

Information on Toxicological Data

Date: 3 December 2017

Raw material name: POTASSIUM ALUM KALUNITE

Study class	Study type	Protocol	Results	Reference
Acute toxicity	Acute oral toxicity	OECD 401	Moderate to low toxic; LD50 rat: 162-750 mg Al/kg LD50 mice: 164-980 mg Al/kg	1
	Acute dermal toxicity	OECD 402	N/A	
	Acute inhalation toxicity	OECD 403	N/A	
Irritation and corrosivity	skin irritation	OECD 404	Slight irritant	2
	Mucous membrane irritation		Irritation of mucous membranes in the mouth, pharynx, oesophagus, and gastrointestinal tract	2
	Eye irritation	OECD 405	Slight irritant	2
Skin sensitisation		OECD 429	N/A	
Dermal/Percutaneous absorption		OECD 428	In vitro study on human skin (with 20% of aluminum chlorohydrate (5% aluminum)), <u>Dermal absorption rate:</u> Intact skin: 0.5%; Damaged skin: 18%	3
Repeated dose toxicity	Repeated dose (28days) oral toxicity	OECD 407	Drinking water rat study (28 days), NOAEL: 52 mg Al/kg (of Aluminum nitrate)	5
	Repeated dose (28days) oral toxicity	OECD 407	Diet feeding rat study (28 days), NOAEL: 288 mg Al/kg (of sodium aluminum phosphate)	4
	Repeated dose (28days) dermal toxicity	OECD 410	N/A	
	Repeated dose (28days) inhalation toxicity	OECD 412	N/A	
	Sub-chronic (90days) oral toxicity	OECD 408	Drinking water rat study (100 days), NOAEL: 52 mg Al/kg (of Aluminum nitrate)	5
	Sub-chronic (90days) dermal toxicity	OECD 411	N/A	

	Sub-chronic (90days) inhalation toxicity	OECD 413	N/A	
	Sub-chronic (26 weeks) oral toxicity	OECD 408	Beagle dog study (26 weeks), NOAEL: 27 mg Al/kg (of sodium aluminum phosphate)	4
	Chronic(> 12month) toxicity	OECD 452		
Reproductive toxicity	reproduction toxicity	OECD 421	Rat study, NOAEL: 13 mg Al/kg (of Aluminum nitrate)	5
	Developmental toxicity	OECD 421	Rat study, NOAEL: 30 mg Al/kg (of Aluminum citrate)	1
Mutagenicity/g enotoxicity	Mutagenicity/genotoxicity in vitro	OECD 471	Non-mutagenic	1
	Mutagenicity/genotoxicity in vivo	OECD 474	Non-mutagenic	1
Carcinogenicity		OECD 451	Non-carcinogenic (IARC); Mice study: No effects found at 5 mg of aluminum (as potassium aluminum sulfate) per kg of diet during their lifetime	5
Toxicokinetics		OECD 417	Aluminum is poorly absorbed through the gastrointestinal tract. The toxicokinetic properties of aluminum will depend on the properties of the complexes formed between Al ³⁺ and dietary or biological ligands.	4
Neurotoxicity		OECD 426	Aluminum is neurotoxicant and cause neurodegenerative disorders like Alzheimer's disease	1
Photo-induced toxicity	Phototoxicity/Photoirritation/photosensitisation	OECD 432	N/A	
	Phototoxicity/Photomutagenicity/photoclastogenicity	OECD 432	N/A	

Reference

1. Scientific Committee on Consumer Safety (SCCS): Opinion on the safety of aluminum in cosmetic products, SCCS/1525/14; 2014
2. MSDS Scientific & Chemical; 2008
3. Afssaps: Risk assessment related to the use of aluminum in cosmetic products, 2011
4. Safety of aluminum from dietary intake, The EFSA Journal (2008) 754, 1-34
5. Aluminum in Drinking-water, WHO/SDE/WSH/03.04/53, 1998

Attachment :

Same as reference

■ Summary

Summary of toxicity data

- Potassium Alum or Potassium aluminum sulfate is used in wide range of cosmetic products such as deodorant, lipsticks and toothpastes.
- Since the toxicological data specific to Potassium alum is not available, read across studies from aluminum containing salts have taken into consideration.
- In animal studies, Aluminum found to be low to moderate toxic and irritant to mucous membrane. The NOAEL established in repeat dose toxicity study with drinking water and diet feeding are 52 mg/kg and 288 mg/kg respectively.
- Aluminum is poorly absorbed after oral intake. The absorption depends on the properties of the complexes formed between Al^{3+} and dietary or biological ligands.
- Based on in vitro study on human skin, Afssaps recommends:
 1. Concentration of aluminum in cosmetic products should not exceed 0.6%
 2. Not to use cosmetics containing aluminum on damaged skin.
- The JECFA Committee established a provisional tolerable weekly intake (PTWI) of 2 mg/kg body weight based on a NOAEL of 30 mg/kg body weight per day and application of a safety factor of 100.

I hereby certify that the above information is all true.

Certified by

Name : Francis Verdan



Signature :

Position : Director