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TRICHLOROETHYLENE

CAS No: 79-01-6

EINECS No: 201-167-4

Summary Risk Assessment Report

2004 **Special Publication I.04.29**

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SUMMARY RISK ASSESSMENT REPORT

Final report, 2004

United Kingdom

This document has been prepared by the UK rapporteur on behalf of the European Union. The scientific work on the environmental part was prepared by the Building Research Establishment Ltd (BRE), under contract to the rapporteur.

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Date of Last Literature Search:	**1995**
Review of report by MS Technical Experts finalised:	**2001**
Final report:	**2004**

(The last full literature survey was carried out in 1995 - targeted searches were carried out subsequently: DCA-related search 1998; air levels search 2000).

PREFACE

This report provides a summary, with conclusions, of the risk assessment report of the substance trichloroethylene that has been prepared by the UK in the context of Council Regulation (EEC) No. 793/93 on the evaluation and control 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 comprehensive Final Risk Assessment Report (Final RAR) that can be obtained from the European Chemicals Bureau[1]. The Final RAR should be used for citation purposes rather than this present Summary Report.

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

CONTENTS

TABLES

1 GENERAL SUBSTANCE INFORMATION

1.1 IDENTIFICATION OF THE SUBSTANCE

CAS-No: 79-01-6
EINECS-No: 201-167-4
IUPAC name: trichloroethylene

1.2 PHYSICO-CHEMICAL PROPERTIES

Trichloroethylene is a colourless liquid at room temperature with a characteristic odour resembling that of chloroform. It is manufactured to a high purity (>99%). The physicochemical properties of trichloroethylene are summarised in **Table 1.1**.

Table 1.1 Summary of physico-chemical properties

Properties	Value
Molecular weight	131.5
Melting Point	-84.8°C
Boiling Point	86-8°C
Density	1.465 g · cm^{-3}
Vapour pressure	86 hPa at 20°C
Water solubility	1,100 mg · l^{-1}
Log octanol/water partition coefficient	2.29
Log sediment/water partition coefficient	2.1 (calculated)
Flammability	lower limit 12.5%, upper limit 90%
Autoflammability	410°C
Vapour density	0.42 kg · m^{-3} (air = 1)
Henry's law constant	1.03 · 10^{-2} atm · m^{3} · mole^{-1}
Surface tension	0.0293 N · m^{-1} at 20°C
Conversion factor	1 ppm = 5.47 mg · m^{-3}

1.3 CLASSIFICATION

Classification and labelling according to the 28th ATP of Directive 67/548/EEC[2]:

Classification

Carc. Cat.2; R45 May cause cancer
Muta. Cat. 3; R68 Possible risk for irreversible effects

[2] The classification of the substance is established by Commission Directive 2001/59/EC of 6 August 2001 adapting to the technical progress for the 28th time Council Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (OJ L 225, 21.8.2001, p.1).

Xi; R36/38	Also irritating to eyes and skin
R67	Vapours may cause drowsiness and dizziness
R52-53	Harmful to aquatic organisms; May cause long-term adverse effects in the aquatic environment

Specific concentration limits: None
Note: 6

Carcinogen Category 2 is for substances which should be regarded as if they are carcinogenic to humans. There is sufficient evidence to provide a strong presumption that human exposure to a substance may result in the development, of cancer, generally on the basis of:

1. appropriate long-term animal studies;
2. other relevant information.

Mutagen Category 3 is for substances which cause concern for humans owing to possible mutagenic effects. There is evidence from appropriate mutagenicity studies, but this is insufficient to place the substance in Category 2.

In addition, Note 6 applies to the labelling of preparations that contain trichloroethylene; such preparations have to be assigned R67 if they meet the appropriate criteria.

<u>Labelling</u>

T
R: 45-36/38-52/53-67

S: 53-45-61	Avoid exposure – Obtain special instructions before use In case of accident or if you feel unwell seek medical advice immediately (show the label where possible) Avoid release to the environment. Refer to special instructions/safety data sheet

2 GENERAL INFORMATION ON EXPOSURE

The quantity of trichloroethylene produced and used in the EU is estimated to be between 51,000 and 225,000 tonnes per year. The major use of trichloroethylene is for vapour degreasing and cleaning of metal parts (WHO, 1985)[3]. It is also used in adhesives, for synthesis in the chemical industry and as a solvent for various products, including insecticides and waxes (WHO, 1985). It is (or has been) used in the leather and textile processing industries and in the paint, lacquers and varnishes industry.

[3] For full references, see comprehensive Risk Assessment Report

3 ENVIRONMENT

3.1 ENVIRONMENTAL EXPOSURE

Environmental releases

The assessment considers releases from the production of trichloroethylene based on specific information from the producers. It also covers the use of trichloroethylene as an intermediate, handling of the solvent, use in metal cleaning, formulation and use of adhesives, formulation and use of consumer products and other uses. From the available measured levels there is evidence for a natural production of trichloroethylene, of similar magnitude or greater than the anthropogenic emissions. These natural emissions are considered to be important on the global scale, but not on the local or regional scale, and are therefore not considered in the assessment. The estimated emissions of trichloroethylene are summarised in **Table 3.1**.

Table 3.1 Summary of emissions of trichloroethylene

Activity	Release (kg/day)								
	Local			Regional			Continental		
	Air	Water	Soil	Air	Water	Soil	Air	Water	Soil
Production	2,930	Site specific		2,410	13.7		214	10.9	
Intermediate use	67	6.7		55	5.5		68	6.8	
Handling	400	0.25		329	0.21		627	0.32	
Metal degreasing	42	4.6		10,898	1211		98,083	10,898	
Adhesives formulation	8.3	1.0	1.67	68.5	8.2	13.7	406	49	81
Adhesives use	19			1,899			17,088		
Consumer product formulation	3.85	0.46	0.77	32	3.8	6.3	285	34	57
Consumer use	0.58	0.064		1,139	127		10,253	1,139	
Others	0.29	0.032		570	63		5,126	570	
Total				**17,400**	**1,432**	**20**	**132,150**	**12,708**	**138**

Environmental fate

Trichloroethylene reacts readily with OH radicals in the atmosphere, with a half-life of ~1 week. The major products of this reaction are formyl chloride and phosgene. Trichloroethylene is not considered to contribute significantly to low-level ozone formation, nor to be a stratospheric ozone depleting substance. It may also react with chorine atoms in the atmosphere, and one of the eventual products of such reactions is dichloroacetic acid. This has herbicidal properties, and a limited risk assessment of this breakdown product has also been carried out.

Trichloroethylene is not readily or inherently biodegradable. It can undergo reductive dechlorination under anaerobic conditions; the extent of such degradation depends on local conditions. In the calculation of the PECs it has been assumed that trichloroethylene does not biodegrade in water, sediment or soil. It has low to moderate sorption, and so is expected to be reasonably mobile in soils. Volatilisation from water is a significant removal process for the aquatic compartment. It has a low bioaccumulation in fish; measured values range from 17-90, and a value of 17.6 is predicted from the log Kow value.

Environmental concentrations

Predicted environmental concentrations (PECs) have been calculated for specific production and processing (use as an intermediate) sites. For other uses a combination of some specific information and the default values from the Technical Guidance Document (TGD) has been used. The methods in the TGD together with the EUSES program were employed. The resulting PECs are in **Table 3.2**.

Table 3.2 Predicted environmental concentrations

Activity	Water (µg/l)	Sediment (µg/kg wet weight)	Air (µg/m³)	Soil (µg/kg wet weight)
Production	66	181	65	31
Intermediate use	28.4	78	16	10
Handling	1.4	3.8	92	1.2
Metal degreasing	19.6	54	10	6.9
Adhesives formulation	4.5	13	2.4	1.5
Adhesives use	0.35	0.95	5.8	0.014
Consumer product formulation	2.3	6.3	1.4	0.7
Consumer use	0.62	1.7	0.63	0.1
Others	0.5	1.3	0.55	0.05
Regional	0.35	0.9	0.47	0.002

There are extensive measurements of trichloroethylene in surface waters, both remote and affected by industrial activity. The calculated values are in reasonable agreement with the measured levels. As it is difficult to assign measured levels to specific activities, the calculated values have been used in the risk assessment. In addition, a value of 10 µg/l has been taken as representative of the higher end of the measured levels, with the vast majority of reported results being below this.

There are also extensive measurements of trichloroethylene in air, and the calculated levels are consistent with these; again the calculated levels have been used in the assessment. There are only a few measured levels in soil, and again the calculated values have been used.

To assess the risk of secondary poisoning, concentrations in fish and worms have been estimated from those in water and soil using the methods in the TGD. For indirect exposure of humans via the environment, measured levels of trichloroethylene in foodstuffs have been used for the local worst-case scenario, and the regional levels from the EUSES calculations used for the background exposure.

For the breakdown product dichloroacetic acid there are a limited number of measurements in rainwater, remote areas having concentrations of 10-20 ng/l and rural areas 50-240 ng/l, with the highest level being 1.2 µg/l. There are no measurements of background levels in surface waters (dichloroacetic acid can be formed during the chlorination of water, so any measurements in surface water need to be interpreted carefully). There are limited measurements of dichloroacetic acid in soils; concentrations up to 0.85 µg/kg have been measured in the top 10 cm of soil, and the average concentration over the top 1 metre of soil at ten sites in the EU was 0.25 µg/kg. A simple calculation of the concentration resulting from deposition in rainfall (at a concentration of 240 ng/l) gives an estimated soil concentration of 0.06 µg/kg.

3.2 EFFECTS ASSESSMENT

Trichloroethylene is volatile, and there are difficulties in maintaining exposure concentrations in aquatic tests. The results have therefore to be interpreted carefully. There are numerous short-term aquatic toxicity test results available, including microorganisms, algae, invertebrates and fish. The lowest effect concentrations from tests considered valid are included in **Table 3.3**.

Table 3.3 Aquatic toxicity of trichloroethylene

Organism	Test duration	Test result (mg/l)	Comments
Methanogens (microorganisms)	24 h IC_{50}	13	Valid
Chlamydomonas reinhardii (algae)	72 h EC_{50}	36.5	Valid
Mysidopsis bahia (invertebrate)	96 h EC_{50}	14	Use with care
Daphnia magna (invertebrate)	48 h IC_{50}	21	Valid
Dab *Limanda limanda* (fish)	96 h LC_{50}	16	Use with care
Fathead minnow *Pimephales promelas* (fish)	96 h LC_{50}	41	Valid
American flagfish *Jordanella floridae* (fish)	96 h LC_{50}	28.3	Valid
Chlamydomonas reinhardii (algae)	72 h EC_{10}	12.3	Valid
Daphnia magna (invertebrate)	21 d NOEC	2.3	Use with care, nominal concentrations
American flagfish *Jordanella floridae* (fish, embryo-larval)	10 d NOEC	5.76	Valid
Ecosystem test, *Daphnia pulex*	11 weeks NOEC	1	Use with care, large variation and unusual endpoints

Table 3.3 also includes results from chronic studies on fish, daphnia and algae. The daphnia result is not considered to be valid for use in the derivation of the PNEC. Daphnia have the lowest acute toxicity result; however, the values for fish and daphnia are in general very similar and it is considered that they are of similar sensitivity. Therefore a factor of 50 is used on the fish long-term NOEC, giving a PNEC aquatic of 115 µg/l. The PNEC for sediment is derived from the aquatic PNEC using the equilibrium partitioning method as 316 µg/kg wet weight. There are limited data on terrestrial toxicity and so the equilibrium partitioning method has been used here to give a PNEC of 202 µg/kg wet weight.

There are indications in some studies of effects of trichloroethylene on plants (spruce and pine trees) through exposure in the air. It is not possible to derive any effect concentrations from these studies. An extensive study on the related substance tetrachloroethylene measured effects on a variety of plant species. The risk assessment for tetrachloroethylene derived a PNEC for plants of 8.3 µg/m^3. For the risk assessment of trichloroethylene it has been assumed that the two substances have similar effects, and a PNEC of 6.5 µg/m^3 has been derived for trichloroethylene assuming equal toxicity on a molar basis.

For the assessment of secondary poisoning through the food chain, there are no toxicity results for birds and so effects data from laboratory studies on mammalian species have been used. A NOEC of 50 mg/kg day for effects on the kidney is the lowest value, which leads to a PNEC of 42 mg/kg in food.

The effects of the breakdown product dichloroacetic acid have also been considered. No test results for the actual substance were found, so the toxicity has been estimated by comparison with that of monochloro- and trichloroacetic acids. The PNEC for aquatic organisms was estimated as 0.72 µg/l and that for terrestrial organisms as 4.2 µg/kg.

3.3 RISK CHARACTERISATION

Aquatic compartment (incl. sediment)

The PEC/PNEC ratios derived for trichloroethylene in water and sediment are included in **Table 3.4**. All the ratios are less than one. As both the PECs and PNEC for sediment are estimated by equilibrium partitioning, the ratios for sediment are the same as those for water. The PEC/PNEC ratios for the wastewater treatment plant (not shown) are also less than one. The conclusion is therefore that there is no risk to the aquatic compartment from exposure to trichloroethylene from current production and use.

Table 3.4 PEC/PNEC ratios for the environment

Activity	Water	Soil	Air	Secondary poisoning
Production	0.57	0.14	10	0.014
Intermediate use	0.25	0.05	2.5	0.005
Handling	0.012	0.006	14	<0.001
Metal degreasing	0.17	0.034	1.5	0.004
Adhesives formulation	0.04	0.007	0.37	<0.001
Adhesives use	0.003	<0.001	0.89	<0.001
Consumer product formulation	0.02	0.003	0.22	<0.001
Consumer use	0.005	<0.001	0.1	<0.001
Others	0.004	<0.001	0.08	<0.001
Regional	0.003	<0.001	0.07	<0.001

For the breakdown product dichloroacetic acid the measured concentrations in rain water are mostly less than the PNEC; the few higher measurements give ratios less than 2. As these measured values do not take account of dilution in surface water, then the concentration in surface water arising from the breakdown of trichloroethylene is considered to be below the PNEC and hence there is no risk: **conclusion (ii)**.

Terrestrial compartment

The PEC/PNEC ratios derived for trichloroethylene in soil are also included in **Table 3.4**. These are all less than one, hence there is no risk to the terrestrial compartment from exposure to trichloroethylene through soil. (The exposure of plants through the air is considered under the atmospheric compartment).

There are limited data on levels of dichloroacetic acid in soil, with concentrations up to 0.85 μg/kg dry weight measured. Concentrations in soil from deposition of dichloroacetic acid have been estimated as 0.06 μg/kg. A PNEC for soil organisms of 1.9 μg/kg has been estimated from the PNEC for trichloroacetic acid. Although limited these data would indicate no concern.

Conclusion(ii).

Atmosphere

A PNEC of 6.5 $\mu g/m^3$ for the effect of trichloroethylene on plants via exposure through the air was calculated by analogy with tetrachloroethylene. Concentrations in air were presented in the section on environmental concentrations. The resulting PEC/PNEC ratios are in **Table 3.4**. Ratios above and below one are obtained. Risks of harm to plants from air emissions of trichloroethylene are identified from sites producing trichloroethylene, from sites using trichloroethylene as an intermediate, from sites formulating trichloroethylene as a solvent ("handling"), and from use in metal degreasing: **conclusion (iii)**. The risk for production applies to two sites, and the risk for intermediate use applies to sites which did not provide emission information.

The PNEC on which this conclusion is based is derived from that for tetrachloroethylene on the basis that both substances would be expected to have similar effects.

It should be noted that the conclusions of the human health risk assessment will require risk reduction action to be taken for this substance. The Solvent Emissions Directive (1999/13/EC) will also have an impact on the emissions of this substance.

Secondary poisoning

Concentrations of trichloroethylene in fish and earthworms have been estimated from the concentrations in water and soil. These have been compared with a PNEC derived from mammalian toxicity data (to represent fish or worm eating animals). All the PEC/PNEC ratios are less than one (**Table 3.4**, values are for fish which are higher than earthworms in all cases), indicating no risk for secondary poisoning: **conclusion (ii)**.

4 HUMAN HEALTH

4.1 HUMAN HEALTH (TOXICITY)

4.1.1 Exposure assessment

Occupational exposure

During the manufacture of trichloroethylene and its use in chemical synthesis, workers may be exposed by the inhalation and dermal routes. Inhalation exposure to the vapour is likely where operators breach the closed plant or as a result of spillages. Dermal exposure may occur where workers come into contact with surfaces contaminated by splashes or condensed vapour or as a result of direct splashes on to the skin.

During the use of trichloroethylene, workers may again be exposed by the inhalation and dermal routes. Inhalation exposure to the vapour will occur during activities such as metal cleaning and the use of adhesives. As in trichloroethylene manufacture, dermal exposure may also occur where workers come into contact with surfaces contaminated by splashes or condensed vapour or as a result of direct splashes on to the skin. This may be particularly evident where operators handle degreased components or directly handle adhesives.

The number of workers exposed to trichloroethylene throughout the EU is estimated to be in excess of 60,000, with about 10,000 of these in the UK. Reasonable worst-case exposure levels for the different occupational scenarios are identified in **Table 4.1**.

Table 4.1 Reasonable worst-case exposure levels for the dermal and inhalation routes

Exposure scenario	Exposure level via inhalation route	Exposure level via dermal exposure
Manufacture and recycling	8-hour TWA [1)] – 10 ppm	0.1 $mg/cm^2/day$
Metal degreasing	8-hour TWA – 50 ppm	1.0 $mg/cm^2/day$
Adhesives (manufacture)	8-hour TWA – 10 – 20 ppm (with LEV [2)]) and 100 – 140 ppm (without LEV)	1.0 $mg/cm^2/day$
Adhesives (use)	8-hour TWA – Wide use, controls uncertain – not quantifiable	1.0 $mg/cm^2/day$
Use as an intermediate	8-hour TWA – 11.5 ppm	0.1 $mg/cm^2/day$

1) TWA: time weighted average
2) LEV: local exhaust ventilation

Consumer exposure

The only consumer use of trichloroethylene appears to be for spot cleaning fabrics. That is, as a cleaner for small patches of grease or oil on cloth. This accounts for approximately 6% of sales of trichloroethylene, some 4,600 tonnes per annum. There is no measured exposure data available on consumer exposure during this cleaning process, but a potential peak user exposure concentration has been estimated of 1.9 g/day for the inhalation route and 2.5 g/day for the dermal route, using computer modelling for a single exposure event.

Humans exposed via the environment

Human intake via the environment is $1.4 \cdot 10^{-4}$ mg/kd/day, at the regional level and 0.037 mg/kd/day at the local level.

Combined exposure

Given the large differences in exposure and the different exposure scenarios for humans via the three different routes, it was not considered useful to produce a combined exposure assessment.

4.1.2 Effects assessment

Studies in experimental animals and humans have shown that trichloroethylene is rapidly and extensively absorbed by all routes of exposure. Once absorbed it readily distributes to all compartments within the body. Although trichloroethylene preferentially partitions into fat rich tissues, there is no evidence of prolonged retention at these sites. Trichloroethylene is predominantly cleared from the body by metabolism, accounting for 50 to 99% of the absorbed dose. The major metabolic pathway in all species results in the production of trichloroethanol and trichloroacetic acid. Most unmetabolised trichloroethylene is exhaled. Metabolites of trichloroethylene are predominantly eliminated in the urine with a small proportion eliminated in the bile and faeces. Other routes of elimination have not been investigated.

The acute toxicity of trichloroethylene has been extensively investigated in animals and humans. The main toxic effect observed in humans inhaling trichloroethylene is CNS depression with a NOAEL of 300 ppm for exposures up to 8 hours. It has low toxicity following acute oral exposure. No useful data are available for the dermal route. There are indications from human experience and studies in animals that liquid trichloroethylene can be irritating to the skin and eyes. Trichloroethylene is not a skin sensitiser and there have been no reports of respiratory sensitisation.

Repeated oral and inhalation exposure studies in animals indicate that kidney toxicity is the most sensitive endpoint, with NOAELs of 50 mg/kg/day and 100 ppm, respectively. Functional CNS disturbance has been established as the most sensitive endpoint in humans, and a NOAEL of 50 ppm can be identified from the available data. Trichloroethylene is an *in vitro* mutagen in the presence of an exogenous metabolic activation system. Although conflicting data exist, the weight of evidence, including certain studies in humans, indicates that trichloroethylene can also exhibit genotoxic activity in somatic tissues *in vivo*. Trichloroethylene is considered to have the potential to cause cancer in humans. The effects of trichloroethylene on fertility and reproductive performance have been extensively investigated in rats and mice. Influences on reproduction were only seen at exposure levels that produce general toxicity, with NOAELs of 350 and 75 mg/kg/day in mice and rats, respectively. Conventional inhalation developmental toxicity studies conducted with trichloroethylene revealed no evidence of developmental toxicity, but the doses used were non-maternally toxic. Non-standard oral studies in rats have raised some concerns about the potential for trichloroethylene to induce developmental neurotoxicity, but these are considered too limited to provide a basis on which to draw conclusions.

4.1.3 Risk characterisation

Workers

For mutagenicity and carcinogenicity, it has not been possible to identify a threshold exposure level below which these effects would not be expressed; there is no evidence that the controls currently in place across all industry sectors in the EU represent best practice for a mutagenic and carcinogenic substance, so there is concern for health for all occupational scenarios. Also for all scenarios, the margins between exposure and the NOAEL for repeated dose kidney toxicity are of insufficient magnitude to provide reassurance that health effects will not occur, and therefore these are of concern. The margins between exposure and the NOAEL for acute CNS depression are low for metal cleaning, adhesive manufacture (without LEV) and adhesive use, and therefore there are concerns. There are also concerns for repeat dose functional CNS disturbance in metal cleaning, adhesive manufacture (irrespective of LEV use) and adhesive use. For all uses, the risk of skin and eye irritation is considered to be low, provided good occupational hygiene practices are in operation.

Consumers

The only identified consumer use for trichloroethylene in the EU is as a fabric spot cleaner. It is assumed that use will be occasional and the exposure can be regarded as a one-off acute experience. The main toxic effect of acute exposure is CNS depression. Although a 4-fold margin of safety based on human data, has been established, consumer exposure is still considered to be cause for concern taking into account the possibility of short-term exposures above the NOAEL, the steepness of the dose-response curve and the potentiating effects of alcohol on this effect. In relation to mutagenicity and carcinogenicity there are concerns. As a result of the category 2 carcinogen classification, the current use of trichloroethylene in consumer products could no longer be acceptable, under existing EC legislation (Directive 76/769/EEC; Marketing and Use Directive).

Humans exposed via the environment

The predicted body burden for trichloroethylene in humans via the environment (0.019 mg/kg/day) is several orders of magnitude greater than the effect level for all endpoints for which a threshold can be established. However, since trichloroethylene is both mutagenic and carcinogenic, there are concerns for these endpoints.

4.2 HUMAN HEALTH (PHYSICO-CHEMICAL PROPERTIES)

Trichloroethylene is not classified as flammable and it is unlikely to be flammable except in exceptional circumstances, perhaps where vapour is contained in a sealed vessel and exposed to high-energy ignition sources. Trichloroethylene is not considered to be explosive. However, violent decomposition is possible under certain conditions in the presence of aluminium. Commercial grades have stabilisers added to prevent such reactions under normal use and storage. Further assessment of the risks arising from physicochemical properties relates to local controls for storage and use and is best addressed at that level. Overall, there are no concerns.

5 RESULTS

5.1 ENVIRONMENT

The environmental risk characterisation considers the production of trichloroethylene and its use as an intermediate, in metal cleaning, in adhesives and consumer products, and other uses. It also considers the potential formation and effects of a breakdown product, dichloroacetic acid.

For the aquatic compartment the PEC/PNEC ratios are less than one for all of the life cycle steps considered for water and sediment. The ratios for wastewater treatment plants are also less than one. For dichloroacetic acid, the concentrations in surface waters are expected to be less than the PNEC.

For the terrestrial compartment, the PEC/PNEC ratios are less than one for trichloroethylene exposure in soil through sewage sludge application or aerial deposition. The measured concentrations of dichloroacetic acid in soil are lower than the PNEC estimated for dichloroacetic acid, which indicates no concern.

For the atmospheric compartment there are indications of effects of trichloroethylene on plant species exposed through the air. It is not possible to derive a no-effect level from this information. A PNEC has been derived from that for tetrachloroethylene for effects on plants. This indicates possible effects on plants from emission to air from production, use as an intermediate, formulation as a solvent and use in metal degreasing.

The assessment of secondary poisoning gives PEC/PNEC ratios less than one for all life cycle steps considered.

<u>Results</u>

Conclusion (iii) There is a need for limiting the risks; risk reduction measures which are already being applied shall be taken into account.

This conclusion applies to the risk of harm to plants from air emissions of trichloroethylene from sites producing the substance, from sites using it as an intermediate, from sites formulating it as a solvent, and from its use in metal degreasing. The conclusion for production applies to two sites, and the conclusion for intermediate use applies to sites which did not provide emission information. The PNEC on which this conclusion is based is derived from that for tetrachloroethylene on the basis that both substances would be expected to have similar effects at similar levels. It should be noted that the conclusions for the human health risk assessment will require risk reduction action to be taken for this substance which may affect emission to the environment. The Solvent Emissions Directive (1999/13/EC) will also have an impact on the emissions of the substance.

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

This conclusion applies to the aquatic compartment (including sediment), to wastewater treatment plants, to the terrestrial environment and to secondary poisoning for all stages in the production and use of trichloroethylene; to the air compartment for formulation and use in adhesives and consumer products; and to the aquatic and terrestrial compartments for dichloroacetic acid produced by the photodegradation of trichloroethylene.

5.2 HUMAN HEALTH

5.2.1 Human health (toxicity)

The key health effects of exposure to trichloroethylene are CNS depression following single exposures, skin and eye irritation, kidney effects following repeated exposures, mutagenicity and carcinogenicity.

<u>Workers</u>

Conclusion (iii) There is a need for limiting the risks; risk reduction measures which are already being applied shall be taken into account.

This conclusion applies to all scenarios in relation to mutagenicity, carcinogenicity and repeat dose kidney toxicity, and to trichloroethylene used in the metal degreasing industries, adhesive manufacture (without LEV) and use in relation to acute CNS depression.

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

This conclusion applies to all scenarios in relation to skin and eye irritation.

<u>Consumers</u>

Conclusion (iii) There is a need for limiting the risks; risk reduction measures which are already being applied shall be taken into account.

This conclusion applies to the only current consumer exposure scenario, i.e. intermittent use as a fabric “spot” cleaner, and is due to possible acute CNS depression and the mutagenic and carcinogenic potential of trichloroethylene. It should be noted that as a result of the classification as a category 2 carcinogen, the current use of trichloroethylene in consumer products would no longer be acceptable, under existing EC legislation (Directive 76/769/EEC; Marketing and Use Directive).

<u>Humans exposed via the environment</u>

Conclusion (iii) There is a need for limiting the risks; risk reduction measures which are already being applied shall be taken into account.

For carcinogenicity and mutagenicity endpoints, there is no identifiable threshold exposure level below which the effects would not be expressed, so there are health concerns at all exposure levels. However, the predicted regional and environmental exposures are very low. Therefore, although there may be some residual risk of mutagenicity and/or carcinogenicity this is likely to be very low. This should be taken into account when considering the adequacy of existing controls and the feasibility and practicability of further specific risk reduction measures.

It is not possible to draw clear conclusions regarding developmental neurotoxicity. Further testing according to OECD TG 426 is needed. However, as the substance is classified as a category 3 mutagen and a category 2 carcinogen, the results of such testing are unlikely to influence the outcome of the risk assessment, as the risk characterisation is based on the assumption that a threshold exposure level for adverse health effects cannot be identified.

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

In relation to acute CNS effects, skin and eye irritation, repeated dose functional CNS disturbance and repeated dose kidney toxicity, there is no significant risk for humans exposed via environmental routes.

Combined exposure

The potential combined exposure is dominated by the occupational exposure. Thus, the conclusions of the risk characterisation for combined exposure reflect those reached for workers.

5.2.2 Human health (risks from physico-chemical properties)

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

If the appropriate conditions of handling and storage are adhered to, there are no concerns for risks to human health arising from the physicochemical properties of trichloroethylene.