



Un nuovo strumento di
competitività per
l'area *regulatory affairs* di
ogni azienda cosmetica

Powered by



Matteo Zanotti Russo
Cosmoprof Bologna, 29 Aprile 2022



Highlights

- PIF, CPSR, Safety Assessment: obblighi o strumenti?
- In pratica
- Criticità ed evoluzioni
- La soluzione proposta: ToxTool™
- Credits

Annex I: il Cosmetic Product Safety Report - CPSR

- Cos'è? Che funzione ha?

CPSR: cosa e come

- Obbligo (Reg. 1223/2009, art.. 10-11, all.I)
- All.I: struttura minima.
- Conclusioni (CPSR-B): «Disco verde» alla immissione in commercio
- Come? Linea Guida 'SCCS Notes of Guidance'

→ Decision Making (si- no – si «se»)

→ Responsible Person: esamina, segue le eventuali indicazioni (condizioni), **approva (e immette in commercio)**

Perché 'documentato'?

Criterio di base: NO pre market approval, Post Market Survey



Autocertificazione



Validazione dei processi e
Controllo Documentato



Controllo del
rischio
(Riduzione)



Sorveglianza
(autorità)

Valutazione della Sicurezza

- Atto Scientifico
- Multifattoriale
- Ponderato



Expert Judgment

DATI



CPSR-A

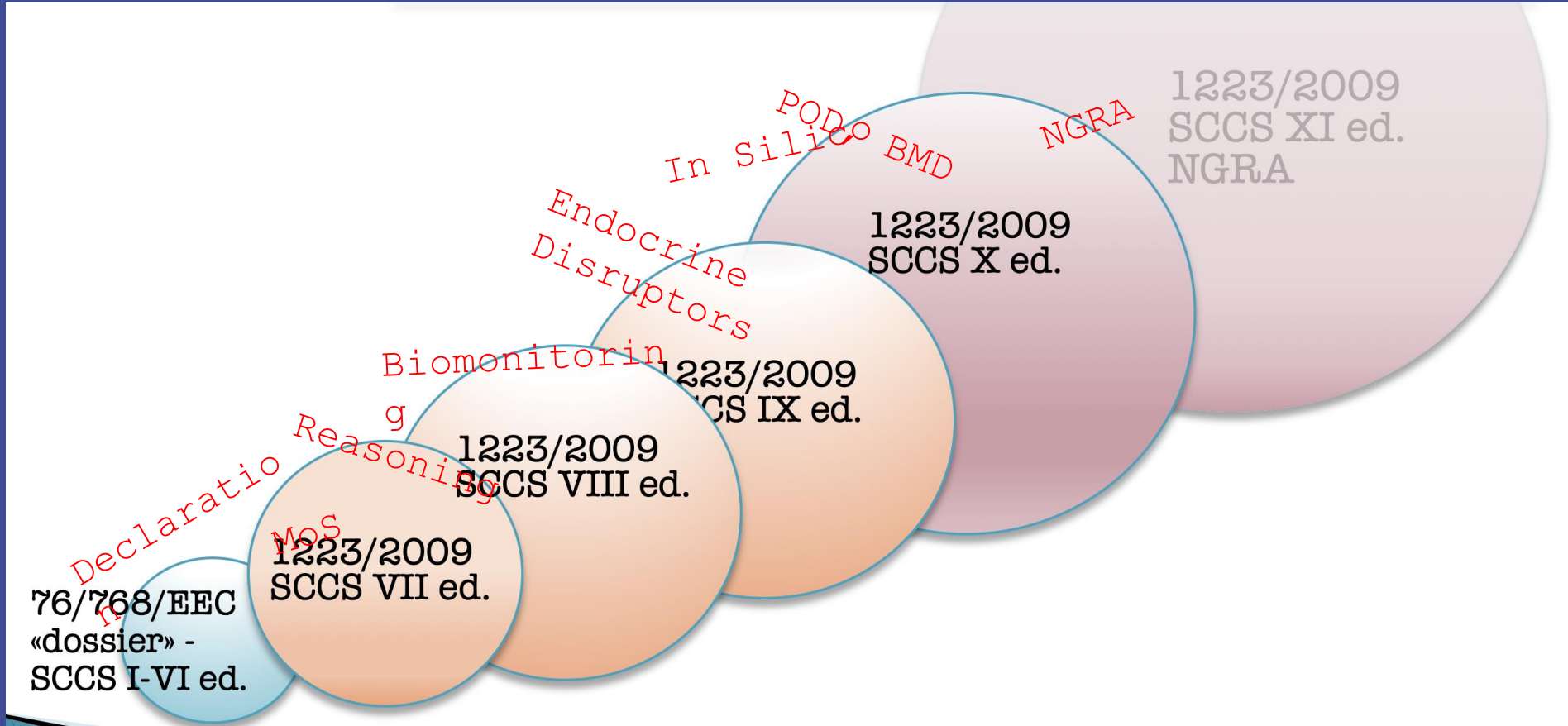


CPSR-B

I DATI nella vita del Safety Assessor: reperimento, trattamento, gestione

- Crescita esponenziale (time consuming)
- Realizzazione, implementazione, aggiornamento
- Si impone la realizzazione di un Database
- Interpretazione (margin di incertezza)
- Conclusioni (decision making)
- Reasoning scientifico
- Responsabilità

Evoluzione: SCCS NoG



Il CPSR nella vita reale: la nostra esperienza

- Auditing: +150 filiere
- Teaching: Università, Corsi Cosmetica Italia Servizi
- EU Working Groups
- Confronto con:
 - Aziende
 - Esperti-Safety Assessors
 - Associazioni Internazionali
 - Autorità Competenti

Criticità di oggi

- Dati incompleti
- Dati non aggiornati
- Reasoning poco strutturati

Criticità di domani

- SCCS NoG XI Ed.: NGRA
- Dati → non più sufficienti a un 'Expert Judgment'
→ Hypotesis Driven, Iterative, Tiered

Il processo decisionale

Dati



Multifactorial Expert Judgment



Decisione

NGRA: Il nuovo processo decisionale



La soluzione?

- Un Database?
- Un elenco?
- Un software?



un Tool
rappresentativo
dinamico
strutturato
aggiornato
user driven
user friendly
condiviso

UDRD-User Driven Reasoned Database

The innovative easy-to-use IT platform for cosmetic safety assessments

[Chi siamo](#)

[✍ Contattaci](#)

Cosa è?

**Un database tossicologico. E molto di più.
Completo, condiviso, ragionato.**

Strutturato, User Driven, Condiviso

Condiviso

I dati sono condivisi fra i Safety Assessor e i contributor che vorranno aiutarci a implementare in maniera sempre più efficace il database. I documenti creati per aiutarti nella realizzazione di PIF e CPSR riporteranno un QR code di sicurezza ToxTool™, così da incrementare la loro rappresentatività



Login to your account

Username



Password

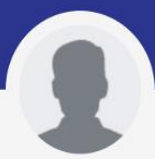


Remember me

[Forgot password?](#)

Login





- Toxicological DB 3916
- Products 6
- My requests 0

3916 records, showing 0-14

- Basic info**
- Substance reasoning
- Regulatory status and scientific literature
- Substance Information
- Toxicological Data

Id	INCI ↑	CAS	EINECS	Cosmetic function
2114	1-HEXYL 4,5-DIAMINO PYRAZOLE SULFATE	1361000-03-4	696-231-5	hair dyeing
2115	1-HYDROXYETHYL 4,5-DIAMINO PYRAZO...	155601-30-2	429-300-3	hair dyeing
2116	1-METHYLHYDANTOIN-2-IMIDE	60-27-5	200-466-7	Skin conditioning
2117	1-NAPHTHOL	90-15-3	201-969-4	hair dyeing
5883	1-NAPHTHOL;	90-15-3	201-969-4	Technically unavoidable imp
2118	1,10-DECANEDIOL	112-47-0	203-975-2	solvent
1982	1,2-HEXANEDIOL	6920-22-5	230-029-6	solvent
2122	1,3-BIS-(2,4-DIAMINOPHENOXY)PROPANE	81892-72-0 / 74918-21-1	279-845-4 / 278-022-7	Hair Dyeing
2123	1,3-BUTANEDIOL	107-88-0	203-529-7	Fragrance Humectant Skin
2124	1,4-BUTANEDIOL	110-63-4	203-786-5	solvent

info@angelconsulting.eu
ANGEL CONSULTING

Tox DB Search...

3916 records, showing 0-14

- **TOXICOLOGICAL DB:** parte comune a tutti gli utilizzatori con le **informazioni condivise** relative agli ingredienti
- **PRODUCTS:** parte riservata alla singola azienda utilizzatrice con le informazioni relative alle **proprie formule...**
- **My Requests?...** Promettente!

Basic Info

3916 records, showing 0-15





















Id	INCI ↑	CAS	EINECS	Cosmetic function
2114	1-HEXYL 4,5-DIAMINO PYRAZOLE SULFATE	1361000-0		
2115	1-HYDROXYETHYL 4,5-DIAMINO PYRAZO...	155601-30		
2116	1-METHYLHYDANTOIN-2-IMIDE	60-27-5		
2117	1-NAPHTHOL	90-15-3		
5883	1-NAPHTHOL;	90-15-3		
2118	1,10-DECANEDIOL	112-47-0		
1982	1,2-HEXANEDIOL	6920-22-5	230-029-6	solvent
2122	1,3-BIS-(2,4-DIAMINOPHENOXY)PROPANE	81892-72-0 / 74918-21-1	279-845-4 / 278-022-7	Hair Dyeing
2123	1,3-BUTANEDIOL	107-88-0	203-529-7	Fragrance Humectant Skin conditioning Solvent V

- CAS
- EINECS
- Funzione
- Data ultima modifica

Substance Reasoning

3916 records, showing 0-15

Basic info **Substance reasoning** Regulatory status and scientific information Toxicological Data

Id	INCI ↑	Safety Assessment
 2116	1-METHYLHYDANTOIN-2-IMIDE 	This compound is also known as...
 2117	1-NAPHTHOL 	1-NAPHTHOL is Petroleum-derived...
 5883	1-NAPHTHOL; 	1-Naphthol, or α-naphthol, is a...
 2118	1,10-DECANEDIOL 	1,10-Decanediol is an alkane diol...
 1982	1,2-HEXANEDIOL 	1,2-Hexanediol is a colorless liquid largely used as solvent in cosmetic products. Available data show...
 2122	1,3-BIS-(2,4-DIAMINOPHENOXY)PROPANE 	1,3-bis-(2,4-Diaminophenoxy)-propane HCl is used as a precursor for hair colours. It reacts with prim...
 2123	1,3-BUTANEDIOL 	Butylene Glycol is an aliphatic diol used as conditioning agent or solvent. Available data show that b...
 2124	1,4-BUTANEDIOL 	1,4-Butanediol, colloquially known as BD, is a primary alcohol, and a organic compound. In its indust...
 5887	1,4-DIHYDROXY-9,10-ANTHRACENEDIONE 	1,4-Dihydroxyanthraquinone, also called quinizarin or Solvent Orange 86, is an organic compound d...
 5896	1,4-DIOXANE 	1,4-Dioxane is a heterocyclic organic compound, classified as an ether. It is a colorless liquid with a f...

1,10-Decanediol is an alkane diol. It may be prepared by reducing diethyl or dimethyl sebacate with sodium metal in ethyl alcohol. It may also be prepared by catalytic hydrogenation of sebacic esters. Clinical tests reported that a mixture of 1,10-Decanediol and propylene glycol was well-tolerated, during the test placebo treated sites showed erythema throughout experiment and 2 subjects showed mild erythema 1 h following patch removal, no other observations were reported. 1,10-Decanediol can be considered safe when used as cosmetic ingredient in products formulated to be non-irritant. Available data showed that this diol was not mutagenic and not cytotoxic.

info@angelconsulting.eu

3916 records, showing 0-15

Basic info

Substance reasoning

Annex III/16 Product Type, body parts: Hair dye substance in oxidative hair dye products concentration in ready for use preparation:/ Other: After mixing under oxidative conditions the maximum concentration applied to hair must not exceed 2,0% Wording of conditions of use and warnings: To be printed on the label: Hair colorants can cause severe allergic reactions. To be printed on the label: The mixing ratio "Hair colorants can cause severe allergic reactions. Read and follow instructions. Hair colourants can cause severe allergic reactions. Read and follow instructions. This product is not intended for use on persons under the age of 16. Temporary 'black henna' tattoos may increase your risk of allergy. Do not colour your hair if: — you have a rash on your face or sensitive, irritated and damaged scalp, — you have ever experienced any reaction after colouring your hair, — you have experienced a reaction to a temporary 'black henna' tattoo in the past Regulation: (EC) 2013/344 Regulation: (EC) 2009/1223

Substance Information

Toxicological Data

Id	INCI ↑	EU	Harmonised CLP classification	Scientific Literature
2116	1-METHYLHYDANTOIN-2-IMIDE		There is no harmonised classification.	-ECHA web
2117	1-NAPHTHOL	Annex III/16 Product Type, body parts: Hair...	Hazard Class and Category Codes: Acute T...	-SCCNFP/04
5883	1-NAPHTHOL;	Annex III/16 Product Type, body parts: Hair...	ECHA: Harmonised Classification Acute To...	ECHA A mo
2118	1,10-DECANEDIOL		There is no harmonised classification	ECHA webs
1982	1,2-HEXANEDIOL		There is no harmonised classification	- ECHA web
2122	1,3-BIS-(2,4-DIAMINOPHENOXY)PROPANE	Annex III/16 Product Type, body parts: (...		Scientific Co
2123	1,3-BUTANEDIOL		There is no harmonised classification.	- ECHA We
2124	1,4-BUTANEDIOL			- ECHA web
5887	1,4-DIHYDROXY-9,10-ANTHRACENEDIONE		Don't have the Harmonised Classification	ECHA webs
5896	1,4-DIOXANE	Annex III/16 Product Type, body parts: (...	ECHA Harmonised Classification Flam. Liq. ...	ECHA webs

Substance Information

3916 records, showing 0-15

Id	INCI ↑	MW
2114	1-HEXYL 4,5-DIAMINO PYRAZOLE SULFATE	
2115	1-HYDROXYETHYL 4,5-DIAMINO PYRAZO...	240.24 g
2116	1-METHYLHYDANTOIN-2-IMIDE	113.12 g
2117	1-NAPHTHOL	144.17 g
5883	1-NAPHTHOL;	144.173 g
2118	1,10-DECANEDIOL	174.28 g
1982	1,2-HEXANEDIOL	118.176 g
2122	1,3-BIS-(2,4-DIAMINOPHENOXY)PROPANE	288.35 g
2123	1,3-BUTANEDIOL	90.12 g/m

- MW
- Log KOW (Octanol-Water)
- Melting point
- Boiling point
- Water solubility
- Other physical/chemical data
- Bioavailability summary
- Dermal absorption
- Oral bioavailability
- Inhalatory bioavailability

Toxicological Data

The screenshot displays the ToxTool web application interface. The top navigation bar includes the ToxTool logo, a user profile for f.robino@angelconsulting.eu, and a search bar. The main content area is titled 'Tox DB' and shows a search bar and a table of 3916 records. The table has columns for 'Id' and 'INCI'. The visible records are:

Id	INCI
2114	1-HEXYL 4,5-DIAMINO PYRAZOLE
2115	1-HYDROXYETHYL 4,5-DIAMINO P
2116	1-METHYLHYDANTOIN-2-IMIDE
2117	1-NAPHTHOL
5883	1-NAPHTHOL;
2118	1,10-DECANEDIOL
1982	1,2-HEXANEDIOL
2122	1,3-BIS-(2,4-DIAMINOPHENOXY)P

- Skin irritation
- Eye irritation
- Skin sensitization
- Photo-induced toxicity
- Dermal sensitization
- Repeated toxicity data
- Acute toxicity data
- Toxicity to reproduction data
- Genetic toxicity / Carcinogenicity data
- Endocrine activity
- Organospecific toxicity
- TTC
- Selected POD

In Silico













- Vermeer Cosmolife : Include Vega, ToxRead, Merlin Expo Erica
- Con nuovi algoritmi specifici per gli ingredienti cosmetici per:
 - NOAEL,
 - Risk Characterisation,
 - TTC



Overview

3916 records, showing 0-17

Basic info Substance reasoning Regulatory status and scienc

Id	INCI ↑		Skin irritation	Eye irritat
 2114	1-HEXYL 4,5-DIAMINO PYRAZOLE SULFATE		1-Hexyl-1H-pyrazole-4,5-diamine sulfate...	Based on
 2115	1-HYDROXYETHYL 4,5-DIAMINO PYRAZO		Data show that it is irritant to rabbit skin.	Data sho
 2116	1-METHYLHYDANTOIN-2-IMIDE		No adverse effect observed (not irritating)	No adver
 2117	1-NAPHTHOL		A 2.5% aqueous suspension of 1-naphtho...	Althoug
 5883	1-NAPHTHOL;		ECHA: Adverse effect observed (irritating)	ECHA: A

Open detail

Dettagli

ToxTool™ f.robino@angelconsulting.eu


1-HYDROXYETHYL 4,5-DIAMINO PYRAZOLE SULFATE
CAS: 155601-30-2

Cosmetic function: hair dyeing
EINECS: 429-300-3
SMILES: OS(O)(=O)=O.NC1=C(N)N(CCO)N=C1
Impurities: -

Created: Giorgia, 01/01/1970 01:00
Last modified: Giorgia, 01/01/1970 01:00

Overview | Substance Information | Toxicity | **Attached Documentation (1)** | Versions (2)

Documents +

-  **1-HYDROXYETHYL 4,5-DIAMINO PYRAZOLE SULFATE.pdf**
f.robino@angelconsulting.eu, 2022-04-20 17:31

Web sites +

No webs...

Monography

Navigation icons: PDF, Mobile, Edit


COSA FA?

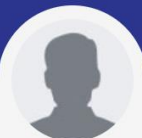
Le sue caratteristiche






Esportazione dei dati

Per una facile introduzione nel Cosmetic Product Safety Report, offre in pochi click una reportistica impeccabile in pdf e compatibile con gli attuali software per la realizzazione PIF

 ToxTool™
 info@angelconsulting.eu
 ANGEL CONSULTING















-  Toxicological DB 3916
-  Products 6
-  My requests 0

 info@angelconsulting.eu

 Products

Show archived formulas



Description ↑	Category	State
 bagnoschiuma	Bath gel	 In progress
 face cream	Face cream	 In progress
 hc	Hand cream	 In progress
 New test product	Bar soap	 In progress
 prova	Bath gel	 In progress
 Shower Gel	Bath gel	 In progress

Prodotti → Upload

The screenshot displays the ToxTool web application interface. The top navigation bar shows the user profile 'f.robino@angelconsulting.eu'. The main content area is titled 'Products' and features a search bar. A table lists several products, all with a status of 'In progress'. A red arrow points to a checkbox labeled '+ Show archived formulas' in the top right corner of the table area.

Description ↑	Company	Category	State
bagnoschiuma	ANGEL CONSULTING	Bath gel	In progress
face cream	ANGEL CONSULTING	Face cream	In progress
hc	ANGEL CONSULTING	Hand cream	In progress
New test product	ANGEL CONSULTING	Bar soap	In progress
prova	ANGEL CONSULTING	Bath gel	In progress
Shower Gel	ANGEL CONSULTING	Bath gel	In progress

Inserimento

New formula ✕

Company *

Description *

Category *

Estimated daily amount applied (g/day)

Application area (cm²)

Retention factor

SAF

Oral exposure

Inhalation exposure

F Air

F Resp

Intended for children under 3 years

Import ingredients from Excel

Ingredienti mancanti? My requests...

Shower Gel
ANGEL CONSULTING

In progress Finalize

Product data | Documentation (0) | Versions (1)

Formula | Tox data | Exp-Dermal | E | QRA

Ingredient not found

Currently, no ingredient with INCI xyz is present in the ToxTool database.

If you believe that the ingredient, in the exact format you entered, is an INCI name that should be included in the ToxTool database, please click on the "Request ingredient" button below. You will be asked for any further information available and the ToxTool team will examine your request. We will keep you posted about your submission.

If you think it might be a spelling error, please click "Cancel" and try again.

Cancel Request ingredient

INCI	Concentration	Status	CAS	EINECS	Function	Description
AQICERIN						
GLYCAMIDOPROPYL BE						
CO						
DIUM LAURETH SUL						
SO						
DE BARBADENSIS LEAF JUICE	2.0000 %	✗	85507-89-3 / 94349-62-9	287-390-8 / 305-181-2	Skin conditioning	Aloe Barbadensis Leaf Juice is th
ALCANTHAN GUM	1.0000 %	✗	11138-66-2	234-394-2	Binding, emulsifying, emulsion stabilising, g...	Xanthan Gum is a polysaccharide juice exp... Pesticides, hec
XANTHAN GUM	1.0000 %	✗	11138-66-2	234-394-2	Binding, emulsifying, emulsion stabilising, g...	Xanthan Gum is a polysaccharide compose...

New ingredient + Import ingredients from Excel



My Requests

info@angelconsulting.eu
ANGEL CONSULTING

My requests

Search...

Show archived requests

INCI	Annotation	Response	State	Created by	Created on ↓
glycerin	ho più dati		Sent	f.robino@angelconsul...	2022-03-17 16:48
caffein	please, add caffein	ok, l'add it	Approved	f.robino@angelconsul...	2021-08-05 10:33

My Requests:

- Invio la richiesta
- Seguo lo stato nel mio account
- Ricevo un feedback (email)
- Trovo il dato nel database (oppure un esperto mi spiega che caffein si scrive caffeine...)

Caffein? Quindi devo stare attento a scrivere gli INCI giusti?

info@angelconsulting.eu
ANGEL CONSULTING


info@angelconsulting.eu

Tox DB

caf

1 records, showing 0-1

Basic info Substance reasoning Regulatory status and scientific literature Substance Information Toxicological Data

Id	INCI ↑	CAS	EINECS	Cosmetic function
 2120	CAFFEINE	58-08-2	200-362-1	masking, skin conditioning

Toxicological DB 3916

Products 6

My requests 0

Tablelle tossicologiche dei prodotti finiti

Shower Gel
ANGEL CONSULTING

In progress Finalize

Bath gel

Estimated daily amount applied (g/day)
18.67

Area for application (cm²)
16,340

Retention factor
0.01

Daily Exposure (g/day)
0.1867

f.robino@angelconsulting.eu

Creation
Federica Robino, 15/02/2020

Last modify
f.robino@angelconsulting.eu, 07/09/2021 15:09

Product data | Documentation (0) | Versions (1)

INCI			CAS	EINECS
AQUA	64.0000 %	×	7732-18-5	231-791-2
GLYCERIN	12.4880 %	×	56-81-5	200-289-5
COCAMIDOPROPYL BETAINE	10.0000 %	×	61789-40-0	263-058-8 931-296-8
SODIUM LAURETH SULFATE	10.0000 %	×	3088-31-1 / 9004-82-4 / 68891-38-3 / 1335-72-4 / 68585-34-2 / 91648-56-5	221-416-0 / 500-234-4 - / 500-223-4 / 293-918-4
ALOE BARBADENSIS LEAF JUICE	2.0000 %	×	85507-69-3 / 94349-62-9	287-390-8 305-181-2
XANTHAN GUM	1.0000 %	×	11138-66-2	234-394-2

New ingredient +

Import ingredients from Excel

AVAILABLE INFORMATION

- CAS
- EINECS
- Function
- Ingredient reasoning
- Possible Impurities
- EU Reg 1223/2009 Annexes
- Scientific literature

Cartella Tox Data

Bath gel

Estimated daily amount applied (g/day)
18.67

Area for application (cm²)

f.robino@angelconsulting.eu

Shower Gel
ANGEL CONSULTING

In progress Finalize

Product data Documentation (0) Versions (1)

3916

6

1

3

INCI	100.0000%	Formula
AQUA	64.0000 % ✗	Safe.
GLYCERIN	12.4880 % ✗	CIR: Non-Human Glycerin was not de
COCAMIDOPROPYL BETAINE	10.0000 % ✗	CIR: In rabbits, CAPB was not consid
SODIUM LAURETH SULFATE	10.0000 % ✗	It has been shown to produce eye an
ALOE BARBADENSIS LEAF JUICE	2.0000 % ✗	The classification provided by compa
XANTHAN GUM	1.0000 % ✗	are not considered irritants
PARFUM (FRAGRANCE)	0.5000 % ✗	
METHYLCHLOROISOTHIAZOLINONE	0.0090 % ✗	Corrosive for eyes, skin and mucoses.
METHYLISOTHIAZOLINONE	0.0030 % ✗	CIR Test substance= Shampoo: The skin ir... CIR: n an ocular irritation study49 in 6 male... CIR: In a study by Bruze et al,6 22 patients ...

New ingredient

Import ingredients from Excel

- Skin irritation
- Eye irritation
- Skin sensitization
- Acute toxicity
- Repeated toxicity
- Toxicity to reproduction
- Genetic toxicity / Carcinogenicity data
- POD
- Scientific Literature
- Other data

Tabella Exp-Dermal → MoS

Shower Gel
ANGEL CONSULTING

In progress Finalize

Bath gel

Estimated daily amount applied (g/day)
18.67

Area for application (cm²)
16,340

Retention factor
0.01

Daily Exposure (g/day)
0.1867

f.robino@angelconsulting.eu

Creation
Federica Robino, 15/02/2020

Last modify
f.robino@angelconsulting.eu, 07/09/2021 15:09

Product data
Documentation (0)
Versions (1)

Formula
Tox data
Exp-Dermal
Exp-Oral
Exp-Inhal
QRA

INCI	100.0000%	POD value (mg/Kg bw/day)	Dermal absorption	External Dermal Exposure (mg/day)	SED (mg/Kg bw/day)			MoS		
					Adult (60 Kg)	Baby (1-3 yr, 12 Kg)	Newborn (0-1 yr, 6 Kg)	Adult (60 Kg)	Baby (1-3 yr, 12 Kg)	Newborn (0-1 yr, 6 Kg)
AQUA	64.0000 % ✗		50.0%	119.488	0.9957	4.9787	9.9573	-	-	-
GLYCERIN	12.4880 % ✗		10.0%	23.315	0.0389	0.1943	0.3886	-	-	-
COCAMIDOPROPYL BETAINE	10.0000 % ✗	500.0	50.0%	18.670	0.1556	0.7779	1.5558	3213.7118	642.7424	321.3712
SODIUM LAURETH SULFATE	10.0000 % ✗	300.0	%	18.670	0.0000	0.0000	0.0000	Infinity	Infinity	Infinity
ALOE BARBADENSIS LEAF JUICE	2.0000 % ✗		50.0%	3.734	0.0311	0.1556	0.3112	-	-	-
XANTHAN GUM	1.0000 % ✗	250.0	10.0%	1.867	0.0031	0.0156	0.0311	80342.7959	16068.5592	8034.2796
PARFUM (FRAGRANCE)	0.5000 % ✗		50.0%	0.934	0.0078	0.0389	0.0778	-	-	-
METHYLCHLOROISOTHIAZOLINONE	0.0090 % ✗	2.8	100.0%	0.017	0.0003	0.0014	0.0028	9998.2146	1999.6429	999.8215
METHYLISOTHIAZOLINONE	0.0030 % ✗	19.0	101.0%	0.006	0.0001	0.0005	0.0009	201519.8842	40303.9768	20151.9884

+
X Import ingredients from Excel

Tabella Exp-Oral → MoS

Shower Gel
ANGEL CONSULTING

In progress Finalize

Bath gel

Estimated daily amount applied (g/day)
18.67

Area for application (cm²)
16,340

Retention factor
0.01

Daily Exposure (g/day)
0.1867

f.robino@angelconsulting.eu

Creation
Federica Robino, 15/02/2020

Last modify
f.robino@angelconsulting.eu, 07/09/2021 15:09


Product data
Documentation (0)
Versions (1)

Formula
Tox data
Exp-Dermal
Exp-Oral
Exp-Inhal
QRA

INCI	100.0000%	POD value (mg/Kg bw/day)	Oral bioavailability (%)	External Oral Exposure (mg/day) (???)	SED (mg/Kg bw/day)			MoS		
					Adult (60 Kg)	Baby (1-3 yr, 12 Kg)	Newborn (0-1 yr, 6 Kg)	Adult (60 Kg)	Baby (1-3 yr, 12 Kg)	Newborn (0-1 yr, 6 Kg)
AQUA	64.0000 % ✗		100.0%	119.488	1.9915	9.9573	19.9147	-	-	-
GLYCERIN	12.4880 % ✗		100.0%	23.315	0.3886	1.9429	3.8858	-	-	-
COCAMIDOPROPYL BETAINE	10.0000 % ✗	500.0	100.0%	18.670	0.3112	1.5558	3.1117	1606.8559	321.3712	160.6856
SODIUM LAURETH SULFATE	10.0000 % ✗	300.0	100.0%	18.670	0.3112	1.5558	3.1117	964.1136	192.8227	96.4114
ALOE BARBADENSIS LEAF JUICE	2.0000 % ✗		100.0%	3.734	0.0622	0.3112	0.6223	-	-	-
XANTHAN GUM	1.0000 % ✗	250.0	100.0%	1.867	0.0311	0.1556	0.3112	8034.2796	1606.8559	803.4280
PARFUM (FRAGRANCE)	0.5000 % ✗		100.0%	0.934	0.0156	0.0778	0.1556	-	-	-
METHYLCHLOROISOTHIAZOLINONE	0.0090 % ✗	2.8	100.0%	0.017	0.0003	0.0014	0.0028	9998.2146	1999.6429	999.8215
METHYLISOTHIAZOLINONE	0.0030 % ✗	19.0	100.0%	0.006	0.0001	0.0005	0.0009	203535.0830	40707.0166	20353.5083

+
Import ingredients from Excel

Tabella Exp-Inhal



Shower Gel
ANGEL CONSULTING

In progress ✓ Finalize

Bath gel

Estimated daily amount applied (g/day)
18.67

Area for application (cm²)
16,340

Retention factor
0.01

Daily Exposure (g/day)
0.1867










f.robino@angelconsulting.eu

Creation
Federica Robino, 15/02/2020

Last modify
f.robino@angelconsulting.eu, 07/09/2021 15:09

Product data
Documentation (0)
Versions (1)

Formula
Tox data
Exp-Dermal
Exp-Oral
Exp-Inhal
QRA

INCI	100.0000%	POD value (mg/Kg bw/day)	Potential product amount inhaled (g/application)	potential product amount inhaled during box 1 (mg/application)	potential product amount inhaled during box 2 (mg/application)	Adult (60 Kg)	Baby (1-3 yr, 12 Kg)	Newborn (0-1 yr, 6 Kg)	Adult (60 Kg)	Baby (1-3 yr, 12 Kg)	Newborn (0-1 yr, 6 Kg)
 AQUA	64.0000 % ✗	0	0	0	0%	NaN	NaN	NaN	-	-	-
 GLYCERIN	12.4880 % ✗	0	0	0	0%	NaN	NaN	NaN	-	-	-
 COCAMIDOPROPYL BETAINE	10.0000 % ✗	500.0	0	0	0%	NaN	NaN	NaN	NaN	NaN	NaN
 SODIUM LAURETH SULFATE	10.0000 % ✗	300.0	0	0	0%	NaN	NaN	NaN	NaN	NaN	NaN
 ALOE BARBADENSIS LEAF JUICE	2.0000 % ✗	0	0	0	0%	NaN	NaN	NaN	-	-	-
 XANTHAN GUM	1.0000 % ✗	250.0	0	0	0%	NaN	NaN	NaN	NaN	NaN	NaN
 PARFUM (FRAGRANCE)	0.5000 % ✗	0	0	0	0%	NaN	NaN	NaN	-	-	-
 METHYLCHLOROISOTHIAZOLINONE	0.0090 % ✗	2.8	0	0	0%	NaN	NaN	NaN	NaN	NaN	NaN
 METHYLISOTHIAZOLINONE	0.0030 % ✗	19.0	0	0	0%	NaN	NaN	NaN	NaN	NaN	NaN

+

✕ Import ingredients from Excel



QRA

Shower Gel
ANGEL CONSULTING

In progress

Finalize

Bath gel

Estimated daily amount applied (g/day)
18.67

Area for application (cm²)
16,340

Retention factor
0.01

Daily Exposure (g/day)
0.1867

f.robino@angelconsulting.eu

Creation
Federica Robino, 15/02/2020

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f.robino@angelconsulting.eu, 07/09/2021 15:09

Product data
Documentation (0)
Versions (1)

Formula

Tox data

Exp-Dermal

Exp-Oral

Exp-Inhal

QRA

INCI	100.0000%	Dimethylaminopropylamine (DMAPA)
		Estimated impurity 0.0000%
AQUA	64.0000 %	-
GLYCERIN	12.4880 %	-
COCAMIDOPROPYL BETAINE	10.0000 %	-
SODIUM LAURETH SULFATE	10.0000 %	-
ALOE BARBADENSIS LEAF JUICE	2.0000 %	-
XANTHAN GUM	1.0000 %	-
PARFUM (FRAGRANCE)	0.5000 %	-
METHYLCHLOROISOTHIAZOLINONE	0.0090 %	-
METHYLISOTHIAZOLINONE	0.0030 %	-

Quantitative Risk Assessment (QRA)*

QRA of amidoamine (AA)*
0% of AA NESIL=0 µg/cm2

Product Category	Used %
Bath gel	?

Product Exposure (µg/cm2)
/ ?

SAF
300.0

AEL
0.0000

QRA of dimethylaminopropylamine (DMAPA)*
0% of AA NESIL=0 µg/cm2

Product Category	Used %
Bath gel	?

Product Exposure (µg/cm2)
/ ?

SAF
300.0

AEL
0.0000

New ingredient

+

X
Import ingredients from Excel

* based on indication provided by CIR (International Journal of Toxicology July/August 2012 vol. 31 no. 4 suppl 77S-111S)

Reportistica - Esportazione

Shower Gel
ANGEL CONSULTING

In progress Finalize

Product data | Documentation (0) | Versions (1)

Documents +

No documents uploaded yet

Bath gel

Estimated daily amount applied (g/day)
18.67

Area for application (cm²)
16,340

Retention factor
0.01

Daily Exposure (g/day)
0.1867

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Creation
Federica Robino, 15/02/2020

Last modify
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Exportable Reports

Download all documents

- Exposure and risk characterisation
- Hazard identification
- Quantitative Risk Assessment (QRA)
- Raw data
- Ingredients monography (summary)



Hazard identification

Shower Gel

Version 2

2022-04-29 06:35



Hazard identification

COCAMIDOPROPYL BETAINE

Ingredient data

INCI: COCAMIDOPROPYL BETAINE

CAS: 61789-40-0

EINECS: 263-058-8 / 931-296-8

Impurities: amidoamine (AA) dimethylaminopropylamine (DMAPA)

Local toxicity

Skin irritation	Eye irritation	Skin sensitization	Photo-induced toxicity
<p>CIR: In rabbits, CAPB was not considered to be a dermal irritant at concentrations up to 50% in most studies. One study of a full-strength CAPB solution (30% active) found the ingredient to be a mild primary irritant with a PII of 0.5.</p>	<p>The classification provided by companies to ECHA in CLP notifications identifies that this substance causes serious eye damage.</p> <p>CIR: CAPB (2.3% active and greater) was mild to moderately irritating to rabbit eyes in the majority of the ocular studies.</p>	<p>A majority of data submitters agree this substance is Skin sensitizing. In fact, results of human studies have shown that CAPB has a low sensitizing potential if impurities with amidoamine (AA) and dimethylaminopropylamine (DMAPA) are low and tightly controlled.</p> <p>CIR: No delayed contact hypersensitivity was observed in guinea pig studies of 0.5% and 0.75% CAPB; however, a guinea pig maximization/Draize study of CAPB at 0.1% and 0.15% was positive for sensitization. A LLNA study was positive for sensitization to CAPB.</p>	<p>CIR: An investigation of the potential of a 3.0% active aqueous solution of CAPB to induce contact photoallergy was tested using 30 human subjects. The 11 subjects who had mild to moderate erythemic responses at the irradiated sites during the induction testing were those that received both UVA and 2 MED of UVB irradiation. These responses were expected from the UVB exposure. CAPB was not a photosensitizer in this study.</p>

Systemic toxicity

Repeated Dose Toxicity Data	Acute Toxicity Data	Toxicity to Reproduction Data	Genetic Toxicity / Carcinogenicity Data	Endocrine activity	Organospecific Toxicity	TTC
<p>ECHA</p> <p>Oral route - systemic effects: No adverse effect observed NOAEL 500</p>	<p>ECHA</p> <p>Acute toxicity</p> <p>Oral route: No adverse effect observed</p>	<p>ECHA</p> <p>Effect on fertility Oral route: No adverse effect observed NOAEL 1 000</p>	<p>ECHA</p> <p>Genotoxicity - InVitro No adverse effect observed (negative) Genotoxicity - InVivo No study available</p>			<p>Classification according Cramer class: High (Class III).</p> <p>TTC according Cramer classification: 0.0015 mg/kg bw/day.</p>



mg/kg bw/day
(subacute, rat)

LD50 5 000 mg/kg
bw
Dermal route:
No adverse
effect observed
LD50 2 000 mg/kg
bw

mg/kg bw/day (subchronic,
rat)

Effect on developmental
toxicity
Oral route:
No adverse effect
observed NOAEL 950
mg/kg bw/day (subchronic,
rat)

CIR:

Carcinogenicity:
An aqueous preparation of a non-oxidative
hair dye formulation containing an unspecified
grade of CAPB at a
concentration of 0.09% active CAPB was
tested for carcinogenicity using groups of 60
male and female random-bred Swiss
Webster mice from the Eppley colony. 64 The
formulation also contained 5% propylene
glycol, 4% benzyl alcohol, 0.6% CIR Panel
Book Page 51
20
Kelzan (xanthan gum), 0.9% lactic acid,
0.04% fragrance, and less than 0.1% each of
the disperse brown, red, yellow, and
blue dyes. A dose of 0.05 ml per mouse was
applied 3 times weekly for 20 months to
interscapular skin that was clipped free
of hair and shaved. Mortality, behavior, and
physical appearance of the mice were
observed daily. Dermal changes in
particular were noted. Body weights were
recorded weekly. Ten males and 10 females
from each group were killed at 9
months for a hematological study, urinalysis,
and necropsy. At termination, all mice were
necropsied, and the tissues were
examined microscopically. No adverse effects
were noted on average body weight gains,
survival, hematological or
urinalysis values in any group. Varying
degrees of chronic inflammation of the skin
were seen in all groups, including
controls. Other lesions occurred, but were
considered unrelated to hair dye treatment.
The incidence of neoplasms in treated
animals did not differ significantly from control
groups



Exposure and risk characterisation

Shower Gel

Version 2

2022-04-29 06:39

Product type: Bath gel

Daily amount applied q_x (g/d): 18.67

Retention factor: 0.01

Dermal exposure: applicable

Oral exposure: unlikely

Inhalation exposure: unlikely



Target population adult (60 Kg)



INCI	%	External Dermal Exposure (mg/day)	POD value (mg/kg bw/d)	SED dermal (mg/ Kg bw/d)	MoS dermal	SED oral (mg/ Kg bw/d)	MoS oral	SED inhalation (mg/ Kg bw/d)	MoS inhalation	Regulatory status	Substance Reasoning
AQUA	64.0000	119.4880		0.9957	0.0000	1.9915	0.0000	NaN	NaN	There is no harmonised classification.	The most common solvent. Safe for all uses in cosmetic products
GLYCERIN	12.4880	23.3151		0.0389	0.0000	0.3886	0.0000	NaN	NaN	There is no harmonised classification.	Glycerin is a naturally occurring alcohol compound and a component of many lipids. There is naturally occurring glycerin, derived from plants and animals, and synthetic glycerin, obtained from non-triglyceride sources. It is traditionally and largely used in cosmetic products, is the third most frequently reported cosmetic ingredient. after water and fragrance. Glycerin is considered generally recognized as safe (GRAS) for food packaging and as a multiple-purpose food substance. The CIR Expert Panel concluded that glycerin is safe when used as cosmetic ingredient up to 78,5%.
COCAMIDOPROPYL BETAINE	10.0000	18.6700	500.0	0.1556	3213.7118	0.3112	1606.8559	NaN	NaN	There is no harmonised classification.	Cocamidopropyl betaine is a synthetic surfactant. Due to the irritation potential of CAPB, it is concluded that the maximum activity of CAPB used in leave-on cosmetic formulations should not exceed 3.0 percent. The limitation is expressed as a 10 percent v/v dilution of a commercial sample that has an activity of 30 percent. The use of CAPB in rinse-off products is considered to be safe as currently applied. The impurities AA and DMAPA are most critical, as they have been shown to be responsible for skin sensitisation reactions. The CIR Expert Panel concluded that, because of these ingredients presence, no other significant toxicity

Substance Reasoning

The most common solvent. Safe for all uses in cosmetic products

Glycerin is a naturally occurring alcohol compound and a component of many lipids. There is naturally occurring glycerin, derived from plants and animals, and synthetic glycerin, obtained from non-triglyceride sources. It is traditionally and largely used in cosmetic products, is the third most frequently reported cosmetic ingredient, after water and fragrance. Glycerin is considered generally recognized as safe (GRAS) for food packaging and as a multiple-purpose food substance.

The CIR Expert Panel concluded that glycerin is safe when used as cosmetic ingredient up to 78,5%.

Cocamidopropyl betaine is a synthetic surfactant. Due to the irritation potential of CAPB, it is concluded that the maximum activity of CAPB used in leave-on cosmetic formulations should not exceed 3.0 percent. The limitation is expressed as a 10 percent v/v dilution of a commercial sample that has an activity of 30 percent. The use of CAPB in rinse-off products is considered to be safe as currently applied. The impurities AA and DMAPA are most critical, as they have been shown to be responsible for skin sensitization reactions.

The CIR Expert Panel concluded that, because of these ingredients presence, no other significant toxicity

Cocamidopropyl betaine is safe for use as cosmetic ingredients when formulated to be nonsensitizing (which may be based on a quantitative risk assessment) .

Sodium Laureth Sulfate is the sodium salt of sulfated ethoxylated lauryl alcohol. The potential to produce irritation exists, but in practice it is not regularly seen to be irritating because of the formulations in which it is used. The CIR Expert Panel concluded that Sodium Laureth Sulfate is safe up to 50% when formulated to be non-irritating.

According to ECHA webpage the dermal absorption value is 0,9%.

According to the classification provided by companies to ECHA in CLP notifications this substance causes serious eye damage, causes skin irritation and may cause an allergic skin reaction.

Aloe Barbadensis Leaf Juice is the juice expressed from the leaves of the aloe, *Aloe barbadensis*, Liliaceae. Aloe is a flowering succulent plant, its leaves are largely used for pharmaceutical purposes.

Aloe has a long history as a medicine and skin care aid. For over 6,000 years aloe was used for a wide range of ailments. The word "Aloe" in pharmacopoeias and formularies refers to the herbal substance derived from the dried leaf juice.

This has always created confusion due to the fact that the leaves are the source of two products: latex and gel. Latex or aloe dried juice is prepared by cutting transversely the leaf near the base and taking it inclined so that the juice contained in the specialised pericyclic cells and sometimes in the adjacent parenchyma flow out in about 6 h.

This juice is allowed to dry with or without the aid of heat. It contains a number of anthraquinones. Aloe gel

is a colourless mucilaginous gel obtained from the parenchymatous cells of the leaves. The mucilaginous parenchymatous tissue is excised from fresh leaves. Therefore the leaves are "filleted", that means that the external green parts of the leaves are peeled. Depending on whether the anthranoid-containing cells beneath are also removed, the gel is free of anthranoids or not. The fillets are immediately utilised for preparations or lyophilised and kept dry until use. In general the dried juice is orally used for its laxative effects while the gel is topically used for cosmetic products. It is important to notice that aloe barbadensis-derived ingredients were generally not toxic, however the anthraquinones identified as impurities, like aloe-emodin, are known to be genotoxic and carcinogen substances and phototoxicant. CIR Expert panel concluded that Aloe Barbadensis Leaf Juice is safe when used as cosmetic ingredient if anthraquinone levels in the ingredients do not exceed 50 ppm.

Xanthan Gum is a polysaccharide composed of glucose, glucuronic acid, 6-acetylmannose, and 4,6-pyruvylated mannose. Largely used in cosmetic products and it is an authorised food additive in the European Union (E 415). Although polysaccharide gums are produced primarily by microbial sources, the cosmetic ingredients are purified during manufacture, thus microbial contamination is not a concern. It appears not to be significantly absorbed through the skin and would have negligible bioavailability, therefore we can consider a precautionary dermal absorption of 10%. The available information indicates that incidental inhalation










would not be a significant route of exposure that might lead to local respiratory or systemic effects. It did not produce systemic toxicity in oral studies; polysaccharide gums are not reproductive or developmental toxicants; are not genotoxic; and are not considered irritants or sensitizers. The CIR Expert Panel concluded that Xanthan Gum is safe to be used as cosmetic ingredient up to 6%

According to the classification provided by companies to ECHA in CLP notifications this substance causes serious eye irritation and causes skin irritation.



Ingredients monography (summary)



-  ALOE BARBADENSIS LEAF JUICE.pdf
-  AQUA.pdf
-  COCAMIDOPROPYL BETAINE.pdf
-  GLYCERIN.pdf
-  METHYLCHLOROISOTHIAZOLINONE.pdf
-  METHYLISOTHIAZOLINONE.pdf
-  PARFUM (FRAGRANCE).pdf
-  SODIUM LAURETH SULFATE.pdf
-  XANTHAN GUM.pdf





Raw data



Salvataggio automatico Raw data.xls - Modalità compatibilità

Home Inserisci Disegno Layout di pagina Formule Dati Revisione Visualizza Dimmi

Condividi Commenti

Arial 12 A⁺ A⁻ Incolla

Testo a capo Generale

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Inserisci Elimina Formato

Ordina e filtra Trova e seleziona

A1 fx id_company


	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q	R	S	T	U	V	W	X	Y	Z	
1	id_comp	id_formu	formula	ingredier	id_ingrec	inci	inecs	function	safety_a	impurity	impuritie	scientific	dermal	attachm	pod_nurr	pod_des	repeated	acute_to	toxicity	genetic	other_da	remarks	systemic	systemic	systemic	local_to	
2	4	3	0	2.0	1988	ALOE BAR	287-390-8	Skin condit	Aloe Barba	0	Pesticides,	- IJT 26(Su	50.0			n/a											
3	4	3	0	64.0	1991	AQUA	231-791-2	Solvent	The most c	0			50.0				Non toxic.	Non toxic.	Non toxic.	Non toxic.							
4	4	3	0	10.0	2039	COCAMID	263-058-8	Antistatic,	(Cocamidop	0	amidoamin	- ECHA We	50.0		500.0	ECHA Re	ECHAOral	ECHAAcut	ECHAEffec	ECHAGenotox	- InVitro	No a					
5	4	3	0	12.488	2054	GLYCERIN	200-289-5	Denaturan	Glycerin is	0	Diethylene	-Glycerol, U	10.0			ECHA: Derr	ECHA: Oral	ECHA: Oral	ECHA: Eff	CIR: CARCINO	GENOTOXICIT	Glycerin					
6	4	3	0	0.009	2070	METHYLCL	247-500-7	Preservativ	Methylchlor	0		- CIR Amer	100.0	Annex V/3:	2.8	SCCSRepr	SCCS/123	CIR: In acu	SCCS/123	SCCS/1238/09	Mutagenicity	and					
7	4	3	0	0.003	2071	METHYLIS	220-239-6	Preservativ	Methylisoth	0		- CIR Amer	101.0	Annex V/3:	19.0	- ECHA Re	ECHANo a	ECHAOral	ECHA: Effe	SCCS/1238/09	Mutagenicity	and					
8	4	3	0	0.5	2079	PARFUM	(1920-229-8	Fragrance	Verify if the	0		IFRA Guid	50.0	IFRA Guidel	ines	n/a											
9	4	3	0	10.0	2101	SODIUM L	221-416-0	Cleansing,	Sodium La	0	1,4-dioxan	ECHA website	-International Jour		300.0	ECHA: Oral	ECHA: Oral	ECHA: Oral	ECHA: Effect	on fertility	Oral route:	No adverse					
10	4	3	0	1.0	2113	XANTHAN	234-394-2	Binding, er	Xanthan G	0		- IJT 35(Su	10.0		250.0	CIR: Repea	CIR: Oral	CIR: LD50	EFSANO	ef EFSAGenotox	icity	No specific					

Versioni-Revisioni


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←



Shower Gel
ANGEL CONSULTING

In progress
Finalize

Bath gel

Estimated daily amount applied (g/day)
18.67

Area for application (cm²)
16,340

Retention factor
0.01

Daily Exposure (g/day)
0.1867

Creation
Federica Robino, 15/02/2020

Last modify
f.robino@angelconsulting.eu, 07/09/2021 15:09






Product data

Documentation (0)

Versions (1)

Version 1

Formula Tox data Exp-Dermal Exp-Oral Exp-Inhal QRA

		Amidoamine (AA)	Dimethylaminopropylamine (DMAPA)		
INCI	100.0000%	Estimated impurity	0.0000%	Estimated impurity	0.0000%
 ALOE BARBADENSIS LEAF JUICE	5.0000%	-	-	-	-
 AQUA	69.0000%	-	-	-	-
 COCAMIDOPROPYL BETAINE	2.0000%	-	-	-	-
 GLYCERIN	12.4880%	-	-	-	-
 METHYLCHLOROISOTHIAZOLINONE	0.0090%	-	-	-	-

Endorsment

CREDITS

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Scientific Supervision: Università di Genova, Dipartimento DISTAV
(Scienze della Terra, Ambiente e Vita)



- **rappresentativo:** presenti fin da subito oltre il 90% degli ingredienti impiegati nel settore cosmetico possono essere richiesti tutti gli ingredienti ancora non presenti
- **in evoluzione:** la *SCCS Notes of Guidance* guida il nostro *tool* con dati e *frame* tossicologici sempre aggiornati e pronti alle nuove sfide
- **strutturato:** i dati di letteratura scientifica sono una base indispensabile. Implementati con le più recenti metodologie *in silico*, grazie alle elaborazioni realizzate dai nostri esperti con piattaforme europee validate da ECHA e SCCS. Un *reasoning* per ogni ingrediente, così da supportare al meglio la valutazione del prodotto finito



- **aggiornato:** un team referenziato con oltre 30 anni di esperienza nel settore e supervisione scientifica universitaria indipendente
- **user driven:** aziende cosmetiche e *safety assessor* hanno costruito le fondamenta di questo strumento con i loro consigli. Gli utenti (*standard e premium*) potranno richiedere dati su ingredienti non ancora presenti nel *tool*



- **user friendly:** non sono necessari corsi, installazioni locali, aggiornamenti, i manuali d'uso.
- **condiviso:** i dati sono condivisi fra i Safety Assessor e i *contributor* che contribuiranno a implementare in maniera sempre più efficace il database. I documenti creati per aiutarti nella realizzazione di PIF e CPSR riporteranno un QR code di sicurezza ToxTool™, così da incrementare la loro rappresentatività

Coming soon...

Maggio 2022: webinar di presentazione

Stay Tuned!





Un nuovo strumento di competitività per
l'area *regulatory affairs* di ogni azienda cosmetica

Grazie per l'attenzione!

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Matteo Zanotti Russo
Cosmoprof Bologna, 29 Aprile 2022

