or less commonly Mn, Cr, Ti, Li, etc.

Z is chiefly Si or Al but also may include Fe3+ or Ti





INCI Name	ACETYL HEPTAPEPTIDE-9		
Description	Acetyl Heptapeptide-9 is the reaction product of acetic acid and Heptapeptide-9		
INCI Name	OLIGOPEPTIDE-10		
Description	Alanine, 15-unit synthetic peptide with leucine, lysine, and phenylalanine		
INCI Name	HYDROLYZED PLACENTAL EXTRACT		
Description	Hydrolyzed Placental Extract is the hydrolysate of swine placental extract derived by acid, enzyme or other method of hydrolysis		
INCI Name	HYDROLYZED PLACENTAL PROTEIN		
Description Protein hydrolyzates, placenta. Substance obtained by acidic, alkaline, or e hydrolysis of placenta composed primarily of amino acids, peptides, and pr may contain impurities consisting chiefly of carbohydrates and lipids along quantities of miscellaneous organic substances of biological origin			

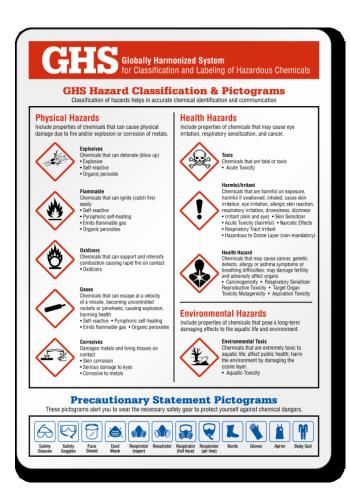


Safety Data Sheet (SDS)

- เอกสารข้อมูลความปลอดภัย ซึ่งเป็นเอกสารที่แสงดข้อมูลเฉพาะของสารเคมี แต่ละตัวเกี่ยวกับลักษณะความเป็นอันตราย พิษ วิธีใช้ การเก็บรักษา การ ขนส่ง การกำจัด และการจัดการอื่นๆ
- GHS (The Globally Harmonized System of Classification and Labelling of Chemicals: กำหนดให้มีการจัดทำ SDS และมีการกำหนด รูปแบบของ SDS
- REACH (Registration, Evaluation, Authorisation and Restriction of chemical)
- สหภาพยุโรปกำหนดให้ใช้เอกสารในห่วงโซ่อุปทานด้วย โดยผู้ประกอบการ ต้องแนบข้อมูลเกี่ยวกับลักษณะและโอกาสที่ผู้เกี่ยวข้องจะสัมผัสกับสารเคมี

องค์ประกอบของ SDS

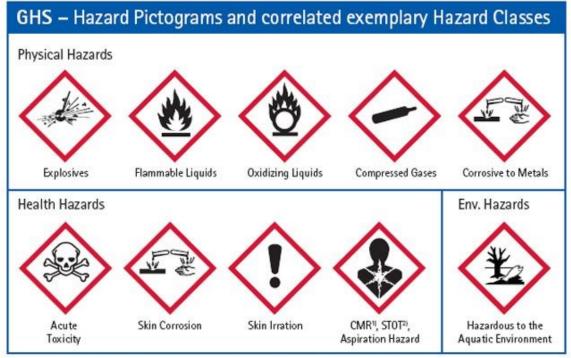
- 1. Identification
- 2. Composition/Information on ingredients
- 3. Hazards Identifications
- 4. First Aid Measures
- 5. Fire Fighting Measures
- 6. Accidental Release Measure
- 7. Handling and Storage
- 8. Exposure Controls/Personal Protection
- 9. Physical and Chemical Properties
- 10. Stability and Reactivity
- 11. Toxicological information
- 12. Ecological Information
- 13. Disposal Consideration
- 14. Transport Information
- 15. Regulation Information
- 16. Others



Hazard Classification

PHYSICAL HAZARDS	ASSOCIATED HAZARD CATEGORY
•	
	Innerdan, I & the less trouveless
•	Canada Lord 2
•	Calculate Land J
•	4 Strange Indials Consequent use Handles
	gas, Drivolved gas, and Rohlgerand
	Insulate and
•	Calauriu I. 4
•	1 1111 1111 1
•	Calcust
•	Catalogue
•	Calculate 1 and 2
•	Cologorius 1 + 3
•	
•	Calarata 1-3
•	
•	Cologory
HEALTH HAZARDS	ASSOCIATED HAZARD CATEGORY
HEALTH HAZARDS	ASSOCIATED HAZARD CATEGORY
Acute lexicity	ASSOCIATED HAZARD CATEGORY
Acute Inschip Sin concern	ASSOCIATED HAZARD CATEGORY
Acute lexicity	ASSOCIATED HAZARD CATEGORY
• Same records • Same records	ASSOCIATED HAZARD CATEGORY
•	Concerns 14 The Concerns of A 18 Concerns Concerns 1A 18 Concerns Co
•	ASSOCIATED HAZARD CATEGORY ASSOCIATED HAZARD CATEGORY
•	Concerns 14 The Concerns of A 18 Concerns Concerns 1A 18 Concerns Co

Hazard Classification



• Explosive: วัตถุระเบิด

• Flammable gas: ก๊าซไวไฟ

• Aerosol: สารละอองลอยไวไฟ

• Flammable liquid: ของเหลวไวไฟ

• Flammable solid: ของแข็งไวไฟ

• Pyrophoric: ลุกติดไฟได้เอง



• Self heating substances and mixtures: สารเคมีและสารผสมที่เกิดความร้อนได้เอง

• Oxidizing: ออกซิไดซ์

• Gas under pressure: ก๊าซภายใต้ความดัน

• Self-reactive substances and mixtures: สารเคมีและสารผสมที่ทำปฏิกิริยาได้เอง

Corrosive to metals: สารกัดกร่อนโลหะ

Health Hazard

- Acute toxicity : ความเป็นพิษเฉียบพลัน
- Target organ system toxicity-single exposure: เป็นพิษต่ออวัยวะเป้าหมายเจาะจง การได้รับ สัมผัสครั้งเดียว
- Target organ system toxicity-repeated exposure: เป็นพิษต่ออวัยวะเป้าหมายเจาะจง การ ได้รับสัมผัสหลายครั้ง
- Aspiration hazardous : อันตรายจากการหายใจ
- Skin corrosive/irritation: กัดกร่อน หรือระคายเคืองต่อผิวหนัง
- Serious eye damage/eye irritation: การทำลายดวงตาอย่างรุนแรง ระคายเคืองต่อดวงตา
- Respiratory or skin sensitization: กระตุ้นให้เกิดการแพ้ระบบทางเดินหายใจ หรือผิวหนัง
- Carcinogenicity: ก่อให้เกิดมะเร็ง
- Germ cell mutagenicity: การกลายพันธุ์ของเซลล์สืบพันธุ์
- Hazardous to the aquatic environment: ความเป็นอันตรายต่อสิ่งแวดล้อมทางน้ำ







Mixture: GHS (กายภาพ)

- มีข้อมูลของสารผสม ให้ใช้ข้อมูลของสารผสม
- หากไม่มีข้อมูลของสารผสม ใช้หลัก Bridging principle
- ไม่มีข้อมูลสารผสม ไม่สามารถใช้หลัก Bridging principle ให้อธิบายไว้ในแต่ละ ประเภทความเป็นอันตรายเพื่อคาดคะเนความเป็นอันตราย

การจำแนกประเภทก๊าซผสมไวไฟโดยวิธีการคำนวณตาม ISO 10156: 1996

ก๊าซผสมประกอบด้วย 2% (H₂), 6% (CH₄), 27% (Ar) และ 65% (He)

$$Ki (Ar) = 0.5, Ki (He) = 0.5$$

คำนวณก๊าซผสมเทียบเท่ากับในโตรเจน โดยใช้ค่า Ki

 $2\% (H_2)+6\% (CH_4)+ 27\% (0.5) (N_2)+65\% (0.5) (N_2) = 54\%$

ปรับค่าผลรวมให้เป็น 100% จะได้เท่ากับ

3.7% (H₂)+11.1% (CH₄)+ 85.2 (N₂)

ค่าสัมประสิทธิ์ T สำหรับก๊าซไวไฟ คือ

$$T(H_2) = 5.7\%$$

$$T(CH_a) = 14.3\%$$

คำนวณค่าความไวไฟ

$$=\frac{3.7}{5.7} + \frac{11.1}{14.3} = 1.42$$

$$\Sigma \frac{V\%}{T} \ge 1$$

V% = ปริมาณของก๊าซไวไฟเทียบเท่า
T = ค่าความเข้มข้นสูงสุดของก๊าซ
ไวไฟในไนโตรเจนที่ยังไม่เป็นส่วนผสม
ไวไฟในอากาศ
Ki = แฟคเตอร์เทียบเท่าสำหรับก๊าซ
เฉื่อยต่อไนโตรเจน

ก๊าซผสมนี้มีความไวไฟในอากาศ (> 1)

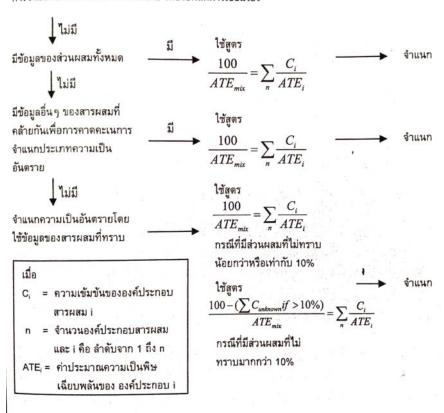
Mixture: GHS (สุขภาพและสิ่งแวดล้อม)

- มีข้อมูลของสารผสม ให้ใช้ข้อมูลของสารผสม
- หากไม่มีข้อมูลของสารผสม ใช้หลักเชื่อมโยง Bridging principle
- การคำนวณ
- อื่นๆ

หลักการเชื่อมโยง

- การเจือจาง (dilution)
- การผลิตในแต่ละครั้ง (Batching)
- ความเข้มข้นของสารผสมที่มีความเป็นพิษสูง (Concentration of highly toxic mixtures)
- การตีความเพื่อให้อยู่ในกลุ่มของความเป็นพิษกลุ่มใดกลุ่มหนึ่ง (Interpolation with one toxic category)
- สารผสมที่มีคุณสมบัติคล้ายคลึงกัน (Substantially similar mixtures)
- สารละอองลอยที่บรรจุในภาชนะปิด (Aerosol)

มีข้อมูลเพียงพอของสารผสมที่คล้ายกันเพื่อการคาดคะเน การจำแนกประเภทความเป็นอันตราย โดยใช้หลักการเชื่อมโยง





ตัวอย่างการเทียบค่า ATE

ทางรับสัมผัส	ค ่ า LD50	ATE
ทางปาก	$0 <$ กลุ่มที่ $1 \leq 5$	0.5
	5 < กลุ่มที่ 2 <u><</u> 50	5
	50 < กลุ่มที่ 3 ≤ 300	100
	300 < กลุ่มที่ 4 ≤ 2000	500
	2000 < กลุ่มที่ 5 <u><</u> 5000	2500

