Human & Environmental Risk Assessment on ingredients of household cleaning products

2-(2-Butoxyethoxy)ethanol
CAS No: 112-34-5

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1. Abstract

2-(2-Butoxyethoxy)ethanol ($C_8H_{18}O_3$, CAS No: 112-34-5) is a high production volume (HPV) chemical, for which a European Union Risk Assessment is available (European Commission, 2000). This EU risk assessment includes an environmental risk assessment for the tonnage of 2-(2-Butoxyethoxy)ethanol (henceforth referred to as DEGBE) used for detergent applications in private use, and also human health risk assessments covering the use of household cleaning products containing DEGBE which are within the scope of HERA.

HERA is determined to avoid any duplication of effort and to discourage effort for the sake of marginal improvements. However, HERA believes that HERA Risk Assessments should be carried out where significant additional risk information can be obtained, and where a refinement of the existing assessments would yield new or significantly different conclusions in particular for the detergent use scenario.

This document solely refers to the information in the EU Risk Assessment which covers DEGBE use in the household cleaning products which are within the scope of HERA. It also contains additional, recent use information collected from the HERA formulator companies in 2002, which shows a substantial subsequent decrease in DEGBE use in household cleaning products (AISE 2002). Additional toxicological data have become available after the finalisation of the EU Risk Assessment (eg high quality 90d drinking water study) that will be published in the framework of the OECD ICCA activities shortly. This information has not been considered here, especially as the risk assessment and its conclusions were not affected.

In the EU risk assessment (European Commission, 2000), approximately 59% of DEGBE production is estimated to be used in cleaning agents, including floor and metal cleaners, of which approximately 17,250 tonnes are used in household cleaning products. The reference year for the data in the EU risk assessment is 1994. More recent HERA information (AISE 2002) indicates that DEGBE use in products within the scope of HERA has since decreased to less than 2900 tonnes per annum.

Human Health:
The EU risk assessment found that DEGBE is used in consumer products as a mutual solvent for soap, oil, and water in household cleaners. A specific scenario covering consumer use of a hard surface cleaner containing 9% DEGBE was used in the risk assessment for consumers. This risk assessment compared the yearly average inhalatory exposure to DEGBE in hard surface cleaners of 0.068 mg/m^3 with the inhalatory NOAEL of 94 mg/m^3 found in the 90-day rat study. It found the margin of safety of 1382 to be sufficient. Thus for DEGBE use in products which come within the scope of HERA the risk assessment reached **conclusion ii -there is at present no need for further information and/or testing or for risk reduction measures beyond those being applied.** The more recent HERA information (AISE 2002) indicates that the maximum DEGBE concentration in products within the scope of HERA has decreased to 6%, as compared with the 9% used in the specific consumer use scenario in the EU risk assessment (European Commission, 2000), for which **conclusion ii** was reached. This would increase the margin of safety to more than 2000.

Man indirectly exposed via the environment was also considered in the EU risk assessment for DEGBE. **Conclusion ii -** there is at present no need for further information and/or testing or for risk reduction measures beyond those being applied **–** was found for repeated exposure to DEGBE via the air. The margin of safety for DEGBE in detergent cleaning products in private use was 1.26 X 10^6. **Conclusion ii** was also reached for the total intake via air, drinking water, and food, where the margin of safety for DEGBE used privately in detergent cleaning products was 3.47 x 10^5. **Conclusion ii** was also reached for reproduction toxicity. Thus for DEGBE use in products which come within the scope of HERA the EU risk assessment found that **there is at present no need for further information and/or testing or for risk reduction measures beyond those being applied - with regard to man indirectly exposed via the environment.** More recent data (AISE 2002) shows that the amount of DEGBE used in products covered by HERA has decreased significantly, thus increasing the margins of safety given in the EU risk assessment (European Commission, 2000).

In the view of the extensive database on toxic effects and the exposure levels in the intended use patterns of the HERA applications, it can be concluded that the use of DEGBE in household cleaning products raises no safety concern for consumers.

Environment:

With respect to the environment, the EU risk assessment for DEGBE (European Commission, 2000) concludes that there is no need for further information and/or testing: **conclusion (ii)**, for DEGBE in products within the scope of HERA (i.e. private use of detergent products). The conclusion applies to the aquatic and terrestrial compartments, and to sewage treatment plants. Thus **DEGBE use in products which are covered by HERA are not a subject of concern in the EU, with regard to the environment**. There has been a significant reduction in DEGBE tonnage used in surface cleaning products (AISE, 2002) since the EU risk assessment was written.

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2. Introduction

2-(2-Butoxyethoxy) ethanol (DEGBE) is a high production volume (HPV) chemical, for which a European Union Risk Assessment is available (European Commission, 2000, Official Journal of the European Union, 1999). This HERA 'short version' report summarises the human and environmental risk assessment of the use of DEGBE in household cleaning applications, supplementing the EU risk assessment with current usage information (AISE 2002).

3. Substance information

Substance Identification
This summary covers 2-(2-Butoxyethoxy) ethanol (DEGBE), $C_8H_{18}O_3$, CAS No: 112-34-5, which has a structural formula CH_3-$(CH_2)_3$-O-CH_2-CH_2-O-CH_2-CH_2-OH and a molecular weight of 162.23 g/mol (European Commission, 2000). Note that the structural formula given in this reference is incorrect.

Physico-chemical Properties
The physico-chemical properties of DEGBE are given in Table 1 (European Commission, 2000).

Table 1. Physical and chemical properties of pure DEGBE (100%)

Property	**Value**
Melting point	-68°C
Boiling point	228-234°C at 1013 hPa
Density	0.948-0.96 g/cm3 (20°C)
Vapour pressure	0.027 hPa (20°C)
Water solubility	miscible
Log Kow	0.56
Flammability	None
Explosive properties	None
Oxidising properties	None

Production and Use

DEGBE belongs to the group of glycol ethers, which are mainly used as solvents. In 1994, approximately 46 600 tonnes of DEGBE were produced, at eight sites in the EU. Imports and exports of DEGBE to/from the EU are thought to be negligible. (European Commission, 2000).

The European Union Risk Assessment (European Commission, 2000) estimated that aapproximately 59% of DEGBE is used in cleaning agents, including floor and metal cleaners. The use is divided between IC 5 (personal/domestic use), IC6 (public domain), and IC 8 (Metal industry), with approximately 22% of production being attributed to industrial use, and 37% attributed to use by the public. Only this 37% of DEGBE production, or approximately 17240 tonnes per annum, is within the scope of HERA. More recent information (AISE, 2002) has found that the only use of DEGBE

in products within the scope of HERA is now in hard surface cleaning products, and that DEGBE use in hard surface cleaning products by the HERA formulating companies has decreased to approximately 2260 tonnes per annum. As these formulators represent approximately 80% of the formulating capacity for products within the scope of HERA, it is estimated that overall use of DEGBE in products within the scope of HERA is less than 2900 tonnes per annum.

The recent AISE data (AISE, 2002) shows that the maximum DEGBE concentration in hard surface cleaning products is 6% (by weight). The typical concentration of DEGBE in surface cleaning products now ranges from 0.01 to 4.8 percent, by weight.

4. Environmental Risk Assessment

Environmental fate

The EU risk assessment for DEGBE (European Commission, 2000) found that emission to water is expected to be the most important entry route to the environment. The general characteristics of DEGBE that are relevant for the exposure assessment are:

Degradation
- No Hydrolysis.
- No direct photodegradation, and an atmospheric half-life through reaction with OH-radicals of about 11 hours.
- Biodegradation: Readily biodegradable.

Distribution
- A relatively low Henry's Law constant of 4.4×10^{-3} Pa·m^3/mol at 20°C was measured. This indicates that volatilisation of DEGBE from surface waters and moist soil is expected to be very low.
- A relatively low log K_{ow} of 0.56. From this logKow a value of K_p for soil of 0.07 is calculated using the methods in the TGD (European Commission, 1996), indicating that DEGBE is expected to be highly mobile in soil.

Accumulation
There are no experimental results on bioaccumulation available. The estimated BCF values (European Commission, 1996) amount to 1.4 l/kg and 2.2 l/kg for fish and worm, respectively, indicating a low bioaccumulating potential in the environment.

The EU risk assessment for DEGBE (European Commission, 2000) used the information above to determine that, for DEGBE in household cleaning products, the local Predicted Environmental Concentration (PEC) values in various environmental compartments are as shown in Table 2.

Table 2. Local PEC values for DEGBE in household cleaning products (European Commission, 2000)

Usage	Local PEC in surface Water (mg/l)	PEC in local STP (PEC for Microorganisms) (mg/l)	Local PEC in soil (mg/kg)	Local PEC in air (mg/m3)
Detergents III Private use	0.07	0.6	0.006	1.3×10^{-5}

More recent data (AISE 2002) shows that the DEGBE tonnage used in products within the scope of HERA has decreased substantially, from the 17240 tpa used in the EU risk assessment to less than 2900 tpa. If this recent data had been used to calculate Table 2, the PEC values in all columns would have been lower by a factor of 6.

The EU risk assessment for DEGBE (European Commission, 2000) found that Local PEC values from all uses of DEGBE ranged from 0.009 to 2.8 mg/l in the sewage treatment plant, and from 0.01 to 0.3mg/l in surface water. Local soil concentrations between 2 and 20 µg/kg were calculated, while calculated air concentrations ranged from 40 $\mu g/m^3$ to less than 0.02 $\mu g/m^3$. Estimated regional PEC values were all much lower than the concentrations near the point sources.

Environmental effects assessment

The EU risk assessment for DEGBE (European Commission, 2000) found that, in the aquatic environment, there are short-term toxicity data for fish, daphnia, algae, and micro-organisms. The PNEC for the aquatic compartment was extrapolated from a NOEC of 53 mg/l for M*icrocystis aeruginosa*, using an application factor of 50. This application factor was chosen because chronic data were available for several species of both algae and micro-organisms, and these two trophic levels seemed to cover the most sensitive taxonomic groups. The extrapolation leads to a **$PNEC_{aquatic}$ of 1 mg/l**.

The EU risk assessment for DEGBE (European Commission, 2000) extrapolated the PNEC for microorganisms from the NOEC for *P. putida* (713 mg/l) using an assessment factor of 10. This results in a **$PNEC_{microorganisms}$ of 71 mg/l.**

The EU risk assessment for DEGBE (European Commission, 2000) derived the PNEC for the terrestrial compartment using the equilibrium partitioning approach, as no experimental data were available. This resulted in **a $PNEC_{terrestrial}$ of 0.2 mg/kg.**

The **$PNEC_{predators}$** of **50 kg/kg** was estimated from the oral NOAEL of 500 mg/kg b.w.d., in the EU risk assessment (European Commission, 2000).

Environmental Risk Characterization

A quantitative risk assessment was performed for aquatic organisms and microorganisms. The EU risk assessment for DEGBE (European Commission, 2000) gave the PEC/PNEC ratios shown in Table 3 for DEGBE in the uses covered by HERA. The assessment concludes that there is no need for further information

Table 3. PEC/PNEC ratios for DEGBE in household cleaning products (European Commission, 2000)

Scenario	Aquatic organisms	Micro-organisms	Terrestrial organisms
Detergents III Private use	0.06	0.08	0.03

and/or testing: **conclusion (ii)** for any of the generic scenarios. The conclusion that no further information or testing was required also applies to the terrestrial compartment. Thus **DEGBE use in household cleaning products is not a subject of concern in the EU, with regard to the environment.**

If the recent tonnage data (AISE 2002) had been used to calculate the PEC/PNEC ratios shown in table 3, the six-fold reduction in PEC due to decreased usage would have given a six-fold reduction in the PEC/PNEC values shown in Table 3. Thus the updated use information strengthens the EU conclusion that DEGBE use in household cleaning products is not a subject of concern with regard to the environment.

5. Human Health

Consumer exposure

The EU risk assessment for DEGBE (European Commission, 2000) found that DEGBE is used in consumer products as a mutual solvent for soap, oil, and water in household cleaners. DEGBE is said to occur in consumer products at typical concentrations of about 5%, and in cleaning agents and detergents at concentrations of about 10% (European Commission, 2000). The EU risk assessment for DEGBE (European Commission, 2000) evaluated the use of a liquid hard surface cleaner containing DEGBE as one of the two consumer use scenarios given in the report.

In the liquid hard surface cleaners use scenario, DEGBE was incorporated into liquid hard surface cleaning products at concentrations of up to 9% to enhance their cleaning effectiveness. Consumers using these products could be exposed by direct dermal contact with the cleaning solution, by inhaling DEGBE during the cleaning task, or by breathing room air after cleaning. Experimental measurements designed to maximise DEGBE concentrations in bathroom air showed peak values between 1 and 3 hours after the task initiation, which gradually decreased with time. The peak concentration did not exceed about 10.8 mg/m^3 in all experiments. The total DEGBE concentration in the air at the time of maximum air concentration accounted for only 1 to 3% of the DEGBE on the washed surfaces. The person doing the cleaning was exposed to average DEGBE concentrations in the breathing zone below about 5.4 mg/m^3 in all experiments. The EU risk assessment for DEGBE (European Commission, 2000) concludes that if DEGBE in hard surface cleaners were used for 1 hour every 3 days, the yearly average exposure would be 0.068 mg/m^3.

The recent AISE data (AISE, 2002) shows that the maximum DEGBE concentration in hard surface cleaning products is 6% (by weight). The typical concentration of DEGBE in surface cleaning products now ranges from 0.01 to 4.8 percent, by weight. If this data had been available for use in the EU Risk assessment (European Commission, 2000), use of the maximum DEGBE concentration found in recent surface cleaning products would have decreased the yearly average exposure to 2/3 of the value found in the EU risk assessment (European Commission, 2000), or approximately 0.046 mg/m^3.

Indirect exposure via the environment

The EU risk assessment for DEGBE (European Commission, 2000) also calculated that use in detergent products would produce a total annual average local concentration in air of 1.3 x 10^{-5} mg/m^3. The total human daily intake of DEGBE via air, drinking water, and food resulting from DEGBE use in detergent products was calculated to be 2.6 X 10^{-3} mg/kg/day. If the recent AISE data (AISE, 2002) showing the reduction in DEGBE usage by a factor of six in detergent products used privately had been available, the EU risk assessment for DEGBE would have shown a six fold reduction in both the annual average concentration in air and in the total human daily intake of DEGBE via air, water, and food.

Toxicity to consumers

Toxicokinetics, metabolism and distribution
The EU risk assessment for DEGBE (European Commission, 2000) found that no human data on the toxicity of DEGBE were available. It was concluded from dermal adsorption studies that complete dermal absorption could not be excluded, and therefore 100% dermal adsorption was used in the risk assessment. For oral and respiratory absorption, the TGD (European Commission 1996) default of 75% was used.

Acute toxicity
The EU risk assessment for DEGBE (European Commission, 2000) concluded that DEGBE has a low acute toxicity by oral and dermal routes. The lowest LD50 values were an oral LD50 of 2406 mg/kg bodyweight for fasted mouse, and a dermal LD50 of 2764 mg/kg bodyweight for rabbit. The data available did not allow a definite conclusion regarding acute toxicity via inhalation.

Irritation and corrosivity
The EU risk assessment for DEGBE (European Commission, 2000) found, based on an eye irritation study in rabbits, that DEGBE is irritating to the eyes. However, DEGBE is not irritating to skin, although repeated dermal exposure to DEGBE caused local skin effects in rabbits and rats. The EU risk assessment for DEGBE (European Commission, 2000) found that DEGBE is not a sensitizing agent, and is not corrosive to skin, eyes, or the respiratory tract.

Repeated dose toxicity
The key **inhalation** study showed that no effects were seen in the 90-day study, in which the rats were exposed for 6 hours per day to DEGBE vapour concentrations up to **94 mg/m^3.** This 90-day study was taken as the starting point for the risk

characterization, although it was recommended that the margins of safety and assessment factors should also consider liver effects seen in another study at 117 mg/m^3, and the NOAEL of 39 mg/m^3 found in a subacute inhalation study.

Two semi-chronic oral studies were carried out in which DEGBE was administered to rats via gavage, which showed that DEGBE caused effects in liver, spleen, kidneys, and on haematological parameters. However, both oral studies had limitations in that only males were considered in one of the studies (a 6 week study), and necessary fore-stomach analysis was not carried out in the other study (of 13 weeks duration), which also had abnormally high, unexplained mortality. From the results of the 6 week, male only study the **oral NOAEL** was established at **<891 mg/kg body weight per day**, but for risk assessment it should be weighed that effects were observed in female rats in the 13 week study at dose levels of 51 and 254 mg/kg body weight per day, and that only males were tested in the 6-week study used to establish the oral NOAEL.

In **dermal studies**, **dose levels up to 2000 mg/kg body weight per day** caused no systemic effects in rats. This level can be used for risk characterization. An overall NOAEL for local effects was not set for use in risk characterization, due to the differences in exposure circumstances and the onset of symptoms seen in the different studies reported. Instead, the EU risk assessment for DEGBE (European Commission, 2000) recommends that the results of the study with the best fit to the exposure circumstances be used in local risk characterisation.

Mutagenicity and Carcenogenicity

The EU risk assessment for DEGBE (European Commission, 2000) found that DEGBE is **not mutagenic**. **No cause for concern** was found regarding **carcinogenicity**.

Toxicity to reproduction

In a one-generation gavage reproduction study with rats the NOAEL for fertility was 1000 mg/kg bw/d (highest dose level tested). The **oral NOAEL for developmental effects was established at 500 mg/kg bw/d**, again based on results from rat tests. DEGBE caused no teratogenic effects after oral administration.

No parental, reproduction, or offspring effects were observed in a **dermal** one-generation rat study at doses up to **2000 mg/kg bw/d**. Neither systemic maternal toxicity nor developmental or teratogenic effects were observed in rabbits dermally exposed to dose levels up to **1000 mg/kg bw/d**, which was taken to be the **NOAEL** for both **systemic maternal toxicity** and for **developmental effects**.

Risk Characterisation

Consumers

The EU risk assessment for DEGBE (European Commission, 2000) compared the yearly average inhalatory exposure to DEGBE in hard surface cleaners of 0.068 mg/m^3 with the inhalatory NOAEL of 94 mg/m^3 in the 90 day rat study. It found the margin of safety of 1382 to be sufficient. Thus for DEGBE use in products which come within the scope of HERA the risk assessment reached **conclusion ii -there is at present no need for further information and/or testing or for risk reduction measures beyond those being applied.** If the recent AISE data (AISE, 2002)

showing the reduction in DEGBE concentration in the product to a maximum of 6% had been available, the margin of safety would have increased by 50%, giving a margin of safety greater than 2000.

Man indirectly exposed via the environment

The EU risk assessment for DEGBE (European Commission, 2000) came to **conclusion ii -**there is at present no need for further information and/or testing or for risk reduction measures beyond those being applied – for repeated exposure to DEGBE via the air. The margin of safety for DEGBE in detergent cleaning products in private use was 1.26 X 10^6. **Conclusion ii** was also reached for the total intake via air, drinking water, and food, where the margin of safety for DEGBE used privately in detergent cleaning products was 3.47 x 10^5. **Conclusion ii** was also reached for reproduction toxicity. Thus for DEGBE use in products which come within the scope of HERA the EU risk assessment for DEGBE (European Commission, 2000) found that **there is at present no need for further information and/or testing or for risk reduction measures beyond those being applied - with regard to man indirectly exposed via the environment.** If the recent AISE data (AISE, 2002) showing the reduction in DEGBE usage by a factor of six in detergent products used privately had been available, the EU risk assessment for DEGBE would have increased these margins of safety by a further factor of six.

Conclusion:

In the view of the extensive database on toxic effects and the exposure levels in the intended use patterns of the HERA applications, it can be concluded that the use of DEGBE in household cleaning products raises no safety concern for consumers.

6. References

AISE (2002). Unpublished data gathered among the HERA formulator companies and aggregated by the Cefic Statistical Services department.

European Commission (2000). **EUR 18998 EN European Union Risk Assessment Report: 2-(2-Butoxyethoxy) ethanol, Volume 2.** *Editors: B. G. Hansen, S.J. Munn, G. Schoening, M. Luotamo, A. van Haelst, C. J. A. Heidorn, G. Pellegrini, R. Allanou, H. Loonen.* Luxembourg: Office for Official Publications of the European Communities. 104 pp. ISBN 92-828-8396-1.

European Commission, Joint Research Centre, Institute for Health and Consumer Protection, European Chemicals Bureau (1996). **Technical Guidance Document** *in support of* Commission Directive 93/67/EEC on Risk Assessment for new notified substances and Commission Regulation (EC) No 1488/94 on Risk Assessment for existing substances **Part II.** Office for Official Publications of the European Communities, Luxembourg, ISBN 92-827-8012-0.

Official Journal of the European Union L 292/42 of 13 November 1999. Commission Recommendation of 12 October 1999 on the results of the risk evaluation and on the

risk reduction strategies for the substances: 2-(2-Butoxyethoxy) ethanol ; 2-(2-methoxyethoxy) ethanol ; Alkanes, C_{10-13}, chloro; Benzene, C_{10-13}-alkyl derivatives.

7. Contributors to the report

This dossier has been prepared by the HERA Secretariat. Additional input was provided by experts of the HERA (Environment and Human Health) Task Forces and the Oxygenated Solvent Producers Association (OSPA). Volume and exposure information for the use of household detergents and cleaners was gathered among the HERA Formulator Companies.