# 2,2-BIS(CHLOROMETHYL) TRIMETHYLENE BIS[BIS(2-CHLOROETHYL) PHOSPHATE] (V6)

CAS No: 38051-10-4

EINECS No: 253-760-2

# SUMMARY RISK ASSESSMENT REPORT

*Final report of May 2008*

Ireland (lead) and United Kingdom

***FINAL APPROVED VERSION***

Rapporteur for the risk assessment of V6 is Ireland (lead) and the United Kingdom. The environmental exposure and property review was undertaken under contract to the rapporteur by Peter Fisk Associates. The human health exposure review was undertaken under contract to the rapporteur by Workplace Environment Solutions Ltd.

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| | |
|---|---|
| **Date of Last Literature Search :** | **28/06/2006(Environment)**<br>**28/05/2007(Human Health)** |
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# PREFACE

The report provides the environmental risk assessment of the substance 2,2-bis(chloromethyl) trimethylene bis[bis(2-chloroethyl) phosphate] (V6) in the frame of Council Regulation (EEC) No. 793/93 on the evaluation and control of the risks of existing substances. For detailed information on the risk assessment principles and procedures followed, the underlying data and the literature references, the reader is referred to the original risk assessment report that can be obtained from the European Chemicals Bureau[1]. The present summary report should preferably not be used for citation purposes.

[1] European Chemicals Bureau – Existing Chemicals – http://ecb.jrc.it

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EUSES calculations can be viewed as part of the report at the website of the European Chemicals Bureau: http://ecb.jrc.it

# TABLES

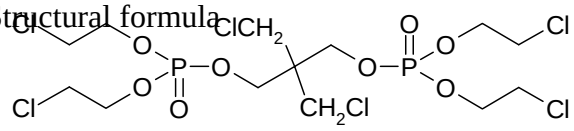
# 1 GENERAL SUBSTANCE INFORMATION

V6 is one of three chloroalkyl phosphate substances[2] that have undergone risk assessment in parallel due to their similar use pattern

## 1.1 IDENTIFICATION OF THE SUBSTANCE

| | |
|---|---|
| CAS Number: | 38051-10-4 |
| EINECS Number: | 253-760-2 |
| IUPAC Name: | 2,2-Bis(chloromethyl) trimethylene bis[bis(2-chloroethyl) phosphate] |
| Synonyms | 2,2-Bis(chloromethyl)-1,3propanediyl bis[bis(2chloroethyl)phosphate<br>Tetrakis(2-chloroethyl) dichloroisopentyldiphosphate<br>Phosphoric acid, 2,2-bis(chloromethyl)-1,3-propanediol tetrakis (2-chloroethyl) ester<br>Phosphoric acid, 2,2-bis(chloromethyl)-1,3-propanediyl tetrakis (2-chloroethyl) ester<br>1,3-Propanediol, bis(2 chloromethyl) and bis(2 chloroethyl), phosphate (1:2)<br>Amgard V6 (trade name)<br>V6: this trade name is used throughout this report |

Structural formula




## 1.2 PURITY/IMPURITIES, ADDITIVES

2,2-Bis(chloromethyl) trimethylene bis[bis(2-chloroethyl) phosphate] (hereafter referred to as V6) is commercially available at a purity of >90% (w/w). The full impurity profile is confidential, but it may contain 4.5-7.5% tris(chloroethyl) phosphate (TCEP[3]).

## 1.3 PHYSICO-CHEMICAL PROPERTIES

General substance information and physicochemical properties are shown in Table 1.1.

[2] The others being TDCP (CAS no. 13674-87-8) and TCPP (CAS no. 13674-84-5).

[3] TCEP (CAS no. 115-96-8) has also been assessed in the ESR programme.

**Table 1.1** Identification and physico-chemical properties of V6

| Property | Value |
|---|---|
| CAS number | 38051-10-4 |
| Molecular formula | $C_{13}H_{24}Cl_6O_8P_2$ |
| SMILES notation | O=P(OCCCl)(OCCCl)OCC(CCl)(CCl)COP(=O)(OCCCl)OCCCl |
| Molecular weight | 583.00 |
| Physical state | Liquid |
| Freezing point | <-50.5 (measured, commercial product) |
| Boiling point | 252°C (decomposes) (measured, commercial product) |
| Relative density | 1.473 at 20°C (measured, commercial product) |
| Vapour pressure | 2.75 x $10^{-06}$ Pa at 25°C (estimated by SRC EPIWIN) |
| Surface tension | 53.9 mN/m at 20°C (measured, commercial product) |
| Water solubility | 232 mg/l at 20°C (measured, commercial product) |
| Partition coefficient n-octanol/water ($K_{ow}$) | log $K_{ow}$ = 2.83 (measured, commercial product) |
| Flash point | 191°C (closed cup; measured) |
| Autoflammability | >400°C (measured) |
| Flammability | Not expected to be flammable. |
| Explosive properties | Not expected to be explosive. |
| Oxidizing properties | Not expected to be oxidising. |
| Viscosity | 2,600 cps at 25.4°C (measured) |
| Henry's Law constant | 6.45 x $10^{-06}$ Pa.$m^3$/mol at 25°C (by calculation from vapour pressure and water solubility) |

## 1.4 CLASSIFICATION

Classification as not dangerous for the environment (not classified) was agreed at EU level in 2005[4].

Based on the data presented in this risk assessment report, it is proposed not to classify V6 for human health effects.

V6 that is currently placed on the market contains 4.5 – 7.5% TCEP as an impurity. The human health classification for TCEP was agreed at EU level in 2005 as T; Repro. Cat 2 R60; Carc Cat 3 R40; R22[5]. Therefore, marketed V6 will also have to be classified as Category 3 carcinogen, R40 and Category 2 for fertility, R60, if its TCEP content exceeds 1.0% and

[4] Commission Working Group on the Classification and Labelling of Dangerous Substances Meeting on Environmental Effects of Existing Chemicals, Pesticides & New Chemicals September 28-30, 2005

[5] Commission Working Group on the Classification and Labelling of Dangerous Substances Meeting on the Health Effects of Pesticides, Existing Chemicals & New Chemicals November 14-18, 2005.

0.5%, respectively. Industry has indicated that purer V6 (known as V66 and TL10) are now being produced and that these will replace the V6 currently marketed.

# 2 GENERAL INFORMATION ON EXPOSURE

V6 is used in the European Union (EU) as a flame retardant additive for polyurethane at typical loadings of ~6% w/w. The treated foams are mainly used in the automotive industry and for furniture. A number of other minor confidential uses have been identified (<5% of the supply volume), although two of these appear to relate to customer trials only and are no longer thought to occur in Europe.

Less than 5,000 tonnes of V6 were produced at a single site in the EU in 2000. Some V6 is exported from the EU, and there are no imports. EU consumption remained stable between 1999 and 2003 – the supply tonnage used in the risk assessment represents the upper limit of sales over this period. Overall the EU is a net exporter of finished automotive and furniture articles.

# 3 ENVIRONMENT

## 3.1 EXPOSURE ASSESSMENT

The environmental fate and behaviour of V6 is characterised by the following properties:

- V6 is expected to degrade in the atmosphere by reaction with hydroxyl radicals, with an estimated half-life of 5.0 hours.
- V6 is not readily biodegradable and does not readily hydrolyse ($t_{1/2}$ >1 year in neutral conditions at ambient temperature); a definitive conclusion on inherent biodegradability cannot be reached on the basis of the existing data set.
- It does not adsorb significantly to organic matter, based on an estimated log $K_{oc}$ of 245, and has a low tendency to volatilise from water, based on a Henry's Law constant of 6.45 x $10^{-6}$ $Pa.m^3/mol$.
- V6 has a low potential to bioaccumulate in fish (the estimated bioconcentration factor (BCF) is 50.8).

Fugacity modelling suggests that if V6 were released to air, it would mostly precipitate to soil; if released to water or soil, it would mostly remain in the compartment of release. There is relatively little movement between soil and water, because transfer via the air compartment is very slow. In water, the modelled adsorption to sediment is very low.

The predicted fate in waste water treatment plant (WWTP) is: 97% to water; 3% adsorbed to sewage sludge; 0% to air; and 0% degraded.

Emissions at the manufacturing stage have been estimated using site-specific data from the producer company. For all life cycle stages concerning polyurethane foams, emission estimates are based on modelling work performed for the purposes of this assessment. Emissions from the confidential minor uses are based on estimates from relevant Emission Scenario Documents, read-across from relevant published risk assessments, site-specific information and WWTP details in some instances. Emissions arising from key recycling applications have also been assessed. Disposal to landfill is considered likely to be the most significant route of disposal of flexible foam and other articles containing V6; however, in the absence of data it has not been possible to evaluate the significance of this potential release.

The major emissions from industry are expected to occur to surface water. Emissions to air are also significant from point sources and over the service life of articles containing V6. At the regional level, total emissions to air are predicted to be significantly higher than to water, mainly as a result of volatilisation from polymer products over their service life. There are no direct emissions to soil, but sewage sludge application and aerial deposition are predicted to be routes of release to soil.

### 3.1.1 Predicted Environmental Concentrations (PECs)

Concentrations in fresh and marine waters and sediments, air, soil, and biota were estimated according to the methods in the EU Risk Assessment Technical Guidance Document (TGD), and these are given in Table 3.1.

**Table 3.1** Summary of PECs for V6

| Media | Release source (local PECs shown as min. – max. ranges) | | |
|---|---|---|---|
| | Production | Downstream use stages | Regional sources |
| Surface water (mg/l) | 6E-06 | 5.4E-06 – 0.046 | 5.43E-06 |
| Sediment (mg/kg wwt) | 3.7E-05 | 3.3E-05 – 0.28 | 3.72E-05 |
| WWTP final effluent (mg/l) | 5.8E-05 | 0 – 0.46 | - |
| Soil (mg/kg wwt) | 1E-04 | 6.5E-05 – 0.33 | 6.36E-05 |
| Air (mg/m$^3$) | 8.3E-10 | 1.1E-09 – 1.3E-06 | 8.3E-10 |
| Secondary poisoning (mg/kg) | 1.6E-04 – 2.9E-04 | 1.2E-04 – 0.31 | - |
| Marine water (mg/l) | 1.2E-06 | 5.5E-07 – 0.0048 | 5.54E-07 |
| Marine sediment (mg/kg wwt) | 7E-06 | 3.4E-06 – 0.029 | 3.51E-06 |
| Marine secondary poisoning (mg/kg) | 3.1E-05 – 4E-05 | 2.8E-05 – 7.6E-04 | - |

No monitoring data are available for comparison with PECs.

## 3.2 EFFECTS ASSESSMENTS

Surface water

The lowest effect values in short-term tests are a 96-h $LC_{50}$ of 52 mg/l for rainbow trout (*Oncorhynchus mykiss*), a 48-hour $EC_{50}$ of 42 mg/l for the invertebrate *Daphnia magna*, and a 72-hour $E_rC_{50}$ and $E_bC_{50}$ of 35 mg/l and 21 mg/l respectively for the alga *Pseudokirchneriella subcapitata*. Two chronic test results are also available: the 21-day NOEC for *D. magna* reproduction is $\geq$3.68 mg/l and the 72-hour NOEC for *P. subcapitata* is 10 mg/l.

A $PNEC_{aquatic}$ of 0.074 mg/l has been derived by dividing the *D. magna* NOEC by an assessment factor of 50. No measured data are available for marine organisms, so the $PNEC_{seawater}$ is a factor of 10 lower, at $7.4 \times 10^{-3}$ mg/l.

Sediment

There are no toxicity data for sediment-dwelling organisms. A $PNEC_{sediment}$ of 0.45 mg/kg wet weight has therefore been derived from the $PNEC_{aquatic}$ by equilibrium partitioning (the $PNEC_{marine\ sediment}$ is 0.045 mg/kg wet weight using the same approach).

WWTP micro-organisms

An $EC_{50}$ of >1,000 mg/l was obtained for WWTP micro-organisms (activated sludge). Dividing this by an assessment factor of 100 gives a $PNEC_{WWTP}$ of >10 mg/l.

Terrestrial compartment

A 14-day NOEC of ≥1,000 mg/kg dry weight was measured using the earthworm *Eisenia foetida*. This is equivalent to a NOEC of ≥340 mg/kg dry weight when corrected to the TGD organic matter default content. Dividing the NOEC by an assessment factor of 1,000 gives a tentative $PNEC_{soil}$ of ≥0.34 mg/kg dry weight (or ≥0.3 mg/kg wet weight).

The $PNEC_{soil}$ derived by the equilibrium partitioning method from the $PNEC_{aquatic}$ is 0.37 mg/kg dry weight. A read-across approach from long-term terrestrial studies for TDCP suggests that the $PNEC_{soil}$ might be closer to 1.7 mg/kg soil dry weight (1.5 mg/kg soil wet weight).

The $PNEC_{soil}$ based on equilibrium partitioning is preferred for risk assessment as a worst case.

Atmosphere

No data are available on the toxicity of V6 to plants or other organisms exposed via air. The possibility of V6 contributing to atmospheric effects such as global warming, ozone depletion and acid rain is likely to be very small.

Non compartment specific effects relevant for the food chain (secondary poisoning)

A $PNEC_{oral}$ of 1.0 mg/kg food has been derived from the available mammalian toxicity data.

## 3.3 RISK CHARACTERISATION

The risk characterisation is performed by comparing the PEC with the relevant PNEC for each environmental compartment/endpoint. A ratio above 1 indicates a concern. Consequently there are:

- No identified risks to the freshwater aquatic and sediment compartments or sewage micro-organisms from local sources associated with any life cycle stage
- No identified risks to the soil compartment from local sources associated with any life cycle stage
- No identified risks of biotic or abiotic effects on the atmosphere
- No identified risks of secondary poisoning of predators (including marine predators) from local sources associated with any life cycle stage
- No identified risks to the marine aquatic and sediment compartments from local sources associated with any life cycle stage.

### 3.3.1 PBT assessment

For the PBT assessment, V6 can be considered to be potentially persistent (P) or potentially very persistent (vP) based on its ultimate mineralisation. The available information on log $K_{ow}$ suggests that V6 does not meet the B or vB criterion. The T criterion is not met for aquatic toxicity.

Areas of uncertainty in the environmental risk assessment

The availability of V6 for release from foams is assumed to be limited. This uncertainty has been considered in a sensitivity analysis, and no additional risks are identified. Significant tonnage increases are not expected in the near future.

# 4 HUMAN HEALTH

## 4.1 HUMAN HEALTH (TOXICITY)

### 4.1.1 Exposure assessment

Occupational exposure

Occupational exposure to V6 may occur during its manufacture and during the manufacture and cutting of polyurethane (PUR) foam. Inhalation of vapours and skin contact are the predominant routes of exposure.

The occupational exposure scenarios considered for V6 are:

1. Manufacture of V6
2. Manufacture of flexible PUR foam
    a. slabstock foams
    b. moulded foams
3. *Cutting of flexible foam
4. Production of foam granules and re-bonded PUR foam
5. Manufacture of automotive parts

*Scenario 3 also covers the cutting of foam by furniture manufacturers where this occurs.

For each exposure scenario, the reasonable worst case (RWC) and typical inhalation and dermal exposures were calculated and these are summarised in **Table 4.1**, below.

**Table 4.1** Summary of RWC and typical exposure values for inhalation and dermal exposure for all scenarios taken forward for risk characterisation

| Scenario | Inhalation exposure (μg/m³) | | Dermal exposure (mg/cm²/day) | | Dermal exposure area (cm²) |
|---|---|---|---|---|---|
| | RWC | Typical | RWC | Typical | |
| 1: Production of V6 | 30 | 1 | 0.8 | 0.2 | 210 |
| 2a: Manufacture of flexible PUR foam | 5.1 | 0.62 | $7.0 \times 10^{-2}$ | $2 \times 10^{-3}$ | 420 |
| 2b: Manufacture of moulded foam | 4.8 | 0.63 | $7.5 \times 10^{-2}$ | $1.5 \times 10^{-3}$ | 420 |
| 3: Cutting flexible foam | 4.1 | 1.9 | $7.1 \times 10^{-3}$ | $9.8 \times 10^{-4}$ | 420 |
| 4: Production of rebonded foam | 4.6 | 0.59 | $1.7 \times 10^{-3}$ | $5.5 \times 10^{-4}$ | 420 |
| 5.Manufacture of automotive products | 4.1 | 1.9 | $7.1 \times 10^{-3}$ | $9.8 \times 10^{-4}$ | 420 |

Consumer exposure

Most of V6 used in flexible foam is for the automotive industry, with some used in furniture. Consumers do not come in direct contact with these foams; the foam is only used in ways in which it is enclosed and therefore it is concluded that exposure to consumers is negligible. From the chamber tests that were performed on two other flame retardants, TCPP and TDCP, a RWC inhalation exposure value of 3.8 μg/m$^3$ 24 hour TWA is determined. This is to allow for people, particularly elderly people, who spend a large proportion of their time indoors in a room with PU foam-containing furniture. A typical exposure value of 2.8 μg/m$^3$ is used for risk characterisation, on the basis of a consumer spending 18 out of 24 hours in rooms where there is PU foam-containing furniture.

For dermal exposure, for the reasonable worst case exposure value is 0.0011 mg/kg. A value for a RWC oral ingestion for children has been taken from the risk assessment for TCEP of 0.2 μg/kg/day, assuming a bodyweight of 9.1 kg. Humans exposed via the environment

Humans exposed via the environment

The highest local total daily adult human intake of V6 from environmental sources is estimated by the EUSES model to be 0.018 mg/kg/d. The exposure at regional level is estimated to be 4E-06 mg/kg/d..

Combined exposure

The combined exposure to V6 has been calculated from consumer exposure and indirect exposure via the environment, by all routes of exposure (oral, dermal and inhalation). As the occupational exposure levels are significantly higher than the estimated exposure to consumers or indirect exposure via the environment, it is not considered necessary to include it in the combined exposure calculation.

The RWC exposures used in calculating the combined exposure are presented in **Table 4.2** below.

**Table 4.2** Exposures taken into account for combined V6 exposure estimate (excluding occupational exposure)

| Source of exposure | Exposure |
|---|---|
| Consumer | |
| Release of TCPP from flexible polyurethane foam | |
| Inhalation | 0.0038 mg/m$^3$ |
| Dermal | 0.0011 mg/kg |
| Man via the environment | |
| Local exposure | 17.9 x 10$^{-3}$ mg/kg/day |
| Regional exposure | 3.9 x 10$^{-6}$ mg/kg/day |

### 4.1.2 Effects assessment

Toxicokinetics, metabolism and distribution

The ADME characteristics of [$^{14}$C]-V6 were investigated by the oral and IV routes in the rat. The bioavailability after the oral low and high doses were > 100% and approximately 50%, respectively. Less than 1% of the parent compound was found in the faeces after the oral dose, indicating practically complete absorption from the gastrointestinal tract. Therefore, 100% absorption by the oral route is assumed. The elimination half life was 99-113 hours, irrespective of the dose, route or sex. The retention of radioactivity was low, with the majority (60%) of the radioactivity excreted by biliary route within 3 days of dosing. Approximately 20% was excreted in urine and a small amount of radioactivity exhaled as $^{14}CO_2$. [$^{14}$C]-V6 or its metabolites were distributed all over the body, but no target organs, other than organs of elimination were identified. The major metabolites which could be identified were found in the faeces.

An *in vitro* percutaneous absorption study using human skin membranes was conducted to determine the rate and extent of absorption following topical application of commercial grade [$^{14}$C]-V6, either "neat" or in an ethanol vehicle, to human skin. The dermal delivery for V6 and V6 in ethanol was 0.51 % and 6 %, respectively. Based on the results of this study, a value of 6 % dermal absorption was used for exposure scenarios where there is potential exposure to "neat" V6 and 12 % dermal absorption is assumed for scenarios where there is potential exposure due to handling of foam containing V6.

No inhalation studies, either in animals or humans, are available and therefore, 100% absorption by the inhalation route is assumed.

Acute toxicity

Studies conducted in rats show that V6 has low acute toxicity by the oral, dermal and inhalation routes.

Irritation

The available data indicate that V6 is non-irritant to the rabbit eye and skin. The lack of any skin or eye irritation and the lack of irritation observed in the acute inhalation studies suggest that V6 would be unlikely to produce significant respiratory tract irritation.

Corrosivity

From the data presented on skin and eye irritation, V6 is not corrosive

Sensitisation

Evidence from a study in guinea pigs indicates that V6 does not possess significant skin sensitisation potential. No information is available on the respiratory sensitisation potential of V6.

Repeated dose toxicity

The main target organs following repeated oral exposure to V6 are the liver and thyroid. In a 28-day study, significantly greater absolute and relative liver weights were noted in females

from the mid dose of 150 mg/kg/day and in males at the highest dose of 600 mg/kg/day. A significant increase in absolute and relative thyroid weight was also noted in the high dose group. The higher liver and thyroid weights were considered treatment-related and correlated with histopathological changes observed in these organs among these animals. A NOAEL for V6 of 15 mg/kg/day was determined from this study, based on the absolute and relative liver weight changes and the correlated liver histopathology.

In a 2-generation reproductive toxicity study, an increase in absolute and relative thyroid weight was observed in mid dose (86 mg/kg/day) males of the F0 generation, and high dose males and females (corresponding to 262 mg/kg and 302 mg/kg, respectively) in both generations. In the F0 generation, the increase in organ weight was accompanied by evidence of an activated state in the thyroid; follicular cell hypertrophy and a reduction in colloid in mid dose males and high dose animals. In both generations, there was an increase in relative liver weight in mid dose males, and absolute and relative liver weight was increased in high dose males and females. In the F0 high dose animals, this was accompanied by hepatocyte hypertrophy. The low dose of 29 mg/kg bw/day is considered to be the NOAEL for parental toxicity (males). This is based on effects on the thyroid at mid and high doses in males following at least 77 days exposure.

Mutagenicity

V6 is not a bacterial cell mutagen and V6 was non-mutagenic in mammalian cell mutagenesis assays. In human lymphocytes *in vitro,* V6 caused a statistically significant increase in the frequency of cells with chromosome aberrations including gaps at the mid dose evaluated (312.5µg/ml) in the presence of metabolic activation only. When gap-type aberration were excluded from the analysis, the increase, while not statistically significant, was greater than the historical maximum seen in the test laboratory. The findings were, however, non-reproducible and in the absence of a dose-response effect, were not considered to be toxicologically relevant. *In vivo,* V6 was not clastogenic in a mouse micronucleus test.

Carcinogenicity

There are no carcinogenicity data for V6. There was no evidence of mutagenicity in either *in vitro* or *in vivo* genotoxicity studies with V6 and there were no indications of a potential concern for carcinogenicity (for example pre-neoplastic and hyperplasic lesions) from repeated dose toxicity studies with V6. In addition, no structurally related analogues were identified for V6 which would lead to a concern for carcinogenicity.

Toxicity for reproduction

In a two-generation reproductive toxicity study with V6, no treatment related differences were observed in pre-coital time, mating index, female fecundity index, male and female fertility index, duration of gestation and post-implantation loss. With the exception of one mid dose dam of the F1 generation, all dams delivered and there were no dams with stillborn pups. The mean number of pups delivered was comparable between the groups. There was no effect on sperm parameters at necropsy and there were no treatment related microscopic findings in the reproductive organs of either generation. No effects on male or female reproductive system were observed up to the highest dose, and therefore, the NOAEL is greater than approx. 262 and 302 mg/kg bw/day for male and female animals, respectively.

The low dose of 29 mg/kg/day is considered to be the NOAEL for parental toxicity in males. This is based on thyroid weight changes in the mid and high dose males of both generations,

and histopathological changes in this organ. The mid dose of approximately 97 mg/kg/day is considered the NOAEL for parental toxicity in females.

From the same study, a NOAEL of 29 mg/kg bw/day is derived for developmental toxicity. This is based on an increase in the number of runts on PN1 and a decrease in mean pup weights observed in the mid and high dose groups of both generations.

### 4.1.3 Risk characterisation

Workers

There is no concern for workers for any endpoint and so **conclusion (ii**) is drawn for all worker exposure scenarios in relation to all toxicological endpoints.

Consumers

There are no concerns for consumers and so **conclusion (ii)** is drawn for consumers for all exposure scenarios. This conclusion applies to all endpoints.

Humans exposed via the environment

There is no concern for man exposed via the environment, and so **conclusion (ii)** is drawn for both regional and local exposures for all endpoints.

Combined exposure

There is no concern for combined exposure and so **conclusion (ii)** is drawn for combined exposure for all endpoints.

## 4.2 HUMAN HEALTH (PHYSICO-CHEMICAL PROPERTIES)

V6 gives no reason for concern to human health in relation to its physico-chemical properties. and so **conclusion (ii)** is drawn.

# 5 OVERALL CONCLUSIONS

## 5.1 ENVIRONMENT

**Conclusion (ii)** There is at present no need for further information and/or testing and no need for risk reduction measures beyond those which are being applied already.

This applies to all compartments for all local life cycle stages, and at the regional scale in all compartments. V6 does not meet the PBT/vPvB criteria.

## 5.2 HUMAN HEALTH

### 5.2.1 Human health (toxicity)

Workers

**Conclusion (ii)** There is at present no need for further information and/or testing and no need for risk reduction measures beyond those which are being applied already.

Conclusion (ii) applies to all worker exposure scenarios in relation to all toxicological endpoints.

Consumers

**Conclusion (ii)** There is at present no need for further information and/or testing and no need for risk reduction measures beyond those which are being applied already.

Conclusion (ii) applies to all consumer exposure scenarios in relation to all toxicological endpoints.

Humans exposed via the environment

**Conclusion (ii)** There is at present no need for further information and/or testing and no need for risk reduction measures beyond those which are being applied already.

Conclusion (ii) applies to both regional and local exposures in relation to all toxicological endpoints.

Combined exposure

**Conclusion (ii)** There is at present no need for further information and/or testing and no need for risk reduction measures beyond those which are being applied already.

Conclusion (ii) applies to combined exposure in relation to all toxicological endpoints.

### 5.2.2 Human health (risks from physico-chemical properties)

**Conclusion (ii)** There is at present no need for further information and/or testing and no need for risk reduction measures beyond those which are being applied already.

Conclusion (ii) applies to all endpoints.