

OSPA response to marketing and use restrictions proposed by the Netherlands for DEGBE (2-(2-butoxyethoxy)ethanol – CAS# 112-34-5

The Oxygenated Solvents Producers Association (OSPA) is surprised and concerned at the proposal made by the Netherlands for stringent restrictions to be introduced on the use of DEGBE in paints. The new proposals go well beyond those previously discussed and tentatively agreed as acceptable by the Commission Working Group on Restrictions on the Marketing and Use of Dangerous Substances and Preparations. These current proposals also go well beyond the Commission recommendations (1999-721-EC) derived from the EU Risk Assessment. At this stage, as representatives of the producers, we would like to make the specific points outlined below in response to the Dutch proposal and the supporting justification.

Hazard assessment

Toxicity by systemic delivery or vapour inhalation: There is no evidence to suggest that the local lung effects are caused by vapour inhalation; the risk assessment does not suggest this either. Neither is there any evidence to suggest that the effects can be caused systemically; indeed, a recent drinking water study with DEGBE (Johnston 2005) established a NOAEL of 250mg/kg (substantially higher than the 40mg/kg dose that results from rats inhaling 350mg/m³ aerosol for 8 hrs¹). It is more appropriate to use this study, which has not been taken into account in the NL proposal, to derive a systemic NOAEL than the inhalation study where exposure to vapour is limited by the low saturated vapour concentration. We believe the working group should therefore only focus on the hazard identified in the risk assessment as relevant for consumers, namely aerosol inhalation and the hypothetical link to local lung effects. The proposal for restrictions on paints where the only exposure can be via inhalation of vapour (brush and roller paints) has therefore no substance and does not take into account recently published hazard data.

Toxicity by inhalation of aerosol: OSPA still maintains reservations about the validity of extrapolating the observations from a 14-day repeat dose study to predict the effects from a single short term exposure, which in the case of a consumer using a spray based paint would be 1-2 hours in a reasonable worst case scenario. There is no evidence of lung toxicity from the 90-day inhalation study and there is no toxicological basis for the hypothesis proposed to explain that absence of effect is through the development of tolerance.

¹ Assumed respiration rate of rat 1 l/5l/8hr.

Two points of note are:

- the particle size of the aerosol used in the 14-day study was more than 92% less than 8.5µm i.e. virtually all respirable. At a concentration of 350mg/m³ this would have resulted in a local tissue dose of ~40,000mg/kg lung tissue over 8hrs in the study².
- inhaling an aerosol effectively introduces xenobiotic liquid directly into the lower respiratory tract and would be expected to produce a non-substance specific pneumonitis; this would be likely to result from inhaling any paint spray in such concentrations. Indeed, ECETOC in their recently updated review of the toxicology of glycol ethers concluded that 'these effects were sequels of un-specific irritation by aerosols' (ECETOC, 2005). Therefore introducing draconian controls on one specific component is disproportionate to the risks posed by other chemicals and solvents and will not reduce the risk from inhaling paint aerosols.

Exposure assessment

Exposure to vapour from paint evaporation: There is no useful measured data available for exposure to DEGBE vapour. This can be explained by the fact that this substance is regarded to be of low hazard and volatility and therefore not a priority substance for assessment. Exposure can be assessed by using validated models. The CONSEXPO 4 vapour exposure model can be used to assess a worse case scenario (very small room, all walls painted in 1 hour – see appendix 1). This model predicts the peak exposure during painting to be 102mg/m³ (4.25mg/m³ daily TWA.) An alternative approach is to use the more specific US EPA Wallpaint exposure model. When the model used with appropriate parameters to simulate the same scenario, a peak exposure of 60mg/m³ is predicted (with an 8hr TWA of 15mg/m³ -see appendix 2).

Exposure to vapour from paint during spray application: The proposal states that quantitative exposure estimates for DEGBE from paint sprays are impossible to derive because neither the evaporation from the spray cloud nor the concentration of particles in the spray area can be estimated. This is not the case! The evaporation for a very low volatility solvent such as DEGBE (vapour pressure = 2.7Pa) can be assumed as zero during the time of flight from the spray gun to the work surface. It is also a worst case assumption when considering aerosol particle inhalation. This can be confirmed using the spray models developed by the solvent manufacturers as part of their solvent evaporation models which predict negligible evaporation of DEGBE in the spray cone between the spray nozzle and the work surface. It can be concluded with reasonable certainty that the contribution to exposure from evaporation of DEGBE from the particles during their time of flight from the spray gun to the work surface is negligible.

Exposure to aerosol: Particle size distributions for spray systems are available. Using the Consexpo 4 spray exposure model with particle size data for a pneumatic assisted spray system (see appendix 3) predicts a short term exposure of

² Measured typical lung weight in study 0.9g.

13mg/m³, a factor of 7-8 lower than the very conservative assumption of the original risk assessment (see appendix 4 for the parameters used). It should be noted that the particle size profile indicates that a substantial majority of the particles in such an aerosol are too large to be respirable. According to information provided by the British Aerosol Manufacturers' Association, aerosol packaged surface spray products are designed to have larger particles sizes to adhere more efficiently on contact. Typical median sizes are >50µm and the percentage of particles below 10µm less than 1%. Consumer aerosol products such as these are therefore not a concern as an insignificant amount of the spray they produce is respirable.

Risk characterisation

Vapour inhalation and systemic effects: There is not an issue with regard to systemic exposure. Based on the 6mg/m³ figure quoted in the Dutch authority's proposal, a 2-hour consumer exposure would result in a systemic dose of 0.036mg/kg³. The NOAEL is ~7000 times this value and the exposure is very occasional, not a daily dose. Using the data from the CONSEXPO model would result in exposure during the application period, assuming that the peak exposure is maintained over the whole application period, of 0.63mg/kg⁴, with an MOS of ~400 compared to the NOAEL. We conclude that there is no concern and never has been from exposure to DEGBE vapour.

Aerosol inhalation: OSPA supports the use of assessment factors but believes that the proposed approach is excessively conservative for the effect in question. The focus should only be on local respiratory irritation (recent studies indicate that there is no systemic component to the effect). The recent risk assessment for 2-butoxyethanol, a very closely related substance, used a single assessment factor of 3 when assessing the risk for respiratory irritation. We believe that this is sufficient for an irritancy end point. The actual MOS is 100/13.5 = 7.4 based on a paint containing 5% DEGBE.

³ Assumed respiration rate of human 12l/min, 2 hours exposure time, 70kg body weight. 60% respiratory uptake

⁴ Assumed respiration rate of human 12l/min, 1 hours exposure time, 70kg body weight. 60% respiratory uptake

Conclusions

OSPA believes there is sufficient information available to make an informed decision on this issue. Based on current data and models, we see no reason to introduce restrictions on the use of DEGBE, (currently only classified as an eye irritant), that are as stringent as those applied to known human carcinogens. A limit of 0.1% for use in spray paint is out of proportion to the highly questionable risks identified. The proposed limit of 5% in other paints is not supported by the risk assessment nor any data published since. Whilst we cannot agree with the underlying justification, OSPA would be prepared to accept a limit of 5% DEGBE only in paints intended to be sprayable applied in order to facilitate closure of this issue.

Yours sincerely

Dorothee Arns
Secretary General

References

ECETOC (2005) The toxicology of glycol ethers and its relevance to man (4th edition), TR95, February 2005, ECETOC, Brussels

Johnson KA et al (2005) Diethylene glycol monobutyl ether: 2 and 13 week drinking water studies in Fischer 344 rats. Food Chem Toxicol. Mar;43(3):467-81



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Appendix 1 - Parameters used in Consexpo 4 model for modelling vapour exposure:

Compound

Compound name :	DEGBE	
CAS number :	112-34-5	
molecular weight	162	g/mol
vapour pressure	2.5	Pascal
KOW	0.15	10Log

General Exposure Data

exposure frequency	4	1/year
body weight	60	kilogram

Inhalation model: Exposure to vapour : evaporation

weight fraction compound	0.05	fraction
exposure duration	60	minute
room volume	15	m3
ventilation rate	2	1/hr
applied amount	2.5	kilogram
release area	25	m2
application duration	60	minute
mol weight matrix	5E3	g/mol
mass transfer rate	2.93E3	m/min

Uptake model: Fraction

uptake fraction	0.6	fraction
inhalation rate	32.9	m3/day

Output

Inhalation (point estimates)

inhalation mean event concentration :	102	mg/m3
inhalation mean concentration on day of exposure:	4.25	mg/m3
inhalation air concentration year average :	0.0465	mg/m3/day
inhalation acute (internal) dose :	1.4	mg/kg
inhalation chronic (internal) dose :	0.0153	mg/kg/day

Integrated (point estimates)

total external dose:	2.33	mg/kg
total acute dose (internal):	1.4	mg/kg
total chronic dose (internal):	0.0153	mg/kg/day

Appendix 2 - Parameters used in US EPA Wallpaint exposure model to predict vapour exposure:

WPEM MODEL INPUTS

16/03/2007

File with Concentration Details: C:\Program Files\wpepm\DEGEBE1.CSV

Title of Run:

Notes:

Length of Model Run: 8 Days

Reporting Interval: 60 minutes

Type of Building: Other

Air Exchange Rate: 1.00 air changes per hour

Volume: 680 ft³

Interzonal Airflow Rate: 117.12 ft³/hour

Percent Painted: 100.0 %

Loading Ratio: 0.25 ft²/ft³

Painted Surface Area: 192.43 ft²

Coverage(ft ² /gal):	Primer: 200	Paint: 400
Gallons of Paint:	Primer: 0.00	Paint: 0.93
Painting Hours:	Primer: 0.00	Paint: 1.00
Work Hours:	Primer: 8.0	Paint: 8.0
Painting Days:	Primer: 8	Paint: 1
Start Day:	Monday	
Type of Paint:	Latex Semi-Gloss	
Density (grams/cc):	Primer: 4800.00	Paint: 4500.00
Chemical Name:	butoxyethoxyethanol	
Molecular Weight:	162.2 g/mole	Vapor Pressure: 0.02 torr
Weight Fraction:	Primer: 0.00001	Paint: 0.00000
Emissions Model:	Primer: Empirical	Paint: Empirical
Chemical Mass (grams):	Primer: 0.00	Paint: 12.75
%Mass 1st Exponential:	Primer: 10.00	Paint: 10.00
Rate Constant 1st Exp:	Primer: 4.66500	Paint: 4.66500
Rate Constant 2nd Exp:	Primer: 0.00847	Paint: 0.00847

Indoor Sink Model: No Sink

WPEM MODEL INPUTS (continued)

16/03/2007

Exposed Individual: Adult

Gender: Non-Specific

Location During Painting: In painted area

Weekday Pattern				
	Zone	Enter Hr	Enter Min	Breathing Rate (m ³ /day)
Line 1	0	0	0	15.0
Line 2	1	8	0	15.0
Line 3	0	16	0	15.0

Weekend Pattern				
	Zone	Enter Hr	Enter Min	Breathing Rate (m ³ /day)
Line 1	0	0	0	15.0

Breathing Rate During Painting: 15.0 m³/day

Lifetime Exposure Events: 10

Years in Lifetime: 75

Avg. Body Weight: 71.8 kg

WPEM MODEL RESULTS

LADD: 8.80E-004 mg/kg-days	LADC: 3.91E-003 mg/m ³	-or-	6.89E-004 ppm
ADD: 1.47E-003 mg/kg-days	ADC: 6.88E-003 mg/m ³	-or-	8.88E-004 ppm
APDR: 1.35E+000 mg/kg-days	Cpeak: 6.08E+001 mg/m ³	-or-	7.33E+000 ppm
APDR Time: 1.98E+000 days	C15-min: 5.01E+001 mg/m ³	-or-	7.58E+000 ppm
Single Event Dose: 1.99E+002 mg	C8-hour: 1.64E+001 mg/m ³	-or-	2.33E+000 ppm

LADD = Lifetime average daily dose

ADD = Average daily dose

APDR = Acute Potential Dose Rate (highest 24-hour dose rate for exposed individual)

LADC = Lifetime average daily concentration

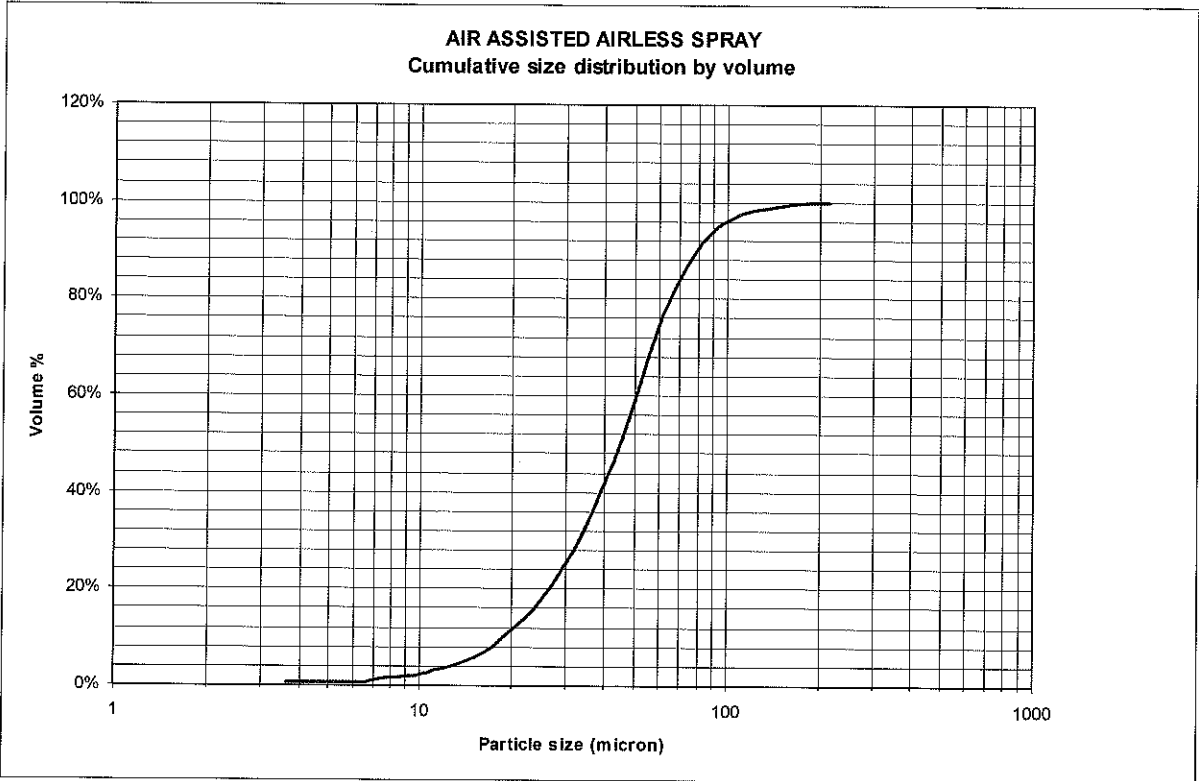
ADC = Average daily concentration

Cpeak = highest instantaneous concentration to which individual is exposed

C15-min = highest 15-minute average concentration to which an individual is exposed

C8-hour = highest 8-hour average concentration to which individual is exposed

Appendix 3 – Particle size distribution for pneumatic assisted spray system



Appendix 4 - Parameters used in Consexpo 4 model for modelling aerosol exposure:

Compound

Compound name :	DEGBE	
CAS number :	112-34-5	
molecular weight	162	g/mol
vapour pressure	2.5	Pascal
KOW	0.15	10Log

General Exposure Data

exposure frequency	4	1/year
body weight	60	kilogram

Inhalation model: Exposure to spray

weight fraction compound	5	%
exposure duration	60	minute
room volume	15	m ³
ventilation rate	2	1/hr
mass generation rate	40	g/min
spray duration	60	minute
airborn fraction	35	%
weight fraction non-volatile	35	%
density non-volatile	1.8	g/cm ³
room height	2.5	meter
inhalation cut-off diameter	15	micrometer
non-respirable uptake fraction	1	fraction
Spraying away from exposed person		

Initial particle distribution:

Distribution function: Normal		
median:	45	micrometer
s.d.:	18	micrometer

Uptake model: Fraction

uptake fraction	0.6	fraction
inhalation rate	32.9	m ³ /day

Output

Inhalation (point estimates)

inhalation mean event concentration :	13.5	mg/m ³
inhalation mean concentration on day of exposure:	0.563	mg/m ³
inhalation air concentration year average :	0.00616	mg/m ³ /day
inhalation acute (internal) dose :	0.185	mg/kg
inhalation chronic (internal) dose :	0.00203	mg/kg/day

Oral non-respirable: point estimates

oral external dose :	0.537	mg/kg
oral acute (internal) dose :	0.537	mg/kg
oral chronic (internal) dose :	0.00588	mg/kg/day

Integrated (point estimates)

total external dose:	0.846	mg/kg
total acute dose (internal):	0.722	mg/kg
total chronic dose (internal):	0.00791	mg/kg/day