



The comparison of alternatives to hazardous substances – A methodology and its implementation to formaldehyde

Symposium of the International Section of the ISSA on Prevention in the Chemistry Industry

"Carcinogenic substances: Risks and Prevention"

Purpose of the work

Request from 5 Ministries

(Environment, Labour, Health,
Agriculture, Consumer affairs)



Formal request

Opinion on the possibility of formaldehyde substitution in various sectors of activity



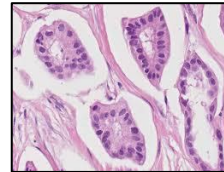
Embalming
processes



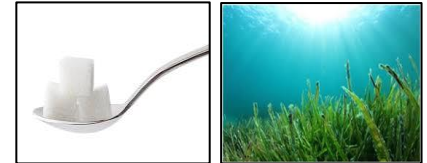
Animal feed



Pathological anatomy
and cytology



Food for human
consumption



Organisation of the work



Working Group (WG)
“Formaldehyde and substitutes”

Expert Committee
(multidisciplinary, independent and collective appraisals)



The Working Group:

1. Development of a method to compare alternatives
2. Implementation in the various sectors of activity

General description of the method

Identification of alternatives through a search in the scientific literature and consultation of stakeholders in the sector of activity

1st sequential step

“Technical performance” module

Exclusion of non-performing alternatives regarding technical performance criteria retained as essential

“Regulation” module

Exclusion of alternatives prohibited via regulations or included in the candidate list for authorisation under REACH

“Hazard” module – Rapid hazard assessment using QCAT tool

Exclusion of substitutes graded F by the QCAT tool

List of 6 to 10 alternatives graded A, B, C or « not assigned » and fulfilling the technical performance criteria retained as essential

General description of the method

List of 6 to 10 alternatives graded A, B, C or « not assigned » and fulfilling the technical performance criteria retained as essential

2nd simultaneous step

“Hazard” module

In-depth assessment of the hazards using GreenScreen tool

“Exposure conditions” module

Assesment of the exposure conditions

“Estimation of substitution costs” module

Study of the direct and indirect costs of substitution

“Other impacts” module

Module to be defined for each sector of activity

Comparative study of alternatives on the basis of available data

General description of the method

Class 1	Insufficient technical performance
Class 2	Inferior technical performance
Class 3	Equivalent technical performance
Class 4	Superior technical performance
Not assigned	Not assigned due to insufficient data

Technical
Performance

Class 1	High exposure conditions
Class 2	Moderate exposure conditions
Class 3	Low exposure conditions
Class 4	Exposure conditions considered negligible
Not assigned	Not assigned due to insufficient data

Exposure
conditions

Hazard

Hazard class 1	Extremely hazardous chemical substance
Hazard class 2	Very hazardous chemical substance
Hazard class 2 _{DG}	Very hazardous chemical substance due to missing data
Hazard class 3	Hazardous chemical substance
Hazard class 3 _{DG}	Hazardous chemical substance due to missing data
Hazard class 4	Low hazard chemical substance
Not assigned	Not assigned due to insufficient data

Substitution
costs

Class 1	Highest related costs
Class 2	Moderate related costs
Class 3	Low related costs
Class 4	Lowest related costs
Not assigned	Not assigned due to insufficient data

Implementation for embalming process

Regulatory information:

- Active substance « Formaldehyde » is under review to be used as Product Type 22 (Embalming and taxidermist fluids) by Germany until December 31, 2022.
- Products containing formaldehyde are currently making available on the market according to transitional measures.

Mortuary care in France:

- Basic funeral care (washing, dressing, make-up, hair-styling)
- Embalming: only performed by a qualified embalmer in France; an embalming fluid, generally containing formaldehyde, is introduced into arterial system, thoracic and abdominal cavities to delay the decomposition process of the body after death

Need for performing embalming:

- Non required by law, except for repatriation to some countries
- Performing basic funeral care or using temporary preservation by refrigeration may avoid performing embalming without prejudicing to family's expectations.
- Embalming may be essential in some cases: depending on the need to improve the appearance of the deceased, according to the duration of the stay of the deceased (at mortuary, at the funeral service or at home) and the number of viewings to relatives.

Working environments of the embalmer:

- Mortuary, funeral chambers, retirement home, house of the deceased
- => Mortuaries and funerary chambers intended to perform embalming are the best equipped and adapted workplaces for the embalmer.

Implementation for embalming process

Identification of alternatives

29 mixtures as potential alternatives to formaldehyde in embalming fluids

1st sequential step

“Technical performance” module

5 alternatives fulfilling the technical performance criteria retained as essential

24 alternatives excluded (lack of data)

Safebalm®, Thanato-Safebalm®, Art Cav Secure®, Thanadès®, Polyvinylpyrrolidone iodine based mixture

“Regulation” module

5 alternatives

0 alternatives excluded (no exclusion by regulation and no substance found on the candidate list for authorisation under REACH)

“Hazard” module
QCAT tool

4 alternatives

1 alternative excluded (grade F – extremely hazardous)

Thanato-Safebalm®, Art Cav Secure®, Thanadès®, Polyvinylpyrrolidone iodine based mixture

Safebalm®

2nd simultaneous step

The 4 alternatives are assessed through the 4 modules of the simultaneous step

“Hazard” module GreenScreen tool

“Exposure conditions” module

“Estimation of substitution costs” module

“Other impacts” module

Results for embalming process



anses

Conclusion of the modules	Formaldehyde	Alternatives			
		Thanadès®	Polyvinylpyrrolidone iodine based mixture	Thanato-Safebalm®	Art Cav Secure®
Final class of the “Technical performance” module	Class 3 (equivalent)	Class 2 (inferior)	Class 2 (inferior)	Class 3 (equivalent)	Class 3 (equivalent)
Final class of the “Hazard” module (GreenScreen)	Class 1 (extremely hazardous)	Class 2 (very hazardous)	Class 2 (very hazardous)	Class 2 (very hazardous)	Class 2 (very hazardous)
Final class of the “Exposure conditions” module	Class 1 (high)	Class 2 (moderate)	Class 3 (low)	Class 1 (high)	Class 3 (low)
Final class of the “Estimation of substitution cost” module	Class 4 (lowest related costs)	Not assigned (lack of data)	Not assigned (lack of data)	Class 1 (highest related costs)	Class 1 (highest related costs)
Identification of “Other impacts”	-	Availability of the product: need of approval of the active substance (PT 22) at EU level and then product authorisation needed	Availability of the product: product authorisation needed	<ul style="list-style-type: none"> • Availability of the product: not yet on the market • Training of the embalmers to use the product 	<ul style="list-style-type: none"> • Availability of the product: product on the market • Training of the embalmers to use the product • Increase of duration of the embalming process • Increase of the volume of infectious clinical waste

Conclusions and recommendations

Final presentation of the results:

Final table showing the various alternatives with their advantages and disadvantages to enable the decision-makers to retain the best option in view of the criteria they consider high-priority and acceptable

Main recommendations of the WG:

1) Avoid risks:

- Avoid to perform embalming when families or the situation do not request it by giving preference to basic funeral care and refrigeration techniques
- Inform objectively and transparently families on situations for which embalming must be performed and not systematically include it in funeral contracts

2) Limit exposure:

- Prohibit embalming outside the specific premises intended for this purpose (home and retirement home not equipped with ventilation system)
- Use existing alternatives to formaldehyde and regulate waste management following embalming

Prohibit the use of formaldehyde for embalming process considering the existence of alternatives

Useful information about the reports



Link to the method (english report)

<https://www.anses.fr/en/system/files/VSR2014SA0236Ra-MethodoEN.PDF>

and to its implementation in the following sectors of activity (reports only available in French):

Embalming processes: <https://www.anses.fr/fr/system/files/VSR2014SA0236Ra-2.pdf>

Animal feed: <https://www.anses.fr/fr/system/files/VSR2014SA0236Ra.pdf>

Pathological anatomy and cytology: <https://www.anses.fr/fr/system/files/VSR2014SA0236Ra-1.pdf>

Food for human consumption – sugar industry: <https://www.anses.fr/fr/system/files/VSR2014SA0236Ra-3.pdf>



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“Formaldehyde and substitutes” WG

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