



Toxicological Risk Assessment

Example PRA



EL-Science Toxicological Product Risk Assessment

Product Name	:	Example
Brand Name	:	Example
ECID Numbers	:	N/A
Supplier	:	EL Science
Product Version	:	V2
Assessment Performed By	:	Shaun Wedgewood
Assessment Date	:	17/9/2020

This assessment is designed to meet the requirements of GPSR 2005

Toxicological Product Risk Assessment - Summary

This product has been assessed against Health Criteria Values (HCVs) within a standard vaping model by EL-Science. The assessment shows that the eliquid poses a non-substantial risk to human health over a prolonged period when used as intended as detailed in the product information leaflet.

Methodology

Health Criteria Value Thresholds (HCVs) are the concentration of specific flavour chemical ingredients at which the toxicology of the given chemical may cease to become non-significant when vaped over a prolonged period. EL-Science have commissioned the assessment of hundreds of flavour chemicals and hold full toxicological monographs as well as extended, toxicological assessment monographs for any chemical which is indicated as having a HCV. All toxicological monographs and any resulting toxicological models to produce the resulting HCVs have been performed by external qualified toxicologists.

EL-Science worked closely with one of the globally leading consultancies in respiratory toxicology to develop thresholds and models bespoke to the inhalation of flavour chemicals. The Product Risk Assessment (PRA) model is designed around the determination of thresholds for each chemical present within the product whilst considering cumulative toxicological pathways.

Using these thresholds, referred to as Health Criteria Values (HCVs) as core base data EL-Science then model the usage of a given product over a prolonged period using a standardised vaping model to determine the daily intake and potential impact of each product on specific toxicological pathways to produce the final assessment.

Sensitising compounds are identified in accordance with GHS/CLP. Sensitisers which do not exceed the GHS/CLP trigger are also presented to inform medical assistance being provided by medical professionals.

For further information or supporting evidence please contact EL-Science at contact@elscience.co.uk or call +44(0) 1733 352553



Toxicological Risk Assessment Summary Information Table

Please see page 4 for the assessment key.

Toxicological Product Risk Assessment - EL-Science					
ECID Number(s)	N/A	Assessment Performed By;		SW	
Brand Name	Example	Assessment Date		16/09/2020	
Product	Example				
Supplier	E L Science	Product Version		V2	
Chemicals where assessment shows no HCV Required					
48 Chemicals with no HCV associated					
Chemicals with HCV Assessment			Toxicity Assessment		
CAS Number	Chemical Name	Sensitiser	Local	Systemic	Overall
3658-77-3	Furaneol	S2		1	1
78-70-6	Linalool	S1	1	1	1
89-78-1	DL-Menthol		3	1	3
104-46-1	Anethole	S1		1	1
6728-26-3	trans-2-Hexenal	S0		2	2
119-36-8	Methyl salicylate			2	2
100-51-6	Benzyl alcohol		1	1	1
5471-51-2	Raspberry ketone			1	1
627-69-0	Propylene glycol 1-acetate		1	1	1
38462-22-5	para-Mentha-8-thiol-3-one	S0	1	1	1
106-24-1	Geraniol	S0	1	1	1
5392-40-5	Citral		1	1	1
4940-11-8	Ethyl Maltol			1	1
23726-91-2	beta-Damascone	S0		1	1
64-19-7	Acetic acid		1		1
142-62-1	Hexanoic acid		1		1
124-19-6	Nonanal		1		1
121-33-5	Vanillin			1	1
107-92-6	Butyric acid		1		1
13419-69-7	trans-2-Hexenoic Acid		1		1
470-82-6	Eucalyptol	S0		1	1
116-53-0	2-Methylbutyric acid		1		1
100-52-7	Benzaldehyde		1		1
123-11-5	p-Anisaldehyde		1		1
5989-27-5	(R)-(+)-Limonene	S0			
105-13-5	Anisyl alcohol	S0			
23696-85-7	Damascenone	S0			



Assessment Summary

Each chemical associated with a HCV is indicated along with an assessment category. The overall PRA has then been reviewed and assigned a Consumption Factor by EL-Science. A flavour with HCV compounds at their maximum threshold would result in a Consumption Factor of 5 would indicate a recommended weekly intake of approximately 30ml per week.

Flavours containing HCV chemicals which are lower than the maximum threshold result in a lower Consumption Factor which effectively correlates to a higher acceptable weekly intake before the potential of increased risk begins to appear in the long term.

In addition, Sensitiser compounds have been highlighted. These are important compounds to communicate to the consumer via labelling and product information leaflets in order to allow susceptible consumers to avoid contact with these compounds.

Assessment Key

Health Criteria Values

There are three categories presented in this summary which are detailed as below;

- 1 - Chemical is significantly below the HCV threshold and poses negligible risk at this concentration.
- 2 - Chemical is below the HCV threshold and poses a non-substantial risk at this concentration so long as batch production is controlled. Further work to reduce this chemical could be undertaken.
- 3 – Chemical is above the HCV threshold (up to 3 x the HCV) and therefore potentially poses a non-negligible risk to the consumer if inhaled over a prolonged period. The product should be further developed to reduce the toxicological profile of the offending chemical(s).
- 4 – Chemical is more than 3 x the HCV level and therefore potentially poses a more substantial risk to the consumer if inhaled over a prolonged period. The product should be further developed to reduce the toxicological profile of the offending chemical(s).

Sensitiser Compounds

- S0 – This compound is classified as a sensitiser but is below the concentration level that would normally cause a concern and therefore poses a negligible risk.
- S1 – This compound is classified as a sensitiser but is below the GHS/CLP labelling trigger. This compound should be communicated to a doctor or medical professional as a precaution should a consumer have an adverse reaction to the product.
- S2 – This compound is classified as a sensitiser and is above the GHS/CLP labelling trigger. This compound should be presented clearly on the product packaging and information leaflet. This compound should be communicated to a doctor or medical professional as a **priority** should a consumer have an adverse reaction to the product.

EL-Science are happy to help you understand this risk assessment document or if you are a legislative body to provide any and all supporting evidence in accordance with the laws of England and Wales. EL-Science have invested approximately £2M in eliquid safety and Toxicology since 2014 and continue to lead the industry forward offering free and confidential advice and are keen to work closely with legislative bodies and steering groups.

You can reach us as contact@elscience.co.uk or call us directly on 01733 352553



Toxicological Product Risk Assessment – Certificate

Product Name	Example
Brand Name	
ECID Number(s)	N/A
Supplier	EL Science
Assessment Date	16/09/2020

Assessment Outcome

EL-Science have invested over £2M in toxicology data and laboratories to develop our robust Product Risk Assessment (PRA) model to provide the consumer with full confidence and adequate information to make an informed choice when choosing an eliquid flavour. Our model is backed up by over 20,000 pages of toxicological data investigating the inhalation pathways for each flavour chemical used to formulate an eliquid and developed by over 20 chemists and toxicologists over a 4 year period.

EL-Science have designed the assessment model to be similar to that currently used in the food industry. With salt for example, if you exceed the recommended daily amount of salt intake you could potentially increase the risk of developing health complications in the long term.

This product has been assessed by EL-Science against Health Criteria Values (HCVs) associated with the Standard Vaping Model and summarised in the table below. To find the recommended weekly intake for this liquid read the appropriate Risk Factor row indicated and find the number 1.0 (or nearest to 1.0) and then read off the value at the bottom for the weekly amount in millilitres (mL).

The consumer should always read the label which may contain specific information on potential allergies. The product may also contain sensitisers which may adversely affect some consumers.

Consumption Factor CF=3	10	0.7	1.0	1.3	1.7	2.0	2.3	2.7	3.0	3.3
	9	0.6	0.9	1.2	1.5	1.8	2.1	2.4	2.7	3.0
	8	0.5	0.8	1.1	1.3	1.6	1.9	2.1	2.4	2.7
	7	0.5	0.7	0.9	1.2	1.4	1.6	1.9	2.1	2.3
	6	0.4	0.6	0.8	1.0	1.2	1.4	1.6	1.8	2.0
	5	0.3	0.5	0.7	0.8	1.0	1.2	1.3	1.5	1.7
	4	0.3	0.4	0.5	0.7	0.8	0.9	1.1	1.2	1.3
	3	0.2	0.3	0.4	0.5	0.6	0.7	0.8	0.9	1.0
	2	0.1	0.2	0.3	0.3	0.4	0.5	0.5	0.6	0.7
	1	0.1	0.1	0.1	0.2	0.2	0.2	0.2	0.3	0.3
	10	15	20	25	30	35	40	45	50	

ml per week

Based on the above information the maximum recommended intake for this liquid is 50ml per week

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For further information or supporting evidence please contact EL-Science at contact@elscience.co.uk or call +44(0) 1733 352553