



Scientific Committee on Consumer Safety

SCCS

OPINION ON

**Potassium hydroxide (KOH)
as callosity softener/remover**

The SCCS adopted this opinion at its 5th plenary meeting
on 27 March 2014

About the Scientific Committees

Three independent non-food Scientific Committees provide the Commission with the scientific advice it needs when preparing policy and proposals relating to consumer safety, public health and the environment. The Committees also draw the Commission's attention to the new or emerging problems which may pose an actual or potential threat.

They are: the Scientific Committee on Consumer Safety (SCCS), the Scientific Committee on Health and Environmental Risks (SCHER) and the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) and are made up of external experts.

In addition, the Commission relies upon the work of the European Food Safety Authority (EFSA), the European Medicines Agency (EMA), the European Centre for Disease prevention and Control (ECDC) and the European Chemicals Agency (ECHA).

SCCS

The Committee shall provide opinions on questions concerning all types of health and safety risks (notably chemical, biological, mechanical and other physical risks) of non-food consumer products (for example: cosmetic products and their ingredients, toys, textiles, clothing, personal care and household products such as detergents, etc.) and services (for example: tattooing, artificial sun tanning, etc.).

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1. BACKGROUND

Potassium hydroxide (KOH) CAS n. 1310-58-3 is regulated in Annex III/15a - List of substances which cosmetic products must not contain except subject to restrictions and conditions laid down- to Cosmetics Regulation (EC) n. 1223/2009¹.

According to the Cosmetics Regulation (EC) n. 1223/2009 the use of Potassium Hydroxide as cosmetic ingredient must be limited as follows:

- (a) Nail cuticle solvent: 5.0% by weight
- (b) Hair straightener: 2.0/ 4.5 % by weight (general/professional use)
- (c) pH adjuster - depilatories: up to pH 12.7
- (d) Other uses as pH adjuster: up to pH 11

Industry requested the amendment of Annex III of the European Cosmetics Directive (76/768/EEC) in order to allow the use of Potassium hydroxide (KOH) as callosity softener/remover with a concentration up to 1.5% by weight.

The Commission asked the EMA Agency for opinion as to whether "a topical product to be applied on the skin and containing Potassium hydroxide (KOH) at a concentration up to 1.5% by weight might fall under the definition of a pharmaceutical product by function".

In October 2013 the Commission received the opinion of EMA on Potassium hydroxide (KOH) with the following conclusion:

In conclusion, a topical product applied on the skin and containing Potassium hydroxide (KOH) at a final concentration up to 1.5% by weight, and used as a keratolytic agent, has no metabolic, immunological or pharmacological mechanism of action, and therefore the presented product does not meet the criteria of a medicinal product as specified in the Article 1(2) of Directive 2001/83/EC².

2. TERMS OF REFERENCE

1. *Does SCCS consider Potassium Hydroxide KOH safe for use as callosity softener/remover with a concentration of maximum 1.5 % taking into account the information provided?*
2. *And/or does the SCCS recommend any further scientific concerns with regard to the use of Potassium Hydroxide KOH in cosmetic products?*

¹ <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:342:0059:0209:en:PDF>

² According to Article 1(2)(b) of Directive 2001/83/EC, the definition of a medicinal product by function is: "any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action".

3. OPINION

Industry has requested the amendment of Annex III of the European Cosmetics Directive (76/768/EEC) in order to allow the use of potassium hydroxide as callosity softener/remover with a concentration up to 1.5% by weight.

Before requesting the opinion of the SCCS, the Commission asked the EMA Agency whether *“a topical product to be applied on the skin and containing potassium hydroxide (KOH) at a concentration up to 1.5% by weight might fall under the definition of a pharmaceutical product by function”*.

The following text is taken from the EMA opinion (Ref. 1):

A callus (or callosity) is a toughened area of skin which has become relatively thick and hard in response to repeated friction, pressure, or other irritation. Although often found on the foot (where the most pressure and friction are applied), calluses can occur anywhere on the body as a reaction to moderate, constant “grinding” pressure. Calluses may be dissolved with keratolytic agents, which chemically dissolve the protein (keratin) that makes up most of the thick layer of dead skin on and around the callosity which usually tops it. It causes the outer layer of the skin to loosen and shed.

The intended purpose of use of potassium hydroxide at a final concentration up to 1.5% by weight is as a keratolytic agent due to its corrosive properties. Its action is mainly based on hydrolysis of amide bonds in keratin i.e. acting on a chemical manner not restoring a physiological function.

The EMA Agency *“... concluded that topical products to be applied on the skin and containing Potassium hydroxide (KOH) at a final concentration up to 1.5% by weight and used as a keratolytic agent to remove calluses (or callosities) do not fall under the definition of a pharmaceutical product by mechanism of action.”*

Taking note of the EMA opinion that the intended purpose of use of potassium hydroxide at a final concentration up to 1.5% by weight is as a keratolytic agent due to its corrosive properties, the SCCS only considered the irritant and corrosive properties of potassium hydroxide for the safety evaluation of potassium hydroxide in this opinion.

Original studies on chemical characterisation, physico-chemical properties and the irritant and corrosive properties of potassium hydroxide were not included in the submitted dossier. The safety evaluation of potassium hydroxide in this opinion was therefore based on the OECD SIDS Initial Assessment Report (OECD 2001).

3.1 Chemical and Physical Specifications

3.1.1 Chemical identity

(Taken from OECD 2001)

3.1.1.1 Primary name and/or INCI name

Potassium hydroxide

3.1.1.2 Chemical names

Caustic potash;
Potassium hydrate;

Potassium lye

3.1.1.3 Trade names and abbreviations

/

3.1.1.4 CAS / EC number

CAS: 1310-58-3
EC: 215-181-3

3.1.1.5 Structural formula

/

3.1.1.6 Empirical formula

KOH

3.1.2 Physical form

White and deliquescent solid

3.1.3 Molecular weight

Molecular weight: 56.11

3.1.4 Purity, composition and substance codes

/

3.1.5 Impurities / accompanying contaminants

/

3.1.6 Solubility

Water: 1100 g/l (25 °C)

3.1.7 Partition coefficient (Log P_{ow})

Log P_{ow}: /

3.1.8 Additional physical and chemical specifications

Melting point: 406 °C
Boiling point: 1327 °C
Flash point: /
Vapour pressure: /
Density: /
Viscosity: /
pKa: /
Refractive index: /

pH: /
 UV_Vis spectrum (..... nm): /

3.1.9 Homogeneity and Stability

Potassium hydroxide is a strong alkaline substance that dissociates completely in water to potassium ions and hydroxyl ions.
 Strongly exothermic dissociation in water.

3.2 Function and uses

According to the Cosmetics Regulation (EC) 1223/2009, the use of potassium hydroxide as cosmetic ingredient must be limited as follows:

- (a) Nail cuticle solvent: 5.0% by weight
- (b) Hair straightener: 2.0/ 4.5 % by weight (general/professional use)
- (c) pH adjuster - depilatories: up to pH 12.7
- (d) Other uses as pH adjuster: up to pH 11

Industry requested the amendment of Annex III of the European Cosmetics Directive (76/768/EEC) in order to allow the use of potassium hydroxide as callosity softener/remover with a concentration up to 1.5% by weight.

3.3 Toxicological Evaluation

3.3.1 Irritation and corrosivity

3.3.1.1 Skin irritation

(Taken from OECD 2001)

Animal data:

In a classical rabbit Draize test with gauze covering, application of 0.5 ml of potassium hydroxide 5% during 4 hours gave a PDII (primary dermal irritation indices) result of 4.8 (moderately irritating). A 10% solution was severely irritating (Nixon et al., 1990). With 19 mm diameter Hill Top Chamber pad covering during 1 or 4 hours and 0.2 ml applied, the 5 and 10% potassium hydroxide solutions were qualified as severely irritating.

A rabbit Draize test with gauze covering and application of 0.1 ml during 24 hours qualified a 5% potassium hydroxide solution as mildly irritating on intact skin and highly irritating on abraded skin (Johnson et al., 1975).

A 10% potassium hydroxide solution was qualified as corrosive on both intact and abraded skin as the result of a Draize occlusive test on rabbits with 4 hours exposure to 0.5 ml of the solution. The results with guinea pigs were similar (Nixon et al., 1975).

In a Draize rabbit test (reliability 3) with gauze covering and application of 0.5 ml of potassium hydroxide solutions during 4 hours, the 1% solution was not corrosive, whereas the 2% solution was corrosive. There was no post-exposure assessment of the lesion (Vernot et al., 1977).

In vitro data:

In *in vitro* tests (reliability 3) with reconstructed human skin cultures Skin²ZS1301 and EpiDerm, and MTT vital dye metabolism, a 10% potassium hydroxide solution was scored as corrosive (Perkins et al., 1996).

In a comparison study (reliability 3) of 4 *in vitro* methods, TER, Corrositex, Episkin and Skin²ZK1350, the 4 methods discriminated potassium hydroxide 10% as highly corrosive or corrosive, while only the 3 first methods discriminated potassium hydroxide 5% as highly corrosive or corrosive (Fentem et al., 1998).

SCCS comment

According to the classification in the CLP Regulation³, potassium hydroxide is a corrosive substance at concentrations from 2% and higher. At concentrations between 0.5% and 2% potassium hydroxide causes skin irritation.

3.3.1.2 Mucous membrane irritation / Eye irritation

(Taken from OECD 2001)

Animal data:

Several concentrations of KOH were tested by a Draize test on rabbits by instilling 0.1 ml, rinsing after 5 minutes or 24 hours of exposure and examining with the aid of fluorescein at 1, 24, 48 and 72 hours, 7 days, and eventually 14-21 days. The results were as follows: 5% / 5 min.: extremely irritant and corrosive. 1% / 5 min.: irritant; 1% / 24 hr.: irritant. 0.5% / 24 hr.: marginal. 0.1% / 24 hr.: negative (Johnson, 1975).

In vitro data:

In an *in vitro* test (reliability 3) with human corneal endothelial cell cultures and cell viability quantification by a 51Cr-release assay, the ED50 result (50% maximal toxicity) of 0.073% was said to correlate with "severe irritating" in the Draize test (Douglas and Spilman, 1983).

SCCS comment

According to the classification in the CLP Regulation³, potassium hydroxide is a corrosive substance at concentrations from 2% and higher. At concentrations between 0.5% and 2%, potassium hydroxide causes eye irritation.

3.3.2 Human data

(Taken from OECD 2001)

The mechanism of injury by alkali skin burns is by saponification of fat, which causes fatty tissue to lose its function with increased damage due to heat reaction; extraction of considerable water from cells due to the hygroscopic nature of alkali; and dissolution of proteins, permitting so deeper penetration of OH⁻ ions and further chemical reactions (Milner et al., 1996).

A 2-year old male was found to have a third degree (full thickness) burn on his right thigh due to exposure to the contents of leaking alkaline batteries (Winek et al., 1999).

A 4-year old boy who had a button battery lodged in his nose for approx. 24 hrs had local tissue corrosion, with a small perforation, caused presumably by the 25% potassium hydroxide electrolyte (Fernando, 1987).

³ REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. Available at: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:353:0001:1355:en:PDF>

Treatment of 32 children suffering of Molluscum contagiosum (a viral skin infection) with a topical 10% potassium hydroxide aqueous solution, twice daily, during a period of 30 days, resulted in clearance of all lesions. The only side effects observed in 12 children were: severe stinging, transitory hypo pigmentation, persistent hypo and hyper pigmentation, hypertrophic scar and secondary infection (Romiti et al., 1999).

Eye damage by alkali burns is most significant around pH 11 - 11.5. Alkali penetrates quickly, saponifies plasma membranes, denatures collagen, and causes vascular thromboses in the conjunctiva, the episclera, and even the anterior uvea. The sequelae of corneal burns include scarring and opacification of the cornea with resultant loss of visual acuity, corneal neovascularization, ulcer formation, and perforation. Other sequelae of untreated or very severe alkali burns include epithelial erosions, secondary glaucoma, progressive cicatrisation which occludes the ducts of main and accessory lachrymal glands and causes destruction of conjunctival goblet cells so as to cause dry eyes, cicatricial entropion, and trichiasis (Milner et al., 1996).

Additional information

Solutions of potassium hydroxide or sodium hydroxide are often used as a hair straightener by Afro-Americans. Despite the frequent use of particularly sodium hydroxide solutions dermatologists very rarely see patients with chemical burns in their clinics.

High concentrations of potassium hydroxide or sodium hydroxide are used in depilatory paste cosmetics to reach a pH of 11.5 to 12.5. Side effects are rarely seen.

A literature search has been performed in order to reveal case reports regarding chemical burns following use of solutions of potassium hydroxide and sodium hydroxide. No case reports were retrieved.

3.3.3 Discussion

Physico-chemical properties

Physico-chemical properties of potassium hydroxide described in this opinion have been taken from OECD (2001).

Information on purity and impurities in OECD (2001) was for industrial grade potassium hydroxide and therefore, this information is not included in this opinion.

Irritation / corrosion

Potassium hydroxide is a corrosive substance at concentrations from 2% and higher. Potassium hydroxide in solutions at concentrations between 0.5% and 2% causes skin and eye irritation.

4. CONCLUSION

In addition to those uses already regulated by the Cosmetics Regulation (EC) n. 1223/2009, the SCCS is of the opinion that potassium hydroxide is safe for use as callosity softener/remover with a concentration of maximum 1.5% by weight.

Other potential uses of potassium hydroxide in cosmetic products cannot be evaluated without further documentation.

The safe use of cosmetic products containing free potassium hydroxide in concentrations from 0.5% depends on responsible risk management (warnings and extensive guidance for use).

5. MINORITY OPINION

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6. REFERENCES

References submission I

1. European Medicine Agency (EMA) Scientific opinion to DG SANCO unit for Health Technology and Cosmetics (B2) on Potassium Hydroxide KOH CAS n. 1310-58-3 and its use in topical products.
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Additional references

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6. Scientific Committee on Consumer Safety, The SCCS's notes of guidance for the testing of cosmetic ingredients and their safety evaluation (7th Revision): SCCS/1416/11.