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ANNEX1 SDSEXPOSURESCENARIO(ES)SODIUMHYDROXIDE

1. EXPOSUREASSESSMENT

The exposure scenarios are organised in 4 mainscenarios:

- Manufacturing of liquidNaOH
- Manufacturing of solidNaOH
- Industrial and professional use ofNaOH
- Consumer use ofNaOH

TheoverviewofexposurescenariosandcoverageofsubstancelifecyclecanbefoundinTable1.The exposureassessmentisprimarilybasedontheexposureassessmentoftheEURARforNaOH(2007).The RAR (2007) and the information collected at that time was used as starting basis for this dossier.When available, newdataandinformationwasaddedtothedossier.

Table 1 Overview on exposure scenarios and coverage of substance lifecycle

Number andtitle	Manufacture	Preparation making	Industrial and/or widedisperseuse	Consumeruse	Article service life	Waste stage
ES1: Manufacturing of liquidNaOH	X					
ES2: Manufacturing of	X					
solidNaOHES3: Industrial and professionaluse ofNaOH		X	X			
ES4: Consumer use				X		

ofNaOH

Note on accidentalexposure

Since accidental exposure is normally excluded from an EU chemical safety assessment andaccidental exposure is considered in the EU RAR (2007; section 4.1.1.3.2, pages 59-62), accidental exposure will notbe further assessed in this dossier. However, the risk management measures forconsumers, identified inthe NaOH risk reduction strategy (EU RRS, 2008) are included in thedossier.

1.1 Exposure Scenario 1: Manufacturing of liquidNaOH

IntheEURAR(2007),therequiredinformationrelatedwithoccupationalexposureattheproductionsiteswascollectedthroughaquestionnaire,developedby Euro ChlorincooperationwiththeRapporteurMember State.In the questionnaire the following issues were addressed: type of products (solid/liquid), number of workers, estimation of exposure based on tasks, exposure measurements and accidental exposure. The questionnaires were sent by EuroChlor to 97% of the European chlorine production sites (a total of 86). A total number of 36 production sites (42%) responded to the questionnaire and based on these data a detailed report has been prepared (EuroChlor, 2004c).

1.1.1 Exposure scenario

1.1.1.1 Short title of the exposure scenario

SU 3, 8: Manufacture of bulk, large-scale substances

PROC 1, 2, 3, 4, 8, 9: use in (closed) continuous or batch process with no likelihood of exposure or where opportunity for exposure arises (industrial setting), including charging, discharging, sampling and maintenance.

PC and AC not applicable for this ES

1.1.1.2 Description of activities and processes covered in the exposure scenario

NaOH is produced commercially by an electrolytic process. Brine, prepared from sodium chloride, is electrolyzed in either a mercury cell, diaphragm cell or membrane cell. The coproducts are chlorine and hydrogen. In the mercury cell process, a sodium-mercury amalgam is formed in the cell. The amalgam is sent to a decomposer where it is reacted with water to form liquid NaOH, hydrogen and free mercury. The free mercury is returned to the electrolytic cell. The resulting NaOH solution is then stored in storage tanks as a 50% solution. The solution is shipped in tank trucks, tank cars or barges. In the membrane process, a solution of approximately 30% in strength is formed in the cell. The solution is then sent to evaporators, which concentrate it to a strength of 50% by removing the appropriate amount of water. The resulting NaOH solution is stored in storage tanks prior to shipment. The diaphragm process is very similar to the membrane process except that a solution of only 10-12% is formed in the cell. Therefore, additional evaporation is required to reach the commercialised concentration of 50%. The anhydrous forms of NaOH are obtained through further concentration of 50% NaOH.

1.1.1.3 Operational conditions

The amount used per worker varies from activity to activity. In the EU RAR (2007), the amount of product sampled ranged between 0.1 and 15 litres. The responses with the highest quantities were "15", "2.2", "2", "3x1" and "few litres per day". The remaining respondents replied that an amount of less than 1 kg was sampled.

The duration considered for this exposure scenario is a full working shift (8h/day) and 200 days/year. For sampling the "task duration in minutes per day" ranged between 1 and 600 minutes and the average duration was 71 minutes.

From the questionnaire and the EU RAR (2007), it can be concluded that nearly all production sites manufacture liquid NaOH with a concentration of about 50%. For 36% of the sites also other liquid products (between 10 and 75%) are manufactured with concentrations which were in general lower than 50%.

1.1.1.4 Risk managementmeasures

1.1.1.4.1 Risk management measures related toworkers

The risk management measures related to workers are summarized in Table 2. A distinction is madebetween measures that are required or compulsory and measures that indicate goodpractice.

Because sodium hydroxide is corrosive, the risk management measures for human health should focus onthe prevention of direct contact with the substance. For this reason automated and closed systems should preferably be used for industrial and professional uses of sodium hydroxide. Respiratory protection isneeded whenaerosolsofsodiumhydroxidecanbeformed.Duetothecorrosivepropertiesappropriateskinandeye protection isrequired.

Table 2 Risk management measures related toworkers

Information	Datafield	Explanation
type Containment plus good work practice required	Good practice: replacing, where appropriated, manual processes by automated and/or closed processes. This would avoid irritating mists and subsequent potential splashes (EU RRS, 2008): • Use closed systems or covering of open containers (e.g. screens) (good practice) • Transport over pipes, technical barrel filling/emptying of barrel with automatic systems (suction pumps etc.) (good practice) • Use of pliers, grip arms with long handles with manual use "to avoid direct contact and exposure by splashes (no working over one's head)" (good practice)	Situation at the time of the EU RAR (2007): The confinement was in general "semi closed" (18 sites). In the remaining cases the confinement was "open" (6 sites) or "totally closed" (9 sites).

Information	Datafield	Explanation
type Local exhaust ventilation required plus good work practice	Local exhaust ventilation is not required but good practice.	To improve air quality and avoid potential respiratory track irritation in working areas Situation at the time of the EU RAR (2007): Only five sites had "local exhaust ventilation".

General ventilation	General ventilation is good practice unless local exhaust ventilation is present	To improve air quality and avoid potential respiratory track irritation in working areas. Situation at the time of the EU RAR (2007): General ventilation was present for 26 sites, while 5 sites had no “general ventilation” during sampling. Four sites had neither “general ventilation” nor “local exhaust ventilation”
Personal protection equipment (PPE) required under regular working conditions	• Respiratory protection: In case of dust or aerosol formation: use respiratory protection with approved filter (P2) (required) • Hand protection: impervious chemical resistant protective gloves (required) o material: butyl-rubber, PVC, polychloroprene with natural latex liner, material thickness: 0.5 mm, breakthrough time: > 480 min o material:nitrile-rubber, fluorinated rubber, material thickness: 0.35-0.4 mm, breakthrough time: > 480 min • Eye protection: chemical resistant goggles must be worn. If splashes are likely to occur, wear tightly fitting safety goggles, face-shield (required) ☐Wear suitable protective clothing, aprons, shield and suits, if splashes are likely to occur, wear: rubber or plastic boots (required)	Situation at the time of the EU RAR (2007): In nearly all cases no PPE was used to protect against inhalation, but in all cases the skin and eyes were protected (e.g. safety glasses, full face mask, gloves, special clothes).

Other risk management measures related to workers. For example: Particular training systems, monitoring/ reporting or auditing systems, specific control guidance.	Next measures are required (from EU RRS, 2008): • workers in the risky process/areas identified should be trained a) to avoid to work without respiratory protection and b) to understand the corrosive properties and, especially, the respiratory inhalation effects of sodium hydroxide and c) to follow the safer procedures instructed by the employer (EU RRS, 2008). • the employer has also to ascertain that the required PPE is available and used according to	

1.1.1.1.1 Riskmanagement measures related toenvironment

Risk management measures related to the environment aim to avoid discharging NaOH solutionsinto municipal wastewater or to surface water, in case such discharges are expected to cause significantpH changes. Regular control of the pH value during introduction into open waters is required. Ingeneral dischargesshouldbecarriedoutsuchthatpHchangesinreceivingsurfacewatersareminimised.Ingeneral most aquatic organisms can tolerate pH values in the range of 6-9. This is also reflected in the description of standard OECD tests with aquatic organisms.

1.1.1.5 Waste relatedmeasures

Liquid NaOH waste should be reused or discharged to the industrial wastewater and further neutralizedif needed (see risk management measures related toenvironment).

1.1.2 Exposureestimation

1.1.2.1 Workersexposure

NaOH is a corrosive substance. For the handling of corrosive substances and formulations, immediatedermal contactsoccuronlyoccasionallyanditisassumedthatrepeateddailydermalexposurecanbeneglected. Therefore according to the NaOH EU RAR (2007), dermal exposure to pure NaOH will not beassessed. Repeated dermal exposure cannot be neglected for these substances and formulations. Ocular exposureis possible due to hand-eye contact but this is notquantified.

NaOH is not expected to be systemically available in the body under normal handling and use conditionsand therefore systemic effects of NaOH after dermal or inhalation exposure are not expected tooccur.
Due to the low vapour pressure of NaOH, the atmospheric concentration of NaOH based on vaporisationfrom theliquidwillbeverylow.AlthoughtheexposuretoavapourofNaOHisestimatedtobeverylow,thetask related data can not be used to predict the exposure to aerosols (mists). An overview of the estimatedand measured exposure concentrations can be found in Table3.

Table 3 Exposure concentrations forworkers

Routes ofexposure	**EstimatedExposure**		**Measuredexposure concentrations**		**Explanation / source ofmeasured data**
	Value	**unit**	**Value**	**unit**	
Dermalexposure	Notavailable		Notavailable		
Inhalation exposure			AM:0.14	mg/m^3	**From EU RAR(2007)** Range: 0.02 – 0.5mg/m^3 Truck loading ofliquid STAT measurement, N=17,
			AM:0.33	mg/m^3	**From EU RAR(2007)** Range: 0.29 – 0.37mg/m^3 Liquid, othertask Spot measurement, N=5,2003
			AM:<0.26	mg/m^3	**From EU RAR(2007)** Liquid, othertask STAT measurement, N=20,2002
			AM:0.01*	mg/m^3	**From EU RAR(2007)** Range: 0.05 – 0.18 mg/m^3* Liquid, pearls, close toinstallation STAT measurement, N=109,2002
	0.02 (typical) 0.04 (RWC)	mg/m^3			**From EU RAR(2007)** Drumming liquidNaOH Typical and reasonable worstcase exposurelevel

STAT - Stationary Air Sample
Spot - Short term stationary sample
N - Amount of measurements
AM - Arithmetic mean
RWC - Reasonable worst-case
* These values are considered not to be correct. A mean value can’t be lower than the range.

<u>Measureddata</u>

In the EU RAR (2007), atmospheric exposure measurements are available for 6 production sites from4 different countries (Czech Republic, Poland, Spain and United Kingdom). In all cases the concentrationswere lowerthan2mg/m^3(seeTable3).MostNaOHproductionsitesrepliedthattheOELwas2mg/m^3intheir country. The data of the production site in Spain are based on measurements of the sodium content,which were performed according to a norm of the National Institute for Worker Safety and Hygiene (NTP-63of 1983). For this production site the sampling duration was 6-8 hours. Other sites reported that the measurements were based on a Polish standard method, a colorimetric method or on atomicabsorption spectroscopy. The sampling duration was unknown for thesesites.

Modelleddata

The ECHA guidance on information requirements proposes ECETOC TRA as the preferred Tier 1tool. ECETOCTRAisbasedonamodifiedversionofEASE.EASEwasthepreferredmodelundertheNew& Existing Substances Directive. EASE is known to overpredict exposures in many cases. The reason for thisis considered to be the fact that EASE relies upon historical exposure data from enforcement activities inknown problem areas, rather than the typical/normal operations that are required for more routine risk assessment.For thisreasonthevaluesfromtheoutputfromEASEwerereviewedandmodifiedaccordinglyintheECETOC TRA. Both the EASE predictions (from EU RAR, 2007) and ECETOC TRA approaches were consideredhere.

InhalationexposuretovapourduetodrummingisestimatedintheEURAR(2007)withEASE2.0.Theexposurer angei sestimated0– 0.17 mg/m^3(0–0.1ppm,20°C), assuming verylowvapourpressure,noaerosolformation andnondispersiveuse.Typicalexposure isestimatedas0.085mg/m^3(middle value ofrange).Thereasonableworstcaseexposureisestimatedas0.17mg/m^3(uppervalueofrange)assumingnoa erosolformationandnondispersiveusewithdilutionventilation.Following thequestionnaire,itisassumedthatinthepresentindustryLEVisnotgenerallyavailable.PresenceofLEV willnotinfluence theexposurerangein thisestimation.AssumingaNaOHconcentrationof50%thetypicalexposureisestimatedtobe0.04mg/m^3 andthereasonableworstcaseexposureisestimatedto 0.085 mg/m^3.Frequencyofexposurefordrummingisestimatedtobeupto200daysperyearwithaduration ofupto4hours/day,whilethenumberofworkersinvolvedisestimatedtobeupto50(expertjudgment). Assuming4hoursofhandlingandzeroexposureduringtheremainderoftheworkingday,8hourTWAtypicalex posureisestimatedas 0.02mg/m^{3}andan8-hourTWAreasonableworstcaseexposureisestimatedas0.04 mg/m^3. InhalationexposuretovapouroraerosolsduetoallPROCsisestimatedintheECETOCTRAandthe inhalation exposure is 0.1 ppm (0.17 mg/m^3), assuming very low vapour pressure, exposure duration ofmore than 4 hours/day and no local exhaust ventilation or respiratoryequipment.

Summary of the exposurevalues

Only one single value will be used for risk characterisation. A summary of exposure concentration forworkers is given in Table4.

Table 4 Summary of exposure concentration forworkers

Routeso f	Concentrati o ns	Justification

Dermal exposure(in mg/cm^2)	Negligible	From EURAR(2007):NaOHproductswithaconcentration>2%arecorrosive,therefore effective control measures are in place to prevent dermalexposure.Furthermoreprotectiveclothingandglovesareconsideredto beusedconsistentlywhen handling corrosive substances. Production companies report the useofprotective gloves, suits and boots while handling pure NaOH. Repeateddailydermalexposuretocommercialproductisthereforeconsidered negligible.Dilutionsof NaOHcontaining<
Inhalation exposure(in mg/m^3)	0.33	From EU RAR (2007): For drumming liquid NaOH the modelled dataare underestimatedbyEASEincomparisonwiththemeasureddata.Because there is a relatively large number of measured data, these will be used for risk characterisation. The value 0.33 mg/m^3 is taken as reasonable worstcase level and 0.14 mg/m^3 is taken as typical exposurelevel.

1.1.2.2 Indirect exposure of humans via the environment (oral)

Indirect exposure to humans, for example through the uptake of drinking water, is not relevant for NaOH.Any potential for exposure to NaOH due to environmental releases will only have relevance at the local scale.Any pHeffectoflocalreleaseswillbeneutralisedinthereceivingwaterattheregionalscale.Thereforeindirect exposure of humans via the environment (oral) is not relevant in the case of NaOH (EU RAR,2007).

1.1.2.3 Environmentalexposure

AsstatedintheEURARonNaOH(2007),theriskassessmentfortheenvironmentisonlyrelevantforthe aquaticenvironment,whenapplicableincludingSTPs/WWTPs,asemissionsofNaOHinthedifferentlife-cyclestages(productionanduse)mainlyapplyto(waste)water.Theaquaticeffectandriskassessmentwill onlydealwiththeeffectonorganisms/ecosystemsduetopossiblepHchangesrelatedtoOH$^-$discharges,as the toxicity of the Na$^+$ ion is expected to be insignificant compared to the (potential) pH effect. Only thelocal scalewillbeaddressed,includingsewagetreatmentplants(STPs)orwastewatertreatmentplants(WWTPs) whenapplicable,bothforproductionandindustrialuse.Anyeffectsthatmightoccurwouldbeexpectedto takeplaceonalocalscale.Thereforeitwasdecidednotmeaningfultoincludetheregionalandcontinental scale in this risk assessment. Furthermore, the high water solubility and very low vapour pressure indicatethat NaOHwillbefoundpredominantlyinwater.Significantemissionsorexposuretoairarenotexpectedydueto theverylowvapourpressureofNaOH.Significantemissionsorexposuretotheterrestrialenvironmentare not expected either. The sludge application route is not relevant for the emission to agricultural soil,as sorption of NaOH to particulate matter will not occur inSTPs/WWTPs.

Theexposureassessmentfortheaquaticenvironmentwillonlydealwiththepossiblep HchangesinSTP effluent and surface water related to the OH$^-$ discharges at the localscale.

1.1.2.3.1 Environmental releases

The production of NaOH can potentially result in an aquatic emission and locally increase the sodium concentration and pH in the aquatic environment. When the pH is not neutralised, the discharge of effluent from NaOH production sites may cause an increase in pH in the receiving water. The pH of effluents is normally measured very frequently and can be neutralised easily.

Since the exposure assessment focussed on possible pH changes in the local aquatic environment, industry collected actual data on pH values in effluent and receiving surface waters at NaOH production sites for the purpose of the EU RAR (2007), based on the results of a questionnaire that was sent to a broad cross section of NaOH producers in the EU via Euro Chlor, representing 97% of NaOH production capacity in the enlarged Europe (Euro Chlor, 2004b). The results of this questionnaire (Euro Chlor, 2004c) provided effluent and receiving water data for 43 out of 84 production sites. The sites are anonymised by numbers. The 43 responding production sites are from 15 different EU countries with a wide geographical spread. The respondents include 34 sites in the old EU member states, 6 sites in the new EU member states, 2 in Norway and 1 in Switzerland (Euro Chlor, 2004c). The three major NaOH production processes, i.e. membrane, diaphragm and mercury process, were well represented among the respondents to the questionnaire. The production capacities of the sites that responded represented a very broad range from several tens of ktonne/year up to several hundreds of ktonne/year (Euro Chlor, 2004b).

The questionnaire revealed that 11 sites do not have effluents which are discharged to the environment. On these specific sites the waste water can be completely recycled due to the specific on-site process conditions. The results also showed that out of 43 sites reporting, 31 sites neutralize their effluent before discharging into the receiving water. A total of 32 sites reported to be legally obliged to neutralize their effluent and 6 sites, which do not have effluents, did not respond to this question. However, 5 sites reported not to have such legal requirements, while 2 of these 5 sites reported actually to neutralize their effluents. One site (site 30) reports a legal obligation to neutralize but they do not adapt their pH, because the pH range of their effluent is already within a narrow range close to neutral.

According to Euro Chlor (2004c), many sites reported pH values for wastewater sub-streams instead of final effluents, even though they are included as ‘effluent data’ This was concluded from the fact that many sites reported broad ranges of pH values, but also indicated that final effluents were neutralised before discharging and from some subsequent checks with respondents. Substreams are normally combined with other wastewater sub- streams on the site before they are finally discharged into the receiving water. Therefore, the first two columns of Table 5 on effluents are the most important with respect to the potential pH effect on receiving waters.

A total number of 36 production sites, including 2 sites (no. 17 and 30) that do not discharge their effluent into the environment, i.e. sewer or receiving water, reported measured pH values of the effluent. Of these 36 sites, 19 sites reported pH values within the range of 6-9 (range of lowest pH to highest pH), 7 sites reported pH values within the range of 5-10 and 10 sites reported pH values outside the range of 5-10. Most importantly, all but one of the sites that discharge effluent into the environment reported to neutralise their effluent before discharge. Only one site (no. 15) reporting a very wide effluent pH rang of 3.0-11.6 and stated not to neutralise its effluent before discharge. After contacting this site it became clear that the reported pH values for this site represented measurements in the wastewater sub-stream, immediately after leaving the production unit. Depending onthe process conditions this can have the listed extreme values, which reportedly only last for 10-15 minutesbecause thewastewatersub-streamisthencombinedwithotherwastewatersub-streamsatthesiteandthepHbecomes circumneutral. Thereafter the final effluent (i.e. the combined wastewater sub-streams) enters a municipalsewage treatment plant before it is discharged into the receiving water. This site is not legally obligedto neutraliseitseffluentbeforedischarge(EuroChlor,2004c).Asallfurthersitesthatreportedahighdifference betweenthelowestandhighest pH oftheeffluentalsoreportedtoneutralisetheireffluent,itcanbeassumedthat for these sites the pH values are also for wastewater sub-streams (that are combined with othersubstreams before neutralisation of the final effluent) and not for the final effluents that are discharged into theenvironment. Theresultsfromthequestionnaire,reportedfor43outof84productionsites,demonstratethatthepHofwaste wat er discharges is controlled and that generally proper regulations are inplace.

Table5EffluentandreceivingwaterdataforNaOHproducersintheEU(EuroChlor,2004c)(From EU RAR,2007)

	Eff luentdat a									R iv r					
№	Effluent discharged inthe Environme	Neutralization before Dischar	Obligationof Neutralization	Continuous Measurement of thepH	pH (avg.)	Lowest pH	Highest pH	Alkalinity (meq/l)	Flow rate avg. (m3/	Typeof receiving	Continuous Measurementof	eL o w e	inH i g h	dA l k a	Flow rate avg.(m3 /d)	Flow rate rang 3
2	Yes	Yes	Yes	Yes	11.8	3.8	13.9		78	Rive	Yes	7^{S}	8e	-		e(m
3	Yes	Yes	Yes	Yes	7.3	6.9	7.9	NA	6,50 0	River	Yes	7 .	8 .	N A	1,000, 000	260 , 000-
1	Yes	No	No	Yes	7.62	3.01	11.5	2.22	10,2	Rive	No	67	47	N	25,532,	4,85
516	Yes	Yes	Yes	Yes	7.3	7	7.95	1.87	3040,606	Riverr	No	7. .	7. .	2A, 6	5,356,064 800	51„6346 8,80
1	No	Yes	Yes	Yes	7.25	7	7.5	NA	26,3	Rive	No	37	87	N	10,972,	NA0-
71	Yes	Yes	Yes	Yes	7.9	3.9	13.2		100,80	River	No	.	.	A	1,978,800 5	15,0
820	Yes	Yes	Yes	Yes	7.5	7	8.5	NA	1730 , 000	Riverr	No	6 .	8 .	N A	8,208,84 000	00483,0, 840-
21	Yes	Yes	No	Yes	12	10	13	NA	10	River	No	57 .	27 .	3 -	172,800 ,000	60,4 80,0
2	Yes	Yes	No	Yes	3	2	4	NA	4,56	Sea		0	8	4		00-
2	No	No	No	No						Estu	No					
52	Yes	Yes	Yes	Yes	7-7.5	6	8.5	3.5	9,60	Riveary	No	8	8	2 ,	400	400 -
62	Yes	Yes	Yes	Yes	7.2	6.1	9.4		1780	River	No		.	8		600
93	No	No	Yes	Yes	7.9	7.5	8.2	NA	5,84	River	No	6	8	N	3,456, 0	NA
032	Yes	Yes	Yes	Yes	7.2	7	7.8		482, 000	Riverr	No	7. .	7 .	A	100,00000 ,000	60,0 00,0
33	Yes	Yes	Yes	Yes	7.8	6.5	8.5	1,004	17,4 61	River	No	17 .	58 .	3, 5	475,200	950-,0 40-
3	Yes	Yes	Yes	Yes	6.7	5	10	NA	3,60	Sea	No	56	16	N6		
43	Yes	Yes	Yes	Yes	5	3	11	NA	1140	Sea	No	7.	7.	NA		
53	Yes	Yes	Yes	Yes	7.7	6.7	8.5		600	Rive	No	8.	8.	A	2,500, 0	? -
739	Yes	Yes	Yes	Yes	12	4	13	NA	300	Sear	Yes	6 .	8 .	N A	2500,920, 000	512,20,9 60,0
4	Yes	Yes	Yes	Yes	7.4	6.6	8.2		25,0	Rive	No	5	0			00-
04	Yes	Yes	Yes	Yes	8	7	9	NA	400,80	Sear	No	N	N	N	NA	NA
14	Yes	Yes	Yes	Yes	7.5	6.6	8.5	NA	1340	Othe	Yes	A4	A1	NA	301	
649	Yes	Yes	Yes	Yes	7.28	7.09	7.48	NA	853	Esturary	No	6. .	08	NA A	1,000,000	

51	Yes	Yes	Yes	Yes	8.2	6.9	8.9	6	728	River	Yes	7.	7.	3	51,000,000	25,000,0
52	Yes	Yes	Yes	Yes	8	4	10		9,4	River	Yes	6.	9		14,077	14,965-
5	No											5				
35	No															
458	Yes	Yes	Yes	Yes	11.5	11	12	3.10^{-3}	4,000	River	Yes	7.	8.		174,744	127 ,744-
60	Yes	Yes	Yes	Yes	7.9	7	8.4	1.3	14,0 97	River	No	57.	58.	4,0	1,309,589	140,832-
61	Yes	Yes	Yes	Yes	6-8	6	8	NA	16,3 44	River	Yes	66.	17.	N5 A	17,460	8,000-
6	No			Yes								9	2			
6	No			Yes												
56	No			Yes												
668	Yes	Yes	Yes	Yes	7	6.9	7.3	NA	374 ,00	River	Yes	7.	8.	N A	96,768,000	30 ,240,0
6	Yes	Yes	Yes	Yes	7.5	5.5	8.5	92	3,50	Sea	No	N7	N1	7		00-
970	No			Yes	7.4/7.8	6.2/6.8	8.4/9.4		480, 312/	River	No	A7.	A8.	5	3,456, 000	? - 7,94
7	Yes	Yes	Yes	Yes	7.5	6	9		4,50	Sea	Yes	N5	N1	N		8,80
17	Yes	Yes	Yes	Yes	7.3	3	9.2	NA	230, 0	Rive	No	NA	NA	NA	450,000	300 ,
27	Yes	Yes	Yes	Yes	7	6	9		33000	Other	No	A7	A7	A		000-
98	No	No	No							r		.	.			
08	No	Yes	Yes	Yes	7.8	6.4	9.4		2,11	Othe	Yes	7	8			
38	Yes	Yes	Yes	Yes	10	6.5	11	30	1,230	Other	Yes	6.	7.	5		
48	Yes	Yes	Yes	Yes	6.6	5.4	9.7	NA	1,090	Laker	No	4.	9.	N		

5 0 . . A

1.1.2.2.1 Exposure concentration in waste water treatment plants(WWTP)

Waste water from NaOH production sites is coming from the salt electrolyses and is an inorganicwastewater stream.Forthisreasonitisnotfeasibletotreatitbiologically.ThereforewastewaterstreamsfromNaOH production sites will normally not be treated in biological waste water treatment plants (WWTPs). NaOHmay be used beneficially, however, for pH control of acid wastewater streams that are treated inbiological WWTP's (EU RAR,2007).

1.1.2.2.2 Exposure concentration in aquatic pelagiccompartment

Ifemittedtosurfacewater,sorptiontoparticulatematterandsedimentwillbenegligible.AnadditionofNaOHtosurfacewatermayincreasethepH,dependingonthebuffercapacityofthewater.Thehigherthe buffer capacity of the water, the lower the effect on pH will be. In general the buffer capacity preventingshifts inacidityoralkalinityinnaturalwatersisregulatedbytheequilibriumbetweencarbondioxide(CO2),the bicarbonate ion ($HCO3^{-}$) and the carbonate ion($CO3^{2-}$):

- +

$CO_2 + H_2O \leftrightarrow HCO_3^- + H^+$ (pKa1 = 6.35)

$HCO_3^- \leftrightarrow CO_3^{2-} + H^+$ (pKa2 = 10.33)

IfthepHis <6,un-ionised$CO_2$is thepredominantspeciesandthefirstequilibriumreaction ismostimportantforthebuffercapacity.AtpHvaluesof6-10thebicarbonate ion(HCO_3^-)isthepredominantspeciesand atpHvalues>10thecarbonateion(CO_3^{2-}) isthepredominantspecies.InthemajorityofnaturalwatersthepHvaluesarebetween6 and10,thusthebicarbonateconcentrationandthesecondequilibriumreactionaremostimportantforthebuffercapacity(Rand,1995;DeGrootetal.,2002;OECD,2002).UNEP(1995)reportedthebicarbonateconcentrationforatotalnu mber of 77 rivers in North-America, South-America, Asia, Africa, Europe and Oceania. The 10th–percentile, mean and90th-percentileconcentrationswere20,106and195mg/l,respectively(OECD,2002).Tounderline theimportanceofthebicarbonateconcentrationforthebuffercapacityinnaturalwaters,Tablesummarisestheconce ntrationofNaOHneededtoincreasethepHfromaninitialpH of8.25-8.35toavalueof9.0,10.0,11.0and12.0atdifferentbicarbonateconcentrations.ThedataofTablearebasedoncalculati onsbutwereconfirmedbyexperimentaltitrations ofbicarbonate(HCO_3^-) concentrationsof20,106and195mg/l,respectively,inpurifiedwater.Thedifferencebetweenthecalculatedandmeasured NaOHconcentrationneededtoobtainacertainpHvaluewasalways<30%(DeGrootetal.,2002;OECD,2002). Thedata inTablefor distilledwaterarefromOECD(2002).

Thealkalinity,definedastheacid-neutralising(i.e.protonaccepting)capacityofthewater,thusthequalityandquantityofconstituentsinwaterthatre sult- inashiftinthepHtowardthealkaline siteofneutrality,isdetermined for >99% by the concentrations of bicarbonate (HCO_3^-), carbonate (CO_3^{2-}) and hydroxide (OH^-) (Rand, 1995),with bicarbonatebeingthepredominantspeciesatpHvaluesintherangeof6-10(seealsoabove).Hydroxideisonly relevantinalkalinewaters.Thus,thedatainTable 6areuseful toestimate pHincreasesinnaturalwaters(mostofthem having a pH value of 7-8), if data on NaOH additions and bicarbonate concentrations are available.The alkalinity is determined from acid/base titration or can be calculated from the calcium concentration, as follows (DeSchampelaere et al., 2003; Heijerick et al.,2003):

Log (alkalinity in eq/l) = - 0.2877 + 0.8038 Log (Ca ineq/l)

Table6ConcentrationofNaOH(mg/l)neededtoincreasethepHtovaluesof9.0,10.0,11.0and12.0 (De Groot et al., 2002; OECD,2002)

Buffercapacity	**FinalpH**			
	9.0	**10,0**	**11.0**	**12.0**
0 mg/l HCO_3^- (distilledwater)	0.4	4.0	40	400
20 mg/l HCO_3^- (10th- percentile of 77rivers)	1.0	8.2	51	413

106 mg/l HCO_3^- (mean value of 77rivers)[1]	3.5	26	97	468
195 mg/l HCO_3^- (90th percentile of 77rivers)	6.1	45	145	525

1) The initial pHofa bicarbonate solution with a concentration of 20-195 mg/l was8.25-8.35

Based on the neutralized environmental releases and the fate in the aquatic compartment described above, there is no environmental impact on the receiving surfacewater.

1.1.2.3.2 Exposure concentration insediments

The sediment compartment is not included in this CSA, because it is not considered relevant for NaOH. If emitted to the aquatic compartment, sorption to sediment particles will be negligible (EU RAR, 2007).

1.1.2.3.3 Exposure concentrations in soil andgroundwater

The terrestrial compartment is not included in this CSA, because it is not considered relevant for NaOH. With respect to the fate of NaOH in soil the following information is available. If emitted to soil, sorption to soil particles will be negligible. Depending on the buffer capacity of the soil, OH^- will be neutralised in the soil pore water or the pH may increase (EU RAR,2007).

1.1.2.2.1 Atmosphericcompartment

The air compartment is not included in this CSA (chemical safety assessment) because it is considered not relevant for NaOH. With respect to the fate of NaOH in air the following information is available from EU RAR(2007). If emitted to air as an aerosol in water, NaOH will be rapidly neutralised as a result of its reaction with CO2 (or other acids), asfollows:

$NaOH + CO_2 \rightarrow HCO_3 + Na^+$

Subsequently, the salts (e.g. sodium (bi)carbonate) will be washed out from the air (USEPA, 1989; OECD, 2002). Thus, atmospheric emissions of neutralised NaOH will largely end up in soil and water. Based on a NaOH concentration of 50% in the aerosol droplets, the atmospheric half-life of NaOH was estimated at 13 seconds. Based on model calculations, this degradation rate results in only 0.4% of the NaOH emitted to air remaining in the air at a point 200 metres from the emission point (U.S. EPA, 1988;1989).

1.1.2.2.1 Exposure concentration relevant for the food chain (Secondarypoisoning)

Bioaccumulation in organisms is not relevant for NaOH. Therefore, there is no need to perform arisk assessment for secondary poisoning (EU RAR, 2007).

1.2 Exposure Scenario 2: Manufacturing of solidNaOH

1.2.1 Exposurescenario

1.2.1.1 Short title of the exposurescenario

SU 3, 8: Manufacture of bulk, large scalesubstances

PROC 1, 2, 3, 4, 8, 9: use in (closed) continuous or batch process with no likelihood of exposure orwhere opportunity for exposure arises (industrial setting), including charging, discharging, samplingand maintenance.

PC and AC not applicable for thisES.

1.2.1.2 Description of activities, processes and operational conditions covered in the exposurescenario

TheprocessesandactivitiesforsolidNaOHincludetheprocessesandactivitiesforliquidNaOH(seesection1. 1.1.2).SolidNaOHresultswhenmoltenNaOH,fromwhichallthewaterhasbeenevaporated,isallowedtocoolandsolidify.FlakeNaOHismadebypassingmoltenNaOHovercooledflakingrollstoformflakesofuniformthickness.Theflakescanbemilledandscreenedintoseveralcrystallineproductswith controlled particle size. The manufacture of NaOH beads involves feeding molten liquor into aprillingtowerundercarefullycontrolledoperatingconditions, producingasphericalbead(OxyChem,2000).

Flakes can be packed in bags (25 or 50 kg). Micro pearls are packed in bags, bulk bags (500 or 1,000 kg) butit isalsodeliveredinbulk(byroad).Castisdeliveredinmetallicdrums(e.g.400kg).However,itshouldbe realised that other packaging forms couldexist.

SolidNaOH(flakes,pearlsorcast)isproducedat23%oftheproductionsites.Theshiftscanbe12hrs/day (40hours/week).

1.2.1.3 Risk managementmeasures

1.2.1.3.1 Risk management measures related toworkers

Relevant risk management measures related to workers are described in section1.1.1.4.1.

1.2.1.3.2 Risk management measures related toenvironment

Relevant risk management measures related to environment are described in section1.1.1.4.2

1.2.1.4 Waste relatedmeasures

There is no solid waste of NaOH. Liquid NaOH waste should be reused or discharged to theindustrial wastewater andfurther neutralizedif needed(seeriskmanagementmeasuresrelatedtoenvironment).

1.2.2 Exposureestimation

1.2.2.1 Workersexposure

NaOHisacorrosivesubstance.Forthehandlingofcorrosivesubstancesandformulations,immediatedermalcontactsoccuronlyoccasionallyanditisassumedthatrepeateddailydermalexposurecanbeneglected.ThereforeaccordingtotheNaOHEURAR(2007),dermalexposuretopureNaOHwillnotbeassessed.Repeateddermalexposure cannotbeneglected for these substances andformulations.

NaOHisnotexpectedtobesystemicallyavailableinthebodyundernormalhandlinganduseconditionsandthereforesystemiceffectsofNaOHafterdermalorinhalationexposurearenotexpectedtooccur.

Anoverviewoftheestimatedand measured exposureconcentrations forinhalationcanbefoundinTable7.

Table 7 Exposure concentrations toworkers

Routes of exposure	EstimatedExposure		Measuredexposure		Explanation / source of measureddata
	Value	unit	Value	unit	
Inhalation exposure			AM:0.84	mg/m^3	**From EU RAR(2007):** Range: 0.1 – 1.8 mg/m^3Drumming/Bagging of liquid, cast,pellets PAS measurement,
			AM:0.09	mg/m^3	**From EU RAR(2007):** Range: 0.01 – 0.27 mg/m^3Drumming/Bagging of liquid, cast,pearls PAS measurement,
			AM:0.05	mg/m^3	**From EU RAR(2007):** Range: 0.01 – 0.1 mg/m^3 Drumming of liquid,cast, pearls STAT measurement, N=20,2003
			AM: 0.11 90P:0.269	mg/m^3	**New industrydata:** Pelletization belt: Range: 0.03 – 0.51mg/m^3Filling: Range: 0.11 – 0.38mg/m^3
	2.5	mg/m^3			Maximum EASE and ECETOC TRAsimulations

PAS - PersonalAirSample
STAT - Stationary AirSample
N - Amount of measurements
AM - Arithmeticmean
90P – 90thpercentile
AM - Arithmeticmean

<u>Measureddata</u>

IntheEURAR(2007),atmosphericexposuremeasurementsareavailablefor6productionsitesfrom4differentcountries(CzechRepublic,Poland,SpainandUnitedKingdom).Inallcasestheconcentrationswerelowerthan2mg/m^3 (see Table 14). Most NaOH production sites replied that the OEL was 2 mg/m^3 in their country. One operationwiththepossibilityofexposureissampling.Itisassumedthatallthemeasurementatdrumming/bag gingw asdonewithsolidNaOH.ThedataoftheproductionsiteinSpainare basedonmeasurementsofthe sodium content,whichwereperformedaccordingto anormoftheNationalInstituteforWorkerSafety and Hygiene(NTP-63of1983).Forthisproductionsitethesamplingdurationwas6-8hours.Othersitesreportedthatthemeasurementswerebasedon aPolish standard method, a colorimetric method or on atomic absorption spectroscopy. The sampling duration was unknown for these sites. In one company, significant higher exposures wereobserved.

Anewdatasetwasgatheredfromanopensystemwithlocalexhaustventilation.Samplingwasdonewithairpump, flow going thorough the filter. NaOH is dissolved in with water and excess of HCl. The rest of HCl is titratedwithKOH.Indicatorismethylred.ThisanalyticalmethodiscompliantwithNIOSH7401.Theexposuretime was340or505minutes.These relate toa8and12hourshiftrespectively.Theexposurewaszeroduringtheremainingtimeoftheshift.Measurements weredoneduringoneshift.Thenumberofworkersis 3per shiftandtheamountofsubstancehandled:7tonpershift.Thesizeofpackingis25-1000kg.The processwasanopensystemand had local ventilation installed (20 m^3/hour). No respiratory protection was used. The ECHA guidanceoninformationrequirementsR.14suggeststotakethe75thpercentileforlargedatabasesandthe90thpercentileforsmallerdatabases.Therefore,the90thpercentileof0.269mg/m^3wasselectedasareasonableworst caseestimate.Also note that no respiratory tract effects were observed among theworkers.

Modelleddata

Considering the particle size distribution (more than 90% larger than µm10) 0o f the substanceother assumptions than the default assumptions “production and processing of powders” were used in the EU RAR (2007) to estimate inhalation exposure to dust with EASE 2.0. Typical exposure is estimated to be 0-1mg/m^3, assuming low dust technique in the presence of LEV. The reasonable worst case exposure is estimated to be0-5mg/m^3,assumingtheabsenceofLEV.Frequencyofexposurefordrummingisestimatedtobeupto200 days per year with a duration of up to 4 hours/day, while the number of workers involved is estimated to beup to 50 (expert judgement). Assuming 4 hours of handling and zero exposure during the remainder ofthe workingday,8-hourTWAtypicalexposureisestimatedas0–0.5mg/m^3andthe8-hourTWAreasonable worst case exposure is estimated as 0 – 2.5mg/m^3.

Considering low dustiness, no LEV and no respiratory protection, ECETOC TRA predicts inhalativeexposure of0.01mg/m^3forPROC1andPROC2,0.1mg/m^3forPROC3andPROC9,0.5mg/m^3forPROC4and PROC8a.FollowingtheEURAR(2007)byassuming4hoursofhandlingandzeroexposureduringthe remainderoftheworkingday,8-hourTWAtypicalexposureisestimatedas0–0.5mg/m^3andthe8-hour TWA reasonable worst case exposure is estimated as 0 – 2.5mg/m^3.

Summary of the exposurevalues

The summary of exposure concentrations to workers, taken forward to risk characterization is given in Table8.

Table 8 Summary of exposure concentration toworkers

Routes ofexposure	**Concentrati**	**Justification**
Dermal exposure(in mg/cm^2)	**ons**Negligible	FromEURAR(2007):NaOHproductswithaconcentration >2% are corrosive, therefore effective control measures are in placeto prevent dermal exposure. Furthermore protective clothingand gloves are considered to be used consistently whenhandling corrosive substances. Production companies report the useof protective gloves, suits and boots while handling pureNaOH. Repeated daily dermal exposure to commercial product istherefore considered negligible. Dilutions of NaOH containing < 2% arenot
Inhalation exposure(inmg/m^3)	0.269	possible for solidNaOH.Highest exposures are measured at the drumming/bagging placeand therefore these values are taken to the riskcharacterisation.

1.2.1.1 Indirect exposure of humans via the environment (oral)

Indirect exposure to humans, for example through the uptake of drinking water, is not relevant for NaOH.Any potential for exposure to NaOH due to environmental releases will only have relrevance at the local scale.Any pHeffectoflocalreleaseswillbeneutralisedinthereceivingwaterattheregionalscale.Thereforeindirect exposure of humans via the environment (oral) is not relevant in the case of NaOH (EU RAR,2007).

1.2.1.2 Environmentalexposure

Sodiumhydroxidewillrapidlydissolveanddissociateinwaterwhenreleasedtowater.Theenvironmental exposure assessment for solid sodium hydroxide is consequently the same as for liquid sodium hydroxide.The reader is referred to section1.1.2.3.

1.3 Exposure Scenario 3: Industrial and professional use of NaOH

To collect the required information related with occupational exposure when using NaOH for the purpose of the EURAR (2007), a questionnaire has been developed by Euro Chlor in cooperation with the Rapporteur Member State Portugal. In September 2004 questionnaires have been sent by e-mail to:

- The Confederation of European Paper Industries (CEPI). They have forwarded the questionnaires to their members (paper producing companies which use NaOH).
- Five different contact persons from Euro Chlor member companies (NaOH producers). Afterwards each producer of NaOH has sent the questionnaire to 20 customers (in most cases end users of NaOH).

The responses were analysed and the results reported by Euro Chlor (2005).

A total number of 58 replies were received, originating from about 10 different EU member states. The majority (59%) originated from the pulp and paper industry and and therefore the data for this sector can be considered as highly representative for the situation in Europe. For the pulp and paper industry one questionnaire was received from Germany (National Federation), which represented the common practice in this country.

The response from other industry customers was less but still covered a broad range of applications of NaOH. A total of 17 questionnaires (29%) were received from the chemical industry (e.g. production of crop protection chemicals, organic pigments, epoxy resins). The remaining 7 questionnaires were received from steel industry, textile industry, rubber production, food industry, metal industry, aluminium industry and distribution. This shows that 23 end users of NaOH replied, while one distributor completed the questionnaire. In most cases the NaOH was used as a reactant during the manufacturing/production of chemicals. In a few other cases it was used for neutralisation (steel industry, rubb er production), cleaning and water treatment (food industry) or for extraction (aluminium industry).

1.3.1 Exposure scenario

1.3.1.1 Short title of the exposure scenario

Sodium hydroxide could be used according to the following process categories (PROC):

PROC1	Use in closed process, no likelihood of exposure
PROC2	Use in closed, continuous process with occasional controlled exposure
PROC3	Use in closed batch process (synthesis or formulation)
PROC4	Use in batch and other process (synthesis) where opportunity for exposure arises
PROC5	Mixing or blending in batch processes (multistage and/or significant contact)
PROC8a/b	Transfer of chemicals from/to vessels/large containers at (non)dedicated facilities
PROC9	Transfer of chemicals into small containers (dedicated filling line)
PROC10	Roller application or brushing
PROC11	Non industrial spraying
PROC13	Treatment of articles by dipping and pouring
PROC15	Use of laboratory reagents in small scale laboratories

The process categories mentioned above are assumed to be the most important ones but otherprocess categories could also be possible (PROC 1 –27).

Sodium hydroxide can be used in many different chemical product categories (PC). It can be used forexample as an adsorbent (PC2), metal surface treatment product (PC14), non-metal-surface treatment product(PC15), intermediate (PC19), pH regulator (PC20), laboratory chemical (PC21), cleaning product (PC35),water softener(PC36),watertreatmentchemical(PC37)orextractionagent.However,itcouldpotentiallyalsobe used in other chemical product categories (PC 0 –40).

Becausesodiumhydroxidehassomanyusesandisusedsowidelyitcanpotentiallybeusedinallsectorsof use (SU) described by the use descriptor system (SU 1-24). NaOH is used for different purposes in a varietyof industrial sectors. The sector with the largest use of NaOH is the production of other chemicals, bothorganics (30%)andinorganics(13%).Otherusesareinthesectorspulpandpaperindustry(12%),aluminiumand metalindustry(7%),foodindustry(3%),watertreatment(3%)andtextile(3%).Theremainderisusedinthe productionofsoaps,mineraloils,bleach,phosphates,cellulose,rubberandothers(EuroChlor,2009).The sector of use 21 (SU21) is considered in Exposure Scenario4.

Although sodium hydroxide can be used during the manufacturing process of articles, the substance isnot expectedtobepresentinthearticle.Thearticlecategories (AC)donotseemapplicableforsodiumhydroxide.

Toassesstheenvironmentalexposureofsubstancesenvironmentalreleasecategories(ERC)havebeendevelopedf or REACH. For sodium hydroxide the following environmental release categories could beapplicable:

ERC1	Manufacture ofsubstances
ERC2	Formulation ofpreparations
ERC4	Industrial use of processing aids in processes and products, not becoming part ofarticles
ERC6A	Industrial use resulting in manufacture of another substance (use ofintermediates)
ERC6B	Industrial use of reactive processingaids
ERC7	Industrial use of substances in closedsystems
ERC8A	Wide dispersive indoor use of processing aids in opensystems
ERC8B	Wide dispersive indoor use of reactive substances in opensystems
ERC8D	Wide dispersive outdoor use of processing aids in opensystems
ERC9A	Wide dispersive indoor use of substances in closedsystems

Theenvironmentalreleasecategoriesmentionedabovearea ssumedtobethemostimportantonesbutother industrial environmental release categories could also be possible (ERC 1 – 12). The wide-dispersive usesare considered in Exposure Scenario4.

1.3.1.2 Description of activities, processes and operational conditions covered in the exposurescenario

TypcialusesforNaOHsolidsare:dilutioninwater,dilutioninmethanol(biodieselindustry)andsolidsas drain unblockers. Typical uses for liquid NaOH are givenbelow.

1.3.1.2.1 Production ofchemicals

NaOHisusedfortheproductionoforganicandinorganicchemicalswhichendupinabroadvarietyofend products (Euro Chlor, 2009). At the production sites of organic and inorganic chemicals, NaOH is used aspH stabiliser or as reactant for synthesis of other chemicals. In all cases NaOH must be added to a reactionvessel and will react after which no NaOH is left. In some plants NaOH is recycled to theprocess.

1.3.1.2.2 Formulation ofchemicals

Occupationalexposurecanoccurduringproductionofformulations.Especiallyduringloadingandmixinga higher exposure can be expected. High exposures can occur during the production process of thecleaning products, when loading concentrated NaOH, which typically involves pumping or pouring a fluid from a barreloradrumintoaprocessvessel.Inhalationexposureduringloadingmaytakeplaceduetovapoursor aerosols formed when the barrel or drum is opened and when adding the product to the process. NaOH willbe diluted after loading into atank.

1.2.1.1.1 Production and whitening of paperpulp

ThemajorapplicationsofNaOHinthepaperandpulpindustryarepHregulation,pulping,bleachingreactant, cleaningagent,watertreatmentforsteamproductionanddemineralisation(EuroChlor,2005).Paperandpulp mills produce acid effluents and NaOH is used in waste water treatment for neutralisation, for exampleof stronglyacidiccondensate fromvaporationofspentliquor.NosurplusNaOHisdischarged to theWWTPand/orin the receiving water (Euro Chlor, 2005). Other examples of pulp and paper processes using NaOHare:

- Kraft pulping (sulfate process), which is full chemical pulping with NaOH and Na2S, pH above 12,800kPa (120 psi). Modern kraft pulping is usually carried out in a continuous digester often lined with stainless steeland exposure to NaOH is then expected to be minimised. The temperature of the digester is raised slowlyto approximately 170°C and held at that level for approximately 3 to 4 hours. The pulp is screened toremove uncooked wood, washed to remove the spent cooking mixture, and send either to the bleach plant or to thepulp machine. At the end of the process step, sodium hydroxide is reformed in the recausticizing plant (EOHS,2001).

- The so-called extended delignification, which are techniques to remove more lignin prior tobleaching. NaOH and heat act to break complex bonds in the lignin to make them soluble in water or volatile. NaOHand heatalsobreakbondsinthecellulosereducingstrengthandyield.Todothis,woodpulpandchemicals (NaOH, Na2S) are cooked together in a pressure vessel (digester) which can be operated on a batchor continuousbasis.Incaseofbatchfillingthedigesterisfilledthroughatopopening.Thiscancauseexposure to the usedchemicals.

- The bleaching process in the so-called alkali extraction where the organic acids and alcohols react withthe NaOH to form organic sodium compounds and water. These organic substances dissolve in water. HereNaOH is used to create a high pH to optimise the bleaching process. NaOH is not the bleaching agent. The purposeof the bleaching is to remove lignin without damaging thecellulose.

- Waste paper recycling: adding water, NaOH, and heat repulps recycled material. The pulp is then usedto make a finished paper product on a paper machine in the same manner as in a virgin papermill.

1.3.1.2.3 Production of aluminium and othermetals

NaOH is used in the treatment of bauxite, from which alumina, the basis of aluminium, isextracted. Aluminium is produced from bauxite by the Bayer process. Mixed with steam and a (strong) NaOHsolution, aluminainthebauxiteformsaconcentratedsodiumaluminatesolutionleavingundissolvedimpurities.The conditions to extract the monohydrate alumina are about 250°C and a pressure of about 3,500 kPa(Queensland AluminaLimited,2004)).AttheendoftheprocessNaOHisreturnedtothestartandusedagain.Relatively highinhalationexposuretoNaOHisexpectedtobecausedduringthemixingofbauxitewithNaOHand steam due to the high temperatures and high concentrations of NaOH. In the stage of surface treatmentof aluminium finished products, NaOH is used for pickling (Euro Chlor,2005).

1.3.1.2.4 Foodindustry

NaOH can be used for a large number of applications in the food industry. In the food production sector, NaOH is regularly used for (Euro Chlor,2005):

- washing and cleaning of bottles, processes andequipment;
- chemical peeling/shelling of fruits andvegetables;
- modification ofstarch;
- preparation of carboxyl methylcellulose;
- preparation of salts such as sodium citrate and sodiumacetate.

•

1.3.1.2.5 Watertreatment

NaOHiswidelyusedinthetreatmentofwater.Insewagetreatmentstations,NaOHallowstheneutralisation of effluent and a reduction in the hardness of water. In industry, NaOH allows the regeneration ofion exchange resins. NaOH is currently used in water treatment with variousobjectives:

- control of the waterhardness;
- regulation of the pH ofwater;
- neutralisation of effluent before the water isdischarged;
- regeneration of ion exchangeresins;
- elimination of heavy metal ions byprecipitation.

NaOH is also used for the cleaning of combustion or incineration flues. Among the technologies used,the washingofgasesinascrubberusingalkalinesolutionsisaprocessofferedbyalargenumberofengineering companies. The concentrations of NaOH solutions used vary according to the application, the levelof performance to be achieved, financial situation, etc. The level of scrubbing performance of this technology allowsreductionsinacidcomponents(HCl,SO2,etc.)andinheavymetals(Hg,Cd,etc.)tocomplywiththe requirements of international and national standards (Euro Chlor, 2004a,2005).

1.2.1.1.1 Production oftextiles

Besides natural materials such as wool, cotton or linen, synthetic fibres are extensively used by thetextile industry. Cellulose textiles, obtained by the viscose process (rayon, spun rayon) have a significantmarket share.Atpresent(2004)annualworldproductionofcellulosetextileseasilyexceeds3milliontonnes.Their manufacture consumes considerable tonnages of NaOH, were 600 kg of NaOH is needed to produce a tonneof cellulosefibres.ThefunctionofNaOHintheproductionofcelluloseisunknown.NaOHisalsousedas general processing aid such asneutralisation.

Intheviscoseprocess,cellulosederivedfromwoodpulpissteepedina sodiumhydroxide solution(20-25%), andtheexcessliquidissqueezedoutbycompressiontoformalkali cellulose.Impuritiesareremovedand, afterbeingtornintoshredssimilartowhitecrumbsthatare allowedtoageforseveraldaysatcontrolledtemperature,theshreddedalkalicelluloseistransferredintoanothertan kwereitistreatedwithcarbondisulphidetoformcellulosexanthate. Thesearedissolvedindilutedsodiumhydroxidetoformaviscousorangeliquidcalledviscose.Theacids andalkalisused intheprocessarefairlydilute,butthereisalwaysdangerfromthepreparingoftheproperdilutionsandsplashesintoth eeyes.Thealkalinecrumbsproducedduringtheshreddingmayirritateworkers’handandeyes.Themajorpart ofthesodiumhydroxideusedinthetextileindustryisusedinthemercerization,bleaching,scouringandwashingofcotton.

1.2.1.1.1 Other industrialuses

NaOH is further applied in various other industrial sectors such as in production of surfactants, soaps,mineral oils,bleach,phosphates,celluloseandrubber(EuroChlor,2009).InmostoftheseapplicationsNaOHalso serves as a process aid, such asneutralisation.

1.2.1.1.1 Professional end use of formulatedproducts

NaOH is used during the production phase of various cleaning products although in most case the amountsin theendproductsarelimited.TheNaOHusedwillinteractwithotheringredientsinacid-basereactionsand thus practically no free NaOH is left in the final product. Product categorization for professionalcleaning products with remaining free NaOH after formulation can be found in the tablebelow.

Producttype	**‘free NaOH’content**	**pHrange**	**Remarks concerningRMM/OC**
Floorstrippers	<10%	>13	
Ovencleaners	5-20%	>13	

Floordegreasers	<5%	>12.5	
Drainopeners	<30%	>13	
Dish washingproducts	5-30%	>13	(concentratedproduct)
Interior heavy dutycleaners	<5%	>12.5	

RMM Risk managementmeasures OC
Operationalconditions

Professional ovencleaners

Ovencleanersarestrongdegreasersandtheyaresuitableforremovingdirtstuckonovens,grills,etc.Oven cleanerscontainstrongalkalineingredients.Strongalkaliisnecessarytoremoveburned-onsoils.Thereare triggerspraysandspraycans.Whenusingaspraycan,foamisformedonthetargetarea.Afterspraying,the ovendoorisclosedandthefoamhastosoak30minutes.Thentheovenis wipedcleanwithawetclothor sponge and one has to rinse frequently. The maximum content of sodium hydroxide in a spray can is 10%.The productiseitheragel,whichleadstolargedropletsuponspraying(100%>10Dm),oraliquidwhichis applied as a foam with a special trigger also leading to lessaerosol.

Thefrequencyofapplicationis1eventperdayandthedurationis10minutesperevent.Sprayingintocold oven,withpotentialexposuretohandsandarms.Onecansprayupto1gproductpersecond,byhand-held ready-to-use trigger spray or foamsprayer.

Professional floorstrippers

Floor strippers in the I&I (Industrial and Institutional) area are not used neat. The highly alkaline

productsare dosed15-20%andper10$m^2$1-2Lstrippersolutionisbroughtontothefloorwithasinglediscmachine. Usually10-15minactingtimearenecessarybetweenlayingdownandscrubbingthefloor.Afterwardsthe stripper/polish mixture is removed by a fat vacuumcleaner.

Draincleaners

Drainopenersopenslowrunningandobstructeddrainsbydissolvingandbylooseninggreaseandorganic waste.Therearedifferentkindsofdrainopeners,productscontainingeithersodiumhydroxideorsulphuric acid. Liquid drain openers have a maximum NaOH content of 30%. The use of liquid drain openersis comparable with the dosing of liquid cleaners. The drain opener must be dosed slowly down the drain.Pellets, which can also be use for opening the drain, have contents up to 100%. The drain opener must be dosedslowly down the drain. One has to wait at least 15 minutes so that the drain opener can clear theblockage.

Professional hair straighteningproducts

Several hair straightening products used by professional hairdressers contain a certain amount of NaOH.Hair straightening products, containing more than 2% of NaOH, are applied to the hair with a brush and aftera periodofinteractionwiththehairtheproductisrinsedoutwithwater.Forestimatingworkerexposureno relevantinhalationexposureisexpectedbecauseofthelowvolatilityandthelackofaerosolformation. Dermal exposure is only relevant when concentrations of NaOH are below 2%, which probably willoccur when the product is rinsed out of the hair. Above 2% the product will be corrosive which meanscontrol measures are expected to prevent dermal exposure. The exposure is therefore expected to occur mainlywhen thehairdresserdecidedtodoafinalrinsingstepafterthefirstrinsingisdone.

1.2.1.1 Risk management measures

1.2.1.1.1 Risk management measures related to industrial workers

The risk management measures related to industrial workers can be found in Table 9. This table applies to both liquid and solid NaOH containing products at concentration > 2%. Because sodium hydroxide is corrosive, the risk management measures for human health should focus on the prevention of direct contact with the substance. For this reason automated and closed systems should preferably be used for industrial uses of sodium hydroxide. Respiratory protection is needed when aerosols of sodium hydroxide can be formed. Due to the corrosive properties appropriate skin and eye protection is required.

Informationtype	Datafield	Explanation

Containment plus good work practice required	Good practice: replacing, where appropriated, manual processes by automated and/or closed processes. This would avoid irritating mists, sprayings and subsequent potential splashes (EU RRS, 2008): • Use closed systems or covering of open containers (e.g. screens) (good practice) • Transport over pipes, technical barrel filling/emptying of barrel with automatic systems (suction pumps etc.) (good practice) ☐ Use of pliers, grip arms with long handles with manual use "to avoid direct contact and exposure by splashes (no working over one's head)" (good practice)	**Situation at the time of the EU RAR (2007) for pulp and paper industry:** Almost all plants (97%) indicated having an automated closed system. Still 50% indicated that handling with NaOH still occurs during (re)filling of tanks/containers, cleaning, maintenance, unloading lorries, adding reactant, emptying drums or bags and sampling (average of 4 workers per plant). **Situation at the time of the EU RAR (2007) for chemical industry:** Highest inhalation exposure is expected to occur by loading NaOH from tanker to process vessel. Most of the industries use a closed and/or automated process and liquid 50% NaOH. **Situation at the time of the EU RAR (2007) for textile industry:** Exposure to NaOH can occur when steeping woodpulp and during dissolving cellulose
Local exhaust ventilation required plus good work practise	General ventilation is good practice unless local exhaust ventilation is present	xanthate. Most of the To improve air quality and avoid potential respiratory track irritation in working areas.

General ventilation	General ventilation is good practiceunless local exhaust ventilation ispresent	To improve air quality andavoid potential respiratory track irritationin workingareas.
Personal protection equipment (PPE) required under regular working conditions	• Respiratory protection: In case of dust or aerosol formation (e.g. spraying): use respiratory protection with approved filter (P2) (required) • Hand protection: impervious chemical resistant protective gloves (required) - material: butyl-rubber, PVC, polychloroprene with natural latex liner, material thickness: 0.5 mm, breakthrough time: > 480 min - material: nitrile-rubber, fluorinated rubber, material thickness: 0.35-0.4 mm, breakthrough time: > 480 min • If splashes are likely to occur, wear tightly fitting chemical resistant safety goggles, face–shield (required) • if splashes are likely to occur, wear suitable protective clothing, aprons, shield and suits, rubber or plastic boots, rubber or plastic boots (required)	**Situation at the time of the EU RAR (2007):** the questionnaire indicated that twentynine percent of the customers replied that inhalation exposure was possible, while 71% answered that skin exposure was possible and finally 75% replied that eye exposure was possible. In most cases no PPE was used to prevent inhalation. To prevent skin exposure, 46% of the respondents reported that gloves were used, while 25% reported that special clothes were used and finally 29% replied that no PPE was used. To prevent eye exposure 67% of the customers answered that safety glasses or a full facemask was used and the

Other risk management measures related to workers. For example: Particular training systems, monitoring/reporting or auditing systems, specific control guidance.	Next measures are required (from EU RRS, 2008): • workers in the risky process/areas identified should be trained a) to avoid to work without respiratory protection and b) to understand the corrosive properties and, especially, the respiratory inhalation effects of sodium hydroxide and c) to follow the safer procedures instructed by the employer (EU RRS, 2008). • the employer has also to ascertain that the required PPE is available and used according to instructions	
Measures related to the design of product (other than concentration) related to workers	☐ High viscosity adjustment with aids (good practice) ☐ Delivery only as barrel commodity and/or in the tank car (good practice)	to avoid splashes

1.2.1.1.1 Risk management measures related to professionalworkers

Because sodium hydroxide is corrosive, the risk management measures for human health should focus onthe prevention of direct contact with the substance. For this reason automated and closed systems should preferably be used for professional uses of sodium hydroxide. Since automated, closed systems andlocal exhaust ventilation may be less feasible to implement, product related design measures that prevent direct eye/skin contact with NaOH and prevent formation of aerosols and splashes are more important next to the personal protective equipmentmeasures.

Product related design measures are required. These include specific dispensers and pumps etc specifically designed to prevent splashes/spills/exposure tooccur.

Table 10 gives an overview of the personal protective equipment recommendations. Based on the NaOH concentration in the preparation, a different degree of restriction isproposed.

Table 10 Personal protective equipment releated to professionalworkers

	NaOH concentrationin product >2%	NaOHconcentration in productbetween 0.5% and2%	NaOH concentration inprodu
Respiratory protection: In case of dust oraerosol formation (e.g. spraying): userespiratory protection with approved filter(P2)	compulsory	goodpractice	No
Hand protection: In case of potentialdermal contact: use impervious chemicalresistant protectivegloves	compulsory	goodpractice	No
Protectiveclothing:Ifsplashesarelikelytooccur,wearsuitableprotectiveclothing,aprons,shieldandsuits, rubber or plastic boots, rubber or plasticboots	compulsory	goodpractice	No
Eye protection: If splashes are likely tooccur, wear tightly fitting chemical resistantsafety goggles, face–shield	compulsory	goodpractice	No

1.2.1.1.1 Risk management measures related toenvironment

Relevant risk management measures related to environment are described in section1.1.1.4.2.

1.2.1.1 Waste relatedmeasures

There is no solid waste of NaOH. Liquid NaOH waste should be reused or discharged to theindustrial wastewater andfurther neutralizedif needed(seeriskmanagementmeasuresrelatedtoenvironment).

1.3.2 Exposureestimation

1.3.2.1 Workersexposure

NaOH is a corrosive substance. For the handling of corrosive substances and formulations, immediatedermal contactsoccuronlyoccasionallyanditisassumedthatrepeateddailydermalexposurecanbeneglected. ThereforeaccordingtotheEURAR(2007),dermalexposuretopureNaOHwillnotbeassessed.Repeated dermal exposure cannot be neglected for these substances andformulations.
Relevant populations potentially exposed to generally corrosive products are workers in the chemicalindustry, aluminium industry and paper industry. Also textile workers and cleaners may have more or less directcontact with (diluted)NaOH.

NaOH is not expected to be systemically available in the body under normal handling and use conditionsand therefore systemic effects of NaOH after dermal or inhalation exposure are not expected tooccur.

Measured exposureconcentrations

The measured exposure concentrations to workers are summarized in Table11.

Table 11 Long-term exposure concentrations to workers (measured exposureconcentrations)

Routes of exposure	Measured exposureconcentr		Explanation / source of measureddata
	Value	unit	
Inhalation			**From EU RAR (2007): end use of**
	<0.11	mg/m^3	**formulatedproducts**Personal + area sampling, sample time: 250 -364 min,locations: mechanic, table outside cleaning room, sidewall on electricalbox, centre on unused equipment, black wall on tool cart (Burton etal., 2000)
			From EU RAR (2007): industrial use in pulp
	<0.5/ 16*	mg/m^3	Locations: woodplant, pulping, bleach/chem.preparation,machine room, recover and recaust, Number: 2-12, Duration: >8 hours, TWA
	0.001- 0.70	mg/m^3	Locations: pulping, refining, etc. of stock, machine, de-inking of waste paper, TWA, total of detects: 1-5, Range: 0.001 – 1.2 mg/m^3) (Korhonen et al.,2004)
			From EU RAR (2007): aluminiumindustry
	0.033 1.1 2.40*** 5.80** 4.70***	mg/m^3AM	Data from 1997-1999, Locations: during caustic dump (at operator location, caustic wash recycle tank,screw conveyor new building, overflow tank filter wach at hoist control, over caustic tank ground filters/normaloperating,drumfilters/normaloperating ,ongroundinfrontoffilter,onworkbenchonfilter,1stfloor valve, 1st floor by conveyor belt, over Launder gate wash, over precipitation tank, caustic wash, descaling launder gates, caustic wash filling sample on top of tank, adjacent to cyclones processing Medium: impinger/filter, 22 sample points with 1-5 5-117min
			New literature: aluminiumindustry
	0.2	mg/m^3GM	Refinery 2, Maintenance, N=19, Range: 0.02-4 mg/m^3, 4 hour
	0.17	mg/m^3GM	Refinery 3, Maintenance, N=8, Range: 0.05-0.6 mg/m^3, 4 hour
	0.11	mg/m^3GM	Refinery 3, Digestion, N=6, Range: 0.05-0.6 mg/m^3, 15 minsample

	0.46	mg/m GM	Refinery 2, Clarification, N=27, Range: 0.1-2.3 mg/m^3, 4 hour
	0.09	mg/m^3GM	Refinery 3, Clarification, N=9, Range: 0.05-1.1 mg/m^3, 4 hour
	0.34	mg/m3 GM	Refinery 1, Precipitation, N=19, Range: 0.1-0.8 mg/m3 , 4 hour TWA (Musk et al., 2000)
	0.19	mg/m3 GM	Refinery 3, Calcination or shipping, N=18, Range: 0.05-0.9 mg/m3 , 15 min TWA (Musk et al., 2000)
	0.56	mg/m3 GM	Refinery 2, Descale, N=11, Range: 0.1-1 mg/m3 , 4 hour TWA (Musk et al., 2000)
	0.4	mg/m3 GM	Refinery 3, Descale, N=12, Range: 0.05-3.5 mg/m3 , 15 min TWA (Musk et al., 2000)
			New data from aluminium industry:
	0.006	mg/m^3 AM	year: 2001, location = digestion, N=18, duration= 8 hours, range TWA= 0.002 – 0.024 mg/m
	0.021	mg/m^3 AM	year: 2001, location = filtration, N=19, duration= 8 hours, range TWA= 0.005 – 0.081 mg/m3
	0.017	mg/m^3 AM	year: 2001, location = precipitation, N=11, duration= 8 hours, range TWA= 0.003 – 0.072 mg/m3
	0.014	mg/m^3 AM	year: 2001, total, N=48, duration= 8 hours, range TWA= 0.002 – 0.081 mg/m3
			From EU RAR (2007): textile industry
	1.7-6.8	mg/m^3 AM	Mercerization, Bleaching , Washing , Mixing and concentration , 1- 13, Storage , workers exposed, N=8-

* A single high reading because of upset conditions at theslaker/causticizer

**Sampleknowntobecontaminatedasnosteam/mistcameincontactwithsamplerduringsampling; samples was taken up-wind of steam source due to prevailing windconditions

*** Samples were taken in very wet steam/ mist clouds; problems with pumps cutting out and pumpsflooding wererecorded

End use of formulatedproducts

InApril1998,ahealthhazardevaluationconcerningthecleaning,overhaulingandrepairofaircraftlavatory tanksandhardwarewasconductedatonecompany.Themainpurposewastostudythepotentialexposureto infectious micro-organisms but also some measurements of NaOH exposure were conducted (Burton etal., 2000). NaOH was a component in the soaps and cleaning agents used in the cleaning room. Onepersonal breathing zone and four area samples (three inside and one outside the lavatory cleaning room) werecollected. The samples were analysed for alkaline dust and mist by acid-base titration according to NIOSH Method 7401.FollowingBurtonetal.(2000)theresultswereexpectedtobelowsincelittlesprayingofthesoapwas done on the day of the monitoring. Because the exact exposure level is unknown, these measurements arenot taken to the risk characterization (EU RAR,2007).

Pulp and paperindustry

In 1988 measurements were conducted in a paper mill (Kennedy et al., 1991). A total of 28 area sampleswere takenatdifferentlocationswithaminimummeasurementtimeof8hours(seeTable11).Itisunclearhow measurementswerecollected.Noneofthemeasurementsexceededthedetectionlevel.Allmeasuredareas where exposed for over 8 hours to a NaOH concentration below 0.5mg/m^3.

In an international epidemiological study of workers exposure to chemical agents in the pulp andpaper industry a database with a total of 3873 measurements were analysed (Korhonen et al., 2004). Most ofthe measurements were from 1980 to 1994 and from a total 12 countries. A total of 15 measurementswere conductedtoNaOH(seeTable11).Twomeasurementsduringpulpingstockandonemeasurementatthe paperboard machine were exceeding the detection limit. When de-inking waste paper all measurementswere exceeding the detection limit with an AM of 0.70 mg/m^3 (range 0.30 – 1.20 mg/m^3). The duration ofthe measurementswasmorethanonehour,buttheexactdurationwasunclear.Itwasnotclearfromthearticle which tasks were conducted during the measurements. These measurements reflect the old situation wherethe properriskmanagementmeasureswerenotsufficientlytakenintoaccount.FollowingTable9,thefollowing RMMs are recommended: 1) to use closed systems as much as possible, 2) to use LEV where appropriate and 3) to use RPE in case of splashes or aerosolformation.

Alumina industry

At company A static measurements were conducted in 1997 and 1999 to "caustic mist" during production of aluminum. In Table 11, a summary is given of these measurements. Measurements were conducted to caustic mist with a 37mm, 0.8µm, MCEF, membrane filter with a cellulose backup pad in a closed face 3 piece cassette or with a SKC midget impinger containing ultra pure water. All measurements performed (see Table 11) are worst-case area samples and many of the locations selected for sampling were ones where high concentrations were expected. The arithmetic mean of all measurements is 0.39 mg/m^3 with a range 0.033-1.1 mg/m^3 (excluding measurements in accidental situations with failing equipment). Mean measurement time is 57 min. Because operators are not routinely present at the measured locations it is assumed that total present time during a day is the same as the approximate mean measurement time (1 hour). Expecting an 8 hour working day with an exposure of 1.1 mg/m^3 for 1 hour and zero exposure during the rest of the day gives a full shift reasonable worst case exposure level of 0.14 mg/m^3. The short-term reasonable worst case value is estimated as 1.1 mg/m^3. Expecting an 8-hour working day with an exposure of 0.39 mg/m^3 for 1 hour and zero exposure rest of the day gives a full shift typical exposure level of 0.05 mg/m^3. The short-term typical exposure value is estimated as 0.39 mg/m^3 (EU RAR, 2007).

Musk et al. (2000) provides occupational exposure data of caustic mist for three alumina refineries in Western Australia. The sample duration is 15 minutes and 4 hour time weight averages. The activities covered are maintenance, digestion, clarification, precipitation, calcination or shipping and descale.

In another study (Fritschi et al., 2001) the results for exposure to caustic mist were qualitatively presented and therefore not suitable for the risk assessment.

These measurements above reflect the old situation where the proper risk management measures were not sufficiently taken into account. Following Table 9, the following RMMs are recommended: 1) to use closed systems as much as possible, 2) to use LEV where appropriate and 3) to use RPE in case of splashes or aerosol formation.

More recent data were collected from the aluminum industry covering various activities (digestion,filtration, precipitation). Multiple samples were collected during the full shift. The maximum observed concentration is

0.021 mg/m^3. This value will be further considered for riskcharacterization.

Textileindustry

In1981measurementswereconductedatdifferenttextileproducingcompaniesinFinland(Nousiainenetal.,1981).Atotalof198areasamplesweretakenatdifferentlocationsforawholeshiftduration(seeTable11). During the measurements the fixed apparatus was positioned so that the best possible approximatevaluesoftheworkerexposurewouldbeobtained,withoutdisturbingnormalworkroutines.Thedistancefromtheouteredgeofthemercerization,leachingorwashingmachinewas1mandthesamplingheightfromthefloororworkplatformwas1-5m.Themeasurementsweremadeatthefront,middleandbackpartofeachmercerizationmachine.Thecontentsmeasuredatthemiddlewereoften highest because thesolution washotthere.Forbleaching themeasurementswerelikewisemadeatdifferentpointsofthemachine.Mostmeasurementswereconducted duringmercerisationandbleachingandthenumber ofworkerspossiblyexposedis,incomparisonwithotherlocations,high.Thesemeasurementsareoutofdateandtheydonotdescribeaworstcasesituation,theydescribethetextileindustry30yearsago.FollowingTable9,thefollowingRMMsarerecommended:1)touseclosedsystemsasmuchaspossible,2)touseLEVwhereappropriateand3)touseRPEincaseofsplashesoraerosolformation.Sotherefore,theseRMMsshouldbeusedtoavoidinhalationexposure.TheuseofNaOHintoday’stextileindustryismostlyinclosedsystemwithoutexposureoftheworkers(seeexamplepicturesofFigure1).Inthosecaseswherethereisstillopenuse,thereisnorelevantexposurebecausethiswouldnotbeasprayingprocessbutadippingprocesswithoutaerosolformation.AnopenusemeasurementforKOHwhichisverysimilartoNaOH(thecleaningofmachinerywhichimpliespossibleexposure) showedlessthan0.06mg/m^{3}andthiswas the detectionlimit.

Figure1:TheuseofNaOHintoday’stextileindustryisinclosedsystemwithoutexposureoftheworkers(left : Distribution NaOH, middle; Storage of NaOH, right: Use of NaOH(dying))

		
		

Estimated exposureconcentrations

Theestimatedexposureconcentrationstoworkersreported intheEU RAR(2007)aresummarized inTable12.

Table 12 Long-term exposure concentrations to workers (estimated exposureconcentrations)

Routes of exposure	Estimated Exposure Concentrations		Explanation / source of measured data
	value	unit	
Dermal exposure	0.42-84	mg/d	Various dermal exposure estimates were calculated in the EU RAR (2007) using EASE for following scenarios: end use of liquid oven cleaner, end use of spray oven cleaner, end use of hair straightening products and use in textile industry.

Inhalation exposure	Typical: 0.04 RWC: 0.08	mg/m3 mg/m	**From EU RAR (2007): formulation of NaOH containing products** Adding liquid NaOH (T = 20°C) to a process (vapour pressure very low, no aerosol formed, LEV present, use pattern non dispersive use), EASE predicts a typical inhalation exposure of 0-0.17 mg/m3 (0 – 0.1 ppm). Assuming NaOH concentration of 50% a typical exposure value of 0.04 mg/m3 (0.025 ppm) is estimated (half of range 0 – 0.05 ppm). Estimating the reasonable worst-case exposure gives a value of 0.08 mg/m3 (0.05 ppm, upper value of the range).

	negligible		**From EU RAR (2007): end use of liquid oven cleaner** EASE estimates (assuming very low vapour pressure, no aerosol formed, direct handling, non-dispersive use) 0 - 0.17 mg/m3 (0 – 0.1 ppm) for typical inhalation exposure. Assuming dilution of 1:50 (oven cleaner is not used purely) and NaOH concentration of 7.5% (mean concentration NaOH) typical inhalation value is estimated (by taken the mean value of the range) as 1.3 . 10-4 mg/m3 (0.02 . 0.075 . 0.085). A reasonable worst case inhalation exposure is estimated by taking the upper range value which gives an estimation of 2.6 . 10-4 mg/m3 (0.02 . 0.075 . 0.17). Both, typical and worst case estimates, can be considered to be negligible.

	0.13	mg/m3	**From EU RAR (2007): end use of spray oven cleaner** NaOH is a non-volatile substance and therefore EASE is not suitable for estimating inhalation exposure occurred by spraying. The EU RAR (2007) refers to a model derived by De Pater et al. (1999) to estimate inhalation exposure to nonvolatile substances during spraying. This model is based on measured exposure levels to poly isocyanates in spray coating and is also considered to be relevant for spray cleaning. Model: $Es = Em \cdot (Cs/Cm)$ Es = the estimated inhalation exposure (mg/m 3), Em = the measured exposure to nonvolaliles (mg/m3) Cs = 1he percentage of the notified substance and Cm = the percentage total non-volatile substances. Assuming a NaOH concentration of 3% (mean concentration of NaOH in spray) Cs is 0.03. Because the measured exposure to non-volatiles and the percentage nonvolatile substances are unknown, the estimates for spray painting are used as indicative values: Em = 10 mg/m3 and Cm = 0.3. This results in an estimated
			inhalation exposure of 1 mg/m3 (10. 0.03/0.3). If spraying occurs 1 hour/day and rest of the day no exposure is assumed, a reasonable worst case of 0.13 mg/m3 is estimated.

	Typical: 0.04 RWC: 0.08	mg/m3 mg/m3	**From EU RAR (2007): EASE simulation for chemical industry, industrial use in pulp and paper and for aluminium industry:** Adding liquid NaOH (T = 20°C) to a process (vapour pressure very low, no aerosol formed, use pattern non dispersive use) EASE predicts a typical inhalation exposure of 0 – 0.17 mg/m3 (0 – 0.1 ppm). Assuming NaOH concentration of 50% a typical exposure value of 0.04 mg/m3 (0.025 ppm) is estimated (half of range 0 – 0.05 ppm). For estimating the reasonable worst case exposure 0.08 mg/m3 (0.05 ppm, upper value of the range) is taken.
	0 – 0.043	mg/m3	**From EU RAR (2007): for textile industry** Steeping cellulose in sodium hydroxide solution can be compared with mixing. In this case cellulose will be added to sodium hydroxide. When assuming a closed system with vapour pressure very low, no aerosol formed and use pattern nondispersive, EASE predicts a value of 0 – 0.17 mg/m3 (0 – 0.1 ppm). If a concentration of 25% NaOH is used, the range will become 0 – 0.043 mg/m3

The estimated inhalation exposure concentrations to workers according to the ECETOC TRA tool are summarized in Table 13. It was assumed that there is no local exhaust ventilation and no respiratory protection unless specified otherwise. The duration of exposure was set at more than 4 hours per day as a worst-case assumption. And professional use was specified where relevant as a worst-case assumption. For the solid, the low dustiness class was selected because NaOH is very hydroscopic. Only the most relevant PROCs were considered in the assessment.

There is no need to quantitatively derive dermal exposure estimations because a DNEL for dermal exposure was not derived.

Table13Longterminhalationexposureconcentrationstoworkers(estimatedexposureconcentrations)

PROC	PROCdescription	Liquid (mg/m^3)	Solid(mg/m^3)

PROC1	Use in closed process, no likelihood ofexposure	0.17	0.01
PROC2	Use in closed, continuous process withoccasional controlled exposure (e.g.sampling)	0.17	0.01
PROC3	Use in closed batch process (synthesis orformulation)	0.17	0.1
PROC4	Use in batch and other process (synthesis)where opportunity for exposurearises	0.17	0.2 (withLEV)
PROC5	Mixing or blending in batch processes for formulationof preparations and articles (multistage and/orsignificant contact)	0.17	0.2 (withLEV)
PROC7	Spraying in industrial settings andapplications	0.17	Notapplica
PROC8a/b	Transfer of substance orpreparation (charging/discharging) from/to vessels/large containersat non dedicated or dedicatedfacilities	0.17	ble0.5
PROC9	Transfer of substance or preparation into smallcontainers (dedicated filling line,	0.17	0.5
PROC10	includingweighing) Roller application or brushing of adhesive andother coating	0.17	0.5
PROC11	Spraying outside industrial settings orapplications	0.17	0.2 (withLEV)
PROC13	Treatment of articles by dipping andpouring	0.17	0.5
PROC14	Production of preparations or articles bytabletting, compression, extrusion,pelettisation	0.17	0.2 (withLEV)
PROC15	Use a laboratoryreagent	0.17	0.1
PROC19	Hand-mixing with intimate contact and only available	0.1 7	0.5
PROC23	Open processing and transfer operations (with minerals) at elevatedtemperature	0.17	0.4 (with
PROC24	High (mechanical) energy work-up of substancesbound in materials and/orarticles	0.17	0.5 (

LE

w

PROC 26 was considered to mainly applicable to metals industry. Handling of inorganic substancesis assumed to be included in the existing PROCsassessed.

Inhalationexposureduringloadingmaytakeplaceduetovapoursoraerosolsformedwhenthebarrelordrum isopenedandwhenaddingtheproducttotheprocess.NaOHwillbedilutedafterloadingintoatank.

Summary of the exposurevalues

The summary of exposure concentrations to workers, taken forward to risk characterization, is given in Table14

Table 14 Summary of exposure concentration toworkers

Routesof exposure	**Concentrations**	**Justification**

Dermal exposure(in mg/cm^2)	84mg/d	From EU RAR (2007): NaOH products with a concentration > 2%are corrosive, therefore effective control measures are expected to be in placeto prevent dermal exposure. Furthermore protective clothing and glovesare considered to be used consistently when handling corrosivesubstances. Productioncompaniesreporttheuseofprotectivegloves,suit andboots while handling pure NaOH. Repeated daily dermal exposure to thepure substance is therefore considerednegligible. Dilutions of NaOH containing less than 2% of the substance do nothave corrosive properties. For this concentration a dermal exposure valueis estimated. A reasonable worst case exposure of 84 mg/day will be taken torisk characterisation for handling concentrations
Inhalation exposure(in mg/m^3)	< 1mg/m^3	<In the EU RAR (2007): following values were selected 2%NaOH. forrisk characterisation: 1 Pulp and paper industry: 0.08mg/m^3 2 De-inking waste paper: 1.20mg/m^3 3 Aluminium: 0.14 mg/m^3. Short-term value: 1.1mg/m^3 4 Textile: 3.4mg/m^3 5 Chemical industry: 0.08mg/m^3 Most measurements reflect an outdated situation where the properriskmanagementmeasureswerenotsufficientlytakenin to account.Following Table9, the following RMMs are recommended: 1) to use closed systems as muchas possible,2)touseLEVwhere appropriateand3)touseRPEincaseof splashesoraerosolformation.ApplyinganRMMefficiencyrateo fmorethan90%woulddecrease the exposure concentrations

1.3.2.2 Indirect exposure of humans via the environment (oral)

Indirect exposure to humans, for example through the uptake of drinking water, is not relevant for NaOH.Any potential for exposure to NaOH due to environmental releases will only have relevance at the local scale.Any pHeffectoflocalreleaseswillbeneutralisedinthereceivingwaterattheregionalscale.Thereforeindirect exposure of humans via the environment (oral) is not relevant in the case of NaOH (EU RAR,2007).

1.3.2.2 Environmentalexposure

AsstatedintheEURARonNaOH(2007),theriskassessmentfortheenvironmentwillfocussolelyonthe aquatic environment, when applicable including STPs/WWTPs, as the emissions of NaOH in the differentlife-cyclestages(productionanduse)mainlyapplyto(waste)water.Theaquaticeffectandriskassessmentwill onlydealwiththeeffectonorganisms/ecosystemsduetopossiblepHchangesrelatedtoOH$^-$discharges,as the toxicity of the Na$^+$ ion is expected to be insignificant compared to the (potential) pH effect. Only thelocal scalewillbeaddressed,includingsewagetreatmentplants(STPs)orwastewatertreatmentplants(WWTPs) whenapplicable,bothforproductionandindustrialuse.Anyeffectsthatmightoccurwouldbeexpectedto take place on a local scale and therefore it was decided as not meaningful to include the regional orcontinental scale in this risk assessment. Furthermore, the high water solubility and very low vapour pressure indicatethat NaOH will be found predominantly in water. Significant emissions to air are not expected due to the very low vapour pressure of NaOH. Significant emissions to the terrestrial environment are not expected either. The sludge application route is not relevant for the emission to agricultural soil, as no sorption of NaOH to particulate matter will occur in STPs/WWTPs.

The exposure assessment for the aquatic environment will only deal with the possible pH changes in STP effluent and surface water related to the OH^- discharges at the local scale.

1.3.2.2.1 Environmental releases

To estimate the environmental releases from the uses of NaOH a questionnaire was organised by EuroChlor, in cooperation with the Portuguese and Dutch authorities, focussing on the major downstream uses (EURAR, 2007). Because the exposure assessment focussed on possible pH changes in the local aquatic environment, data were requested on the pH control at user sites. Based on the experience with the results from the questionnaire to producers (see Section 1.1) it was envisaged that the pH of discharges would also be strictly controlled by the industry involved, often in response to local requirements. Therefore, the environmental part of the questionnaire was simplified in agreement with the rapporteur, asking the following two questions: ‘does your final waste water which is discharged to the receiving water still contain NaOH?’ and ‘if yes: what do you do to prevent an impact from NaOH discharge’? The results of the user questionnaire have been reported in detail in Euro Chlor (2005).

The paper and pulp industry was addressed via CEPI, the Confederation of the European Paper Industries and received 34 replies. For the paper and pulp industry one questionnaire was received from Germany (National Federation), which represented the common practice in this country.

Other industries were approached via five large producers of NaOH who each sent out a questionnaire to 20 of their customers, in nearly all cases end users of NaOH. A reply had been received from 24 customers, representing a response of 24%. From these 24 customers, 8 responses were received from Spain. The other customers were located in Belgium, France, Germany, The Netherlands and United Kingdom. The majority originated from the chemical industry (17 replies). One reply was received from the steel industry, textile industry, rubber production, distribution, food industry, metal industry and aluminium industry. In one case a distributor completed the questionnaire, which is not an end user of NaOH.

For the pulp and paper industry the average amount of NaOH used per day was 14 tonnes (range from 0.005– 160 tonnes), while the remaining end users used an average amount of 24 tonnes/day (range from 1.5– 110 tonnes). For the paper and pulp sector 32 respondents answered that the final waste water did not contain NaOH, but in two cases it did. For these cases it was stated that the impact was controlled. For the 23 other end users questioned (excluding the distributor), 21 indicated to have no NaOH in the final effluent. For two sites, from the chemical industry, the final effluent contained NaOH. For these sites it is not specifically known if they neutralised their effluent. Normally, local procedures are in place to prevent discharges outside the range required by authorities, such as recycling, mixing with other streams for neutralisation or discharge to a WWTP when that is considered favourable.

The results from the questionnaires for the use sites demonstrate that in most cases the final effluents did not contain NaOH anymore. Usually, the pH of waste water discharges is controlled and almost always proper regulations are in place. Nevertheless, for some use sites, emitting their effluents to the environment, it cannot be excluded that they do not neutralise their effluents and have no legal obligation to neutralise.

As stated above, the emissions of NaOH mainly apply to (waste) water. Furthermore, the high water solubility and very low vapour pressure indicate that NaOH will be found predominantly in water. In water (including soil or sediment pore water), NaOH is present as the sodium ion (Na^+) and hydroxyl ion (OH^-), as solid NaOH rapidly dissolves and subsequently dissociates in water.

1.3.2.2.2 Exposure concentration in waste water treatment plants (WWTP)

Referring to the RMMs related to the environment to avoid discharging NaOH solutions into municipal wastewater unless neutralization is carried out, the pH of the influent of a municipal wastewater treatment plant is neutral and therefore, there is no exposure to the biological activity.

1.3.2.2.3 Exposure concentration in aquatic pelagic compartment

The exposure concentration in aquatic pelagic compartment is similar to the assessment done in ES 1(see section 1.1.2.3.3).

1.3.2.2.4 Exposure concentration in sediments

The exposure concentration in sediment compartment is similar to the assessment done in ES 1 (see section 1.1.2.3.4).

1.3.2.2.5 Exposure concentrations in soil and groundwater

The exposure concentration in soil and groundwater compartment is similar to the assessment done in ES 1 (see section 1.1.2.3.5).

1.3.2.2.6 Atmospheric compartment

The exposure concentration in atmospheric compartment is similar to the assessment done in ES 1 (see section 1.1.2.3.6).

1.3.2.2.7 Exposure concentration relevant for the food chain (Secondary poisoning)

The exposure concentration relevanty for the food chain is similar to the assessment done in ES 1 (see section 1.1.2.3.7).

1.4 Exposure Scenario 4: Consumer use of NaOH

1.4.1 Exposure scenario

1.4.1.1 Short title of the exposure scenario

SU21: private households

PROC not applicable for this ES

PC 20, 35, 39 (neutralisation agents, cleaning products, cosmetics, personal care products). The other PCs are not explicitly considered in this exposure scenario. However, NaOH can also be used in other PCs in low concentrations e.g. PC3 (up to 0.01%), PC8 (up to 0.1%), PC28 and PC31 (up to 0.002%) but it can be used also in the remaining product categories (PC0-40).

AC not applicable for this ES

1.4.1.2 Description of activities, processes and operational conditions covered in the exposure scenario

NaOH (up to 100%) is also used by consumers. It is used at home for drain and pipe cleaning, wood treatment and it also used to make soap at home (Keskin et al., 1991; Hansen et al., 1991; Kavin et al., 1996). NaOH is also used in batteries and in oven-cleaner pads (Vilogi et al., 1985). Following uses are briefly described:

1.4.1.2.1 Floor strip products

Floor strippers are used to remove old protective layers. The maximum content of sodium hydroxide in floor strippers is 10%. For stripping the floor of the living room, 550 g of the product is needed for an area of 22 m^2. This is done with the undiluted product. The product is sprinkled on a cloth and is manually rubbed on the floor.

1.4.1.2.2 Hair straighteners

The maximum content of sodium hydroxide in hair straighteners for use by the general public is 2% (EU Cosmetics Directive). Sodium hydroxide as a caustic type of chemical will actually soften hair fibres. It will also cause the hair to swell at the same time. As the sodium hydroxide solution is applied of the hair, it penetrates into the cortical layer and breaks the cross-bonds. The cortical layer is actually the middle of inner layer of the hair shaft that provides the strength, elasticity and shape of the curly hair.

1.4.1.2.3 Oven cleaners

Oven cleaners are strong degreasers and they are suitable for removing dirt stuck on ovens, grills, etc. Oven cleaners contain strong alkaline ingredients. Strong alkali is necessary to remove burned-on soils. There are trigger sprays and spray cans. When using a spray can, foam is formed on the target area. After spraying, the oven door is closed and the foam has to soak 30 minutes. Then the oven is wiped clean with a wet cloth or sponge and one has to rinse frequently. The maximum content of sodium hydroxide in a spray can is 5%. For the purpose of the exposure calculations, the product is assumed to contain 0.83% NaOH (which is 2.5% of a 33% aqueous NaOH solution). The product is a milky-white gelatinous liquid. Formulation as a gel leads to large droplets upon spraying (100% >10 um). The frequency of application is 1 event per day and the duration is 2 minutes per event. Spraying into cold oven, with potential exposure to hands and arms. One can spray up to 1 g product per second, by hand-held ready-to-use trigger spray.

1.4.1.2.4 Drain openers

Drain openers open slow running and obstructed drains by dissolving and by loosening grease and organic waste. There are different kinds of drain openers, products containing either sodium hydroxide or sulphuric acid. Liquid drain openers have a maximum NaOH content of 30%. The use of liquid drain openers is comparable with the dosing of liquid cleaners. The drain opener must be dosed slowly down the drain. Pellets, which can also be use for opening the drain, have contents up to 100%. The drain opener must be dosed slowly down the drain. One has to wait at least 15 minutes so that the drain opener can clear the blockage.

1.4.1.2.5 Other cleaning products

NaOH is used during the production phase of various cleaning products although in most case the amounts are low and NaOH additions are mainly for pH adjustment. The amounts used will interact with other ingredients in acid-base reactions and thus practically no NaOH is left in the final consumer product.However, hypochloriteproductsmaycontain0.25-0.45%ofNaOHinthefinalformulation.Sometoiletcleanersmay contain up to 1.1% and certain soaps contain up to 0.5% of NaOH in the finalformulation.

1.4.1.2.6 Consumer use, service life and waste stage of NaOH inbatteries

Aqueoussodiumhydroxideisemployedastheelectrolyteinalkalinebatteriesbasedonnickel-cadmiumand manganesedioxide-zinc.Eventhoughpotassiumhydroxideispreferredoversodiumhydroxide,NaOHcan still be present in the alkaline batteries, but here this substance is strictly confined in the battery screeningand doesn't come in contact with theconsumer.

The industrial and professional uses of NaOH in batteries (incl. recycling operations) are coveredunder Exposure Scenario 3. This ES focuses on the consumer use, the service life and the end-of-life stage ofNaOH in batteries. Given that batteries are sealed articles and that NaOH involved in their maintenance isnot intended for direct release exposure to and emission from NaOH in these life-cycle stages should beminimal.

1.4.1.3 Risk managementmeasures

1.4.1.3.1 Risk management measures related to consumers (all exceptbatteries)

The risk management measures related to consumers are mainly related to prevent accidents. <u>Measuredrelatedto the design of theproduct</u>

- Itisrequiredtouseresistantlabelling-packagetoavoiditsautodamageandlossofthelabelintegrity, under normal use and storage of the product. The lack of quality of the package provokes the physical lossof information on hazards and useinstructions.
- Itisrequiredthathouseholdchemicals,containingsodiumhydroxideformorethan2%,whichmay be accessibletochildrenshouldbeprovidedwithachild-resistantfastening(currentlyapplied)andatactile warning of danger (Adaptation to Technical Progress of the Directive 1999/45/EC, annex IV, Part Aand Article 15(2) of Directive 67/548 in the case of, respectively, dangerous preparations and substancesintended for domestic use). This would prevent accidents by children and other sensitive groups ofsociety.
- Itisrequiredthatimproveduseinstructions,andproductinformationshouldalwaysbeprovidedto the consumers.Thisclearlycanefficientlyreducetheriskofmisuse.Forreducingthenumberofaccidentsin which(young)childrenorelderlypeopleareinvolved,itshouldbeadvisabletousetheseproductsint he absence of children or other potential sensitive groups. To prevent improper use of sodiumhydroxide, instructions for use should contain a warning against dangerousmixtures
- It is advisable to deliver only in very viscous preparations It is advisable to delivery only in smallamounts

<u>Instructions addressed toconsumers</u>

- Keep out of reach ofchildren.
- Do not apply product into ventilator openings orslots.

<u>PPE required under regular conditions of consumeruse</u>

	NaOH concentration	NaOH concentration in productbetween 0.5% and2%	NaOH concentrationin product
Respiratory protection: In case of dustor aerosol formation (e.g. spraying):use respiratory protection with approved	required	goodpractice	no
Hand protection: In case of potentialdermal contact: use impervious chemicalresistant protectivegloves	required	goodpractice	no
Eye protection: If splashes are likely tooccur, wear tightly fitting goggles, face–shield	required	goodpractice	no

1.4.1.1.1 Risk management measures related to consumers(batteries)

<u>Measuredrelatedtothedesignoftheproduct:</u>Itisrequiredtousecompletelysealedarticleswithalong service lifemaintenance.

1.4.1.1.2 Risk management measures related toenvironment

There are no specific risk management measures related toenvironment.

1.4.1.2 Waste relatedmeasures

This material and its container must be disposed of in a safe way (e.g. by returning to a publicrecycling facility). If container is empty, trash as regular muncipalwaste.

Batteries should be recycled as much as possible (e.g. by returning to a public recycling facility). Recoveryof NaOHfromalkalinebatteriesincludesemptyingtheelectrolyte,collectionandneutralizationwithsulphuric acidandcarbondioxide.Theoccupationalexposurerelatedtothesestepsisconsideredintheexposure scenario on industrial and professional use ofNaOH.

1.4.2 Exposureestimation

1.4.2.1 Consumerexposure

For consumer exposure it is important to stress, that sodium hydroxide exposure is an externalexposure. Contact with tissue and water will give sodium and hydroxide ions. These ions are abundantly available inthe body.

A significant amount of sodium is taken up via the food because the normal uptake of sodium via food is 3.1-6.0 g/day according to Fodor et al. (1999). In the NaOH EU RAR (2007), external exposure concentrationsin mg/kg were calculated and compared with the sodium intake via food to see whether this is a relevant exposureroute.Severalscenarioswereassessed:floorstrippers,hairstraighteners,ovencleanersanddrain openers. Overall, it was concluded that the sodium uptake due to the use NaOH containing productsis neglibible compared to the daily dietary intake of sodium ions (EU RAR, 2007). The effect of sodium intakeis not further considered in this sodium hydroxidedossier.

Since accidental exposure is normally excluded from an EU chemical safety assessment andaccidental exposureisconsideredintheEURAR(2007,Section4.1.3.2,pages59-62),accidentalexposurewillnotbe further assessed in this dossier. However, the risk management measures for consumers, identified inthe NaOH risk reduction strategy (EU RRS, 2008) are included in thedossier.

1.4.2.1.1 Acute/Short termexposure

Acute/shorttermexposurewasassessedonlyforthemostcriticaluse:useofNaOHinasprayovencleaner
InhalationexposuretoNaOHintheovencleanerwasestimatedusingdifferent modellingapproaches:

1) ConsExposoftware(version4.1,http://www.consexpo.nl;Proud'hommedeLodderetal.,2006):default product: oven cleaner (application: spraying), default values apply to triggerspray
2) SprayExpo (Koch et al., 2004): release pattern: wall area (surrogate for the use assessedhere)

Conditions of use and inputparameters

Theconditionsofuseweregivenbythemanufactureroftheproductasshowninthefollowingtable.This tableonlylistsspecificvaluesandtheirrationalebutdoesnotincludethedefaultvaluesusedinthedifferent models:

Parameter	Value
Package	375 ml triggerspray
Amount used	120 g[1]
Sprayduration	120 sec[1]
Calculated mass generationrate	1 g/sec[1]
Distance nozzle toface	0.5m
Distance nozzle to ovenwall	0.3m
Weight fractioncompound	0.025 (2.5% ingredient (33% NaOH) assumed tobe relevant for possibleirritation)
Median of the particle sizedistribution	273 µm [1] (mean of three measurements for onepackage; lowest value from three different packagestested)
Coefficient of variation (fraction) of themedian	1.15 [1] (seetext)
Maximum particlesize	670 µm (estimated from graphical droplet sizedistribution)

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[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 massgeneration rate in this model wasreduced.

Roomvolume	15 m^3[1]
Airexchange	2.5/h (ConsExpo default, also used
Inhalation cut-offdiameter	670 µm (set to maximum value of the distributionsince exposure at the nose

The product-specific data slightly differ from the ones used in ConsExpo 4.1 (Proud'homme de Lodder etal., 2006).Theseauthorsreportamassgenerationrateof0.78g/secforgeneralovencleaners.Thevaluetaken hereissomewhathigherbutstilllowerthanthevalueof1.28g/secgivenbythesameauthorsforananti-grease cleaning triggerspray.

Theparticlesizedistributionwastakenfromproduct-specificmeasurements.Threedifferentpackagesoftheproductweretestedwiththree measurementsforeachpackage.Inaddition,measurementswereperformedwithdistancesof10and20cm,respectively,betweennozzleandlaserbeam.Fortheexposureassessment,the10cmdistancetrialsweretaken andthelowestvalue(meanofthreemeasurements)waschosen.

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

- a 10th percentile of 103µm
- a 50th percentile of 273µm
- a 90th percentile of 314µm

UndertheassumptionofalognormaldistributionProud'hommedeLodderetal.,2006),thesoftware@risk (version 4.5.2, Pallisade Corporation, 2002) was used to define a "product-specific distribution" withthe followingvalues:

- Median = 273µm
- 10th percentile: 104µm
- 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 forConsExpo software).The@risksoftwarealsoallowsderivingthepercentagesrepresentingdefinedsizeclasses(which are required for SprayExpomodelling).

SeeAnnexfordetailedresultsofthemodellingwithbothmodels.Pleasenote:aconcentrationof2.5%(of 33%NaOHinwater)wasusedinthemodellingexercises.Resultstherefore weredividedby3toderivethe results as shown in Table15.

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[1] ThisisthedefaultvaluefromConsExpoforakitchen.TheroomsizeinSprayExpo(lowestpossible room height: 3 m) was adapted to result in an identical roomvalue.

Other exposureestimates

The EU Risk Assessment Report (2007) on sodium hydroxide estimates occupational exposure to NaOHfrom

theuseofovencleaners.Theestimateisbasedonanassumedexposureconcentrationof10mg/m^{3}for aerosols.Thisvalueisderivedfromexperienceswithspraypainting.Withaconcentrationof3%NaOHand 30% non-volatile substances in the oven cleaner a short-term inhalation exposure (during spraying) of 1 mg/m^3 wasestimated.
Accordingly, with a NaOH concentration in the product of 0.83% (this product) an inhalationexposure concentration of 0.3 mg/m^3 wouldresult.

Modellingresults

ResultsforthedifferentmodellingapproachesareshowninTable15.Aningredientconcentrationof2.5% (withtheingredientbeing33%NaOHinwater)wasusedinthemodellingexercises.Therefore,modelling results as given in the Annex were divided by 3 to arrive at results for pureNaOH.

Table 15 Acute exposure concentrations toconsumers

Routesof exposure	**EstimatedExposure Concentrations**		**Measuredexposure**		**Explanation / source ofmeasured data**
	Value	**Un**	**Value**	**Un**	
Inhalation exposure	0.012 (mean)* 0.33 (peakconcentratio	**it**mg /m 3		**it**	ConsExpo 4.1: Spraying for 2 minutes, 60 minutes exposureperiod
	n)1.6	mg /m			SprayExpo: mean for sprayingperiod (5minutes)
	0.3	3 mg			According to EU RAR,2007

* 0.012 mg/m^3 represents the mean for a total exposure period of 60 minutes, as calculated by ConsExpoand includes 58 minutes without application. As here the mean concentration during application is sought, thepeak concentration (0.33 mg/m^3) is used as a conservative estimate of the averageconcentration.

Summary of the short-term exposurevalues

Table 16 Summary of acute exposure concentrations toconsumers

Routes ofexposure	**Concentration**	**Justification**
Oral exposure (in mg/kgbw/d)	**s**	Notapplicable

Dermal local exposure (in mg/cm^2)		Not applicable
Dermal systemic exposure (in mg/kgbw/d)		Not applicable
Inhalation exposure (in mg/m^3)	0.3 to 1.6	See modelling results above

1.4.2.1.1 Long-term exposure

Exposure to oven cleaner spray 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.

NaOH is not expected to be systemically available in the body under normal handling and use conditions and therefore systemic effects of NaOH after dermal or inhalation exposure are not expected to occur.

If the recommended RMMs are respected, local exposure through inhalation will not be higher compared to inhalation exposures in ES3. Therefore, the consumer exposure through inhalation is not further quantitatively assessed.

Consumer exposure to NaOH in batteries is zero because batteries are sealed articles with a long service life maintenance.

1.4.2.2 Indirect exposure of humans via the environment (oral)

Indirect exposure to humans, for example through the uptake of drinking water, is not relevant for NaOH. Any potential for exposure to NaOH due to environmental releases will only be relevant at the local scale. And any

1.4.2.3 Environmentalexposure

Consumer uses relates to already diluted products which will further be neutralized quickly in the sewer,well before reaching a WWTP or surfacewater.

1.5 Regional exposureconcentrations

Anyeffectsthatmightoccurwouldbeexpectedtotakeplaceonalocalscaleandthereforeitwasdecidedas not meaningful to include the regional or continental scale in this risk assessment (EU RAR, 2007). Predicted environmentalconcentrations(PECs)cannotbecalculated.Onlyasummaryofmeasuredlevelsisprovided (EU RAR,2007).

The emissions of NaOH during production and use mainly apply to the aquatic environment. For sodium, other anthropogenic sources are for instance mining and the use of road salt (sodium chloride). Inwater (including pore water of sediment and soil), NaOH dissociates into the sodium ion (Na^+) and hydroxylion (OH^-), both having a wide naturaloccurrence.

1.5.1 Freshwater (surfacewaters)

Theconcentrationofhydroxylions(OH^-)intheenvironmenthasbeendeterminedveryextensivelyviapH measurements. Geochemical, hydrological and/or biological processes mainly determine the pH of anaquatic ecosystem.ThepHisanimportantparameterofaquaticecosystemsanditisastandardparameterofwater quality monitoring programs. The most important freshwater aquatic ecosystems of the world revealedaverage annual pH values between 6.5 and 8.3 but lower and higher values have been measured in otheraquatic ecosystems. In aquatic ecosystems with dissolved organic acids a pH of less than 4.0 has been measured,while inwaterswithahighchlorophyllcontentthebicarbonateassimilationcanresultinpHvaluesofhigherthan 9.0 at midday (OECD, 2002, from UNEP1995).

Also sodium (Na^+) has been measured extensively in freshwater aquatic ecosystems. For example, the 10thpercentile,meanand90th-percentileconcentrationsforatotalnumberof75riversinNorth-America,SouthAmerica,Asia,Africa, Europe and Oceania were 1.5, 28 and 68 mg/l, respectively (OECD, 2002, from UNEP,1995).

For European freshwaters, there are extensive databases on physico-chemical properties, includingpH, hardness(calculatedfromthemeasuredcalciumandmagnesiumconcentration),alkalinity(determinedby acid/base titration or calculated from the calcium concentration) and sodium concentration. In theframework of the EU Risk Asessment Report on Zn Metal (The Netherlands, 2004), data on physicochemicalproperties of freshwaters in individual European countries and the combined data for freshwaters in Europeancountries were collected and reported by De Schampelaere et al. (2003) and Heijerick et al. (2003). Thecombined Europeandatafortheabovephysicochemicalproperties,allrelevantforpHchanges,aresummarisedin Table17.Thedatainthistablearebasedon1991-1996datafor411Europeanlocations,extractedfromthe ‘GEMS/Waterdatabase’(GlobalEnvironmentalMonitoringSystem)thatismainlyaimedonthelargeriver systems. A correlation analysis on the data from all 411 locations indicate that all parameters listed in Table17 arepositivelycorrelated,i.e.anincreasedpHisassociatedwithincreasedconcentrationsofCa,MgandNa and increased hardness and alkalinity (De Schampelaere et al., 2003; Heijerick et al.,2003).

Thevariation intheabovephysico-chemicalpropertiesofthelargeriversystemsin differentEuropeancountriesisrathersmall,withexceptionofsomeareasintheNordiccountries(Denmark,Sweden,NorwayandFinland)whicharecharacterisedby‘softwater’conditions,i.e.ahardness<24mgCaCO3/landlowpH .Forexample,inSwedenthe50thpercentilevalueforhardnessis15mgCaCO3/l,whichis10-

timeslowerthanthatforwholeEurope.InSweden the50thpercentilevalueforpHisjustbelow7,whichisabout1 pHunitlowerthanthatforwholeEurope(De Schampelaere et al., 2003; Heijerick et al., 2003; The Netherlands,2004).

DataonpH(andforsomesitesdataonalkalinity)insurfacewaters,receivingeffluentofNaOHproducers,aregivenin Table17.Inall but3ofthereceivingwatersforwhichpHvaluesareavailable,thepHvaluesarewithintherangeof6.5-8.5.Thesewatersincludefreshwater(rivers)andseawater;eachofthesewatershaveamorenarrow range of pH values, usually within one pH unit (most waters: pH range of 7.0 to 8.0). Thus, in mostreceiving waters the pH values are in the range that is expected in most EU waters (see Table 17). In one riverthe pHrangedfrom6.5-9.0andintwowaterstherewasanevenwiderrangeofpHvalues,viz.4.2-9.2inalakeand 4.510.0 in another, unspecified water type. There is no data on sodium concentrations in the receiving waters at theNaOH production sites (a question on the sodium content was not included in thequestionnaire).

Table 17 Physico-chemical properties of European freshwaters (De Schampelaere et al., 2003;Heijerick et al., 2003) (From EU RAR, 2007)

Percentilevalue	pH	Hardness1(mg/l, as$CaCO_3$)	Alkalinity(mg/l, as$CaCO_3$)	Ca(mg/l)	Mg (mg/l	Na(mg/l)
5thpercentile	6.9	26	3	8	1.5	3
10thpercentile	7.0	41	6	13	2	5
20thpercentile	7.2	70	15	23	3	7
30thpercentile	7.5	97	31	32	4	10
40thpercentile	7.7	126	53	42	5	13
50thpercentile	7.8	153	82	51	6	17
60thpercentile	7.9	184	119	62	7	22
70thpercentile	7.9	216	165	73	8	29
80thpercentile	S.O	257	225	86	10	40
90thpercentile	8.1	308	306	103	12	63
95thpercentile	8.2	353	362	116	15	90

1) Hardness: total hardness, calculated from the Ca and Mgconcentration

Seawater

In over 97% of the seawater in the world, the salinity (the amount of dissolved inorganic constituents), is 35% (promille, in g/kg), but can be lower. (Commonly use classification of watertypes based on salinity: seawater: salinity > 20 o /oo, brackish water: salinity 5-20 o /oo, freshwater: salinity < 5 o /oo) The major constituents of seawater at 35 0/00 are Cl- (19.35 g/kg), Na+ (10.77 g/kg), SO4 2- (2.71 g/kg), Mg2+ (1.29 g/kg), Ca2+ (0.41 g/kg), K + (0.40 g/kg) and HCO3 - (0.142 g/kg, being the carbonate alkalinity expressed as though it were all HCO3 - , as this is the dominant species in seawater; the concentrations of CO2 and CO3 2- in seawater are very low compared to that of HCO3 -) (Stumm et al., 1981).

The pH of seawater (ocean water) is normally 8.0-8.3, which is very similar to the 80th to 95th percentile values in European freshwaters (8.0-8.2, Table). The total range of pH values reported for seawater is 7.5-9.5 (Caldeira et al., 1999) and data from several sources on the internet). The sodium

(Na) concentration in seawater (10,770 mg/kg, equivalent to 10,450 mg/l) is 115-times higher than the 95th percentile value in European freshwaters (90 mg/l). The bicarbonate (HCO_3^-) concentration in seawater (142 mg/kg, equivalent to 137 mg/l) is between the mean HCO_3^- concentration (106 mg/l) and the 90th percentile HCO_3^- concentration (195 mg/l) in European freshwaters, indicating a relatively high buffer capacity in seawater. The total hardness of seawater (6,100 mg/l, as $CaCO_3$, calculated from the Ca and Mg concentration) is 17-times higher than the 95th percentile value in EU freshwaters, due to the much higher Ca and especially Mg concentration in seawater compared to freshwater.

Abbreviations andacronyms

AC	articlecategory
CEPI	ConfederationofEuropeanPaperIndustries
CSA	chemicalsafetyassessment
DNEL	derivedno-effectlevel
EASE	Estimation and AssessmentofSubstanceExposure
ECETOC	EuropeanCentreforEcotoxicologyandToxicology of Chemicals
ES	ExposureScenario
ERC	environmentalreleasecategory
EU RAR	European Risk AssessmentReport
LEV	Localexhaustventilation
OC	Operationalconditions
OEL	OccupationalExposureLimit
PC	chemicalproductcategory
PPE	Personalprotectionequipment
PROC	processcategory
RMM	Risk managementmeasures
RPE	Respiratory protectiveequipment
SCOEL	ScientificCommitteeonOccupationalExposureLimit
STP	sewagetreatmentplant
SU	sectorofuse
TRA	TargetedRiskAssessment
TWAvalue	Time Weighted Averagevalue
WWTP	wastewatertreatmentplant

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