

**REACH Practical Guide** on Exposure Assessment and Communication in the Supply Chains

**Examples to Part III: Mixtures under REACH**



**Case Study 8: Downstream User Chemical Safety Report / NaOH**

This example illustrates a downstream user chemical safety report. It refers to the use of NaOH in oven cleaners. This use has not been covered by the exposure scenario of the supplier of NaOH.

***March 2010***

***Version: 1***

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**Important note to the reader**:

This case study has been prepared by the author within a VCI working group as part of the joint Cefic/VCI project to develop tools and guidances for industry – in respect of Chemical Safety Assessments, Chemical Safety Reports and Exposure Scenarios.

The REACH Practical Guide on Exposure Assessment and Communication in the Supply Chains developed in this project comprises several parts. An overview is given in the preface of Part I.

The structure and the contents of the REACH Practical Guide are described on the following web sites:

VCI: <http://www.vci.de/default~cmd~shd~docnr~125022~lastDokNr~102474.htm>

CEFIC: <http://cefic.org/templates/shwPublications.asp?HID=750>

All related documents can be downloaded from this site. In addition you find there information on related issues and actual developments.

These case studies have been prepared for REACH – related trainings purposes and educational purposes. It is not intended for the fulfilling of legal requirements. Case studies can be used as examples also by third parties if the source is cited.

It is mentioned in the description of the individual example if specific priorities have been set for the preparation of the example.

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Downstream User

CHEMICAL SAFETY REPORT

**on**

**use of NaOH in oven cleaners  
(aerosol exposure to consumer product)**

**Substance Name: SODIUM HYDROXIDE**

**EC Number: 215-185-5**

**CAS Number: 1310-73-2**

**Registrant’s identity Company XY**

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Introductory Remarks

This is an example for a downstream user chemical safety report according to Annex XII of Regulation (EC) No. 1907/2006 (REACH), which was prepared as part of the work on the VCI/CEFIC “Practical Guide on Exposure Assessment and Communication in the Supply Chains”.

**Disclaimer: This example CSR has been created based on current knowledge for demonstration purposes only. Information from this example should not be used without own scrutiny for registration or other purposes with legal consequences.**

For the purpose of this example it was assumed that

* Sodium hydroxide (NaOH) has been registered by a European manufacturer under REACH
* In his registration dossier the manufacturer has advised against any use, which is related to inhalation exposure to aerosols containing NaOH. Use of consumer products containing NaOH, which lead to dermal exposure are considered safe in the registrant’s CSR.
* The manufacturer of an oven cleaner (ready-to-use spray can) containing NaOH takes the initiative to demonstrate safe use of his product with respect to inhalation exposure by preparing a **downstream user CSR for a substance in a mixture.**

**REACH Annex XII states that**

“Where available and appropriate, an assessment carried out under Community legislation, (e.g. risk assessments completed under Regulation (EEC) No 793/93) shall be taken into account in the chemical safety assessment and be reflected in the Chemical Safety Report. Deviations from such assessments shall be justified.”

An EU Risk Assessment Report completed under Regulation (EEC) No 793/93 exists for NaOH (Vol. 73, 4th Priority List, 2007). In this report use of the substance in oven cleaner for consumer use is considered (although only shortly). The report states (page 58):

(citation from EU Risk Assessment Report in *italics*):

*Inhalation exposure*

*For certain specific uses, e.g. cleaning ovens and disinfection of sheds the use of a trigger spray is possible and the formation of aerosols can not be excluded completely. Aerosols of sodium hydroxide are not stable. They are rapidly transformed due to an uptake of carbon dioxide from the atmosphere resulting in the formation of sodium bicarbonate and sodium carbonate. The transformation of respirable sodium hydroxide aerosols into sodium carbonate aerosols can occur in seconds (Cooper et al., 1979). The maximum weight fraction of sodium hydroxide in a trigger spray is assumed to be 5%. The cleaner will be used indoors for a relatively short period of time per event (about 13 seconds). Because of this short-term use and the fact that sodium hydroxide is unstable in air, inhalatory exposure following the use of oven cleaners is considered to be negligible.*

By reference to this evaluation the downstream user would be able to terminate his downstream user CSR and consider safe use of his product proven, as far as conditions assumed in this assessment are applicable (e.g. concentration of NaOH in his product does not exceed 5%).

For the purpose of this example an own assessment of this specific use is developed.

Part B

# identity of the substance and physical and chemical properties

Substance Name: Sodium hydroxide

EC Number: 215-185-5

CAS Number: 1310-73-2

Physico-chemical properties: as provided in SDS

# maNufacture and uses

In this DU CSR the only use of NaOH considered is its role as an ingredient in oven cleaners for consumers: “Use of NaOH in oven cleaner gel in ready-to-use trigger spray”.

The concentration in this product is 0.83 % (2.5% of 33% NaOH in water).

Descriptors:

SU 21 Consumer uses;

PC35 Washing and Cleaning Products (including solvent based products)

# classification and labellingenvironmental fate properties

The hazard and PBT assessment provided by the supplier in the SDS is considered adequate.

# Human health hazard assessment

The hazard and PBT assessment provided by the supplier in the SDS is considered adequate. Under “real-life” conditions it is expected that DNELs are available from the supplier’s SDS, which can readily be used for the DU Chemical Safety Assessment. So, the DU Chemical Safety Assessment would focus on the exposure assessment, without further discussing the hazard properties of the substance.

For the purpose of this example (no assessment under REACH for the substance is yet available) the assessment as given in the EU Risk Assessment Report for NaOH under Regulation (EEC) No 793/93 (EU RAR, 2007)[[1]](#footnote-1) is used to obtain DNELs as a starting point of this DU Chemical Safety Assessment.

In the Risk Assessment Report the following information has been used to assess inhalation exposure:

Respiratory tract irritation was observed in humans exposed at the workplace under chronic exposure conditions. In the study by Fritschi et al. (2001), exposure concentrations up to 1 mg/m3 were not considered adverse with regard to local effects to the respiratory tract.

In the EU Risk Assessment Report 1 mg/m3 was used as a NOAEL to evaluate possible risks from chronic inhalation exposure and, hence, this concentration will be used as a basis for the assessment in this exemplary CSR.

* To consider potential inter-individual differences in susceptibility according to ECHA Guidance on Information Requirements and CSR, Chapter R.8, an assessment factor of 10 for the general population should be used.
* In the case of the oven cleaner only short time exposures occur (see below) with a duration of 2 minutes. If a 2 minutes exposure would be averaged over one day (24 h) only, an “attenuation factor” of 720 would result. For a conservative approach an attenuation factor of 100 is used.

Based on these considerations (assessment factor of 10 to consider inter-individual variation, factor of 0.01 for using chronic data for exposure duration of 2 minutes) a (surrogate) DNEL of 10 mg/m3 is used in this exemplary DU CSR.

# Human health hazard assessment of physicochemicaL properties

The hazard and PBT assessment provided by the supplier in the SDS is considered adequate.

# Environmental hazard assessment

The hazard and PBT assessment provided by the supplier in the SDS is considered adequate.

# PBT and VPVB assessment

The hazard and PBT assessment provided by the supplier in the SDS is considered adequate.

# Exposure assessment

Overview of exposure scenarios

Table : Overview on exposure scenarios and coverage of substance life cycle

| **ES number** | **Volume (tonnes)** | **Manufacture** | **Identified uses** | | | **Resulting life cycle stage** | | **Linked to Identified Use** | **Sector of Use (SU)** | **Preparation Category (PC)** | **Process category (PROC)** | **Article category (AC)** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Formulation** | **End use** | **Consumer use** | **Service life (for articles)** | **Waste stage** |
| ES 1 |  |  |  |  | *X* |  |  |  | **SU21** | *PC35* | *-* | *-* |
|  |  |  |  |  |  |  |  |  |  |  |  |  |

## Use of NaOH in oven cleaner gel in ready-to-use trigger spray

### Exposure scenario 1

|  |  |
| --- | --- |
| 1. **Title** | |
| **Free short title** | Use of NaOH in oven cleaner gel in ready-to-use trigger spray |
| **Systematic title based on use descriptor** | SU 21 Consumer uses  PC35 Washing and Cleaning Products (including solvent based products) |
| **Processes, tasks activities covered** | Use of oven cleaner gel spray product by consumers for oven cleaning |
| **Assessment Method\*** | Inhalation exposure considered as the only relevant pathway |
| 1. **Operational conditions and risk management measures** | |
| Environmental release:  For the purpose of this exemplary DU CSR it is assumed that environmental release from cleaning products is covered by the registrant’s CSR and is not further discussed here. Furthermore, no relevant environmental release is assumed for this specific use. Small amounts of NaOH will be absorbed to paper towels or floor cloths and ultimately reach the waste water system, but will immediately be neutralised. | |
| **2.1 Control of consumers exposure** | |
| **Product characteristic** | |
| 0.83% NaOH in product (2.5% of 33% aqueous NaOH)  Product is a milky-white gelatinous liquid. Formulation as a gel leads to large droplets upon spraying (100% > 10 µm) | |
| **Amounts used** | |
| Use of approx. 120 ml product per event | |
| **Frequency and duration of use/exposure** | |
| 2 min per event, 1 event per day | |
| **Human factors not influenced by risk management** | |
| Spraying into cold oven, with potential exposure to hands and arms (for the purpose of this exemplary DU CSR dermal exposure to such low concentrations of NaOH is assumed to be covered by the registrant’s CSR and is not further discussed here). | |
| **Other given operational conditions affecting consumers exposure** | |
| Spraying of up to 1 g product per second, by hand-held ready-to-use trigger spray | |
| **Conditions and measures related to information and behavioural advice to consumers** | |
| Keep out of reach of children.  Do not apply product into ventilator openings or slots. | |
| **Conditions and measures related to personal protection and hygiene** | |
| none | |
| **2.2 Control of environmental exposure** | |
| **Product characteristics** | |
| - | |
| **Amounts used\*** | |
| - | |
| **Frequency and duration of use** | |
| - | |
| **Environment factors not influenced by risk management** | |
| - | |
| **Other given operational conditions affecting environmental exposure** | |
| - | |
| **Conditions and measures related to municipal sewage treatment plant** | |
| - | |
| **Conditions and measures related to external treatment of waste for disposal** | |
| - | |
| **Conditions and measures related to external recovery of waste** | |
| - | |
| 1. **Exposure estimation and reference to its source** | |
| 0.3 to 1.6 mg/m3 based on modelling estimates obtained with ConsExpo and SprayExpo and based on considerations in EU Risk Assessment Report for Sodium Hydroxide, 2007 | |
| **4. Guidance to DU to evaluate whether he works inside the boundaries set by the ES**  Not applicable | |

### Exposure estimation

#### Workers exposure

Not applicable.

#### Consumer exposure

##### Acute/Short term exposure

For the purpose of this exemplary DU CSR dermal exposure to such low concentrations of NaOH in a mixture is assumed to be covered by the registrant’s CSR and is not further discussed here.

Inhalation exposure to NaOH in the oven cleaner was estimated using different modelling approaches:

1. ConsExpo software (version 4.1, <http://www.consexpo.nl>; Proud’homme de Lodder et al., 2006): default product: oven cleaner (application: spraying), default values apply to trigger spray
2. SprayExpo (Koch et al., 2004): release pattern: wall area (surrogate for the use assessed here)

Conditions of use and input parameters

The conditions of use were given by the manufacturer of the product as shown in the following table. This table only lists specific values and their rationale but does not include the default values used in the different models:

|  |  |
| --- | --- |
| Parameter | Value |
| Package | 375 mL trigger spray |
| Amount used | 120 g 1 |
| Spray duration | 120 sec 1 |
| Calculated mass generation rate | 1 g/sec 1 |
| Distance nozzle to face | 0.5 m |
| Distance nozzle to oven wall | 0.3 m |
| Weight fraction compound | 0.025 (2.5% ingredient (33% NaOH) assumed to be relevant for possible irritation) |
| Median of the particle size distribution | 273 µm 1 (mean of three measurements for one package; lowest value from three different packages tested) |
| Coefficient of variation (fraction) of the median | 1.15 1 (see text) |
| Maximum particle size | 670 µm (estimated from graphical droplet size distribution) |
| Room volume | 15 m3 2 |
| Air exchange | 2.5/h (ConsExpo default, also used for SprayExpo) |
| Inhalation cut-off diameter | 670 µm (set to maximum value of the distribution since exposure at the nose is estimated) |

1 These data deviate from the default values of the models, see text for details. SprayExpo requires a minimum spray duration of 300 seconds. In order to retain the total amount used of 120 g, the mass generation rate in this model was reduced.

2 This is the default value from ConsExpo for a kitchen. The room size in SprayExpo (lowest possible room height: 3 m) was adapted to result in an identical room value.

The product-specific data slightly differ from the ones used in ConsExpo 4.1 (Proud’homme de Lodder et al., 2006). These authors report a mass generation rate of 0.78 g/sec for general oven cleaners. The value taken here is somewhat higher but still lower than the value of 1.28 g/sec given by the same authors for an anti-grease cleaning trigger spray.

The particle size distribution was taken from product-specific measurements. Three different packages of the product were tested with three measurements for each package. In addition, measurements were performed with distances of 10 and 20 cm, respectively, between nozzle and laser beam. For the exposure assessment, the 10 cm distance trials were taken and the lowest value (mean of three measurements) was chosen.

The respective distribution is described by (rounded to 3 significant figures):

a 10th percentile of 103 µm

a 50th percentile of 273 µm

a 90th percentile of 314 µm

Under the assumption of a lognormal distribution (Proud’homme de Lodder et al., 2006), the software @risk (version 4.5.2, Pallisade Corporation, 2002) was used to define a “product-specific distribution” with the following values:

Median = 273 µm

10th percentile: 104 µm

μ = ln(GM) (corresponds to ln(median)) = ln(273) = 5,61

δ = ln(GSD) = 0.75

leading to a standard deviation of 314 and a C.V. of (314/273 =) 1,15 (the latter is required for ConsExpo software). The @risk software also allows deriving the percentages representing defined size classes (which are required for SprayExpo modelling).

See Annex for detailed results of the modelling with both models. Please note: a concentration of 2.5% (of 33% NaOH in water) was used in the modelling exercises. Results therefore were divided by 3 to derive the results as shown in table 2.

Other exposure estimates

The EU Risk Assessment Report (2007) on sodium hydroxide estimates occupational exposure to NaOH from the use of oven cleaners. The estimate is based on an assumed exposure concentration of 10 mg/m3 for aerosols. This value is derived from experiences with spray painting. With a concentration of 3% NaOH and 30% non-volatile substances in the oven cleaner a short-term inhalation exposure (during spraying) of 1 mg/m3 was estimated.

Accordingly, with a NaOH concentration in the product of 0.83% (this product) an inhalation exposure concentration of 0.3 mg/m3 would result.

Modelling results

Results for the different modelling approaches are shown in the next table.

Table : Acute exposure concentrations to consumers (note: an ingredient concentration of 2.5% (with the ingredient being 33% NaOH in water) was used in the modelling exercises. Therefore, modelling results as given in the Annex were divided by 3 to arrive at results for pure NaOH..

| **Routes of exposure** | **Estimated Exposure Concentrations** | | **Measured expo­sure con­centra­tions** | | **Explanation / source of measured data** |
| --- | --- | --- | --- | --- | --- |
| **value** | **unit** | **Value** | **unit** |
| Inhalation exposure | 0.012 (mean) \* 0,33 (peak concen­tration) | mg/m3 |  |  | ConsExpo 4.1: Spraying for 2 minutes, 60 minutes exposure period |
| 1,6 | mg/m3 |  |  | SprayExpo: mean for spraying period (5 minutes) |
| 0.3 | mg/m3 |  |  | According to EU RAR, 2007 |

\* 0.012 mg/m3 represents the mean for a total exposure period of 60 minutes, as calculated by ConsExpo and includes 58 minutes without application. As here the mean concentration during application is sought, the peak concentration (0.33 mg/m3) is used as a conservative estimate of the average concentration.

Summary of the short-term exposure values

Table : Summary of acute exposure concentrations to consumers

|  |  |  |
| --- | --- | --- |
| **Routes of exposure** | **Concentrations** | **Justification** |
| Oral exposure  (in mg/kg bw/d) |  | Not applicable |
| Dermal local exposure  (in mg/cm2) |  | Not applicable |
| Dermal systemic exposure  (in mg/kg bw/d) |  | Not applicable |
| Inhalation exposure  (in mg/m3) | 0.3 to 1.6 | See modelling results above |

##### Long-term exposure

Exposure is restricted to few minutes per event with up to 1 event per day (worst case assumption, in practice a lower frequency of approx. once per week is reasonable). Therefore, no long-term exposure has to be considered.

#### Indirect exposure of humans via the environment (oral)

For the purpose of this exemplary DU CSR it is assumed that environmental release from cleaning products is covered by the registrant’s CSR and is not further discussed here. Furthermore, no relevant environmental release is assumed for this specific use. Small amounts of NaOH will be absorbed to paper towels or floor cloths and ultimately reach the waste water system, but will immediately be neutralised.

#### Environmental exposure

For the purpose of this exemplary DU CSR it is assumed that environmental release from cleaning products is covered by the registrant’s CSR and is not further discussed here. Furthermore, no relevant environmental release is assumed for this specific use. Small amounts of NaOH will be absorbed to paper towels or floor cloths and ultimately reach the waste water system, but will immediately be neutralised.

# Risk characterisation

## Use of NaOH in oven cleaner gel in ready-to-use trigger spray

### Human health

#### Workers

Not relevant.

#### Consumers

Table : (Semi) Quantitative risk characterisation for consumers

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **Route** | **ES 1- exposure concentrations (EC)** | **Leading toxic end point / Critical effect** | **DN(M)EL** | **Risk characterisation ratio (RCR)** |
| Acute - systemic effects | Dermal | mg/kg bw/d | Not applicable |  |  |
| Inhalation | mg/m3 | Not applicable |  |  |
| Acute - local effects | Dermal | mg/cm2\* | Not applicable |  |  |
| Inhalation | mg/m3\*\* | 0.3 – 1.6 | 10 | 0.03 – 0.16 |
| Oral | mg/kg bw/d | Not applicable |  |  |
| Combined routes |  |  |  | *RCR Inhalation- systemic + RCR Dermal- systemic* |
| Long-term - systemic effects | Dermal | mg/kg bw/d | Not applicable |  |  |
| Inhalation | mg/m3 | Not applicable |  |  |
| Oral | mg/kg bw/d | Not applicable |  |  |
| Combined routes |  |  |  | *RCR Inhalation- systemic + RCR Dermal- systemic* |
| Long-term – local effects | Dermal | mg/cm2/d | Not applicable |  |  |
| Inhalation | mg/m3\*\*\* | Not applicable |  |  |

\* per day or event, whichever is more relevant

\*\* same value as “Acute systemic effects-inhalation exposure concentration”

\*\*\* same value as “Long-term systemic effects-inhalation exposure concentration” \* per day or event, whichever is more relevant

\*\* same value as “Acute systemic effects-inhalation exposure concentration”

\*\*\* same value as “Long-term systemic effects-inhalation exposure concentration”

The risk characterisation results in a RCR of <1, indicating safe use of the product under the conditions of use described. Safe use is further assured by the following considerations.

1. The product is formulated as gelatinous liquid. Aerosols formed by using this formulation in a trigger spray have droplet sizes with a median of 273 µm with 100% of particles being above 10 µm. Thus, the aerosols are not respirable and potential irritating effects would be restricted to the upper nasal passages only. These aerosols are also expected to be less harmful than those present in occupational health studies, which led to the derivation of the DNEL.
2. According to EU RAR (2007) and Cooper et al. (1979) aerosols of sodium hydroxide are not stable. They are expected to be transformed within seconds due to transformation to sodium bicarbonate and sodium carbonate by uptake of carbon dioxide.

#### Indirect exposure of humans via the environment

Not relevant.

### Environment

Not relevant.

## Overall exposure (combined for all relevant emission/release sources)

Not relevant, see Chapter 9.1.1.2.

## 

# references

Cooper et al., 1979   
A critique of the U.S. standard for industrial exposure to sodium hydroxide aerosols.   
Amer. Ind. Hyg. Ass. J. **40**, 365-371.

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Arbeitsplatzbelastungen bei der Verwendung von Biozid-Produkten. Teil 1: Inhalative und dermale Expositionsdaten für das Versprühen von flüssigen Biozid-Produkten  
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Prud’homme de Lodder, L. C. H., Bremmer, H. J., van Engelen, J. G. M., 2006  
Cleaning Products Fact Sheet. RIVM report 320104003/2006  
RIVM, Rijksinstituut voor Volksgezondheid en Milieu, Bilthoven, Netherlands, 2006

# Annex

ConsExpo results

**ConsExpo 4.1 report**

Report date: 24/07/2009

**Product**

Oven cleaner

**General Exposure Data**

exposure frequency 26 1/year

body weight 65 kilogram

**Inhalation model: Exposure to spray**

weight fraction compound 2.5 %

exposure duration 60 minute

room volume 15 m3

ventilation rate 2.5 1/hr

mass generation rate 1 g/sec

spray duration 2 minute

airborne fraction 0.2 fraction

weight fraction non-volatile 0.1 fraction

density non-volatile 1.8 g/cm3

room height 2.5 meter

inhalation cut-off diameter 670 micrometer

non-respirable uptake fraction 1 fraction

**Initial particle distribution:**

Distribution function: LogNormal

median: 273 micrometer

coefficient of variation: 1.15

**Uptake model: Fraction**

uptake fraction 1 fraction

inhalation rate 24.1 liter/min

**Output**

**Inhalation (point estimates)**

inhalation mean event concentration : 0.0361 mg/m3

inhalation mean concentration on day of exposure: 0.00151 mg/m3

inhalation air concentration year average : 0.000107 mg/m3/day

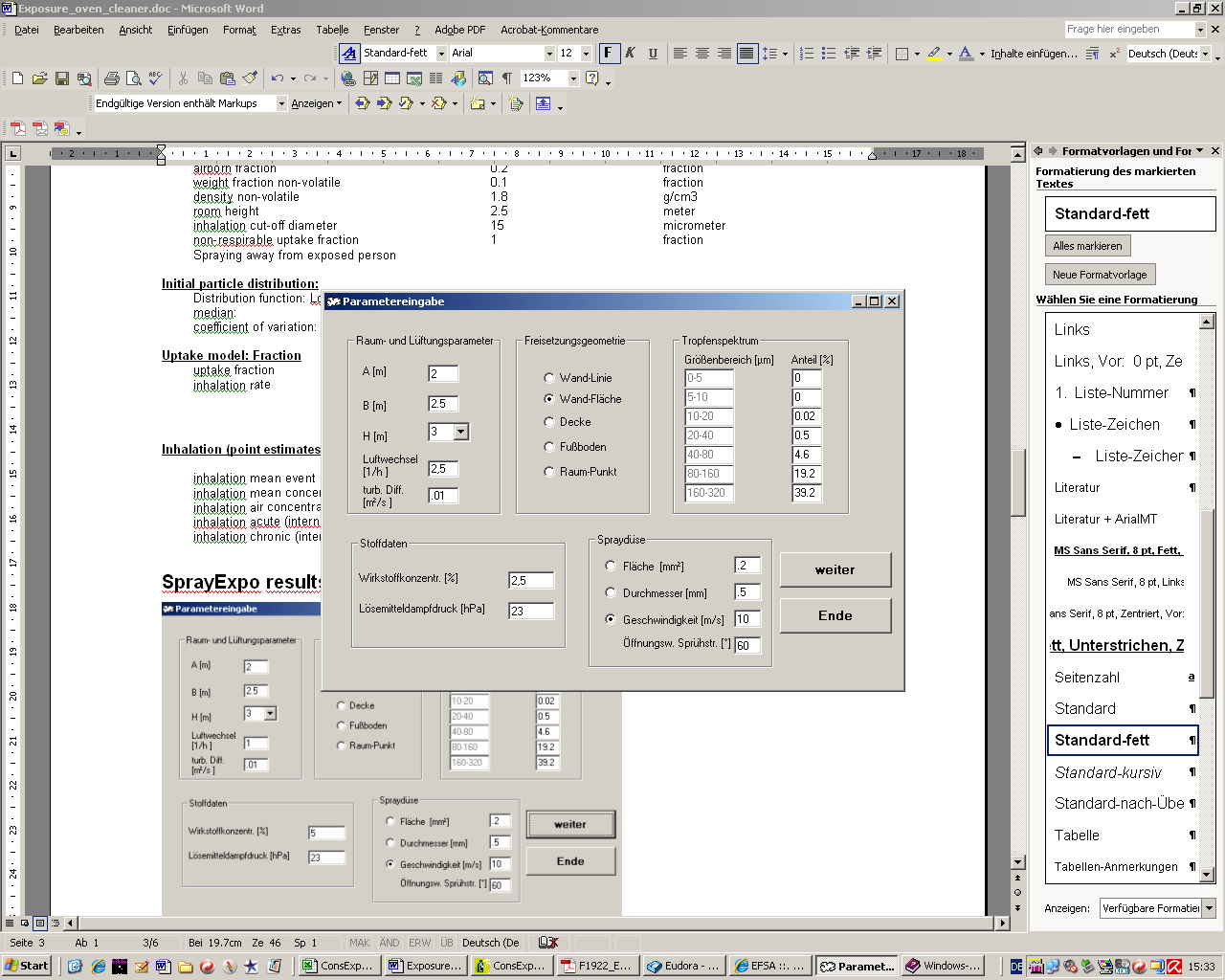
inhalation acute (internal) dose : 0.000804 mg/kg

inhalation chronic (internal) dose : 5.72E-5 mg/kg/day

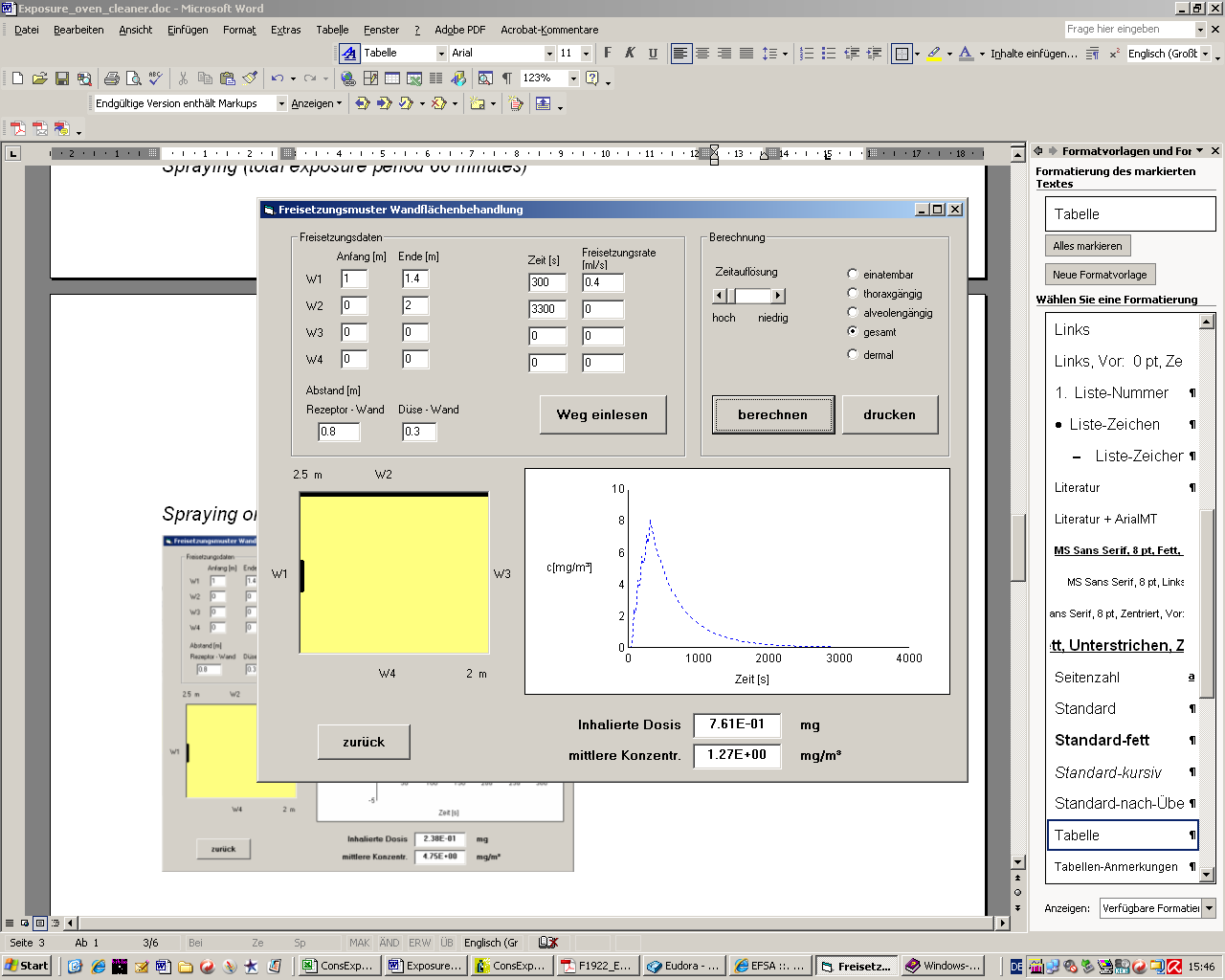


SprayExpo results

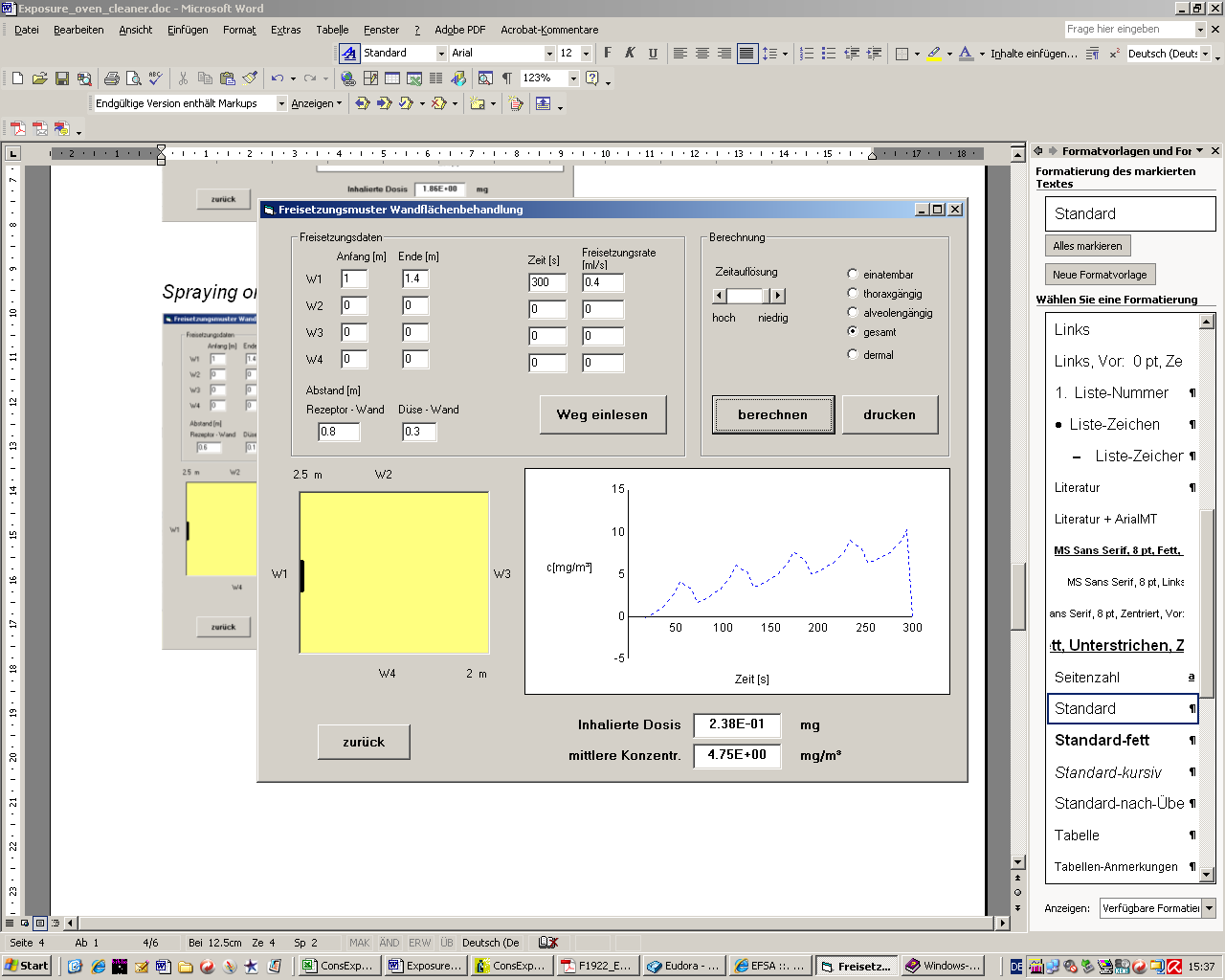
Input



Spraying (total exposure period 60 minutes)



Spraying only



1. European Union Risk Assessment Report SODIUM HYDROXIDE (CAS No: 1310-73-2, EINECS No: 215-185-5), TARGETED RISK ASSESSMENT (Vol. 73, 4th Priority List, 2007) [↑](#footnote-ref-1)