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# New IFRA 49<sup>th</sup> standard: regulatory updates for fragrances field



# Presenters

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F&B, EHS, Cosmetics  
industries all over the world



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Europe, North America, Asia, Australia.

# devex

Formula-based product lifecycle  
management (PLM) software

# hazex

SDS Authoring  
Software



**selerant**  
create. comply. connect.

**Product  
Portfolio**

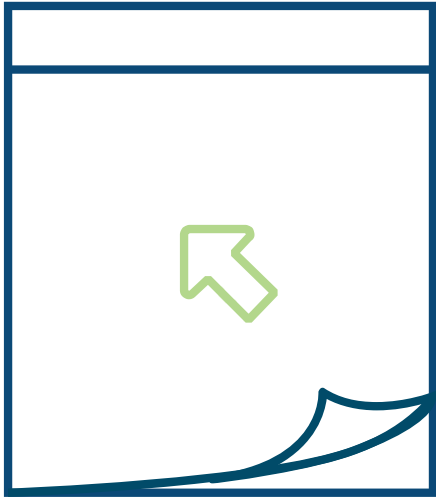
# ecodex

ISO certified  
eco-design tool

# compliance<sub>cloud</sub>

Real-time food safety monitoring system  
and compliance assessment reporting

# Agenda



**IFRA Introduction**



**IFRA 48th and IFRA 49th**



**IFRA module in the Selerant's solution**



**Q&A Session**

# IFRA Introduction



# What's IFRA?

IFRA  International FRAGRANCE Association.

## IFRA's purpose

The purpose of this association is to promote a safe use of fragrances in mixtures and products.

## IFRA standards

The IFRA Code of Practice - of which the IFRA Standards is a major part

# Products involved in IFRA standards



## Fine fragrance

Perfumes, skin care, color cosmetics, beauty gift sets...



## Household products

Textile washing, dishwashing, surface cleaners, air fresheners, scented candles, polishes, waxes...






## Cosmetics

Personal care products, hair care, personal hygiene, soaps, deodorants, baby care...

Source: <https://ifrafragrance.org/>



# Standards types: which are?

Prohibition		The substance cannot be used in any product
Restriction		The usage of the substance has to respect maximum concentrations limits, related to the product type (i.e. category).
Specification		The usage of the substance is related to purity criteria or to the usage with other materials

# IFRA certificate

Purpose of the certificate is ensuring companies that fragrances used conform with the IFRA Standards.

To ensure the conformity and the safety of the fragrances, on the certificate is reported the maximum level of usage (%) for each category



## CERTIFICATE OF CONFORMITY OF FRAGRANCE MIXTURES WITH IFRA STANDARDS

This Certificate assesses the conformity of a fragrance mixture with IFRA Standards and provides restrictions for use as necessary. It is based only on those materials subject to IFRA Standards for the toxicity endpoint(s) described in each Standard.

---

Certifying party:	Certifier information:
	Certifier address:
Customer:	N/A
Product:	EXAMPLE FRAGRANCE PRODUCT

---

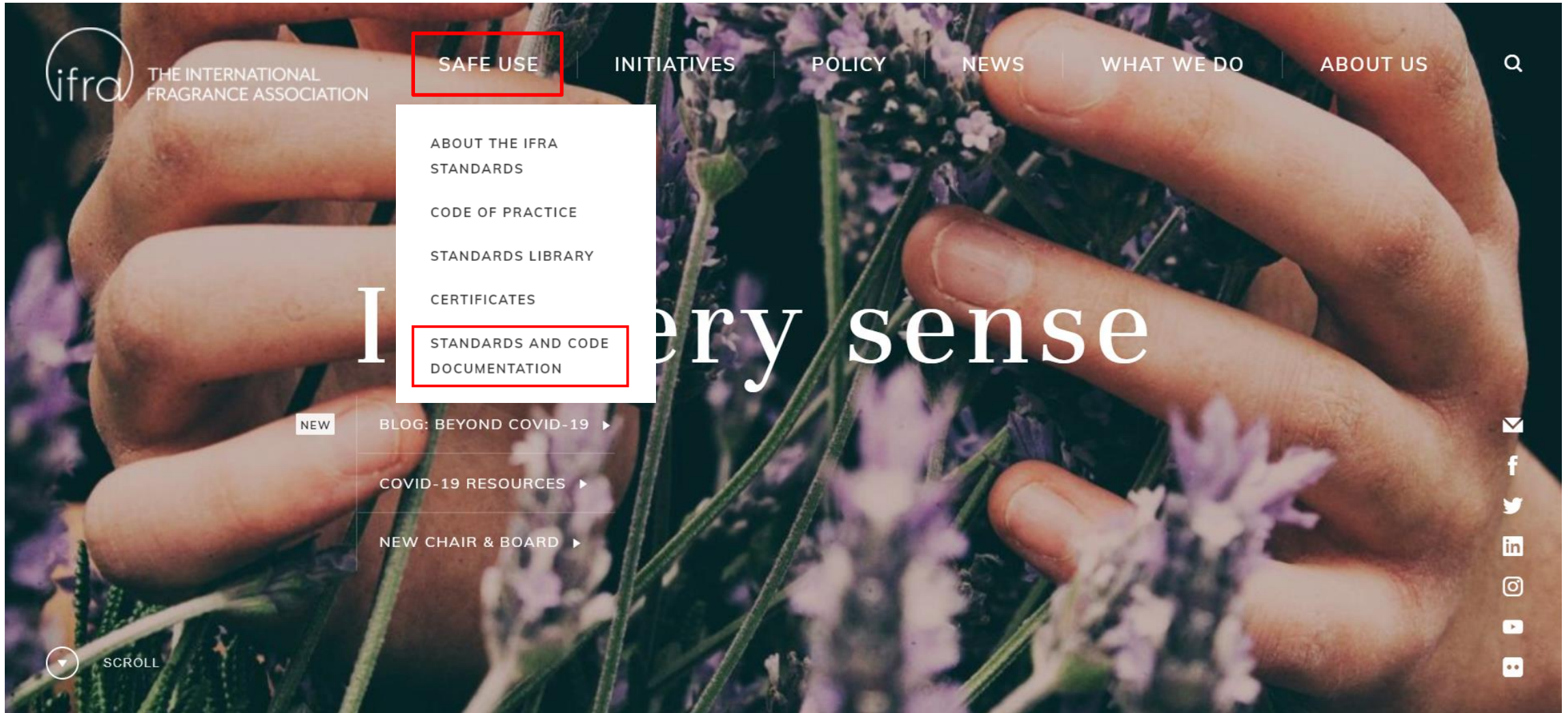
We certify that the above mixture is in compliance with the Standards of the INTERNATIONAL FRAGRANCE ASSOCIATION (IFRA), up to and including the 49th Amendment to the IFRA Standards (published January, 2020), provided it is used in the following category(ies) at a maximum concentration level of:

IFRA Category(ies)	Level of use (%)*
Category 1	0,58%
Category 2	1,667%
Category 3	0,29%
Category 4	1,6%
Category 5A	2%
Category 5B	0,58%

# Where to find the info?

<https://ifrafragrance.org/>

# Where to find the info?



# IFRA 48°



# IFRA 48<sup>th</sup> categories and classes

**IFRA 48:** 11 Categories QRA (dermal sensitization) + Categories related to systemic toxicity (ex: leave on, rinse off, EDT ...) -> Classes from 1 to 11 (in total 22 classes)

QRA INFORMATIONAL BOOKLET VERSION 7.1



Table 4: Guidance for preparing IFRA Certificates.

Product Type (QRA)	Category for systemic toxicity	Max use level for Methyl eugenol	Max use level for Estragole	Phototox	Food use approval	Class for IFRA Certificate
<b>Category 1</b>						
Lip Products of all types (solid and liquid lipsticks, balms, clear or colored, etc.)	leave-on	4 ppm	0.01%	Applicable	YES	<b>Class 1</b>
Children's Toys	leave-on	4 ppm	0.01%	Applicable	YES	<b>Class 1</b>
<b>Category 2</b>						
Deodorant and Antiperspirant Products of all types including any product with intended or reasonably foreseeable use on the axillae or labelled as such (spray, stick, roll-on, under-arm, deo-cologne and body spray, etc.)	leave-on	4 ppm	0.01%	Applicable		<b>Class 2</b>
Nose pore strips	leave-on	4 ppm	0.01%	Applicable		<b>Class 2</b>
Fragranced Bracelets	leave-on	4 ppm	0.01%	Applicable		<b>Class 2</b>

# How IFRA 48<sup>th</sup> standards are implemented?

Product Type (QRA)	Category for systemic toxicity	Max use level for Methyl eugenol	Max use level for Estragole	Phototox	Food use approval	Class for IFRA Certificate
<b>Category 7</b>						
Intimate Wipes	leave-on	4 ppm	0.01%	Not applicable		Class 7.A
Baby Wipes	leave-on	4 ppm	0.01%	Not applicable		Class 7.A
Insect Repellent (intended to be applied to the skin)	leave-on	4 ppm	0.01%	Applicable		Class 7.B
<b>Category 8</b>						
Make-up Removers of all types (not including face cleansers)	leave-on	4 ppm	0.01%	Applicable		Class 8.A
Hair Styling Aids Non-Spray of all types (mousse, gels, leave-in conditioners, etc.)	leave-on	4 ppm	0.01%	Applicable		Class 8.A
Nail Care	leave-on	4 ppm	0.01%	Applicable		Class 8.A
Powders and talcs, all types (except baby powders and talcs)	leave-on	4 ppm	0.01%	Applicable		Class 8.A
Hair Dyes	rinse-off	10 ppm	0.01%	Not applicable		Class 8.B

# IFRA 49°





# IFRA 49° – What's new

New scientific approach for determining the safe use of fragrance ingredients.

## New methodology

- Quantitative Risk Assessment for fragrance ingredients (QRA2)
- New approach of combining the QRA2, phototoxicity and systemic toxicity assessment in one exercise

## New Product categorization

- 12 Categories (+ sub-categories).
- The concept of “IFRA classes” becomes obsolete.
- Categorization based on functional type, area of use (head, face, axillae, etc.) and whether they are rinse-off or leave-on applications.

# IFRA 49 – category list

Table 9: IFRA Standard categories by product type.

Category	Product type
1	Products applied to the lips
2	Products applied to the axillae
3	Products applied to the face/body using fingertips
4	Products related to fine fragrance
5	Products applied to the face and body using the hands (palms), primarily leave-on:
5A	Body lotion products applied to the body using the hands (palms), primarily leave on
5B	Face moisturizer products applied to the face using the hands (palms), primarily leave on
5C	Hand cream products applied to the hands using the hands (palms), primarily leave on
5D	Baby Creams, baby Oils and baby talc
6	Products with oral and lip exposure
7	Products applied to the hair with some hand contact
7A	Rinse-off products applied to the hair with some hand contact
7B	Leave-on products applied to the hair with some hand contact
8	Products with significant anogenital exposure
9	Products with body and hand exposure, primarily rinse off
10	Household care products with mostly hand contact:
10A	Household care excluding aerosol products (excluding aerosol/spray products)
10B	Household aerosol/spray products
11	Products with intended skin contact but minimal transfer of fragrance to skin from inert substrate
11A	Products with intended skin contact but minimal transfer of fragrance to skin from inert substrate without UV exposure
11B	Products with intended skin contact but minimal transfer of fragrance to skin from inert substrate with potential UV exposure
12	Products not intended for direct skin contact, minimal or insignificant transfer to skin

## IFRA sub-categories

Subdivision of **categories 5 and 10** for taking into account **systemic toxicity** considerations

Subdivision of **categories 7 and 11** for taking into account **phototoxicity** considerations

# IFRA 48 vs IFRA 49

- **IFRA 48:** 11 Categories QRA + Categories related to systemic toxicity --> Classes from 1 to 11 (in total 22 classes)
- **IFRA 49:** 12 Categories + sub-categories -> in total 18 categories

IFRA Category Product Type	IFRA Category rationale Comments	IFRA Sub- category	Flavour use	Phototoxicity	IFRA category for Certificate of Conformity of fragrance mixtures with IFRA Standards	Old Categorization (QRA1 – 48 <sup>th</sup> Amendment)
<b>Category 3</b>	<b>Products generally applied to the face using fingertips</b>					
Eye products of all types (eye shadow, mascara, eyeliner, eye make-up, eye masks, eye pillows, etc.) including eye care and moisturizer			NO	Applicable (leave-on products)	Category 3	Category 3
Facial make up and foundation			NO	Applicable (leave-on products)	Category 3	Category 5 (women facial make-up)
Make-up remover for face and eyes			NO	Applicable (leave-on products)	Category 3	Category 8
Nose pore strips			NO	Applicable (leave-on products)	Category 3	Category 2

# IFRA 48 vs IFRA 49 : from QRA to QRA2

Product Type (QRA)	Category for systemic toxicity	Max use level for Methyl eugenol	Max use level for Estragole	Phototox	Food use approval	Class for IFRA Certificate
<b>Category 8</b>						
Make-up Removers of all types (not including face cleansers)	leave-on	4 ppm	0.01%	Applicable		Class 8.A
Hair Styling Aids Non-Spray of all types (mousse, gels, leave-in conditioners, etc.)	leave-on	4 ppm	0.01%	Applicable		Class 8.A
Nail Care	leave-on	4 ppm	0.01%	Applicable		Class 8.A
Powders and talcs, all types (except baby powders and talcs)	leave-on	4 ppm	0.01%	Applicable		Class 8.A
Hair Dyes	rinse-off	10 ppm	0.01%	Not applicable		Class 8.B



For IFRA 48<sup>th</sup>

QRA1 (old) Category 8
<p>Make-up removers of all types (not including face cleansers) to new IFRA Category 3</p> <p><i>In the new IFRA Categorization (QRA2), all the make-up products are included in Category 3.</i></p>
<p>Hair styling aids non-spray of all types (mousse, gels, leave-in conditioners, etc.) to new IFRA Category 7B.</p>
<p>Nail Care to new IFRA Category 5C</p>
<p>Powders and talc, all types (except baby powders and talc) to new IFRA Category 5A</p>
<p>Hair dyes to new IFRA Category 7A (rinse-off hair dyes) and to new IFRA Category 7B (leave-on hair dyes)</p>



For IFRA 49<sup>th</sup>

# IFRA 48 vs IFRA 49 – standards updates

## IFRA Standards modifications:

- 25 New standards
- Many existing standards will have **updated limits** due to the new criteria

IFRA 48

Material	CAS Number	Amendment	Limits in the finished product (%)										
			Category 1	Category 2	Category 3	Category 4	Category 5	Category 6	Category 7	Category 8	Category 9	Category 10	Category 11
Cyclamen aldehyde	103-95-7	47	0,17	0,22	0,89	2,67	1,40	4,28	0,45	2,00	5,00	2,50	Not Restricted

IFRA 49

Name of the IFRA Standard	CAS numbers	Category 1 (%)	Category 2 (%)	Category 3 (%)	Category 4 (%)	Category 5A (%)	Category 5B (%)	Category 5C (%)	Category 5D (%)	Category 6 (%)	Category 7A (%)	Category 7B (%)	Category 8 (%)	Category 9 (%)	Category 10A (%)	Category 10B (%)	Category 11A (%)	Category 11B (%)	Category 12 (%)
Cyclamen aldehyde	103-95-7	0,11	0,14	0,038	0,95	0,45	0,076	0,076	0,025	0,076	0,076	0,076	0,025	0,23	0,23	0,72	0,025	0,025	16

# IFRA 49 – Revised Certificate of Conformity

The certificate of conformity is based on IFRA categories, the nomenclature «classes» has become obsolete.

**COMPULSORY INFORMATION:**

We certify that the above mixture is in compliance with the Standards of the INTERNATIONAL FRAGRANCE ASSOCIATION (IFRA), up to and including the **xx** Amendment to the IFRA Standards (**published Month, Year**), provided it is used in the following category(ies) at a maximum concentration level of:

IFRA Category(ies) [see Table 12 in Guidance for the use of IFRA Standards for details]	Level of use (%)*
<b>Category 4</b>	<b>12%</b>
<b>Category 5.C</b>	<b>2.1%</b>

\*Actual use level or maximum use level

For other kinds of application or use at higher concentration levels, a new evaluation may be needed; please contact **(name of the fragrance supplier)**.

**(OPTIONAL INFORMATION):**

Information about presence and concentration of fragrance ingredients subject to IFRA Standards in the fragrance mixture **(name of the product)** is as follows:

Materials under the scope of IFRA Standards:	CAS number(s):	Recommendation from IFRA Standard:	Concentration (%) in fragrance mixture or finished product:
<b>trans-2-Hexenal (example)</b>	<b>6728-26-3 (example)</b>	<b>Restriction (example)</b>	<b>to be completed</b>
<b>Citral (example)</b>	<b>5392-40-5 (example)</b>	<b>Restriction (example)</b>	<b>to be completed</b>
<b>.....</b>	<b>.....</b>	<b>.....</b>	<b>to be completed</b>

IFRA 49<sup>th</sup> certificate reports categories instead of classes. Classes are now obsolete and have been removed from the standards

# IFRA 49 – Revised Certificate of Conformity

The certificate of conformity now reports notes about the substances in the formulation.

[Logo of the CERTIFYING PARTY]

Materials under the scope of IFRA Standards:	CAS number(s):	Recommendation from IFRA Standard:	Concentration (%) in fragrance mixture or finished product:
Toluene (example)	108-88-3 (example)	Specification: level that should be lower than 100ppm in fragrance mixture (example).	to be completed
Safrole, Isosafrole, Dihydrosafrole (example)	94-59-7 120-58-1 94-58-6 (example)	Specification: level should be lower than 0.01% in finished consumer product, only if such level is due to natural contributions containing Safrole, Isosafrole and/or Dihydrosafrole (example).	to be completed

On the certificate, we also have notes related to the specifications

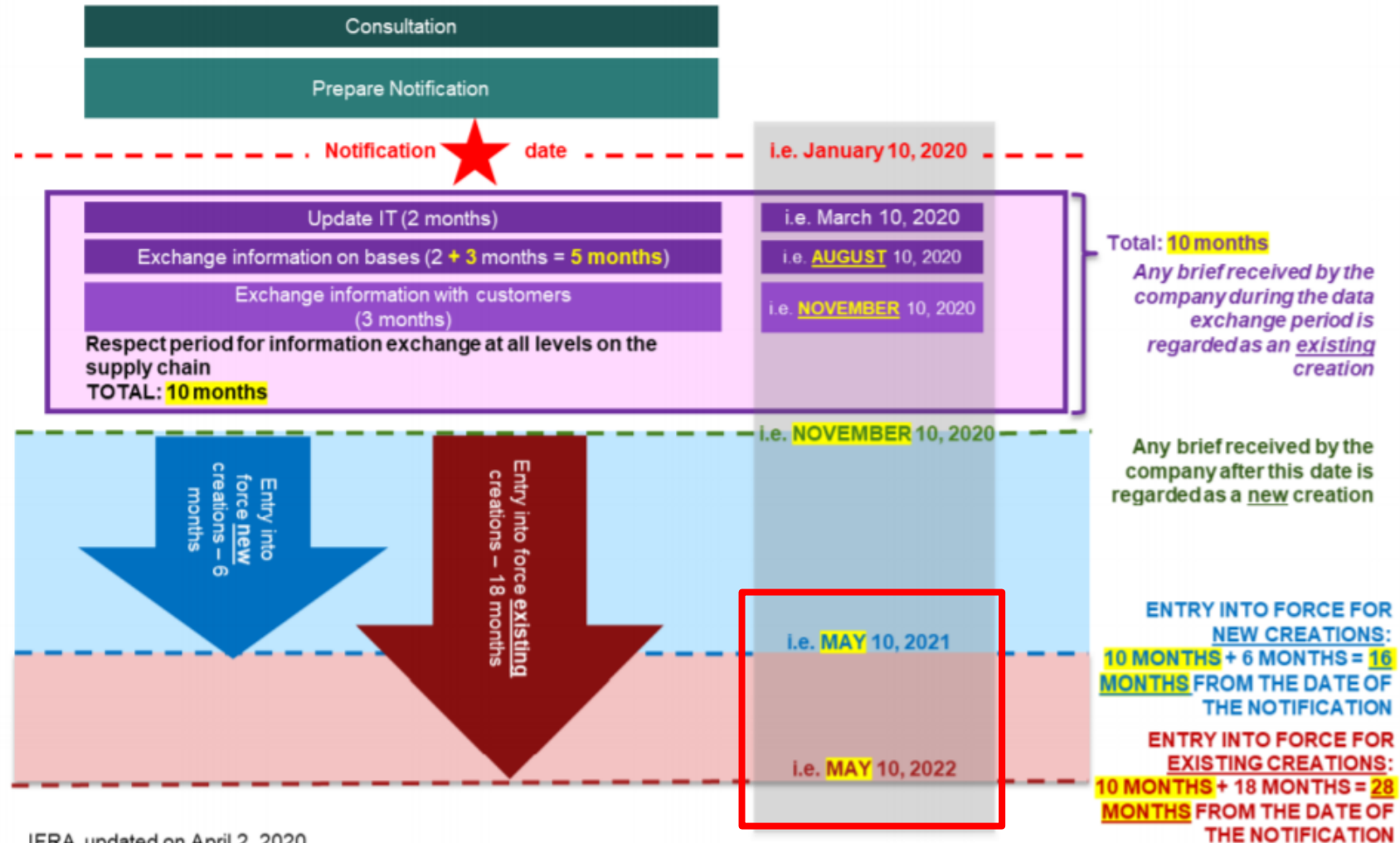


# IFRA 49 – Compliance timelines for Amendment

IFRA Standards	Date for Standards entering into force for new creations	Date for Standards entering into force for existing creations
Standards prohibiting or restricting the use of ingredients	6 months after the completion of information exchange across the supply chain (which is 7 months after the Notification date). In total, this is 13 months after the date of Notification (i.e. <b>February 10, 2022</b> ).	6 months after the completion of information exchange across the supply chain period (which is 7 months after the Notification date). In total, this is <b>25 months</b> after the date of Notification (i.e. <b>February 10, 2022</b> ).
Standards introducing a specification on the use of a fragrance ingredient	Annually for the 49 <sup>th</sup> Amendment there is no difference in the timeline for Specification Standards. Therefore, the timeline for Specification Standards is also 13 months after the date of Notification (i.e. <b>February 10, 2022</b> ).	Annually for the 49 <sup>th</sup> Amendment there is no difference in the timeline for Specification Standards. Therefore, the timeline for Specification Standards is also <b>25 months</b> after the date of the date of Notification (i.e. <b>February 10, 2022</b> ).



# IFRA 49 – COVID-19 timelines postponement



IFRA, updated on April 2, 2020

# Selerant's solutions



# IFRA 49 on Devex

Manage Panels

Physical

Restrictions

New Restriction

Copy

More

Export

Please check also Group Restrictions and Clustered Group Restrictions

Revision	Guideline Name	Application 1	Restriction Type	Upper Limit	UM	Legislation Source	Status	Actions
There are no entries								

Show 50 per page

1

<<

1

>>

1

No records to view

# IFRA 49 restrictions input

NEW RESTRICTION

ID0Revision0

Restriction List

IFRA Standard (49th Amd.) categories - Restriction List - 49

Material

IFRA - CEDRENE

Restriction Type

Application

Allowed (GMP)

Allowed (GMP)

Banned

Limited in end application

Limited in Formula

Filter

Clear

☐Category text

☐Category 1

☐Category 2

☐Category 3

☐Category 4

☐Category 5A

☐Category 5B

☐Category 5C

Cancel

Ok and New

OK

# IFRA 49 restrictions input

NEW RESTRICTION

☐ Category 8

☐ Category 9

☐ Category 10A

☐ Category 10B

☒ Category 11A

☒ Category 11B

☐ Category 12

Material Origin

Any

Concern

Upper Limit

5.8

UM

% w/w

Creation Date

Creator

Modification Date

Modifier

Valid From

Valid To

Notes

Cancel

Ok and New

OK

# IFRA 49 Standard type and Specification input

☆ CYCLAMEN ALDHEHYDE | Regulatory Substance: Generic plant / SB000009

Actions ▾ Custom Script Go to ▾ Reports ▾ SCP ▾ Security

Manage Panels

Physical Toxicity Ecotoxicity OEL GHS info Transport input data Test missing UDF Detergents module input **DXFF\_IFRA49\_\_0\_input** DXFF\_IFRA\_\_4\_input

IFRA standard type

- Restriction Specification ▾
- Prohibition
- Prohibition Restriction
- Prohibition Specification
- Restriction
- Restriction Prohibition
- Restriction Specification**
- Specification

Prohibited fragrance ingredient notes

Restricted ingredients notes

Intrinsic property driving the risk management measure

Dermal sensitization and systemic toxicity

Restricted ingredient due to phototoxicity considerations notes

Cyclamen aldehyde should not contain more than 1.5% of Cyclamen alcohol.

Specified ingredient notes

# IFRA 49 Calculation

## CALCULATION

<input type="checkbox"/>	Customer restriction Calculation	2	CURRENT
<input type="checkbox"/>	EHS DETERGENT	0	CURRENT
<input type="checkbox"/>	EU Ingredient List Analysis	2	CURRENT
<input type="checkbox"/>	European Cosmetic Regulation 1223/2009/EC for Cosmetic Product	1	CURRENT
<input type="checkbox"/>	EUSDS Seveso (Par.15.1)	0	CURRENT
<input type="checkbox"/>	FIAP - Food Improvement Agent Package	1	CURRENT
<input type="checkbox"/>	Flavour and Fragrance GMO Calculation	0	CURRENT
<input type="checkbox"/>	GHS - Multiple Country Authority Calculation	0	CURRENT
<input type="checkbox"/>	Halal Analysis	0	CURRENT
<input type="checkbox"/>	IFRA (48th Amd.) Analysis	4	CURRENT
<input checked="" type="checkbox"/>	IFRA (49th Amd.) Analysis	0	CURRENT
<input type="checkbox"/>	Kosher Analysis	0	CURRENT
<input type="checkbox"/>	Quali-Quantitative Analysis of Cosmetic product	0	CURRENT
<input type="checkbox"/>	SED MOS	0	CURRENT
<input type="checkbox"/>	Vegan Analysis	1	CURRENT
<input type="checkbox"/>	WGK Analysis	0	CURRENT

Available both  
IFRA 48<sup>th</sup> and 49<sup>th</sup>


Show 20 per page1<<1>>11 - 20 of 20 items shown

# IFRA 49 Calculation report

IFRA calculation report allows you to:


- Immediately check IFRA compliance
- Know the limiting ingredient for each category
- Review the details of IFRA restrictions, specifications and notes for all the ingredients

### CALCULATION

 Calculation Results: IFRA (49th Amd.) Analysis

DXFF\_IFRA49.0

Overall Result


 Requires User Review


Execution Mode

Standard

Comparison Result

Same as the Previous Calc.

 Input Parameters


 Summary Results

IFRA 49th Compliance


Yes

### IFRA 49TH ANALYSIS


Appl.1	IFRA Compliance	Max. Dosage	Reason	
Category 1	Yes	0,58%	SB000010	
Category 2	Yes	1,4%	SB000009	
Category 3	Yes	0,29%	SB000010	
Category 4	Yes	1,6%	SB000010	

 IFRA Categories Information (18 Results)

IFRA standard Categories by product type

 IFRA Standards - Ingredients (4 Results)

Fragrance ingredients subject to IFRA Standards

 IFRA Standard - Restrictions (72 Results)

List of components with IFRA Standard restrictions



# IFRA 49 certificate

After IFRA 49 calculation, IFRA 49 certificate can be generated

Document Type

IFRA Certificate - 49th Amd.

Language

ENGLISH

Export Type

PDF

Description

IFRA Certificate - 49th Amd.

Subject

Customer

☐ Send Me an Email

☐ Show Preview Only

Cancel

Ok

## CERTIFICATE OF CONFORMITY OF FRAGRANCE MIXTURES WITH IFRA STANDARDS

This Certificate assesses the conformity of a fragrance mixture with IFRA Standards and provides restrictions for use as necessary. It is based only on those materials subject to IFRA Standards for the toxicity endpoint(s) described in each Standard.

Certifying party: Certifier information:  
Certifier address:  
Customer: N/A  
Product: FRAGRANCE 1

We certify that the above mixture is in compliance with the Standards of the INTERNATIONAL FRAGRANCE ASSOCIATION (IFRA), up to and including the 49th Amendment to the IFRA Standards (published January, 2020), provided it is used in the following category(ies) at a maximum concentration level of:

IFRA Category(ies)	Level of use (%)*
Category 1	0,58%
Category 2	1,4%
Category 3	0,29%
Category 4	1,6%
Category 5A	2%
Category 5B	0,58%
Category 5C	0,58%
Category 5D	0,19%
Category 6	0,76%
Category 7A	0,58%
Category 7B	0,58%
Category 8	0,19%
Category 9	0,87%
Category 10A	0,87%
Category 10B	3,2%
Category 11A	0,19%
Category 11B	0,19%
Category 12	97%

*\*Actual use level or maximum use level*

For other kinds of application or use at higher concentration levels, a new evaluation may be needed; please contact the supplier.

# IFRA 49 certificate: second part

List of the ingredients subject to IFRA:

- Name and CAS
- Concentration
- Type of IFRA standard and Specification notes

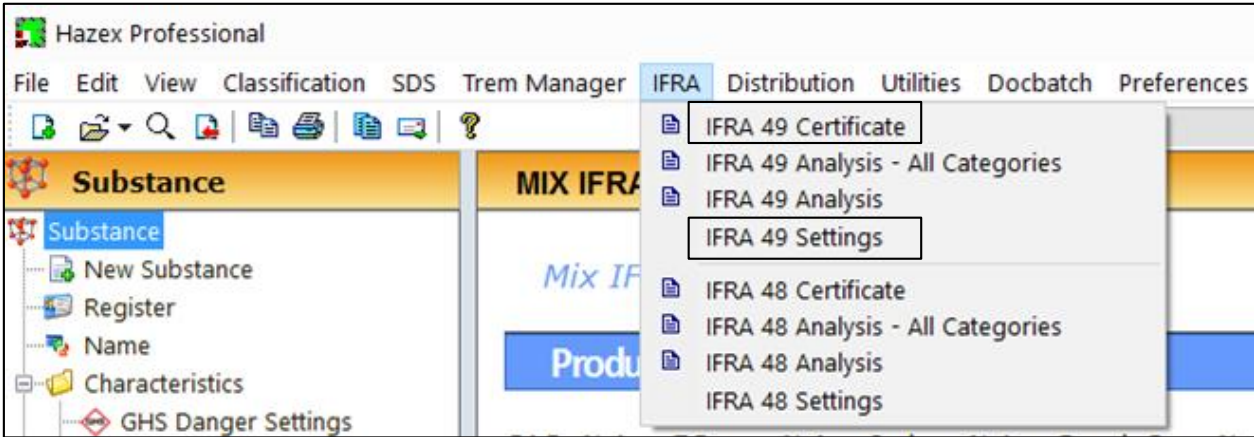
Information about presence and concentration of fragrance ingredients subject to IFRA Standards in the fragrance mixture FRAGRANCE 1 is as follows:

Materials under the scope of IFRA Standards	CAS Registry Number	Conc.(%)	Recommendation from IFRA Standard
CYCLAMEN ALDHEHYDE	111-76-2	10%	Restriction Specification Specification note: Cyclamen aldehyde should not contain more than 1.5% of Cyclamen alcohol.
GERANIOL	106-24-1	5%	Restriction.
METHYLEUGENOL	93-15-2	0,1%	Restriction.

Signature  
(If generated electronically, no signature)

Date  
apr 23, 2020

# IFRA 49 on Hazex Professional – in progress



IFRA49\_ENTRY.FPL (EWL1,en,NNN)

File Edit View

Ok Save Print < > IFRA GUIDELINES - EWL1 - Amendment: 49

IFRA limits

	IFRA certificate category	Limit %	Admitted
1	Category 1	10	Limited
2	Category 5.A	1.5	Limited
3			
4			
5			
6			
7			
8			
9			
10			
11			
12			
13			

IFRA type

Prohibition Specification Custom cutoff

CERTIFICATE OF CONFORMITY WITH IFRA STANDARDS

Mix IFRA 1

This Certificate assesses the conformity of a fragrance mixture with IFRA Standards and provides restrictions for use as necessary. It is based only on those materials subject to IFRA Standards for the toxicity endpoint(s) described in each Standard.

Certifying party [certifier information]  
[certifier address]

Customer: N/A

Product: Mix IFRA 1

We certify that the above mixture is in compliance with the Standards of the INTERNATIONAL FRAGRANCE ASSOCIATION (IFRA), up to and including the 49th Amendment to the IFRA Standards (published January, 2020), provided it is used in the following category(ies) at a maximum concentration level of:

IFRA category(ies)	Level of use (%)*
Category 1	0
Category 2	5.5000
Category 3	22.2500





# Thank you!

For any further questions please contact:

EHS Technical Support: [help@selerant.com](mailto:help@selerant.com)

EHS Regulatory Support: [regulatory@selerant.com](mailto:regulatory@selerant.com)

EHS Sales: [sales-ehs@selerant.com](mailto:sales-ehs@selerant.com)

