Establishing and explaining a baseline of octamethylcyclotetrasiloxane (D4) and decamethylcyclopentasiloxane (D5) in end-exhaled air and urine.

Published: 20-06-2012
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Biomonitoring of healthy volunteers in order to establish a baseline for D4 or D5 exposure in the general population and response to dermal exposure in an experiment under controlled exposure conditions.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON36073

Source
ToetsingOnline

Brief title
Establising an explaining a baseline of D4/D5.

Condition

- Other condition

Synonym
aggregated exposure

Health condition

synergistische blootstelling

Research involving

Human

Sponsors and support

Primary sponsor: CEFIC LRI
Source(s) of monetary or material Support: CEFIC LRI

Intervention

Keyword: baseline, decamethylcyclopentasiloxane, end-exhaled air, octamethylcyclotetrasiloxane

Outcome measures

Primary outcome

The concentration D4/D5 in end-exhaled air.

Secondary outcome

The concentration of D4/D5 in urine.

Study description

Background summary

Humans are regularly exposed to different consumer products that contain siloxanes. Siloxanes make up a class of synthetic silicon-containing compounds characterized by alternating atoms of silicon and oxygen. Exposure to octamethylcyclotetrasiloxane (D4) or decamethylcyclopentasiloxane (D5) occurs daily in 200 million individuals in the general population and hundreds of individuals in the workplace.

Baseline concentrations in end-exhaled air and urine from daily exposure to octamethylcyclotetrasiloxane (D4) and decamethylcyclopentasiloxane (D5), due to use of personal care products (PCPs), has not been established as far as we know. This study will give information about the dermal absorption of D4/D5 by use of PCPs.

Study objective

Biomonitoring of healthy volunteers in order to establish a baseline for D4 or D5 exposure in the general population and response to dermal exposure in an

experiment under controlled exposure conditions.

Study design

Observational exposure study

Intervention

The volunteers will be exposed to:
- 2 g pure substance D4
- 2 g pure substance D5
- a crème containing D4 or D5
- a deodorant containing D4 or D5
- a crème + deodorant containing D4 or D5

Study burden and risks

The study subjects will be asked to refrain from using personal care products for 24 hours. They will be exposed to D4 as a pure substance, D5 as a pure substance, a deodorant containing D4 or D5, a skin crème containing D4 or D5 and a combination of deodorant + crème. The administered dose will be in the same range as occuring in normal daily use by consumers. Adverse events are therefore not expected.
For the exposures and the measurements the study subjects will have to visit the laboratory. First, will visit to give one urine sample and an end-exhaled air sample in triplicate, to create a baseline. This will take approximately half a hour. After that the exposure studies will take place, for which the study subjects will have to come to the laboratory five times for approximately 8 hours per time. During these 8 hours end-exhaled samples will be collected in triplicate, which leads to a total number of 51 samples. At the same time urine samples will be collected in those 8 hours. The number of samples will depend on the study subject, but be approximately between 4 and 6 samples. The study subjects will also be asked to complete a questionnaire, to describe conditions of the use of personal care products. To get a detailed overview of the use of personal care products, the study subjects will be asked to complete a 24 hour diary.
If the concentration of D4 or D5 in the end-exhaled air samples are much higher than the concentrations in end-exhaled air samples from other study subject, the involved study subject will be contacted to provide a buccal smear sample for genotyping. This procedure will be discussed with the study subjects, prior to the start of the experiments.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

good general health
above 18 years of age

Exclusion criteria

pregnancy
women who are not taking birth control measures
skin diseases (in which hyperkeratoses occurs)
specific occupations: dry cleaner, make-up artist, hairdresser

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	25-02-2013
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	20-06-2012
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL35794.091.11