

VERDAN SWITZERLAND SARL

NEUENBURGSTR. 54, 3236 GAMPELEN/SUISSE

TEL. 0041 32 846 2359 FAX 0041 32 846 2560

WWW.VERDAN.COM

**Information on Toxicological Data**

Date: 3 December 2017

**Raw material name: POTASSIUM ALUM KALUNITE**

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| **Study class** | **Study type** | **Protocol** | **Results** | **Reference** |
| **Acute toxicity** | **Acute oral toxicity** | OECD 401 | Moderate to low toxic; LD50 rat: 162-750 mg Al/kgLD50 mice: 164-980 mg Al/kg | [1](#a) |
| **Acute dermal toxicity** | OECD 402 | N/A |  |
| **Acute inhalation toxicity** | OECD 403 | N/A |  |
| **Irritation and corrosivity** | **skin irritation** | OECD 404 | Slight irritant | [2](#b) |
| **Mucous membrane irritation** |  | Irritation of mucous membranes in the mouth, pharynx, oesophagus, and gastrointestinal tract | [2](#b) |
| **Eye irritation** | OECD 405 | Slight irritant | [2](#b) |
| **Skin sensitisation** | OECD 429 | N/A |  |
| **Dermal/Percutaneous absorption** | OECD 428 | In vitro study on human skin (with 20% of aluminum chlorohydrate (5% aluminum)),Dermal absorption rate: Intact skin: 0.5%;Damaged skin: 18% | [3](#c) |
| **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](#e) |
| **Repeated dose (28days) oral toxicity** | OECD 407 | Diet feeding rat study (28 days), NOAEL: 288 mg Al/kg (of sodium aluminum phosphate)  | [4](#d) |
| **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](#e) |
| **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](#d) |
| **Chronic(>12month) toxicity** | OECD 452 |  |  |
| **Reproductive toxicity** | **reproduction toxicity** | OECD 421 | Rat study, NOAEL: 13 mg Al/kg (of Aluminum nitrate) | [5](#e) |
| **Developmental toxicity** | OECD 421 | Rat study, NOAEL: 30 mg Al/kg (of Aluminum citrate) | [1](#a) |
| **Mutagenicity/genotoxicity** | **Mutagenicity/genotoxicity in vitro** | OECD 471 | Non-mutagenic | [1](#a) |
| **Mutagenicity/genotoxicity in vivo** | OECD 474 | Non-mutagenic | [1](#a) |
| **Carcinogenicity** | OECD 451 | Non-carcinogenic (IARC); Mice study: No effects found at 5 mg of aluminum (as potassium aluminumsulfate) per kg of diet during their lifetime | [5](#e) |
| **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 Al3+ and dietary or biological ligands. | [4](#d) |
| **Neurotoxicity** | OECD 426 | Aluminum is neurotoxicant and cause neurodegenerative disorders like Alzheimer’s disease  | [1](#a) |
| **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

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| 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 Al3+ 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.
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◼ Summary

**I**

**I hereby certify that the above information is all true.**

Certified by

Name : Francis Verdan

Signature : 

Position : Director