

SCIENTIFIC COMMITTEE ON CONSUMER SAFETY (SCCS)

**Request for a scientific opinion: Polidocanol CAS No 3055-99-0. EC No 221-284-4
Submission II**

1. Background

Polidocanol (CAS 3055-99-0) with the INCI-name laureth-9 is polyethylene glycol ether of Lauryl alcohol, where the average value of ethylene oxid units is 9. The chemical name of polidocanol is 3,6,9,12,15,18,21,24,27-nonaoxanonatriacontan-1-ol according to ECB¹.

The first opinion (SCCP/1130/07) on the substance was adopted by the SCCP the 2nd October 2007 with the conclusion:

"The data included in this dossier demonstrate that polidocanol is of low toxicity and does not pose a risk to the health of the consumer when used up to 3% in leave-on and up to 4% in rinse-off cosmetic products.

Recent scientific evidence does not confirm the assumed local-anaesthetic effect of polidocanol. Thus, its presence in cosmetics and skin care products will not affect cutaneous sensation".

According to the applicant the substance is used in rinse-off products as a non-ionic emulsifier and co-surfactant, particularly in shampoos and hair conditioners in concentrations from 1 to 4%. It is also used in leave-on products, such as body and face creams, up to a concentration of 3%.

At least one Member State has authorized polidocanol for use in a topical drug formulation at a concentration of 2%. A drug for injection has been approved in concentrations as from 0.5%.

Meanwhile more data was submitted by Member States in order to ensure that all available documentation of the inherent local anaesthetic effects and the ability to curb pruritus that Polidocanol possesses have been properly assessed by the Scientific Committee, and especially the use of polidocanol in leave-on products should be revisited. Furthermore, Member States are asking whether adverse effect has been considered like bradycardia/hypotension and sensitisation reactions. .

At the same time, the Commission was asked to request the SCCS to evaluate the homologue substance Laureth-7 together with polidocanol, as this substance is considered to be even more potent than polidocanol with respect to the local anaesthetic properties. However, not much data was submitted to support that purpose.

2. Terms of reference

1. *Does SCCS consider it necessary to change its conclusion on the safe use of polidocanol, especially its safe use in leave-on products or other use conditions taken into account the documentation provided?*
2. *And/or does the SCCS have any further concerns regarding the use of polidocanol in cosmetic products?*
3. *On the data provided, can the SCCS express an opinion on the safe use of laureth-7 in cosmetic products?*

¹ ECB – European Chemicals Bureau (ECB)