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CYCLOHEXANE

CAS No: 110-82-7

EINECS No: 203-806-2

Summary Risk Assessment Report

2004 **Special Publication I.04.22**

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SUMMARY RISK ASSESSMENT REPORT

Final report, 2004

France

The French rapporteur for the risk evaluation of cyclohexane is the Ministry of the Environment with the Ministry of Health and the Ministry of Labour.

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PREFACE

This report provides a summary, with conclusions, of the risk assessment report of the substance cyclohexane that has been prepared by France 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

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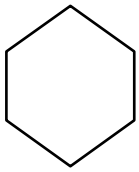
1 GENERAL SUBSTANCE INFORMATION

1.1 IDENTIFICATION OF THE SUBSTANCE

CAS-No.: 110-82-7
EINECS-No.: 203-806-2
IUPAC name: cyclohexane
Molecular weight: 84.16
Molecular formula: C_6H_{12}
Structural formula:



1.2 PHYSICO-CHEMICAL PROPERTIES

Table 1.1 Summary of physico-chemical properties

Property	Value
Physical state	Liquid
Melting point	6.5°C
Boiling point	80.7°C
Density	0.779 –0.784 at 20°C
Vapour pressure	10,300 Pa at 20°C
Water solubility	58 mg/l at 25°C
Henry's law constant	14,900 Pa · m^3/mol
Log Kow	3.44
Flash point	-20°C
Autoflammability	260°C

1.3 CLASSIFICATION

The classification and labelling of cyclohexane has recently been discussed (November 2000) and provisional agreement has been reached that the safety phrase S25 ("Avoid contact with eyes") should be added to the current classification in Annex I of Directive 67/548/EEC. :

Classification F; R11
Xn; R65
Xi; R38
R67
N; R50-53

Labelling	F; Xn; N
	R: 11-38-65-67-50/53
	S: (2-)9-16-25-33-60-61-62

R 11:	Highly flammable
R 65:	Harmful: may cause lung damage if swallowed
R 38:	Irritating to skin
R 67:	Vapours may cause drowsiness and dizziness
R 50/53	Very toxic to aquatic organisms / may cause long-term adverse effects in the aquatic environment
S9:	Keep container in a well-ventilated place
S 16:	Keep away from sources of ignition – No smoking
S 25:	Avoid contact with eyes
S 33:	Take precautionary measures against static discharges
S 2:	Keep out of the reach of children (only for consumer products)
S 60:	This material and/or its container must be disposed of as hazardous waste
S 61:	Avoid release to the environment. Refer to special instructions/safety data sheet

2 GENERAL INFORMATION ON EXPOSURE

Approximately 900,000 tonnes per year of cyclohexane are currently manufactured in the EU. Almost all of the produced cyclohexane (96%) is used as an intermediate in chemical synthesis in the first step of nylon manufacture, either nylon 6 or nylon 66. Other uses are as a solvent, in the chemical industry and as a component of products. Cyclohexane is used as an auxiliary in chemical production processes, mainly as a precipitating and extraction agent, but also as a reaction enhancer. It is also used as a component of products (mainly adhesives) in various industrial sectors (formulation and use of products), in craft industries (artisans) and in the general public field. The use pattern used for this assessment is presented in **Table 2.1**.

Table 2.1 Use pattern

Description	Quantity	Fraction
Intermediate in the chemical industry	864,000 t/a	96%
Solvent in chemical production processes	18,000 t/a	2%
Solvent in adhesives and coatings	18,000 t/a	2%

3 ENVIRONMENT

3.1 ENVIRONMENTAL EXPOSURE

The major characteristics of cyclohexane relevant for the exposure assessment are:

- no expected hydrolysis in water;
- readily biodegradable;
  (based on this screening result, half-lives in surface water, soil and sediment of respectively 15, 30 and 300 days can be estimated for cyclohexane)
- an atmospheric half-life of 52 hours.

Cyclohexane is very volatile from water (Henry's law constant H = 14,900 $Pa \cdot m^3/mol$ at 20°C). With a log Kow value of 3.44, a Koc-value of 770 l/kg can be estimated. Bioconcentration factors of 31-129 have been measured in fish. Based on the model SIMPLETREAT, it is estimated that in sewage treatment plants, 62.5% of any discharged cyclohexane will be stripped to air, 27.8% will be degraded, 6.3 % will adsorb to sludge, with the remaining 3.4% being released with the aqueous effluent.

Release information

Releases from production, use as an intermediate, use as an extraction solvent and use as a solvent in adhesives have been estimated from site-specific as well as industry-specific information. The overall estimated releases are shown in **Table 3.1**.

Table 3.1 Total estimated releases to wastewater, surface water and air

Life-cycle step	Waste water (t/a)		Surface water (t/a)		Air (t/a)	
	continental	regional	continental	regional	continental	regional
Production	-	-	1.4	1.0	544	230
Use as a chemical intermediate	-	-	3.9	0.43	864	500
Use as a solvent in chemical production processes	810	90	-	-	15,400	1,710
Use as a solvent in adhesives and coatings						
Formulation	negligible	negligible	-	-	405	45
Application	negligible	negligible	-	-	14,580	1,620
Total	**810**	**90**	**5.3**	**1.43**	**31,793**	**4,105**

The methods in the Technical Guidance Document (TGD) were used to estimate predicted environmental concentrations (PECs) for water, sewage treatment plants, air, and soil. Due to the low adsorption potential of cyclohexane and due to the absence of test results with benthic organisms or positive sediment monitoring results, the concentrations in sediment were not estimated. **Table 3.2** shows the PECs due to local releases calculated for the various stages of the life cycle of cyclohexane, including regional concentrations in the different environmental compartments.

Table 3.2 PECs calculated for the various stages of the life cycle of cyclohexane

Life cycle step	PEClocal$_{water}$ [µg/l]	PEClocal$_{air}$ [µg/m^3]	PEClocal$_{soil}$ [µg/kg wwt]
Production	< 1	213	0.9
Use as a chemical intermediate	0.56	463	63
Use as a solvent in chemical production processes	4.5	1060	86
Use as a solvent in adhesives and coatings Formulation Application	 negligible negligible	 33 146	 0.14 0.6

3.2 EFFECTS ASSESSMENT

Surface water

Acute toxicity test results are reported for fish, aquatic invertebrates, algae and microorganisms. The lowest 96-hour LC50 reported for fish is 4.53 mg/l (*Pimephales promelas*). The lowest 48-hour EC50 for invertebrates is 0.9 mg/l (*Daphnia magna*). The lowest 72-hour EC50 for algae (*Selenastrum capricornutum*) is 3.4 mg/l (inhibition of biomass). No longer-term studies have been performed.

For surface water, a $PNEC_{water}$ of 9 µg/l is estimated based on these results. An assessment factor of 100 was chosen, as it can be assumed that cyclohexane acts by a non-specific mechanism.

Sediment

No toxicity test results are available for sediment organisms with cyclohexane. Using the equilibrium partitioning approach, the risk characterisation result for sediment will be essentially the same as for surface water. Therefore a separate PNEC has not been derived for sediment organisms.

Sewage treatment plant

For microorganisms in sewage treatment plants, a PNEC of 2.9 mg/l is derived using an assessment factor of 10 with a 15-hour EC50 from a respiration inhibition test with activated sludge.

Atmosphere and terrestrial compartments

The available test results do not allow to estimate a PNEC for plants exposed via the atmosphere, nor for terrestrial organisms exposed via soil. For soil, a PNEC of 130 µg/kg (wet weight) is estimated with the equilibrium partitioning method using the PNEC for the aquatic ecosystem.

Secondary poisoning

Although cyclohexane presents a BCF in fish greater than 100, a risk assessment for secondary poisoning does not seem to be necessary, as it is not classified as "Toxic" or "Harmful" with at least R48 or R60-R64. No PNEC for predators was therefore derived.

3.3 RISK CHARACTERISATION

Aquatic compartment (incl. sediment and sewage treatment plants)

The highest value estimated for a municipal STP outlet (excluding production and transformation sites which usually have their own treatment plant adapted to cyclohexane) is 232 µg/l. With a PNEC of 2,900 µg/l for microorganisms in a STP, the PEC/PNEC ratio amounts to 0.08 and therefore a risk to microorganisms in STPs is not expected: **conclusion (ii)**. In **Table 3.3** the comparison between PEC and the PNEC in surface waters for all relevant exposure scenarios is presented.

Table 3.3 PEC/PNEC in the aquatic environment for all relevant exposure scenarios

Life cycle step	$PEClocal_{water}/PNEC_{water}$
Production	< 0.1
Use as a chemical intermediate	0.06
Use as a solvent in chemical production processes	0.5
Use as a solvent in adhesives and coatings Formulation Application	 negligible negligibe

As all calculated PEC/PNEC ratios are below 1, it can be concluded that there is no risk to aquatic organisms through cyclohexane: **conclusion (ii)**.

As the chemical is only moderately hydrophobic, it can be assumed that the risk assessment for the sediment is covered by the risk assessment for surface water. The same conclusions as described above would therefore apply: **conclusion (ii)**.

Atmosphere

The available test results on effects upon plants exposed via the gas phase do not allow the derivation of a PNEC and therefore a risk characterisation cannot be performed. Due to the low atmospheric lifetime (half-life of 52 hours) as well as the absence of Cl and Br atoms, abiotic effects upon the atmosphere, like global warming and ozone depletion are not to be expected from cyclohexane. On the other hand a high potential for tropospheric ozone formation has been reported. No conclusion can be drawn for possible atmospheric effects.

Terrestrial compartment

All estimated PECs (see **Table 3.2**) are lower than the estimated PNEC for soil of 130 µg/kg (wet weight). It can be concluded that there is no risk to terrestrial organisms through cyclohexane: **conclusion (ii)**.

Secondary poisoning

Although cyclohexane presents a BCF in fish greater than 100, a risk assessment for secondary poisoning does not seem to be necessary, as it is not classified as “Toxic” or “Harmful” with at least R48 or R60-R64: **conclusion (ii)**.

4 HUMAN HEALTH

4.1 HUMAN HEALTH (TOXICITY)

4.1.1 Exposure assessment

Cyclohexane is a liquid at standard temperature and pressure. Consequently the inhalation, dermal and oral routes of exposure are relevant for the risk assessment. However, as cyclohexane is volatile, producing a colourless vapour, the inhalation route of exposure is the most relevant to both the working population and the general population.

Occupational exposure

Four scenarios can be described for occupational exposure to cyclohexane:

- production: closed system;
- use as an intermediate or solvent in the chemical industry: 98% in closed systems for synthesis of caprolactam;
- formulation and industrial use of cyclohexane containing products: mainly adhesives, coatings, inks and varnishes. Exposure concerns mainly footwear industry;
- use of cyclohexane containing products in craft industries: mainly carpet layers and shoes repairers.

Exposure data are available for Scenarios 1, 2 and 3. For Scenario 4, due to the very large panel of use, the EASE model is preferred for estimating exposure (this model is considered to be the worst case). Occupational exposure data are summarised in **Table 4.1**.

Table 4.1 Occupational exposure estimates

Scenario	Estimated inhalation exposure ppm (mg/m^3) [a]		Estimated skin exposure (mg/cm^2/day) [b]
	Long term (8-hour TWA)	Short term	
1-Production	20 (69)	30 (103)	0-0.1
2-Intermediate	20 (69)	30 (103)	0-0.1
3-Formulation and industrial use of products	300 (1,032)		0.03-0.3
4-Use of products in craft industries	200-1,000 (688–3,440)		1.5-4.5

a) Values derived from measured data and expert judgement for Scenarios 1, 2 and 3 and derived from EASE model for Scenario 4
b) Values derived from EASE dermal exposure model

Consumer exposure

Consumer exposure can occur where cyclohexane is used as a solvent in adhesives, paints, inks, varnishes, floor polishes and waxes and possibly, in other household products. The lack of information about the actual application makes it difficult to define the exposure assessment and to propose different scenarios. The upper range of the EASE–estimates (1,000 ppm) will be used as a reasonable worst case for acute consumer exposure during carpet laying.

Humans exposed via the environment

The estimation of the indirect exposure of humans via the environment resulted in total doses of 0.006-0.115 mg/kg/d due to local releases and $9 \cdot 10^{-5}$ mg/kg/d based on regional

concentrations. The main contribution is due to atmospheric releases (87-99% of total dose). The atmospheric concentrations vary between 27 and 521 μg/m^3 (0.008-0.15 ppm) for local releases and the regional atmospheric concentration amounts to 0.35 μg/m^3 (0.0001 ppm).

In addition to the indirect exposure due to the industrial use of cyclohexane, humans are exposed through car exhausts. The measured concentrations of cyclohexane in the vicinity of busy roads are approximately 1-10 μg/m^3 (0.0003-0.003 ppm).

4.1.2 Effects assessment

Toxicokinetics, metabolism and distribution

Cyclohexane is almost completely absorbed by the oral and inhalation routes. Via the dermal route, the absorption depends on the concentration. It can be assumed that dermal absorption of pure liquid cyclohexane in contact with the skin is 5%.

Cyclohexane is readily distributed to all tissues with a preference to adipose tissues. Cyclohexane is rapidly metabolised in the liver leading to the formation of various quantities of cyclohexanol, cyclohexanone, 1,2-cyclohexanediol and 1,4-cyclohexanediol. In humans, the main metabolic pathway leads to the formation of a majority of 1,2- and 1,4-cyclohexanediols excreted unchanged for 1,4-cyclohexanediol and in glucuronide form for 1,2-cyclohexanediol.

Elimination via the lungs is the major route of excretion (higher with increasing doses of cyclohexane) as unchanged cyclohexane or CO_2. Elimination of the metabolites is quite slow in the urine. The biological half-lives were estimated to be about 10-15 hours in rats by oral route and to be 5 hours in humans by inhalation. An excretion via the milk is possible.

Acute toxicity

Available LD50s and LC50s show that cyclohexane is of low toxicity via all routes of administration. The low viscosity of cyclohexane which leads to the classification Xn, R65, give concerns in case of oral ingestion.

Neurobehavioural toxicity studies performed on both rats and humans show that cyclohexane has narcotic properties. For these properties, a NOAEL of 400 ppm (1,400 mg/m^3) in rats and 250 ppm (860 mg/m^3) in humans can be fixed.

Irritation

From the available animal data, cyclohexane is considered to be a skin irritant. The irritant properties of cyclohexane are delayed and persistent. Cyclohexane is slightly irritating to the eyes both in animals and humans. Cyclohexane also exhibited slight respiratory irritating properties in mice and in humans.

Sensitisation

Available tests demonstrated that cyclohexane is not a sensitiser.

Repeated dose toxicity

Studies performed on cyclohexane via the inhalation route in mice and rats showed that slight liver effects were induced after sub-acute or sub-chronic exposure. Increases in mitotic index figures and in absolute and relative liver weight and centrolobular hypertrophy were noted in both rats and mice at dose levels between 6,000 and 7,000 ppm. The NOAEL for hepatic

effect is estimated to be 2,000 ppm (6,880 mg/m^3). This value is very conservative since the effects observed in the liver from 6,000 ppm upwards may be of an adaptive nature.

No signs of neurotoxicity were observed in subacute or subchronic studies performed on both rats and humans.

Mutagenicity

The available *in vitro* mutagenicity studies do not indicate that cyclohexane has genotoxic properties. For *in vivo* studies, negative results were found for a drosophila sex linked recessive lethal assay. In a micronucleus test, slight effects unrelated to dose were noted but these were considered to be of no biological importance.

Carcinogenicity

It was demonstrated in a questionable study that cyclohexane might have a weak promotion potential. Despite the lack of a conventional two-year carcinogenicity test, cyclohexane is not considered likely to be carcinogenic.

Toxicity for reproduction

In a 2-generation study, no effect was seen on reproductive parameters. A slight decrease of the pups body weight was observed at 7,000 ppm, this decrease being accompanied by a slight maternal toxicity. A NOAEL of 2,000 ppm (6,880 mg/m^3) can be determined for pups whereas a NOAEL of 500 ppm (1,720 mg/m^3) can be derived for maternal toxicity.

No toxic effect was observed in the foetuses in two developmental studies performed in rats and in rabbits. Toxic effects were noted in the dams and were consistent with those observed in the other studies (narcotic effects). The highest dose tested in these studies (7,000 ppm (24,080 mg/m^3)) can be considered to be the NOAEL for foetuses with a NOAEL of 500 ppm (1,720 mg/m^3) for dams. A summary of reproductive toxicity studies is presented in **Table 4.2**.

Table 4.2 Summary of reproductive toxicity studies

Fertility			
Species	**Administration protocol**	**Objectives of the tests**	**NOAEL**
Rat	inh. 90 d	two-generation study	dams: 500 ppm (1,720 mg/m^3) pups: 2,000 ppm (6,880 mg/m^3)
Developmental toxicity study			
Species	**Administration protocol**	**Objectives of the tests**	**NOAEL**
Rat	inh. gestational day 7-16		dams: 3,000 ppm (10,320 mg/m^3) pups: > 3,000 ppm (10,320 mg/m^3)
Rat	inh. gestational day 7-16		dams: 500 ppm (1,720 mg/m^3) pups: > 7,000 ppm(24,080 mg/m^3)
Rabbit	inh. gestational day 7-19		dams: 7,000 ppm (24,080 mg/m^3) pups: > 7,000 ppm (24,080 mg/m^3)

4.1.3 Risk characterisation

Workers

No concerns were identified for acute lethal effects in any exposure scenario: **conclusion (ii)**. For neurologic effects the NOAEL of 250 ppm is taken into consideration, as this is the lowest dose without effects in humans. **Table 4.3** summarises the calculated MOS for each scenario.

Table 4.3 MOSs for neurologic effects

Scenario	Estimated inhalation exposure (ppm)	MOS
	Long term (8-hour TWA) / Short term	Long term / short term
1 - Production	20 / 30	12.5 / 8.3
2 - Intermediate	20 / 30	12.5 / 8.3
3 - Formulation and industrial use of products	300	0.83
4 - Use of products in craft industries	200 / 1000	1.25 / 0.25

For Scenarios 1 and 2, the MOSs are considered to be sufficient: **conclusion (ii)**. For Scenarios 3 and 4, the MOSs are considered to be insufficient and a risk to workers cannot be excluded: **conclusion (iii)**.

Regarding irritation, risk reduction measures already exist in the EU regulation, including classification and labelling, safety data sheet and the thereby invoked engineering controls and personal protective equipments. Consequently, there is no need for risk reduction measures beyond those which should already be applied: **conclusion (ii)**.

No concerns were identified concerning sensitisation: **conclusion (ii)**.

Regarding chronic effects slight hepatic effects were seen in mice and rats at doses of 7,000 ppm leading to a NOAEL of 2,000 ppm for these effects. **Table 4.4** summarises the MOSs calculated for this end point.

Table 4.4 MOSs for chronic effects

Scenario	Estimated inhalation exposure (ppm)	MOS
1 - Production	20	100
2 - Intermediate	20	100
3 - Formulation and industrial use of products	300	6.66
4 - Use of products in craft industries	1000	2

For Scenarios 1 and 2, the MOSs are considered to be sufficient: **conclusion (ii)**. For Scenarios 3 and 4, The MOSs are considered to be insufficient and a risk to workers cannot be excluded: **conclusion (iii)**.

No concerns are identified for mutagenicity, carcinogenicity or toxicity for reproduction: **conclusion (ii)**.

Consumers

Considering the possible use of cyclohexane by consumers, the only effect of concern is acute toxicity and especially neurobehavioural toxicity. Exposure of 1,000 ppm can be anticipated as a worst case leading to the calculation of a MOS of 0.25 (250 ppm / 1000 ppm). This MOS is not acceptable for this effect and there is a need for limiting the risks: **conclusion (ii**i).

Humans exposed via the environment

The highest estimated "worst case" indirect exposure of humans is due to air concentration in the vicinity of sites using cyclohexane as a solvent for chemical production processes, ca. 0.15 ppm. Compared with the lowest available NOAEL of 250 ppm (neurotoxicity) a MOS of 250/0.15 = 1,666 can be derived. In addition to the indirect exposure due to the industrial use of cyclohexane, humans are exposed through car exhausts. As seen above, the measured concentrations of cyclohexane in the vicinity of busy roads are approximately 0.0003-0.003 ppm. A MOS of 83,333 can be derived. These MOSs are considered to be sufficient and no risk is expected for humans exposed via the environment: **conclusion (ii)**.

4.2 HUMAN HEALTH (PHYSICO-CHEMICAL PROPERTIES)

4.2.1 Exposure assessment

Workers

Cyclohexane is a volatile, highly flammable liquid, its use without taking controlled measures can rapidly lead to dangerous concentrations in air.

In industry, either during manufacture or industrial use, effective controlled measures are taken in accordance with current regulations (ventilation of work areas, regulations regarding electrical equipment).

Such measures are not always taken during use in craft industries. It should be noted, however, that in this case, cyclohexane is never used alone but is mixed with other solvents many of which are also flammable.

Consumers

Consumer exposure cannot be assessed, as few data could be obtained on the cyclohexane content of commercial products, neither from the chemical industry, nor through literature research.

Consumers are exposed to the flammability hazard in case of use as a solvent in do-it-yourself products not only because of cyclohexane but also of other solvents combined with it. The only preventative measures possible are precautions to be taken by the user himself, particularly by staying away from flames or sparkles, in a well-ventilated place, without smoking; this information must be on a label directly on the container.

4.2.2 Hazard identification

Explosivity

Cyclohexane is not likely to have explosive properties.

Flammability

Cyclohexane is a highly flammable liquid (flash point: -20°C) with an auto flammability temperature of 260°C. It is a volatile liquid (vapour pressure 13 kPa at 20°C). The vapours can form flammable and explosive mixtures with air within the range of 1.33 % to 8.35 volume %. Cyclohexane is a static accumulator.

Oxidizing potential

Cyclohexane is not likely to have oxidizing properties.

4.2.3 Risk characterisation

Regarding its physico-chemical properties, flammability is the only property of concern for cyclohexane since it is a volatile liquid which is highly flammable and can form explosive mixtures with air.

In production and in occupational use, the flammability risk is not of concern provided adequate safety measures are taken. Information is provided on the label and in the safety data sheet.

Concerning use by consumers, information about the flammability risk and precautionary measures must be given by a label on the containers: in the EU, symbol, risk phrases and safety phrases are used for the labelling of highly flammable substances and preparations (mixtures).

Conclusion

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

5 RESULTS

5.1 ENVIRONMENT

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.

The production and use of cyclohexane as a chemical intermediate, as a solvent in chemical production processes and as a solvent in adhesives and coatings is unlikely to pose a risk to the environment. In addition, risks to the function of sewage treatment plants are expected to be very low for both production and all uses.

5.2 HUMAN HEALTH

5.2.1 Human health (toxicity)

Workers

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 is reached because of concerns for acute toxicity (neurobehavioural effects) and general systemic toxicity (hepatic effects) as a consequence of inhalation exposure arising from formulation and industrial use of products containing the substance as well as from use of products containing the substance in craft industries.

Consumers

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 is reached because of concerns for acute toxicity (neurobehavioural effects) as a consequence of exposure arising from use of products containing the substance.

Humans exposed via the environment

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.

5.2.2 Human health (risks from physico-chemical properties)

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.