

Arvin Substances

Safety evaluation

elisana

EUROPEAN LIGHT STABILISERS
AND ANTIOXIDANTS ASSOCIATION



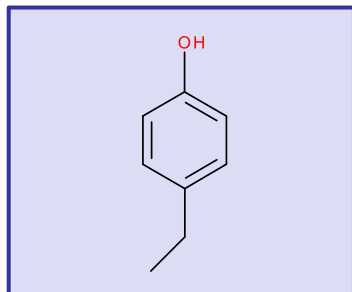
A sector group of Cefic 

European Chemical Industry Council - Cefic aisbl

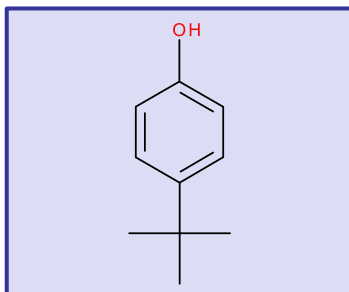
EU Transparency Register n° 64879142323-90

Arvin substances

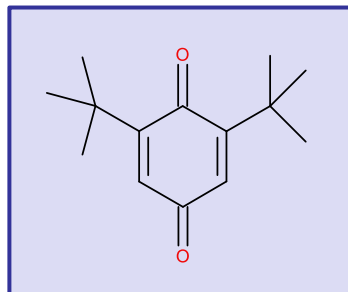
Arvin 1
CAS 123-07-9
4-ethylphenol



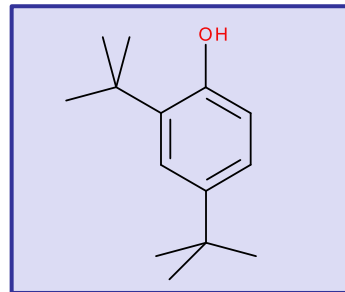
Arvin 2
CAS 98-54-4
p-tert-butylphenol



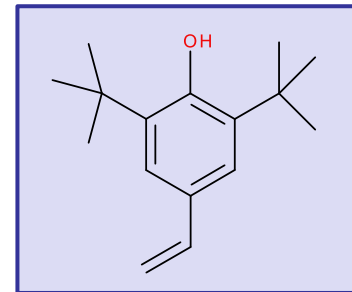
Arvin 3
CAS 719-22-2
2,6-di-tert-butyl-p-benzoquinone



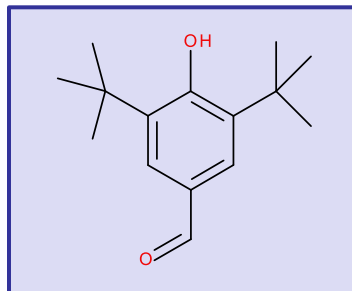
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2,4-di-tert-butylphenol



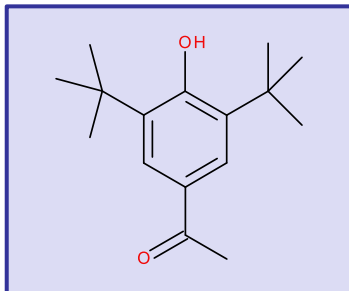
Arvin 5
CAS 19263-36-6
3,5-di-tert-butyl-4-hydroxystyrene



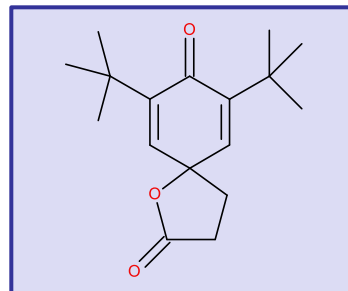
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CAS 1620-98-0
3,5-di-tert-butyl-4-hydroxybenzaldehyde



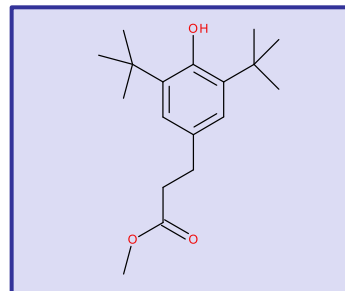
Arvin 7
CAS 14035-33-7
3,5-di-tert-butyl-4-hydroxy acetophenone



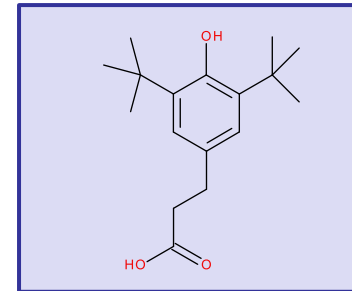
Arvin 8
CAS 82304-66-3
7,9-di-tert-butyl-1-oxaspiro(4,5)deca-6,9-diene-2,8-dione



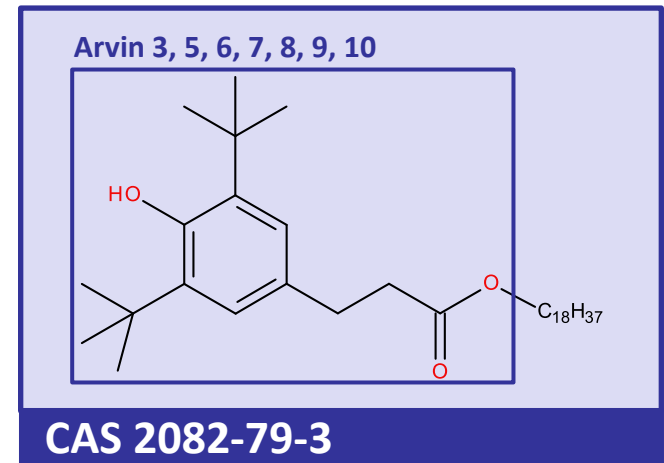
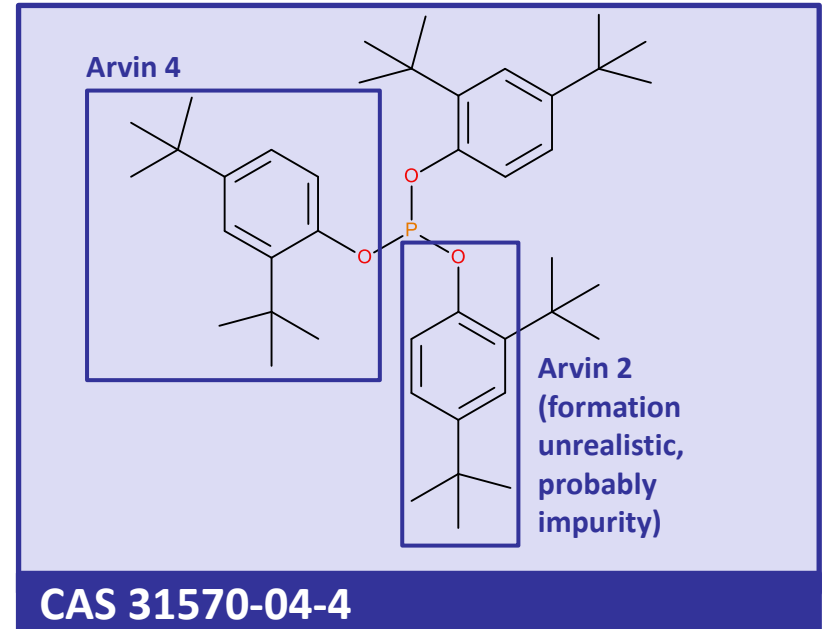
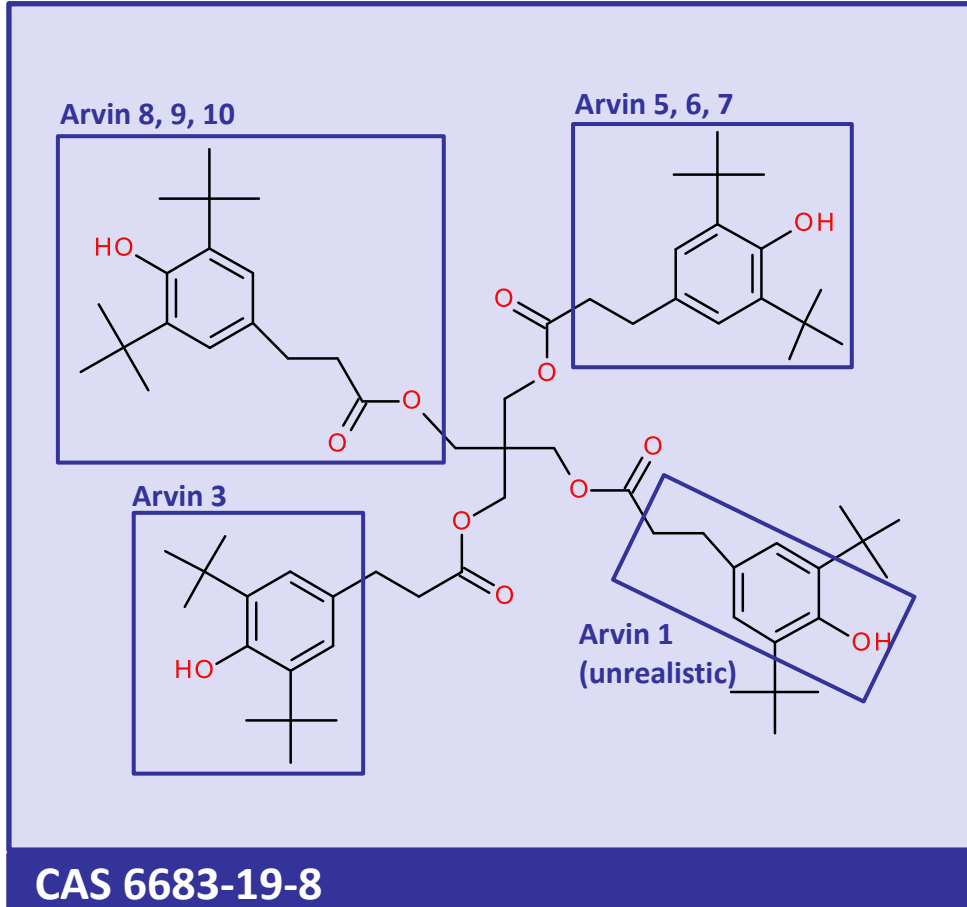
Arvin 9
CAS 6386-38-5
3-(3,5-di-tert-butyl-4-hydroxyphenyl) methylpropanoate



Arvin 10
CAS 20170-32-5
3-(3,5-di-tert-butyl-4-hydroxyphenyl) propanoic acid



Possible Formation of Arvin substances



Elisana's approach to determine safety thresholds*:

- Self-derived Tolerable Daily Intake (sTDI)
 - Self-derived TDIs have been calculated based on available data and the proposed read-across approach
- Drinking Water Positive List Limit (DWPLL)
- Specific Migration Limit (SML)
- Threshold of Toxicological Concern (TTC)
 - Substances with **negative genotoxic** test results are assigned to **Cramer Class III** with max. **TTC exposure limit of 1.5 µg/kg body weight (EFSA)**
 - Corresponds to **TTC of 4.5 µg/l** for drinking water

*: using EFSA and KTW guidelines

Summary on Safety Evaluation

Safety Values: Threshold of Toxicological Concern (TTC), self-derived Tolerable Daily Intake (sTDI), Drinking Water Positive List Limit (DWPLL)

Substance	TTC* (EFSA)	Self-derived TDI (sTDI)**	Conclusion on Genotoxicity	Self-derived DWPLL	Safety Conclusion
CAS 123-07-9 (Arvin 1)	4.5 µg/l	0.5 mg/kg b.w.	negative	1500 µg/l	No concern
CAS 98-54-4 (Arvin 2)	4.5 µg/l	50 ppb (established SML ¹)	negative	2.5 µg/l	No concern
CAS 719-22-2 (Arvin 3)	4.5 µg/l	0.24 mg/kg b.w.	negative	720 µg/l	No concern
CAS 96-76-4 (Arvin 4)	4.5 µg/l	0.75 mg/kg b.w.	negative	2250 µg/l	No concern
CAS 19263-36-6 (Arvin 5)	(no data)	no data	Not detected	0.1 µg/l (based on HPV ²)	No concern
CAS 1620-98-0 (Arvin 6)	4.5 µg/l	0.083 mg/kg b.w.	negative	250 µg/l	No concern
CAS 14035-33-7 (Arvin 7)	4.5 µg/l	0.083 mg/kg b.w.	negative	250 µg/l	No concern
CAS 82304-66-3 (Arvin 8)	4.5 µg/L	Testing is ongoing	negative	Testing is ongoing	Pending
CAS 6386-38-5 (Arvin 9)	4.5 µg/l	0.2 mg/kg b.w.	negative	600 µg/l	No concern
CAS 20170-32-5 (Arvin 10)	4.5 µg/l	0.25 mg/kg b.w.	negative	750 µg/l	No concern

* Substances with negative genotoxic test results are assigned to Cramer Class III with max. TTC exposure limit of 1.5 µg/kg body weight (EFSA) -> corresponds to TTC of 4.5 µg/l drinking water

** Self-derived TDIs have been calculated based on available data and the proposed read-across approach

¹ Specific Migration Limit, ² Health-based Parametric Value

- The key studies used to develop the TTC and sTDI values belong to various companies
- Elisana itself cannot provide copies of these key studies
- Elisana can assist in bringing study owners and study requestors together to discuss data sharing arrangements

- EFSA, 2016. Recent developments in the risk assessment of chemicals in food and their potential impact on the safety assessment of substances used in food contact materials. EFSA Journal 2016;14(1):4357, doi:10.2903/j.efsa.2016.4357, published: 28 January 2016
- EFSA/WHO, 2016. Review of the Threshold of Toxicological Concern (TTC) approach and development of new TTC decision tree. EFSA supporting publication 2016:EN-1006, published: 10 March 2016
- German Environment Agency, 2016. Guideline on the hygienic assessment of organic materials in contact with drinking water (KTW Guideline). As at: 07 March 2016

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