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1,3-BUTADIENE

CAS No: 106-99-0

EINECS No: 203-450-8

Summary Risk Assessment Report

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SUMMARY RISK ASSESSMENT REPORT

2002

United Kingdom

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PREFACE

This report provides a summary, with conclusions, of the risk assessment report of the substance 1,3-butadiene that has been prepared by the United Kingdom 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 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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1 GENERAL SUBSTANCE INFORMATION

Buta-1,3-diene (referred to as 1,3-butadiene in this summary) is a gas at room temperature. It is manufactured to a high purity (>99%). It contains an inhibitor, 4-tert-butyl pyrocatechol, at 0.01-0.02% w/w to prevent self-polymerisation of the product on storage. The physicochemical properties of 1,3-butadiene are summarised in **Table 1.1.**

Table 1.1 Physicochemical properties

Properties	Value
Physical state	gas
Molecular weight	54.09
Melting point	-108.9°C
Boiling point	-4.4°C
Relative density	0.62
Vapour pressure	240.0 kPa at 20°C
Water solubility	0.735 g/l at 20°C
Log octanol/water partition coefficient	1.99
Flash point (closed up)	-85°C
Autoflammability	415°C
Explosive limits in air	Lower explosive limit: 1.4 % v/v Upper explosive limit: 16.3 % v/v
Conversion factor for air levels (v/v)	1 ppm = 2.21mg/m^3at 25°C

2 GENERAL INFORMATION ON EXPOSURE

The quantity of 1,3-butadiene produced and used in the EU is estimated as 1,892,000 tonnes per year. 1,3-butadiene is used as a monomer and co-monomer in the production of a range of polymeric products. It is used in the manufacture of synthetic rubbers such as styrene-butadiene rubber (SBR) and polybutadiene rubber, of thermoplastic resins such as acrylonitrile-butadiene-styrene (ABS), and of styrene-butadiene latex. It is also used in the manufacture of other chemicals used as intermediates, for example hexamethylenediamine which is used in nylon production.

3 ENVIRONMENT

3.1 ENVIRONMENTAL EXPOSURE

3.1.1 Environmental releases

The releases from production and the major use processes were estimated using emission factors from a US report, which gathered data from the US chemical industry. The amounts produced or used on representative sites were taken from information in IUCLID or from statistics produced by the IISRP (International Institute of Synthetic Rubber Producers) or the largest site in the UK in the case of ABS. Unreacted monomer may be present in polymeric products. Possible releases from this source were estimated by taking the highest measured residual level and applying this to the annual tonnage of products made from 1,3-butadiene, assuming that all releases occurred in the first year of use of the products.

There are also a number of indirect sources of 1,3-butadiene emissions. It is a component of both gasoline and diesel vehicle exhausts (although not of the original fuel). Emissions from this source were estimated based on emission factors per mile (derived from measurements) and statistics on total vehicle mileage in the EU. Emissions in cigarette smoke were also estimated. Forest fires and biomass burning are also sources of 1,3-butadiene, but emissions from these sources within the EU could not be quantified.

The release estimates are summarised in **Table 3.1.**.

Table 3.1 Summary of releases of 1,3-butadiene

Source	Route of release	Amount released/site (local model) (tonnes/year)	Amount released in regional model (tonnes/year)	Amount released in continental model (=total EU release-regional release) (tonnes/year)
1,3-Butadiene production	wastewater	93.6	89	797
	air	3.2	3	27.3
Styrene-butadiene rubber/latex production	wastewater	24	21	185
	air	576	495	4,459
Polybutadiene rubber production	wastewater	9.6	5	45
	air	248	129	1,161
Polychloroprene production	wastewater	9	2	18
	air	120	26.6	239
Nitrile-butadiene rubber/latex production	wastewater	0.18	0.09	0.79
	air	70	35	317
Acrylonitrile-butadiene-styrene resin production	wastewater	6	3	27.3
	air	105	53	477
Adiponitrile / hexamethylene diamine production	wastewater	0.5	0.15	1.4
	air	3	0.9	8.2
Vehicle exhaust emissions	air	/	663	5,970
Cigarette smoke	air	/	28.6	257
Polymers (residual 1,3-butadiene)	air	/	1.2	10.9
Total	wastewater		120	1,074
	air		1,435	12,926

3.1.2 Environmental fate

1,3-butadiene is reactive in air; the main process is reaction with hydroxyl radicals, with an estimated half-life of 5.8 hours. At night, reaction with ozone will become more important; the half-life of this process is estimated as 1.9 days. The substance is not expected to hydrolyse in water.

There is very little evidence regarding biodegradation, and it would be very difficult to test such a volatile substance. Although there are some indications of degradability, as a worst-case approach the assessment assumes that 1,3-butadiene is not biodegradable.

Volatility from water is expected to be rapid. The log Kow is 1.99, so sorption to organic matter in soil and sediment is not expected to be important and 1,3-butadiene is not expected to accumulate from water or food.

3.1.3 Environmental concentrations

The methods in the Technical Guidance Document were applied to the emissions in Section 3.1. The fate of 1,3-butadiene in wastewater treatment was estimated as 95% volatilised, 1% to sludge and 4% to water. The concentrations calculated for surface water were compared with monitoring data from 11 production and 12 processing sites in the EU. Concentrations were also calculated for all production and processing sites, using actual capacities and actual or default information on emissions and effluent dilution as appropriate. The measured levels were much lower than those predicted from the TGD defaults. The calculations for individual sites gave a maximum concentration of 25 μg/l for production sites and 16 μg/l for processing sites. These were taken as representative of the levels in water arising from production and use. Concentrations in sediment of 48 and 30 μg/kg wet weight respectively were estimated for processing and production.

Concentrations in air have been monitored widely; these show that traffic is an important source in urban areas and that 1,3-butadiene is not transported over significant distances from the source of release. Concentrations in air were also calculated using the Technical Guidance methods from the emissions from Section 3.1 (including emissions to air from waste water treatment). The calculated values agree reasonably well with the available measurements.

Concentrations on the regional and continental scales were calculated using the EUSES programme and the combined releases from Section 3.1. For air, a typical measured value of 1.5 $\mu g/m^3$ was used for the regional concentration, as representing a concentration likely to occur as a result of vehicle emissions. As this is derived from measured values it will include a contribution from biomass burning and forest fires.

The Predicted Environmental Concentrations are summarised in **Table 3.2**.

Table 3.2 Summary of PECs

Source	Surface water µg/l	Sediment µg/kg	Soil µg/kg	Air µg/m³
1,3-Butadiene production PEC_{local}	25	48	29	67
Styrene-butadiene rubber/latex production PEC_{local}	16	30	7.8	439
Polybutadiene production PEC_{local}	16	30	3.1	189
Polychloroprene production PEC_{local}	16	30	2.8	91
Nitrile-butadiene rubber/latex production PEC_{local}	16	30	0.11	53
ABS production PEC_{local}	16	30	1.9	80
Adiponitrile production PEC_{local}	16	30	0.16	2.3
$PEC_{regional}$	0.04	0.051	0.0001	0.03

3.2 EFFECTS ASSESSMENT

There are no aquatic toxicity test results for 1,3-butadiene, and the nature of the substance means that it would be very difficult to obtain meaningful results from such tests. In the absence of data on 1,3-butadiene, test results for two analogues, isoprene (2-methyl-1,3-butadiene) and 1,3-pentadiene, were reviewed. QSAR predictions of toxicity based on the log Kow value were also obtained for 1,3-butadiene and for the two analogues. **Table 4** compares the QSAR estimates and measured values for the two analogues.

Table 3.3 Comparison of QSAR estimates and measured aquatic toxicity data for 1,3-pentadiene and isoprene

Endpoint	QSAR estimate	Measure data
1,3-pentadiene (log Kow = 2.3 (calculated; from IUCLID) or 1.5 (estimated; OECD assessment)		
Fish 96h-LC_{50}	30.8 mg/l or 147 mg/l	139.9 mg/l
Daphnia 48h-EC_{50}	21.3 or 123 mg/l	221.5 mg/l
Algae 72h-EC_{50}	20.1 or 127 mg/l	174.6 mg/l
Isoprene (log Kow =2.3 (calculated ClogP (Bol et al., 1993))		
Fish 96h-LC_{50}	30.8 mg/l	42.5-240 mg/l
Daphnia 48h-EC_{50}	21.3 mg/l	140 mg/l
Algae 72h-EC_{50}	20.1 mg/l	>1,000 mg/l

The QSAR estimates generally agree with the measured values to within an order of magnitude, and the QSAR estimate is almost always lower than the measured value. Therefore, the QSAR estimates for 1,3-butadiene will be taken as realistic estimates of the toxicity of the substance. The values are:

72h-EC_{50} for algae = 32.6 mg/l
48h-EC_{50} for Daphnia = 33.3 mg/l
96h-LC_{50} for freshwater fish (Fathead minnow) = 44.8 mg/l

16 day NOEC for Daphnia reproduction/growth = 6.2 mg/l
28 day NOEC for B. rerio and P. promelas = 4.4 mg/l

To derive the PNEC, a factor of 1,000 was applied to the acute toxicity predictions, and a factor of 100 to the longer term predictions. The lowest result from this, 32.6 μg/l, was taken as the PNEC. The equilibrium partitioning method was used for the PNECs for soil and sediment.

Tests on plants using exposure through the air have shown some effects; these are most likely due to trace amounts of ethylene present in the 1,3-butadiene, but a PNEC of 2.2 mg/m^3 was derived. A PNEC of 1.38 mg/m^3 was derived from the results of inhalation tests on mammals.

1,3-butadiene is reactive in air and hence may contribute to low-level ozone formation. A photochemical ozone creation potential (POCP) value of 105 has been calculated; this compares with a value of 100 for ethylene, a substance considered important in low level ozone formation.

3.3 RISK CHARACTERISATION

The risk characterisation step involves the comparison of the PEC values with the PNECs. The resulting PEC/PNEC ratios are in **Table 3.4**.

Table 3.4 PEC/PNEC ratios for 1,3-butadiene

Process	Water	Soil	Air - plants
1,3-butadiene production	0.77	0.63	0.03
Styrene-butadiene rubber/latex production	0.49	0.17	0.20
Polybutadiene production	0.49	0.07	0.09
Polychloroprene production	0.49	0.06	0.04
Nitrile-butadiene rubber/latex production	0.49	0.002	0.02
ABS production	0.49	0.04	0.04
Adiponitrile/hexamethylene diamine production	0.49	0.003	0.001
Regional	0.001	$2x10^{-6}$	0.0007

The ratios for sediment are the same as those for water.

All the ratios are less than one. The conclusion of the risk assessment for all compartments is therefore:

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

1,3-Butadiene may play a role in photochemical smog and low-level ozone formation. The major source of atmospheric 1,3-butadiene is from vehicle exhausts. However, vehicles fitted with catalysts are thought to emit much less 1,3-butadiene than non-catalyst vehicles. Therefore, the increasing use of catalyst equipped vehicles in future will reduce the potential for these effects.

4 HUMAN HEALTH

4.1 HUMAN HEALTH (TOXICITY)

4.1.1 Exposure assessment

4.1.1.1 Occupational exposure

Occupational exposure data obtained from companies across the EU indicate that the majority of personal 8-hour TWA airborne exposures to butadiene during monomer and polymer production are very low, generally below 5 ppm (8-hour TWA). In monomer production, 90% of exposures are below 1 ppm, with 70% of results in polymer production less than 1 ppm. Exposures in excess of 10 ppm (8-hour TWA) are likely to be rare, and will arise as a result of unplanned releases. There is the potential for short-term exposures of the order of about 30 - 70 ppm (15-minute reference period) to occur during certain specific operations, particularly during sampling and loading/unloading operations. Where there is the potential for high exposure, EU industry indicates that exposures can be adequately controlled with LEV, changes in work practices or the wearing of appropriate respiratory protective equipment during specific operations. Personal exposure in situations such as sampling and loading/unloading will be mitigated by the use of appropriate respiratory protective equipment.

The concentration of 1,3-butadiene in end-use products is low. Therefore, airborne exposure during the handling and use of such products will be minimal, with the majority of exposures below the limit of detection.

4.1.1.2 Consumer exposure

1,3-Butadiene is not supplied for use directly in consumer products. Consumer use of items manufactured from synthetic butadiene-based polymers may give rise to exposure as a result of release of any free monomer from the polymer. The two main potential sources are from indoor air (primarily due to release from carpet backings) and from butadiene-based food packaging materials. In addition, adventitious sources of exposure have been identified. Estimates of exposures arising from two adventitious sources - motor fuel vapour and cigarette smoke – have been derived for information only, to provide a relevant context within which to consider the other sources of exposure included in this assessment. They are not included for the purposes of risk characterisation.

The only available measured data for the presence of monomer in indoor air suggest that indoor levels are generally below 2.2 µg/m^3 (equivalent to 0.001 ppm), giving rise to an estimated daily dose of $5 \cdot 10^{-4}$ mg/kg/day for an adult or $7 \cdot 10^{-4}$ mg/kg/day for a toddler. The predicted reasonable worst-case oral dose of 1,3-butadiene as a result of leaching from packaging into foodstuffs is about $2.1 \cdot 10^{-4}$ mg/kg/day for an adult and $1.2 \cdot 10^{-3}$ mg/kg/day for a toddler.

The combined exposure from indoor air and leaching from packaging into foodstuffs amounts to a predicted reasonable worst-case dose of $7 \cdot 10^{-4}$ mg/kg/day for an adult and $1.9 \cdot 10^{-3}$ mg/kg/day for a toddler.

In relation to adventitious sources, as a reasonable worst-case, a heavy smoker may receive a dose of 0.23 mg/kg/day. A person in a smoke-filled room would receive a dose of about 2.2 µg/kg/day if daily exposure is for 12 hours. Exposure to 1,3-butadiene may occur as a result of inhalation of petrol vapour when filling a car fuel tank, giving an estimated dose of approximately 1 µg/kg/event.

4.1.1.3 Humans exposed via the environment

The greatest predicted exposures to 1,3-butadiene via the environment are from air. The local predicted environmental concentration ($PEC_{local(air)}$) is 222 µg/m^3 (0.1 ppm), due to release from 1,3-butadiene plant, leading to an estimated daily dose of 0.05 mg/kg/day. The predicted regional environmental concentration (PECregional) in air, from all known sources, is considerably lower, 1.5 µg/m^3 (0.00068 ppm). This exposure would give rise to a daily dose of $3.5 \cdot 10^{-4}$ mg/kg/day. While it is recognised that these exposures are based on model predictions (but from real emissions data), it is noted that some measured data are available from the US, and in general, the measured data support the model predictions.

4.1.1.4 Combined exposure

Someone who works in and lives locally to a butadiene plant, is a heavy smoker (40 cigarettes/day) and is exposed via indoor air and monomer leaching from packaging into foodstuffs, could have a very approximate combined exposure/intake (dose in brackets) of 12 - 60 mg/day (0.17 - 0.86 mg/kg/day) from an 8-hour shift in the workplace, 16 mg/day (0.23 mg/kg/day) from cigarettes, and between 7 µg/day (0.10 µg/kg/day) (exposure inside the home) and 2.45 mg/day (0.03 mg/kg/day) (exposure outside the home local to the factory). The in-home and outside-home figures are based upon a 16-hour day. If remote from local emissions, the environmental exposure is calculated to be 0.3 µg/kg/day. Clearly, the exact contribution from each source is almost impossible to state, depending upon a considerable range of local and individual factors. Equally clearly, for smokers, cigarettes make a major contribution to butadiene dose.

4.1.2 Effects assessment

Butadiene is absorbed via the lungs in humans and animals; this is the main route of exposure and uptake. Once absorbed, butadiene is widely distributed throughout the body. The first step in the metabolic pathway is the formation of epoxybutene. Further metabolism of epoxybutene can proceed by a number of different pathways, with possible conjugation with glutathione, hydrolysis to butenediol, or further epoxidation to diepoxybutane. Further epoxidation and/or hydrolysis reactions can then take place, ultimately leading to erythritol formation. CO_2 is also produced at some stage during metabolism. The main route of elimination of butadiene and its metabolites is urinary excretion or exhalation in the breath. Minor faecal excretion also occurs.

1,3-Butadiene is of low acute toxicity in animals and in humans. There is no evidence that butadiene is irritant to the skin. Eye irritation is reported in humans only at very high exposure concentrations. Although there are no data on skin or respiratory sensitisation in animals or in humans, no such effects have been reported in humans and overall it is considered that butadiene is not a sensitiser. There is very little useful information on the health effects in humans of repeated exposure to butadiene, although no excesses of morbidity nor haematological changes

were observed in workers employed for a minimum of 5 years, exposed to an estimated 8-hour TWA concentration of 3.5 ppm butadiene, in one limited study. Evidence from animal studies shows marked species differences and shows the mouse to be particularly susceptible. In mice, increased mortality occurs in both sexes at $\geq$ 20 ppm, and tumour development and ovarian toxicity also occurs in females at 6.25 ppm, the lowest exposure concentration tested. In rats, there is some evidence of toxicity at 8,000 ppm following 2 years of exposure. Consideration of the available human data, although limited in terms of well documented information on exposure levels, indicates that humans are not as susceptible as mice to the effects of repeated exposure to butadiene.

1,3-Butadiene and its two epoxide metabolites, epoxybutene and diepoxybutane, are mutagenic *in vitro* and in somatic cells and germ cells *in vivo*. It is a potent multi-site carcinogen in the mouse, probably acting via a genotoxic mechanism. In rats, tumour formation occurs at much higher dose levels than in the mouse. The known quantitative species differences in the metabolism of butadiene may explain in part the very marked difference in toxicity of butadiene between rats and mice.

There are some suggestions that butadiene may be mutagenic in humans, at exposure concentrations of the order of 0.3 - 1 ppm (8-hour TWA), although the available data do not allow clear conclusions to be drawn. There is clear evidence from one recent, large epidemiology study in SBR workers, that occupational exposure to butadiene, but not styrene, is associated with an excess of leukaemia. Further analysis of the data from this study also raises the possibility that peak exposures could be an important factor in relation to the excess of leukaemia. However, the data do not allow a clear distinction to be drawn between the relative importance of cumulative versus peak exposure as the critical factor. Among workers exposed to butadiene alone in the manufacturing industry, although an excess of lymphohematopoietic cancers has been found, where qualitative exposure estimates are available, the pattern of results does not clearly indicate an association between butadiene exposure and excess cancer mortality, nor is there any clear evidence for excess leukaemia mortality, as in the SBR industry. However, no quantitative exposure data are available and the cohorts studied in the butadiene monomer industry are considerably smaller than those investigated in the SBR industry, and thus have a lower statistical power to detect any excess cancer mortality risk.

Although the most recent study has undertaken a sophisticated occupational exposure modelling assessment, these data are not sufficiently reliable to derive a dose-response relationship for the carcinogenic effect. The extent and quality of exposure data from other studies are limited. Overall, it is not possible to offer a reliable estimate of the dose-response relationship for the carcinogenic effect in humans.

There are no human data available in relation to reproductive parameters. There are no adequate fertility studies in animals, although no evidence for an adverse effect on male fertility was seen in three mouse dominant lethal assays. The results of long-term studies in rodents suggest that the ovaries and/or testes are a target organ. Ovarian atrophy was seen in a 2-year study in the mouse, at the lowest exposure concentration tested, 6.25 ppm, and uterine atrophy developed after 9 months exposure to 200 ppm and above. The effects on the ovary at 6.25 ppm were seen only towards the end of the 2-year exposure period, when there would be general senescence of the reproductive system. Atrophy of the testes was seen following exposure to 625 ppm and above, for several months, with a NOAEL at 200 ppm for 2 years exposure. However, other severe effects, including increased mortality rates and/or tumour development also occurred at the exposure levels causing gonadal atrophy in mice. When considering the implications of the

1,3-butadiene-induced gonadal effects in mice for human health, it is noted that both the toxicokinetic and epidemiological data suggest that quantitatively, humans are less susceptible than mice to 1,3-butadiene toxicity. In relation to effects on development, the results of developmental studies in the rat and mouse suggest that any effects are secondary to maternal toxicity and therefore are of lesser concern for human health.

4.1.3 Risk characterisation

4.1.3.1 Workers

The key areas of concern are for mutagenicity and carcinogenicity. The available data do not allow the identification of a threshold level of exposure below which there would be no risk for the development of mutagenic or carcinogenic effects in humans. In view of this, there are potential health concerns at all exposure levels.

In relation to repeated exposure, the animal data indicate a marked species difference in toxicity. Neither species is an appropriate model for humans and thus the calculation of margins of safety is not appropriate. In mice, the most susceptible species, the only useful information in relation to repeated dose toxicity comes from short-term studies, in which non-neoplastic effects of concern occur only at very high exposure concentrations, three orders of magnitude above contemporary occupational exposure levels (1-5 ppm). Overall, concerns for repeated exposure toxicity are overridden by the concerns for genotoxicity and carcinogenicity.

Although ovarian atrophy has also been identified in mice following long-term repeated exposure to concentrations as low as 6.25 ppm, the concentrations producing such damage also produced other severe signs of systemic toxicity in this species. As previously noted, mice appear to be particularly susceptible to 1,3-butadiene-induced toxicity, and there are no indications that humans respond in a quantitatively similar fashion. For testicular atrophy, a NOAEL of 200 ppm for 2 years has been identified in mice; this is two orders of magnitude above contemporary occupational exposure levels. Overall, it is considered that the risk of gonadal damage in workers is extremely low and there are no concerns for this endpoint.

In relation to irritation, slight irritation of the eyes, nose and mouth have been reported in humans exposed to thousands of ppm of 1,3-butadiene. This is two orders of magnitude higher than the peak exposures which occur in the occupational setting and thus there is negligible risk of local irritation effects.

4.1.3.2 Consumers

The two main sources of consumer exposure to 1,3-butadiene (excluding adventitious sources) are from indoor air (primarily due to release from carpet backings) and from food packaging materials. The most recent information indicates that the release of free monomer from carpet backings is not detectable. The release of free monomer from food contact materials is currently regulated by Directive 90/128/EEC and amendments.

In view of the very low exposure levels, the only potential concern for health effects is for mutagenicity and carcinogenicity. For these endpoints, the available data do not allow the identification of a threshold level of exposure below which there would be no risk for the

development of these effects. The level of risk to human health under current levels of consumer exposure in the EU is uncertain, but in view of the very low estimated exposure levels, it is predicted that there would be negligible residual risk.

4.1.3.3 Humans exposed via the environment

In view of the very low environmental exposure levels, the only potential concern for health effects is for mutagenicity and carcinogenicity. In relation to these endpoints, the available data for butadiene do not allow the identification of a threshold level of exposure below which there would be no risk for the development of these effects. The risks to human health under contemporary environmental exposure conditions in the EU are uncertain. However, given that the exposure levels are very low, it is concluded that there would be a negligible residual risk.

4.1.3.4 Combined exposure

In relation to mutagenicity and carcinogenicity, the available data for butadiene do not allow the identification of a threshold level of exposure below which there would be no risk for the development of these effects. The risks to human health under conditions of combined exposure to butadiene are uncertain. Setting aside exposure from smoking, the combined exposure is dominated by the occupational exposure. Therefore the conclusions reached for the occupational setting will apply.

4.2 HUMAN HEALTH (PHYSICOCHEMICAL PROPERTIES)

There are hazards associated with the extremely low flash point, high vapour pressure and flammability of this substance. 1,3-Butadiene has a flash point of -76°C and autoignition temperature of 420°C. Cylinders should be stored in dry, well-ventilated areas and the temperature should not be allowed to exceed 52 °C (125 °F). Outside or detached storage is preferred, and there should be no sources of ignition in areas of storage or use. 1,3-Butadiene is incompatible with oxidisers and should not be stored near compounds of this type. It should be shipped and stored with an inhibitor/antioxidant to prevent polymerisation, with a recommended maximum storage time for inhibited product of 12 months. General warnings to this effect are recommended, and are currently in practice. If the appropriate handling and storage measures are applied, there are no concerns for risks to human health.

5 RESULTS

5.1 ENVIRONMENT

5.1.1 Aquatic compartment

It is expected that any 1,3-butadiene present in surface water will volatilise rapidly. Therefore, even if 1,3-butadiene is released to surface water from point sources, the concentration would be expected to decrease markedly with increasing distance from the source. Thus, any potential problems are likely to be associated with the area immediately downstream of a point source discharge.

Result

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.

5.1.2 Terrestrial compartment

There is no toxicity information available for terrestrial organisms exposed via soil. Given the physical properties of 1,3-butadiene, soil is not thought to be a significant route of exposure. **Conclusion (ii)**.

5.1.3 Atmosphere

Plants

The risk to plants exposed to 1,3-butadiene via the atmosphere is small. **Conclusion (ii)**.

Other effects

1,3-Butadiene may play a role in photochemical smog and low-level (tropospheric) ozone formation. A major source of atmospheric 1,3-butadiene is from vehicle exhausts. However, vehicles fitted with catalysts are thought to emit much less 1,3-butadiene than non-catalyst vehicles. Therefore, the increasing use of catalyst equipped vehicles in future will reduce these effects. **Conclusion (ii)**.

5.1.4 Secondary poisoning

1,3-Butadiene has a low bioaccumulation potential and so is of low concern with regard to secondary poisoning. The main source of exposure of higher animals to 1,3-butadiene is likely to be via inhalation and the predicted levels of 1,3-butadiene at the regional level are unlikely to be of concern in this respect. The highest predicted local air concentrations provide a margin of safety of approximately 20 for effects seen towards the end of a 2-year study in the most sensitive mammalian species. Thus, 1,3-butadiene is unlikely to be of concern with regard to secondary poisoning. **Conclusion (ii)**.

5.2 HUMAN HEALTH

5.2.1 Human health (toxicity)

5.2.1.1 Workers

The main route of occupational exposure to 1,3-butadiene is by inhalation of the vapour. While the potential for oral and dermal exposure cannot be ruled out, this is considered to represent a very minor route of exposure, particularly if good occupational hygiene practice is assumed.

When considering the risks to human health arising from occupational exposure to butadiene during the manufacture of monomer and polymers, the key areas of concern are for mutagenicity and carcinogenicity. In relation to worker exposure, the available mutagenicity and carcinogenicity data for butadiene do not allow the identification of a threshold level of exposure below which there would be no risk for the development of these effects. In view of this, there are potential health concerns at all exposure levels and consequently conclusion (iii) is reached. Although high standards of control are available in these industry sectors, representing best practice for a substance with these properties, there is no evidence that these standards are currently applied consistently across all EU industry. Thus, there is no evidence that the appropriate equipment is in place in all EU workplaces and that it is used and maintained in the correct manner. Therefore, it is considered that risk reduction measures are required, and conclusion (iiib) applies.

Result

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

Conclusion (iiib) is reached for manufacture of butadiene monomer and for production of polymers, in view of the carcinogenic and genotoxic nature of 1,3-butadiene.

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.

Conclusion (ii) is reached for all occupational exposure scenarios for all other endpoints of potential concern.

5.2.1.2 Consumers

Although butadiene is not added to consumer products as such, consumer exposure arises as a result of cigarette smoking, including passive smoking, and exposure to residual monomer in products manufacture from synthetic polymers. The main source of consumer exposure is from cigarette smoke, and in comparison, exposure from synthetic polymer products is minimal and considered to be of very low concern. In view of the very low exposure levels which occur, the only potential concern for health effects is for mutagenicity and carcinogenicity. For these endpoints, the available data for butadiene do not allow the identification of a threshold level of exposure below which there would be no risk for the development of these effects. It is recognised that the highest potential exposure arises as a result of cigarette smoking, with the next highest exposures as a consequence of passive smoking. In relation to the contribution from

these adventitious sources, the exposures arising as a result of potential release of monomeric 1,3-butadiene from consumer products give rise to very low doses. The risks to human health under current consumer exposure levels are uncertain, but in view of the very low estimated exposure levels, it is predicted that there would be negligible residual risk.

Result

Conclusion (iiia) Risks cannot be excluded for all other exposure scenarios, as the substance is identified as a non-threshold carcinogen. The adequacy of existing controls and the feasibility and practicability of further specific measures should be considered. However, the risk assessment indicates that risks are already 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.

Estimations indicate that consumer exposure is very low. Although thresholds cannot be reliably identified, the risk of mutagenicity and/or carcinogenicity is considered to be very low.

5.2.1.3 Humans exposed via the environment

Indirect exposure to butadiene via the environment occurs mainly as a result of emissions to the air from butadiene plant. The other potential source of exposure is from vehicle exhaust emissions. However, the latter exposures are low compared with the local exposures to the predicted airborne emissions from butadiene plant. However, in view of the very low exposure levels which occur, the only potential concern for health effects is for mutagenicity and carcinogenicity. In relation to these endpoints, the available data for butadiene do not allow the identification of a threshold level of exposure below which there would be no risk for the development of these effects. The risks to human health under current environmental exposure levels are uncertain. However, given that the exposure levels are very low, it is concluded that there would be a negligible residual risk.

Result

Conclusion (iiia) Risks cannot be excluded for all other exposure scenarios, as the substance is identified as a non-threshold carcinogen. The adequacy of existing controls and the feasibility and practicability of further specific measures should be considered. However, the risk assessment indicates that risks are already 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.

Conclusion (iiia) is reached for all exposure scenarios because exposures are very low and although thresholds cannot be reliably identified, the risk of mutagenicity and/or carcinogenicity is considered to be very low.

5.2.1.4 Combined exposure

Accurate predictions of the contributions made by individual sources to combined exposure and dose are always imprecise. However, such exposures could occur, comprising the workplace, smoking, the local environment and consumer exposures from polymeric materials, with

intermittent exposures derived from filling petrol tanks. In view of the very low exposure levels which occur, the only potential concern for health effects is for mutagenicity and carcinogenicity. In relation to these endpoints, the available data for butadiene do not allow the identification of a threshold level of exposure below which there would be no risk for the development of these effects. The risks to human health under current environmental exposure levels are uncertain. Setting aside exposure from smoking, the combined exposure is dominated by the occupational exposure. Therefore, the conclusions reached for the occupational setting will apply.

Result

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

5.2.2 Human health (risks from physicochemical properties)

There are no significant risks to humans from the physicochemical properties of butadiene.

Result

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.